D3.3: Survey of REC approaches and codes for human enhancement

[WP3 – Human enhancement: ethical, legal and social analysis]

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Abstract

This report describes the outcome of task 3.3, the current coverage of ethical guidelines by professional organisations, ethics advisory groups, and research ethics committees for human enhancement. For this task the SIENNA partners searched for documents which could give normative guidance (excluding legislation) for stakeholders in human enhancement. Three kinds of documents were searched for in different EU countries and internationally:

1. professional ethics codes;
2. documents from ethics advisory groups; and
3. guidance documents on how to write research ethics protocols in different EU countries and internationally.

Furthermore, representatives of research ethics committees were asked for the following information in an online survey:

- to what extent are they aware of human enhancement technologies and ethical issues associated with them; and
- how do they currently approach these issues and do they have plans to more explicitly feature them.

Document history

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Information in this report that may influence other SIENNA tasks

Linked task	Points of relevance
Task 2.3, Task 4.3 – Current coverage by research ethics committees and in ethical codes	Tasks 2.3 and 4.3 are strongly connected to task 3.3. The same methodology was used for the national and international searches and the opinions and knowledge of REC members was examined via one online survey for all three SIENNA areas.

Task 2.2, 3.2, 4.2 – Analysis of legal and human rights requirements in and outside the EU	Ethical frameworks or normative rules are sometimes regulated via soft law. Therefore, there might be overlaps between the X.3 and the X.2 tasks. Although the X.2 tasks focused only on normative frameworks (not on legally binding documents).
Task 2.4, 3.4, 4.4 – Analysis of current and future ethical issues	The results of the X.3 tasks will also be useful for the X.4 tasks in which partners will review existing ethical theories and approaches regarding the three fields.
WPX.7	The outcome of the X.3 task will help us develop the ethical frameworks.
WP5	The outcome of the X.3 tasks will be the basis for the work in WP5, in which operational guidelines, ethics codes and proposals for improved ethical and legal frameworks will be developed.

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Executive summary

This report was developed in the context of a European Commission (EC) funded SWAFS[1] project called SIENNA, which began in October 2017. In the project, SIENNA partners study ethical, legal and social issues (ELSI) arising in three areas of technology: Human Genomics (HG), Artificial Intelligence & Robotics (AI&R), and Human Enhancement Technologies (HET). This report is one of the deliverables completed for Work Package (WP) 3 which addresses the ELSI of HET. We report herein how and to what extent different ethical normative documents explicitly or implicitly address HET. In particular, we studied normative documents issued by three different types of groups: i) professional organisations, ii) (ethical) advisory groups, and iii) research ethics committees. The same research has been conducted for HG (WP2, D2.3) and AI&R (WP4, D4.3).[2]

The national and international search for relevant documents brought a few HET specific results and many results which are useful for ethical guidance in HET in a broader sense. For the most relevant findings we answered questions related to focus/content, target group and values/principles mentioned.

The documents we found focus on specific fields of HET, e.g. neuroenhancement, physical enhancement, gene editing. It is striking that one topic is addressed in codes and guidelines more often than others, namely the non-medical use of drugs, followed by HET for children. There is no code on HET in general. Although, there are many documents which do not explicitly mention HET, but could nevertheless give ethical guidance for this technology area, e.g. the Belmont Report[3]. The codes we found address either health professionals (like physicians, psychiatrists, pharmacologists), researchers, society as a whole or particularly vulnerable groups, like children (or rather parents of children). In the documents we found, the same values and principles were mentioned, especially autonomy and self-determination, beneficence, non-maleficence, no-harm, fairness and justice.

Beside these results on focus/content, target group and values/principles of the codes, we learned from the search that codes and guidelines need clear objectives. To have a positive effect, a code or a recommendation must be precise and useful. Furthermore, a code or a recommendation must be pragmatic. If a code is based on values and principles it needs some practical explanation to make the terminology clear and useful. At least there should be no room for varying interpretations of terminology.

We found no HET specific guidance documents on how to write research ethics protocols for researchers doing research in this field. Although we found general guidance documents. Our online survey with REC representatives showed that most REC members address or offer no special guidance for researchers working on HET.

[1] SWAFS = Science with and for Society, https://ec.europa.eu/programmes/horizon2020/en/h2020-section/science-and-society

[2] Since task 3.3 is very strongly connected with task 2.3 and 4.3 this report contains text modules which are also used in D2.3 and D4.3.

[3] Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

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List of acronyms/abbreviations

Abbreviation	Explanation
AI&R	Artificial Intelligence & Robotics
D	Deliverable
DoA	Description of Action
ELSI	Ethical, Legal and Social Implications
EU	European Union
GDPR	General Data Protection Regulation
HET	Human Enhancement Technologies
HG	Human Genomics
IAEG	International Advisory/Ethics group
NAEG	national advisory/ethics groups
PEC	professional ethics codes
REC	Research Ethics Committee
REP	Research Ethics Protocol
SIENNA	Stakeholder-informed ethics for new technologies with high socio-economic and human rights impact
SOP	Standard Operating Procedure
WP	Work package

Table 1: List of acronyms/abbreviations

Glossary of terms

Term	Explanation
Ethics advisory bodies	"Ethics advisory bodies" can be defined as independent groups of ethics experts giving advice to a researcher, or research group on specific ethical, regulatory, social or philosophical issues raised by science and innovation.
Human Enhancement	A modification aimed at improving human performance and brought about by science-based and/or technology-based interventions in or on the human body.
Professional ethics codes	Guidelines to help members, workers, management or researchers conduct themselves in accordance with common values and/or ethical standards.
Professional organisations/groups	Professional organisations or groups usually bring together people working for a special profession to represent their interests.
Research ethics committees	Committees that review research applications and give opinions about whether research is ethical.
Research ethics protocols	Sets out how a study or project will deal with issues that are challenging from an ethical perspective.

Table 2: Glossary of terms

1. Introduction

One of the main goals of SIENNA is the development of ethical frameworks and codes for HET (WP3, task 3.7 and WP5 tasks 5.1-5.5) for the three technology areas, namely human genomics, artificial intelligence & robotics and human enhancement technologies. As a basis for this work, we need to have a good overview of already existing relevant documents. Therefore, we took the following steps:

1. **National search**: With the help of our partners we conducted national searches in 12 countries. Every partner searched in his/her country and in his/her language for three kinds of HET relevant documents:
   - professional ethics codes
   - guidance documents or recommendations from ethics advisory groups, and
   - guidance documents on how to write research ethics protocols.
2. **International search**: We searched for the same three kinds of documents internationally.
3. **Online survey with research ethics committees (RECs)**: Via a survey addressed to representatives of RECs, we assessed to what extent RECs are aware of these technologies and ethical issues associated with them, how they currently approach them, and if there are plans to more explicitly feature them in the future.

The key results are described in sections 2 and 3. In the three annexes, the reader will find detailed reports on the country studies (annex 1), the international search (annex 2) and the online survey (annex 3).

We aimed to obtain a wide range of normative documents to capture as many (types) of the salient normative statements as possible. This goal, along with the time allotted to this task, means that we cannot claim to have conducted a strictly systematic search, nor that we retrieved all existing normative documents. However, our search approach should have revealed the most important/influential documents, and we are confident that the material is sufficient to guide us further in tasks WP3, task 3.7 and WP5, tasks 5.1-5.5.

2. Ethical codes and guidelines for HET

2.1 National search in twelve countries

SIENNA partners searched for HET relevant ethics codes and guidelines on how to write research ethics protocols in Brazil, China, France, Germany, Greece, the Netherlands, Poland, South Africa, Spain, Sweden, the UK and the USA. The country reports in full-lengths are available in annex 1 of this document.

Lack of HET specific professional organisations

Most partners reported from their countries that it was difficult to find HET specific codes and guidelines. One of the reasons for this might be the fact that there are no professional organisations specifically focussing on HET. This result was the same in all twelve countries and stands in total difference to the other two SIENNA fields – in HG and AI&R specific professional organisations have been established. The lack of rigorous scientific publications on the ethics of HET might be explained by the fact that this is not a field that, contrary to HG or AI&R, clearly falls within one scientific discipline. Another reason for difficulties in finding HET specific ethical codes and guidelines might be that outside of the academic debate HET is (at least in some countries) not really a topic, for instance in **Brazil**. The expression "human enhancement" has currently no equivalent in Brazilian Portuguese. Since HET has not been publicly perceived as a social phenomenon in its own right, neither policy makers nor professional associations have felt the urge to publish ethical recommendations in this area. In **China** HET is often discussed in the academic field. Experts and scholars defined and classified HET, and also investigated its ethical issues. Although HET is receiving more and more attention, there are no professional organisations or associations established for it, or any official documents or policies to regulate it specifically. The **French** scene on HET is rather underdeveloped. Few recognised institutions in ethics have produced reports specifically dedicated to this topic. In **Germany** HET is a widely discussed topic in both academic and non-academic fields. There are ethical recommendations on HET by single authors or groups of authors, e.g. on brain doping and doping in sports, neuro enhancement and life style drugs or plastic surgery. However, these documents reflect single opinions and cannot necessarily count as professional codes. HET specific professional groups are missing in Germany as well. In **Greece** not only professional organisations for HET are missing, but also HET in research has not been considered in any depth in the wider academic community or society. The partners from the **Netherlands** described that there are professional medical organisations, especially in neurology, psychology and orthopaedic and cosmetic surgery, which deal with HET relevant ELSI. Yet, none of the documents from professional organisations found specifically addresses HET or any other deviation from therapy or healing. In **Poland** there is no HET professional organisation. A Polish Transhumanist Association[4] exists, however it has not adopted any codes or guidelines. In **South Africa** not much work has been done with regard to the development of professional codes for HET. For instance, although the national ethics code does include some discussion of genetics research, it does not cover HET and the use of CRISPR-Cas9. In **Spain** there are no codes or guidance documents on HET because the professions most related to these technologies (doctors, pharmacists, bio-engineers etc.) maintain therapy and complements to therapy as sole professional objectives. The partner from **Sweden** analysed four documents (potentially) relevant to HET. Two of them are issued by professional organisations of dentists and pharmacists and contain rather general recommendations and principles for these two groups of professionals. Although, none of these documents addresses the issue of HET

[4] http://www.psth.pl/

explicitly. Nonetheless, explicitly some recommendations and principles outlined therein may be relevant to HET practices within these two professions. There are no professional organisations specifically focussed on HET per se in the **UK**. The organisations identified have various missions, focuses and significance. Also in the **USA** ethical codes or guidelines for HET were not developed by special professional organisations, since they do not exist.

Codes and recommendations from professional organisations that address ELSI on HET in some way

Despite the lack of HET specific professional organisations, there are of course numerous professional organisations in the health sector, in the whole pharmaceutical field and in the sports sector which have developed HET relevant ethical codes or guidelines.

In **China** drugs, biomedicine and cutting-edge medical technology address HET. Therefore, it is necessary to focus on the relevant policies and regulatory documents in these fields. China has issued laws and policies to supervise and manage employees from the professional ethics level. In order to guarantee the quality of drugs and to maintain the safety and effectiveness of public medication, the *China Pharmaceutical Association* has formulated the *Convention on Professional Ethics* for Members of the Chinese Pharmaceutical Association. The *State Council of the People's Republic of China* classifies and prescribes the use and dosage of psychotropic drugs in the Regulations on Management of Narcotic Drugs and Psychotropic Substances. It is clearly stated that a prescription must be issued by a licensed physician and that some types of psychotropic drug may not be sold to minors. Although the above document does not directly mention HET, the regulations on safety and effectiveness of technology, risk avoidance, etc. can apply to the management and regulation of HET.
The search for HET relevant professional codes in **Germany** brought only two results: The national anti-doping code, developed by the *national anti-doping agency (NADA)* and a *Code of Transparency* for interaction with Healthcare Professionals and Healthcare Organisations, developed by the German Association FSA *Voluntary Self-regulation for the pharmaceutical industry* ("Freiwillige Selbstkontrolle für die Arzneimittelindustrie"). The *Association of German Aesthetic Plastic Surgeon*s (VDÄPC) and the *German Association for Neurology*, have not developed any relevant codes, guidelines or recommendations which include ELSI.
The **Polish** *Society of Plastic, Reconstructive and Aesthetic Surgery* has developed a code of ethics which could be considered in some way HET-adjacent. However, it makes no clear indication of HET, but focuses on principles of professional conduct. The *general Code of Medical Ethics* mentions the issue of doping in sports and states that it should be considered unethical.
In the **UK** we identified eight relevant codes of professional organisations (covering ethical aspects) that are relevant to HET. The codes deal with a variety of specific topics such as emerging science and bioethics, health technology, pharmaceuticals, prosthetics and orthotics, cosmetic/plastic surgery, and medicines (and their advertisement). The examined codes cover a broad range of ethical principles (depending on the topic). E.g., acceptable use of medical terminology, accuracy of information, acknowledgment, clear and respectful communications, confidentiality, continuity of care, data privacy and protection, equity of service provision, equivalence, patient autonomy and welfare, personal and professional integrity and competence, proper documentation and record keeping, quality, reflection and consent, respect for patients, safe and effective use of health technology, separation (not misusing interactions between industry and healthcare organisations), transparency and truthfulness (e.g., regarding medicinal advertisement).

The professional groups for medical fields in the **USA** that are expected to include HET options in the future currently make no clear indication about HET (generally) in their ethical codes. However, a few groups have issued policy statements regarding some HET domains, including a statement on performance-enhancing drugs issued by AAOS (the *American Academy/Association of Orthopaedic Surgeons*) and detailed position statements from the *American Academy of Neurology* on neuro-enhancement for adults and paediatric patients in separate documents. The *President's Council on Bioethics* during former President George W. Bush and Barack Obama's administrations both released insightful documents acknowledging HET in part (focused on neurotechnology's during Obama's tenure) or whole (the report, Beyond Therapy, from Bush's administration covers virtually every topic that was discussed at the time).

Ethical codes and guidelines from national advisory groups

In **China** HET is often understood as the intervention in the cognition, emotion and physical ability of healthy subjects through biomedicine, drugs and emerging medical technology. In the documents found in the national search for China, the protection or regulation of stakeholders and the hierarchical and classified management of various medical technologies and drugs are forward-looking avoidance of many ethical issues involved in HET.

The search for national advisory and ethics groups dealing with HET in **Germany** yielded some results. The *German ethics council* discussed the topic in various conferences and workshops and published relevant books, although guidelines, codes and recommendations on HET are currently still missing. The *German medical association* published guidelines on ADHD and on the use of pharmaceuticals, which are in a broad sense relevant. Very relevant is a document developed and published by the *Office of Technology Assessment* at the German Bundestag (TAB) in 2013 with the title "The Pharmacologically Improved Human". This document is very broad and focuses on different forms of HET. It gives an overview of potential areas for required activities in the field of HET. Furthermore, a statement developed by the *central ethics committee at the German Medical association* (Bundesärztekammer) (ZEKO) published in 2009 on doping and medical ethos is quite interesting for the SIENNA work (see Table in annex 1).

In **France** HET issues are addressed in documents that engage with the two other SIENNA areas – HG and AI&R. For instance, the CERNA's report on "ethics of research in robotics" has two pages on HET (pp. 38-40). The report by the Parliamentary Office (OPECST) "Toward a Controlled, Useful and Demystified AI" also touches on issues related to HET. It is also important to note that there has been some engagement with HET as part of the national consultation that took place in 2018 in relation to the revision of the bioethics law. The research has therefore shown that there is a paucity of documents produced by recognised institutions that address specifically the ethics of HET. This means that the general debate on this technology in France is rather dominated by opinions held by groups or individuals that tend to lack scientific substance. There are some strong supporters of HET in France, such as the Dr Laurent Alexandre or the Transhumanist French Association[5]; however, the French population appears generally resistant to it. In any case, the discussion on this topic is rather polarised and filled up by naïvely enthusiastic views or dystopian perspectives.

The search in **Greece** brought two opinions on HET by the National Committee on Bioethics.

The search for national advisory/ethical groups dealing with HET in the **Netherlands** was more successful. The main contributors for policy recommendations are the *Rathenau Institute* and the *Centrum voor Ethiek en Gezondheid* (The Netherlands Centre for Ethics and Health).–Both have

[5] https://transhumanistes.com

published specific advisory reports targeted at the government as well as policy-makers Together, the reports managed to cover most of the different areas within HET and thus give a representative overview of HET guidelines for policy-making and the public debate in the Netherlands. The reports on Wish-fulfilling medicine and nanotechnology do not focus on HET as such, but are useful adjacent sources providing a different approach and view on HET which could be useful for SIENNA's ethical codes and protocols. Other reports cover policy recommendations for each HET specifically and cover legal recommendations and recommendations on grounds of justice and national security.
SMER – the **Swedish** National Council on Medical Ethics, which is a parliamentary advisory body to the government, issued guidelines on cosmetic interventions and "brain doping" (see annex 1). Both documents refer to HET ELSI. The reports first shortly introduce the topic, report on relevant foreign documents, comment on it, and express SMERs own opinion/comments on the topics. These two documents contain recommendations on the related topics (for example, in the document on brain doping: "Research results in this area should be interpreted and communicated visible to avoid a "hype" around possible effects of the methods.") and a Swedish perspective on them, which may be somehow relevant or important and, thus, should be taken into account when designing the SIENNA guidelines. Overall, there are very few ethics guidance documents for HET in Sweden. There seems to have been an initiative to "start" addressing it by the national ethics advisory body, but nothing directly explicit to HET from professional organisations. And even what is presented by the SMER is still more reflective than normative.
The identified nine NAEG documents from the **UK** have been issued by organisations such as *General Medical Council, College of Optometrists, the National Health Service (NHS), the British Standards Institution (BSI)* and national associations and the Royal Academies. Some of the documents have a general focus (i.e., GMC Guidance) but some are more specific (e.g. apply to prescribing medicine, or plastic surgery, or cognitive enhancing drugs) and target a range of audiences.
Even though a large portion of the academic literature on HET continues to emerge from American institutes, few professional organisations/societies have addressed the topic in terms of ethical codes or guidelines in the **USA**. Regarding official government institutions, the *NIH (National Institute of Health)* includes institutes and centres that may be expected to produce minor research on HET or research that could be considered HET-adjacent in the near future, such as via the *National Institute on Aging (NIA)* or the *National Institute of Biomedical Imaging and Bioengineering (NIBIB),* such that one might expect to find, if nothing else, positions on some HET issues within NIH departments. However, the results of the study failed to discover documents from any NIH institutes specifically focused on HET ELSI. The *National Centre for Complementary and Integrative Health (NCCIH)* currently includes a page on what they call sexual enhancements, but this is geared toward consumers/individuals and does not focus on research ethics or technological guidance.

Guidance documents on how to write research ethics protocols for HET research projects

We searched in twelve countries for HET specific guidance documents for REC members and found general guidance documents, but no HET specific ones. Also, our online survey of REC representatives showed that most REC members neither address nor offer any special guidance for researchers working on HET. Here a few insights from the country reports:

- Netherlands: The search was not able to find any guidance documents on research ethics protocols that address issues in HET.

- Poland: There are no HET-relevant documents on writing ethical codes. No policy statements regarding HET research have been issued.
- South Africa: Local ethics guidelines (for local ethics committees) pertinent to genetic or other enhancement are not existent.
- Spain: Scrutinising the websites of the National Association of Research Ethics Committees, the Network of Ethics Committees of Universities and Research Centres in Spain, and the Spanish Medicines and Health Products Authority did not yield any results.
- UK: In our search for guidance on writing research ethics protocols, we found no guidance specific to 'human enhancement' issued by NRECs. However, we found some guidance issued by various national bodies on writing research ethics protocols at the national level some of which might apply to researchers in HET. There is general and discipline-specific institutional guidance on research ethics protocols and templates but these are not specific to 'human enhancement'.
- USA: Whilst searching for relevant material on HET, the study failed to uncover any relevant documents on writing ethical codes that specifically address HET issues. Few relevant documents were found overall, demonstrating that even in the United States the subject has yet to take root at a policy/regulatory level. Existing enhancement technologies (performance-enhancing drugs, cosmetic surgery, limited cognitive enhancement options) have been acknowledged by the most relevant bodies (i.e., the American Academy of Neurology for cognitive enhancement), but it appears there are few official policy documents that offer anything more than recommendations for addressing emerging issues.

Challenges during the national searches

In our methodology we defined that we exclude documents written by single authors or author groups. Included were only documents from professional organisations or groups and/or national (ethics) advisory groups. One of the main challenges in the national searches was that it was not always clear which organisation can be considered as "professional" organisation or rather what counts as a valid group or organisation. This was partially difficult for HET, since it is not really clear what a professional group is. We recommended the partners to make use of the column "comments" in these cases and write down their uncertainties regarding these issues there.

2.2 International search

In our search for relevant documents from international professional organisations we found only a few relevant documents. Human enhancement is targeted in different professions and therefore we searched for ethics codes and guidance documents in the following fields:

- Doping in sports
- Genedoping
- Plastic and aesthetic surgery
- Lifestyle drugs (mood and personality enhancement)
- Neuro-enhancement
- Cognitive enhancement

Based on these fields we searched for relevant professional organisations and found the following:

- The World Anti Doping Agency (WADA)
- The International Association of Aesthetic Plastic Surgery (ISAPS)
- The European Association of Societies of Aesthetic Plastic Surgery Societies (EASAPS)

- International Pharmaceutical Federation (FIP)
- World Federation ADHD

Furthermore, we found relevant documents from the European and international advisory/ethics groups, e.g.

- United Nations Office on Drug and Crime (UNODC)
- The European Group on Ethics in Science and New Technologies (EGE)

We searched via google and especially at the websites of these professional organisations and international advisory/ethics groups for relevant ethics codes or guidance documents that might help us to develop ethical frameworks regarding research in HET for the SIENNA project. The main outcome of our search is that currently only very few guidance documents exist. The WADA published the World-Anti-Doping-Code which is well accepted internationally. The other professional organisations published a lot of guidelines and other normative documents, yet nothing regarding ethical implications of HET technologies. The EGE developed a few relevant documents, e.g. an opinion on the ethical aspects of ICT implants in the human body in 2005.[6]

2.3 Overview of HET relevant codes and guidelines

All relevant documents that were found in the national and international searches are listed in annex 1 of this report. The partners responsible for national searches determined which documents are most relevant for SIENNA. For those documents which are very relevant for SIENNA's work the following questions were answered (in some countries only one relevant document was identified, in others five or more):

- Who is the stated audience?
- What definition of HET is used in the document?
- What forms of HET are described/covered in the document?
- Which ethical issues are addressed in the document?
- How are the ethical issues addressed? Are solutions offered? If so, which ones?
- Format of the document (checklist, continuous text, other)?
- How is the document structured?
- Why is the document important/useful for your country?
- Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.

There are many relevant documents. Here is an overview for some of them (for more insights see annex 1 and 2):

The non-medical use of prescription drugs. Policy direction issues[7]
published by the United Nations Office on Drugs and Crime (UNODC) in 2011 (international)

The UNODC recommends on pp. 47-48:

- Raising awareness among policymakers and clinicians, parents, young people, and teachers;
- Training health-care professionals on an ongoing basis on how to prevent, recognize and manage the non-medical use of prescription drugs and related consequences;

[6] http://ec.europa.eu/archives/bepa/european-group-ethics/docs/avis20_en.pdf
[7] https://www.unodc.org/documents/drug-prevention-and-treatment/nonmedical-use-prescription-drugs.pdf

- Taking an official stance by addressing the issue of non-medical use of controlled prescription drugs directly in drugs legislation;
- Researching whether and how to tailor prevention and treatment efforts for the non-medical use of prescription drugs;
- Researching how to treat polysubstance users and those with a co-morbid illness;
- Doing further research on the risk and protective factors for the non-medical use of prescription drugs, with particular attention to specific risk populations, such as young people, women, older adults and health professionals;
- Providing clear guidelines to physicians on good practices for prescribing the use of strong psychoactive medication, including both initiation and time limits;
- Using systems of supervised daily dosing for strong psychoactive medication when appropriate;
- Providing incentives for medical practitioners to not overprescribe strong psychoactive medication;
- Providing disincentives for the overprescription of strong psychoactive medication.

Code of ethical business practice[8]
published by the Association of British Healthcare Industries in 2018 (UK)

The Code sets out standards for ethical behaviour and to govern ethical promotion and sales practices in the medical devices industry in the UK ("the Industry"). Its website provides illustrative summaries of complaints. The code has a good structure, dedicated website and complaints adjudication process.

Regulations on Management of Narcotic Drugs and Psychotropic Substances
published by the State Council of the People's Republic of China in 2005 (China)

This document regulates drug abuse in various aspects and can serve as a regulation for HET. Article 13, Chapter 2 indicates that the clinical trials of narcotic drugs and class I psychotropic drugs should not be conducted ~~by~~ on healthy subjects. There are detailed regulations on the cultivation, experimental research, production, marketing, use and storage of drugs, e.g. narcotic drugs and class I psychotropic drugs are not permitted to be sold. The second category of psychotropic drugs should be sold in prescribed dosage according to the prescription issued by medical practitioners and should be kept for two years for reference. It is prohibited to sell psychotropic drugs of category 2 in excess of dosage or without prescription. The second type of psychotropic drugs may not be sold to minors. These regulations, formulated in accordance with the drug administration law and other relevant laws, strengthen the administration of narcotic drugs and psychotropic substances, ensure the legal, safe and rational use of narcotic drugs and psychotropic substances, and prevent their flow into illegal channels.

Use of biomedical techniques for the 'neuro-enhancement' of the non-sick person: ethical stakes[9]

[8] http://www.abhicodeofpractice.org.uk/multimedia/New%20Folder/ABHI%20Code%20of%20Business%20Practice%20V2%20-%20October%202016.pdf

[9] English: https://www.ccne-ethique.fr/sites/default/files/publications/ccne.avis_ndeg122eng.pdf

published by the National Ethics Consultative Committee for Life Sciences and Health in France (CCNE), 2013 (France)

The document is important as it emanates from a highly recognised ethics group in France. It can be useful as it provides an in-depth exploration of neuro-enhancement and presents the view of the CCNE on the ethical challenges of HET. The document concludes with recommendations (pp. 28 ff.). The CCNE points out that "the long-term risk-benefit ratio of neuroenhancement techniques is often unknown. In these situations, that means if a lack of knowledge and a potential risk co-exist, the CCNE advises in the strongest terms against the use by children, adolescents and vulnerable individuals. (p. 28). Furthermore, the CCNE thinks it is "essential that everyone, and members of the medical professions in particular, be adequately informed on the various issues involved in biomedical neuroenhancement so as to inform the debate on the role of physicians and of medicine in the face of this phenomenon" (p. 28).
Concerning the person and life in society, the CCNE recommends:

- To recognise the pressures on freedom of choice in the use of these technologies in the current context characterised by competition and performance.
- To recognise the risk of a reduction of human complexity.
- To recognise the importance of the sense of the self, a sense that cannot be reduced to its performance.
- And more generally, the document identifies the need to pursue ethical vigilance on these questions.

Code of Practice for the Pharmaceutical Industry[10]
published by the Association of the British Pharmaceutical Industry in 2016 (UK)

The Code covers, inter alia, aspects that present ethical issues such as, appropriate use of medicines, discredit to, and reduction of confidence in, the industry, marketing authorisations, prescribing information, disparaging references, high standards, format, suitability and causing offence, sponsorship, provision of reprints and the use of quotations, distribution of material, disguised promotion, clinical trials and non - interventional studies of marketed medicines, inducements and inappropriate payments, relationships and contracts with certain organisations , transfers of value to health professionals and healthcare organisations etc.
The code is well-formulated, it makes a connection with other Codes and legislation and is available in interactive format and PDF.

Opinion on the 'Enhancement' of human characteristics-natural characteristics
published by the National Committee of Bioethics in Greece, 2013 (Greece)

HET is seen in principle as a valid purpose. Aesthetic surgery is accepted, unless the patient suffers from diseases such as Body Dysmorphic Disorder or the purpose of the surgery is to help a criminal become unrecognizable. The conditions of ~~a~~ valid informed consent in aesthetic surgery are stricter.
The Committee suggests that a Code of Ethics in Aesthetic Surgery be compiled. The Committee lays down the terms of a valid enhancement of physical characteristics such as strength, skill, speed, punctuality in moving etc. In this case the use of artificial 'drugs' etc must be severely controlled by the

[10] http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf

authorities, and the person recommending the use bears responsibility. Third parties in the domain of sports must be protected against doping, as well as athletes who use these drugs.

Wish-fulfilling medicine
Published by the centrum voor Ethiek en Gezondheid in 2015 (Netherlands)

This document takes a different approach to HET by looking at it as wish-fulfilling medicine. It states the professional legal and financial frameworks. Recommendation: The government should hold back and only interfere if the medicine has exceeded the ethical boundaries or causes harm to the population. The government also has the responsibility to inform the public and provide transparency.

The Pharmacologically Improved Human. Performance-Enhancing Substances as a Social Challenge
published by the Office of Technology Assessment by the German Bundestag in 2013 (Germany)

Recommendations:

- With regard to research the question arises what investigational questions and objections are significant enough to be supported by public funding.
- With regard to regulation, it must be investigated whether the available statutory regulations and their procedural and institutional implementation appear appropriate.
- With regard to the current use of putative performance-enhancing agents, there is a need for unbiased consumer information, public healthcare, and workplace health and safety measures.
- With regard to the future debate, it must be asked whether and how societal debate and opinion formation can be actively promoted.

Ethical guidelines for pharmacists[11]
published by the Ethics Council established by the Swedish Federation of Swedish Medicines in 2013 (Sweden)
"The six ethical guidelines for pharmacists are based on the basic principles of biomedical ethics, which summarize the ethical core of a variety of normative documents of the above kind:

- Goodness principle: strive to do good, to prevent and reduce suffering.
- Human dignity principle: not to harm or kill, respect all people's equal value and human rights.
- Autonomy principle: respect others' right to privacy and self-determination).
- Justice principle: Equal cases should be treated equally, distributing goods fairly."

The principles can be discussed in the context of enhancement to see whether there are any enhancement issues not addressed here.

Responding to requests from adult patients for neuroenhancements. Guidance of the Ethics, Law and Humanities Committee[12]

[11] https://www.sverigesfarmaceuter.se/globalassets/2-dokument/kanslirelaterat/styrelse-fortroendevalda--rs/ovriga-engagerade/etikradet/etiska-riktlinjer-sveriges-farmaceuter.pdf
[12] https://n.neurology.org/content/neurology/early/2009/09/23/WNL.0b013e3181beecfe.full.pdf

published by the American Academy of Neurology's Guidance of the Ethics, Law and Humanities Committee in 2019 (USA)

The following challenges were stated: Authority for off-label prescribing, beneficience & nonmaleficence, respect for autonomy, conflicts of interest.
Solutions offered are: Issues are described and discussed. The solution offered is that physicians prescribing medications "have no obligation to do so and may ethically refuse to do so. Neurologists must exercise their clinical and ethical judgment to decide whether to prescribe medications for neuroenhancement. It is ethically permissible for neurologists to prescribe such therapies, provided that they adhere to well-known bioethical principles of respect for autonomy, beneficence, and nonmaleficence" (p6).
It is one of very few documents offering official guidelines on an HET issue for practicing physicians published by a professional organisation.
The document offers insight into current policy on neuroenhancement for adults.

Pediatric neuroenhancement: Ethical, legal, social, and neurodevelopmental implications[13]
published by the American Academy of Neurology in 2013 (USA)
Challenge: "the special fiduciary roles and obligations of the physician within doctor-child-parent relationships" and "physicians asked to prescribe pharmacologic neuroenhancement drugs for presumably healthy children and adolescents" (p2)
Solution: The issues are discussed at length, considering trends of use, development of pharmacological drugs, and more. The authors find "Physicians have the authority and the obligation to refuse requests for inappropriate treatment" (p6) and "at the present time that neuroenhancement in legally and developmentally nonautonomous children and adolescents is not justifiable. In nearly autonomous adolescents, the fiduciary obligation of the physician may be weaker, but the prescription of neuroenhancement is inadvisable because of numerous social and neurodevelopmental issues (p8).
The AAN is a large and highly influential academy in the United States.

2.4 Key findings

In the national and international search for professional ethics codes and documents from ethics advisory bodies we found a few HET specific documents and many documents which are applicable for HET in a broader sense.

In the documents we found different **forms of HET** are described. We cluster them as follows:

- Use of performance enhancing substances, brain doping, neuro-enhancement, cognitive enhancement,
- Physical enhancement, prosthetics, cosmetic surgery, aesthetic enhancement, doping in sports
- Enhancement of children
- Non-therapeutic gene editing
- Assisted human production

We found the most codes and recommendations for the use of performance enhancing drugs, followed by using HET for children. For cosmetic surgery and other aesthetic enhancement techniques we found only a few specific ethical codes and guidelines. The same applies for non-therapeutic gene editing.

[13] https://n.neurology.org/content/80/13/1251.full

In the documents identified in the national and in the international search, the following **ethical values and principles** are in focus:

- Health and well-being
- Beneficience
- Nonmaleficence
- No-harm
- Justice
- Self-determination
- Respect for autonomy
- Privacy
- Fairness and equity
- Non-discrimination
- Transparency
- Trust
- Security

In the relevant documents the following **ethical challenges** were addressed:

- Impacts on justice and fairness (unfair distribution)
- Missing long term risk-benefit-ratio
- Impacts on well-being
- Impacts on responsibility
- Impacts on autonomy
- Impacts on the society as a whole
- Difficulties to distinguish between therapeutic and non-therapeutic, ill and not-ill, medical and life-style enhancement

The codes we found all have a similar **target group**, mostly

- Physicians, including clinicians, surgeons, orthopaedic professionals
- Psychiatrists and Psychologists
- Pharmaceutical professionals, Member of pharmaceutical association
- Patients
- Parents
- Health professionals
- Researchers
- Research funders
- Sponsors and industry
- Policy makers
- General public, the society

3. Online survey with REC members

To determine to what extent representatives of RECs are aware of the three SIENNA areas of technologies and ethical issues associated with them, how they currently approach them, and if there are plans to more explicitly feature them (in guidelines for researchers), we developed and sent out an online survey. We decided to develop one survey for all three SIENNA areas together and worked out 18 questions. Most of them could be answered by multiple choice. The full list of questions and answers can be found in annex 3.

Based on the experience that there is a much higher response rate by online surveys, compared to questions send via email or in a document, we created an online survey via Google forms. With the time allotted to this task in view, we decided to send the online survey first only to the members of the European Network of Research Ethics Committees (EUREC). EUREC members have broad expertise in research ethics and come from different European countries, which guarantees a good geographic distribution. Sending the survey to EUREC members can be seen as a first round. For task 5.1 (the development of elements for operational guidelines for RECs beyond biomedical research) EUREC will conduct semi-structured interviews with REC members. EUREC will include the most important questions from the online survey in these semi-structured interviews. This shall lead to further insights.

The online survey was developed with Google forms in June/July 2018 and distributed by EUREC to its members in August 2018 by sending a link via email. Unfortunately, August is for many people summer holiday time, which is likely to have impacted ~~on~~ the response rate negatively. However, due to the deliverable's deadline of 1st October, we were not able to send out the survey earlier or later. The mail was sent to 30 EUREC members and 13 respondents completed the online survey (after a reminder).

The majority of the respondents were slightly aware of technologies in Human Genomics, Human Enhancement and AI & Robotics. A few REC members indicated they were fully aware of technologies in HG. No one was more than slightly aware of technologies in HET and AI&R. Furthermore, the majority of respondents were slightly aware of the ELSI relating to HG, HET and AI&R. Only a few of the REC members who participated described themselves as experts in all three SIENNA areas. The answers to the question "Does your REC address or offer any special guidance for researchers working in HG/HET/AI&R" showed that most RECs offer no special guidance (HG: 75% no, HET: 93% no, AI&R: 86% no).

One REC member stressed that guidance documents on how to assess research ethics protocols are not needed, since general principles of research ethics would apply in any case. Other members pointed to specific documents that have been developed by (national) committees on genomics.

To the question if there are any future plans to deal with the ELSI of HG, HET and AI&R we received the following answers. Please note that identifying details such as locations have been coded:

Human Genomics:

- "RECs normally have limited control on the researches submitted to them. The region around the [X] presents itself as the [important health area]. This is therefore likely that there will be increased research activities in this field. The REC will then adapt itself to this evolution (see remarks above)."
- "we have published guidelines"
- "We plan to help researchers to balance health needs and risks of high expectations, exploitation"

Human Enhancement:

- "It all depends on what is meant by human enhancement. Advance research is done on exoskeleton and repairing brain damages. There is also a lot of activities around doping. This is therefore likely that there will more activities in this field in the future (see remark on human genomics)."

AI & Robotics:

- "RECs normally have limited control on the researches submitted to them. The region around the [X] presents itself as the "important health area". This is therefore likely that there will be increased research activities in this field. The REC will then adapt itself to this evolution (see remarks above)."
- "[Y] is organising a symposium, specifically designed for members of the [country] ethics committees, on ethical, legal and social issues of artificial intelligence, in [Z] in 2018"
- "Topics like data protection and validation of research are more important in big data"

To the question if the REC members think there is a need to offer additional guidance for people doing research in HG/HET/AI&R we received the following feedback:

Human Genomics:

- "As recent (and past) history, most abuses do not happen due to a lack of norms but rather a lack of consideration for them and their underlying principles. Producing more norms has been a trend in research ethics and regulation since WWII. As Jay Katz said in 1969: "The proliferation of such codes testifies to the difficulty of promulgating a set of rules that does not immediately raise more questions than it answers. At this stage of our confusion, it is unlikely that codes will resolve many of the problems, though they may serve a useful function later. Even the much endorsed Declaration of Helsinki – praised, perhaps, because it is the newest and therefore the least examined – will create problems for those who wish to implement it".
- "There has been limited progress in raising the ethical mentality within research institutions. Of course, this would be less lucrative for ethics centers as the industry and others are less likely to finance virtues behaviour rather than workshops and other publications."
- "There is a need for the informed consent in this field"
- "risk management, realistic expectations"
- "Ethically difficult issue with rapid development"

Human Enhancement:

- "Not only the same remarks apply than for human genomics, but the very concept of "human enhancement" is at best confusing, at worst the entry door to totalitarianism. The very idea that humans need to be enhanced is worrying, especially if you refer to the previous time in history when similar proposals were formulated and, even worst, tested. As Hans Jonas said in 1969 (again), ""Let us not forget that progress is an optional goal, not an unconditional commitment, and that its tempo in particular, compulsive as it may become, has nothing sacred about it". The best guidance in fact would be to explain to researchers why "human enhancement" should be banned as a concept."
- "a guide for REC members regarding the ethical concerns such research projects may raise and possible approaches to deal with them could be useful"
- "The knowledge about these issues and their development is scarce. Identifying the ethical problems they pose is the first step"
- "risk Management, use and abuse,"
- "It is necessary to draw a line between enhancement and mere addiction to anything new"

AI & Robotics:

- "a guide for REC members regarding the ethical concerns such research projects may raise and possible approaches to deal with them could be useful"
- "The knowledge about these issues and their development is scarce. Identifying the ethical problems they pose is the first step"
- "consequences of automated decision support"
- "Quite dangerous research with unpredictable progress"

Furthermore, our last set of questions showed us that almost all respondents think that there is a need to offer additional education and training for REC members to learn more about the ELSI in HG, HET and AI&R.

4. Conclusion

The relevant documents we found will be a valuable resource for SIENNA's upcoming work, especially for tasks 5.3 (development of a professional code for HET) and 5.5 (enhancement of the ethical framework). We conclude that a lot of relevant codes and guidelines exist, which are usable for HET. There are some open questions we will have to decide upon before we can start the development of the SIENNA code(s) on HET (task 5.3):

Due to the fact that HET is located in a variety of research fields, there is a lack of professional organisations for HET and, furthermore, a lack of specific codes for HET. One possibility to close this gap could be to set up new umbrella organisations covering the field of HET. However, it is not clear if this is the right way. Do we really need HET specific professional organisations? Or rather, do we really need to close this gap?

Focus and content

A question which is strongly connected with the above mentioned is what should be in focus of the SIENNA code on HET? One possibility is to develop codes and guidelines with a broad focus, while another possibility is to develop codes and guidelines for different fields of HET, e.g. cognitive enhancement, physical enhancement, enhancement of children, gene editing. The HET specific recommendations we found all focus on specific fields. There is no code on HET in general and keeping in mind that HET covers a wide range of actions, it seems impossible to deal with the various ethical issues in one code. An option could be the development of a basic code applicable to all HET fields and special recommendations for each HET field.

Target group

Furthermore, we have to decide about the target group or rather the potential users of our code. As outlined above, the codes we found address either health professionals (like physicians, pharmacologists, psychiatrists) or researchers, or society as a whole or special vulnerable groups, e.g. parents (in the context of using HET for children). It is important to address all clusters of target groups. However, it is probably challenging to write one code for all clusters.

Values and principles

In the documents we found the same values and principles were mentioned, especially autonomy and self-determination, beneficence, non-maleficence, no-harm, fairness and justice. Should we base our codes on certain values and principles, as many codes we found are doing it? If yes, what are the most

important values and principles for us? And how should we implement these in our code? We have to find answers to these questions.
Beside this, we learned from the search that codes and guidelines need clear objectives. To have a positive effect, a code or a recommendation must be precise and useful. Furthermore, a code or a recommendation must be pragmatic. In the international search, codes were found that are not pragmatic enough and might present several difficulties in implementation. If a code is based on values and principles it needs some practical explanation to make its terminology clear and useful. There should be no room for varying interpretations of terminology. It is also important that the codes and recommendations must entail a plan on sustainability. In the search codes were found that have provisions for feedback and revision, in different formats. A similar plan could be considered.

Regarding our search for guidelines for REC members, we can conclude that there are no HET specific documents out there. Nevertheless, the responses to our online survey show that addressing the ELSI of HET would be supported by the large majority of respondents in the context of research ethics. Respondents were in agreement that additional education on the ELSI of HET would be helpful. We need to clarify in more detail how these trainings must look like and if RECs do need HET specific guidelines to review research in this field. We will do so in task 5.1.

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Annex 1: Country reports of the national search

The following summaries and reports were prepared by:

Country	Institution	Contruíbutor(s)
Brazil	Universidade Federal do Rio de Janeiro (UFRJ)	Marcelo de Araujo, Clara Dias
China	Dalian University of Technology (DUT)	LIU Hongzuo
France	Sciences Po Paris	Anaïs Rességuier
Germany	European Network of Research Ethics Committees (EUREC)	Lisa Tambornino, Dirk Lanzerath
Greece	Ionian University	Maria Bottis
Netherlands and USA	University of Twente (UT)	Tanne Ditzel, Philip Jansen, Sean R. Jensen
Poland	Helsinki Foundation for Human Rights (HFHR)	Zuzanna Warso
South Africa	University of Cape Town (UCT)	Jantina de Vries
Spain	University of Granada (UGR)	Javier Valls
Sweden	University of Uppsala	Heidi Howard, Emilia Niemiec
UK	Trilateral Research Ltd (TRI)	Rowena Rodrigues, David Wright

Table 3: List of contributors for the country reports

Brazil

Over the last few years, there have been some reports in the press about the widespread use of Ritalin (methylphenidate) and Stavigile (modafinil) among Brazilian students. In a television interview in 2015, one police officer went as far as to state that the illegal trade of Ritalin had become more difficult to deal with than the traffic of cocaine.14 Concern over the emergence of "designer babies" in the future has also often been reported in the Brazilian press, after a team of Chinese scientists published a paper on the use of CRISPR on human embryos in 2015. And the increasing use of AI systems in a variety of applications, which has the potential to augment our cognitive and physical capacities in the future, has been the subject matter of stories published in the press or on television. However, in Brazil, outside of the academic debate, there has not been a systematic attempt to correlate these phenomena and to understand them in terms of different forms of "human enhancement". Maybe for this reason the expression "human enhancement" has currently no standard counterpart in Brazilian Portuguese. In the academic debate it has been translated as "aprimoramento", "aperfeiçoamento", or sometimes also as "melhoramento humano". And because the quest for HET has not been publicly perceived as a social phenomenon in its own right, which raises a variety of legal and ethical issues, neither policy makers nor professional associations have felt the urge to publish documents with guidelines for regulation or recommendations in this area. Some documents do indeed refer to the threat of "eugenics", or the perils involving the use of medicines for non-therapeutic purposes, but no systematic attempt to comprehend and to define the quest for HET has been detected in the NAEG, GDREP, PEC, and REC documents that we have gathered for this report.

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Names and emails of persons who did the work (if different from above)	Dr. Marcelo de Araujo / Dr. Maria Clara Dias
Your organisation	UFRJ – Universidade Federal do Rio de Janeiro
Your country (again)	Brazil
Search conducted in which language	Portuguese
Acknowledgements (any researcher who helped you to complete this task)	Fabiana Pompermayer (UFRJ, Doctoral Candidate in Bioethics & Health Policy)

[14] JORNAL DA GLOBO. (4 July 2015) "Polícia Federal está de olho nas compras irregulares de ritalina". Available at: http://g1.globo.com/jornal-da-globo/noticia/2015/07/policia-federal-esta-de-olho-nas-compras-irregulares-de-ritalina.html

TABLE 2: LIST OF ALL RELEVANT PROFESSIONAL ETHICS CODES

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments
HG / HET / AI&R	Rigor e Integridade na Condução da Pesquisa Científica - Guia de Recomendações de Práticas Responsáveis (Rigour and Integrity in the Pursuit of Scientific Research. A Guide with Recommendations for Responsible Practices)	http://www.abc.org.br/IMG/pdf/doc-4559.pdf [13p.]	2013	ABC – Academia Brasileira de Ciências http://www.abc.org.br (Brazilian Academy of Sciences)	Researchers; doctoral and postdoctoral students	Very general. The document does not address specific question relative to the responsible use of HG, HET, AI&R.
HET	Código de Ética Profissional da Associação Brasileira de Ortopedia Técnica (Profissional Ethics Code of the Brazilian Association of Technical Orthopedics)	http://www.abotec.org.br/ilustracoes/codigodeeticaprofissional-abotec.pdf [9p.]	2007	ABOTEC – Associação Brasileira de Ortopedia Técnica http://www.abotec.org.br (Brazilian Association of Technical Orthopedics)	Orthopaedic professionals	The document does indeed exhort orthopedics professionals to "to fight for the technological and scientific development of the orthopedic profession" (Chapter II, art. 2, § v). But the document does not mention the use of prosthetic limbs as a possible means of HET.
HG / HET	Resolução nº 2, de 5 de março de 2002 - "Aprova o Código de Ética do Profissional Biólogo"	http://www.cfbio.gov.br/artigos/RESOLUcaO-N%C2%BA-2-DE-5-DE-MARcO-DE-2002 [web page]	2002	Conselho Federal de Biologia – CFBio (Brazilian Council of Biology)	Biologists; biology researchers	The document is very general, but explicitly forbids eugenic experiments (Chapter 5, art. 22). The document

	(Resolution nº 2, 5 March 2002 "Approves the Ethical Code of the Professional Biologist)					also recommends the use of the "precautionary principle" with genetically modified organisms (Chapter 5, art. 21).
HG / HET	Código de Ética da Profissão de Biomédico (Ethics Code of the Biomedicine Professionals)	http://cfbm.gov.br/legislacao/codigo-de-etica-da-profissao-de-biomedico/ [web page]	2011	CFBM – Conselho Federal de Biomedicina (Brazilian Federal Council of Biomedicine)	Biomedicine professionals	The document is very general, but explicitly forbids eugenic experiments (Chapter 3, xi)
HET	[document 1] Código de Ética da Profissão Farmacêutica (Ethical Code of the Pharmaceutical Profession) [document 2] Resolução nº 596 de 21 de fevereiro de 2014. (Resolution nº 596, 21 February 2014)	[document 1] http://www.cff.org.br/userfiles/file/Código%20de%20Etica%2003fev2014.pdf [56p.] [document 2] http://www.cff.org.br/userfiles/file/resolucoes/596.pdf [24p.]	2014	CFF – Conselho Federal de Farmácia http://www.cff.org.br (Brazilian Federal Council of Pharmacy)	Pharmaceutical professionals	Document 1 explicitly forbids "eugenic" experiments (Chapter IV, art. 14, I). It also forbids the promotion or commercialization of substances for non-therapeutic purposes (Chapter IV, art. 14, XXXVI). Document 2 does not substantially differ from Document 1.
HG / HET	Código de Ética Médica. (Code of Medical Ethics)	https://portal.cfm.org.br/images/stories/biblioteca/codigo%	2009	CFM – Conselho Federal de Medicina http://portal.cfm.org.br	Physicians, including clinicians;	This is an important document. It specifically addresses issues relative

		20de%20etica%20medica.pdf [74p.] Also available at: http://www.portalmedico.org.br/novocodigo/integra_1.asp [web page]		(Brazilian Federal Council of Medicine)	surgeons; psychiatrists	to informed consent, eugenics, and genetic modification of human embryos (Chapter 3, art. 15). It forbids non-therapeutic gene editing. It also forbids germline modification for whatever purposes (Chapter 3, art. 16).
AI&R / HET	Código de Ética dos Profissionais das Técnicas Radiológicas (Code of Ethics of Radiology Professionals)	http://conter.gov.br/uploads/legislativo/codigodeetica.pdf [14p.]	2011	CONTER – Conselho Nacional de Técnicos em Radiologia http://conter.gov.br (National Council of Radiology Professionals)	Radiology professionals	The document is very general and does not mention, for instance, fMRI or its possible use in the domain of brain machine interface research.

TABLE 3: LIST OF ALL RELEVANT DOCUMENTS FROM NATIONAL ADVISORY/ETHICS GROUPS

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments
HET	Código Brasileiro Antidopagem	http://www.abcd.gov.br/arquivos/Cdigo_Brasileiro_Antidopagem_Retificado(1).pdf [94p.]	2016	ABCD – Autoridade Brasileira Controle de Dopagem	Professional athletes; sport association	Forbids the use of performance enhancing substances. Athletes who need substances that have the

	(Brazilian Anti Doping Code)			http://www.abcd.gov.br/legislacao (Brazilian Anti Doping Authority)	s, coachers, etc.	potential for performance enhancement must apply for a TUE (Therapeutic Use Exemption).
HG / HET	1° Relatório de Amostras Seminais para uso em Reprodução Humana Assistida (1st report on seminal samples for assisted human reproduction)	http://portal.anvisa.gov.br/documents/33840/3484451/1%C2%B0+Relat%C3%B3rio+de+Importa%C3%A7%C3%A3o+de+Amostras+Seminais+para+uso+em+Reprodu%C3%A7%C3%A3o+Humana+Assistida/33c91fcf-18bb-4825-b659-a8a45053113f [19p.]	2017	ANVISA – Agência Nacional de Vigilância Sanitária http://portal.anvisa.gov.br (National Sanitary Surveillance Agency)	Policy makers; clinicians; fertility clinic; press; public at large	The document shows that between 2011 and 2016 the importation of seminal samples for assisted reproduction increased in 2.625% in Brazil.
HG / HET	Resolução CFM nº2.168/2017 (Resolution CFM nº2.168/2017)	https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2017/2168 [10p.]	2017	CFM – Conselho Federal de Medicina http://portal.cfm.org.br (Brazilian Federal Council of Medicine)	Physicians; professionals working in fertility clinics	This is an important document. It establishes ethical guidelines for assisted human reproduction. It forbids non-therapeutic use of IVF and sex selection (see Part 1, §2, art. 5).
HG / HET	Resolução nº 466, de 12 de dezembro de 2012	http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf [12p.]	2012	CNS – Conselho Nacional de Saúde http://conselho.saude.gov.br	Physicians; clinicians; surgeons; researchers	The document establishes ethical guidelines for research with human beings, including research on assisted human reproduction, IVF, biobanks,

	(Resolution nº 466, 12 December 2012)			(Brazilian National Council of Health)		iPSCs. It does not directly address HET.
HG / HET	Resolução Normativa nº 16, de 15 de janeiro de 2018 (Normative Resolution nº 16, January, 2018)	http://www.mctic.gov.br/mctic/opencms/legislacao/outros_atos/resolucoes/Resolucao_Normativa_CTNBio_n_16_de_15012018.html [web page] also available at: https://goo.gl/KtveFN [web page]	2018	CTNBio – Comissão Técnica Nacional de Biossegurança http://ctnbio.mcti.gov.br (National Technical Board on Biosecurity)	Researchers and entrepreneurs in the domain of biotechnology	This document establishes rules for the use genome editing tools such as CRISPR.

TABLE 4: LIST OF ALL RELEVANT GUIDANCE DOCUMENTS ON HOW TO WRITE RESEARCH ETHICS PROTOCOLS

Name of national REC	Title of document (original + English translation)	URL	Year	Stated audience	comments
Sistema CEP-CONEP http://plataformabrasil.saude.gov.br/login.jsf (CEP-CONEP-System) CEP = Comitê de Ética na Pesquisa (Research Ethics Committee)	Norma Operacional nº 001/2013 (Operational Norm nº 001/2013)	http://conselho.saude.gov.br/Web_comissoes/conep/aquivos/CNS%20%20Norma%20Operacional%20001%20-%20conep%20finalizada%2030-09.pdf [17p.]	2013	CNS – Conselho Nacional de Saúde http://conselho.saude.gov.br (Brazilian National Council of Health)	This document describes procedures that govern work performed within the CEP-CONEP-System as a whole. This document builds on Resolution nº 446, August, 2011, which is listed below.

CONEP = Comissão Nacional de Ética em Pesquisa (National Board for Research Ethics) The local CEPs are ruled by CONEP, which is a section of the CNS – Conselho Nacional de Saúde http://conselho.saude.gov.br (Brazilian National Council of Health) CNS is a section of the "Ministério da Saúde" (Ministery of Health) http://portalms.saude.gov.br An updated directory of current RECs in Brazil can be accessed by following the link "Consultar Comitê de Ética em Pesquisa" at: http://plataformabrasil.saude.gov.br/login.jsf	Manual Operacional para Comitês de Ética em Pesquisa (Operational Handbook for Research Ethics Committees)	http://conselho.saude.gov.br/biblioteca/livros/manual_operacional_miolo.pdf [138p.]	2007	CNS – Conselho Nacional de Saúde http://conselho.saude.gov.br (Brazilian National Council of Health)	This document is a handbook of principles and procedures for writing ethics protocols.
	Resolução CNS nº 441, de 12 de maio de 2011. (Resolution CNS nº 441, May 2011)	http://conselho.saude.gov.br/resolucoes/2011/Reso441.pdf [4p.]	2011	CNS – Conselho Nacional de Saúde http://conselho.saude.gov.br (Brazilian National Council of Health)	This document establishes ethical guidelines for the ethical assessment of research projects that involve the use of biobanks.
	Resolução nº 446, de 11 de agosto de 2011 (Resolution nº 446, August, 2011)	http://plataformabrasil.saude.gov.br/login.jsf [6p.] [There is no direct link to the PDF file. Please follow link for "Resolução e Normativas]	2011	CNS – Conselho Nacional de Saúde http://conselho.saude.gov.br (Brazilian National Council of Health)	This document describes procedures that govern work performed within the CEP-CONEP-System as a whole.
	Resolução nº 340, de 8 de julho de 2004 (Resolution nº 340, de 8 de julho de 2004)	http://plataformabrasil.saude.gov.br/login.jsf [5p.] [There is no direct link to the PDF file.	2004	CNS – Conselho Nacional de Saúde http://conselho.saude.gov.br (Brazilian National Council of Health)	This document establishes ethical guidelines for the ethical assessment of research projects in HG.

		Please follow link for "Resolução e Normativas]			

TABLE 6: MOST RELEVANT DOCUMENTS IN HET [Document 1]

Document found via (national associations or Google or another database)	Google	
Title of document	Código de Ética da Profissão Farmacêutica (Ethical Code of the Pharmaceutical Profession)	
Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	CFF – Conselho Federal de Farmácia (Brazilian Federal Council of Pharmacy)	
Year the document was published (between 2005-2018)	2014	
Document saved in folder as	SIENNA X.3 BRAZIL - Table 2 - CFF 2014 - Ethical Code of the Pharmaceutical Profession.pdf	
Who is the stated audience	Pharmaceutical professionals	
Which definition of enhancement is used in the document?	No specific definition is provided. The document only refers to non-therapeutic use of substances and raises concern over issues related to eugenics.	
Which forms of enhancement are described in the document?	None	
Which targets of enhancement are described (what is enhanced)?	Not specified	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering	☐ Other, please specify:

	☐ genetic engineering ☐ Prosthetics	
Which motivations/intentions of enhancement are described?	Not specified	
Which life stage is addressed in the document?	Not specified	
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☒ Others: Not specified	
Which ethical challenges are addressed in the document?	Not specified	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Not specified	
Which format is used in the document (checklist, continuous text, other)?	Continuous text	
How is the document structured?	Chapter, section, subsection	
Why is the document important/useful for your country?	It is one of the few documents that raises concerns over the non-therapeutic use of pharmaceutical substances. But it does not explicitly refer to HET.	
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. The document may be compared to other documents, which rule the work of pharmaceutical professionals in other countries.	

TABLE 6: MOST RELEVANT DOCUMENTS IN HET [Document 2]

Document found via (national associations or Google or another database)	Google	
Title of document	Código de Ética Médica (Code of Medical Ethics)	
Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	CFM – Conselho Federal de Medicina (Brazilian Federal Council of Medicine)	
Year the document was published (between 2005-2018)	2009	
Document saved in folder as	SIENNA X.3 BRAZIL - Table 2 - CFM 2009 - Code of Medical Ethics.pdf	
Who is the stated audience	Physicians, including clinicians; surgeons; psychiatrists	
Which definition of enhancement is used in the document?	No specific definition is provided. The document only refers eugenics, and genetic modification of human embryos (Chapter 3, art. 15).	
Which forms of enhancement are described in the document?	None	
Which targets of enhancement are described (what is enhanced)?	Not specified	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Not specified	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal	

Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☒ Others: Not specified
Which ethical challenges are addressed in the document?	Not specified
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Not specified
Which format is used in the document (checklist, continuous text, other)?	continuous text
How is the document structured?	Chapter, section, subsection
Why is the document important/useful for your country?	It is one of the few documents that explicitly raise concerns of the prospect of eugenics through biotechnology.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, as an example of a ethics codes in an area that differs substantially from country to country as far as its regulation is concerned.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET [Document 3]

Document found via (national associations or Google or another database)	Google
Title of document	1° Relatório de Amostras Seminais para uso em Reprodução Humana Assistida (1st report on seminal samples for assisted human reproduction)
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	ANVISA – Agência Nacional de Vigilância Sanitária (National Sanitary Surveillance Agency)
Year the document was published (between 2005-2018)	2017
Document saved in folder as	SIENNA X.3 BRAZIL - Table 3 - ANVISA 2017 - Report for Assisted Human Reproduction.pdf
Who is the stated audience	Policy makers; clinicians; fertility clinic; press; public at large

Which definition of enhancement is used in the document?	No specific definition of enhancement is provided.	
Which forms of enhancement are described in the document?	Genetic enhancement via selection of features of sperm donors	
Which targets of enhancement are described (what is enhanced)?	Cognitive enhancement, physical enhancement, aesthetic enhancement	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ Tissue engineering ☐ genetic engineering ☐ Prosthetics	☒ Other, please specify: Genetic enhancement via selection of features of sperm donors
Which motivations/intentions of enhancement are described?	Not specified	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☒ Prenatal	
Which context is addressed?	☒ Private life ☐ Employment ☐ Military ☒ Others: family building	
Which ethical challenges are addressed in the document?	The document shows that between 2011 and 2016 the importation of seminal samples for assisted reproduction increased in 2.625% in Brazil. The commercialization of human seminal samples is forbidden in Brazil, but its importation from foreign sperm banks is not. As the report shows, an increasing number of women are resorting to foreign sperm banks, such as Fairfax Cryobank, which lists a wide range of features that are attributed to the sperm donors (eye color, height, level of educations, etc). The American sperm bank	

	Fairfax Cryobank has now a website in Portuguese for its Brazilian clients (https://fairfaxcryobank.com). Although HET per se is not mentioned in the report, it is clear that prospective parents, mostly women, use the information provided by the sperm bank in order to select for donors with enhanced features (highest educational level, for instance).
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The report, as such, does not propose normative measures to rule the practice of assisted human reproduction. This is a task incumbent on CFM (Brazilian Federal Council of Medicine). See Resolution CFM nº2.168/2017, mentioned in Table 5 (document 2).
Which format is used in the document (checklist, continuous text, other)?	Report
How is the document structured?	Text, graphics, bullet points, and list of references at the end.
Why is the document important/useful for your country?	There was no systematic survey on the profile of prospective parents who currently resort to foreign sperm banks that operate in Brazil for the purpose of assisted reproduction before the publication of this document.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, the document deals with a form of HET that is not usually recognised as such.

China

In China, HET is often discussed in the academic field. Experts and scholars defined and classified HET, and also investigated its ethical issues. Although HET is receiving more and more concern, there seems to be no organisation or association established for it, or any official documents or policies to regulate it. Drug, biomedicine and cutting-edge medical technology are the three approaches to facilitate HET; therefore, it is necessary to focus on the relevant policies and regulatory documents.

First of all, China has issued relevant laws and policies to supervise and manage employees from the professional ethics level. In order to guarantee the quality of drugs, provide qualified drugs, carry out pharmaceutical services, and spare no effort to maintain the safety and effectiveness of public medication, the China Pharmaceutical Association has formulated the Convention on Professional Ethics for Members of the Chinese Pharmaceutical Association. Chinese Medical Doctor Association conducts a systematic and comprehensive evaluation on the technical characteristics, safety, effectiveness, economic characteristics and social adaptability (society, law, ethics and politics) of health technology (including drugs and medical devices) in the Management Methods of Health Technology Assessment. The State Council of the People's Republic of China classifies and prescribes the use and dosage of psychotropic drugs in the Regulations on Management of Narcotic Drugs and Psychotropic Substances. It is clearly stated that a prescription must be issued by a licensed physician and that the second type of psychotropic drug may not be sold to minors. Although the above document does not directly mention HET, the regulations on the safety and effectiveness of technology, risk avoidance, etc. can also apply to the management and regulation of HET.

Second of all, a series of documents released by the relevant authorities in China have potentially played a role in regulating HET. In order to protect the legitimate rights and interests of the subjects, safeguard the dignity of the subjects and promote the development of biomedical research, National Health Commission of the People’s Republic of China has issued the Measures for the Ethical Review of Biomedical Research Involving Human Beings. Six ethical principles should be clearly stated in the document. China Food and Drug Administration has formulated policies and regulations on the rights and interests of subjects in the Specification for Quality Management of Clinical Trials of Drugs. Ministry of Health of the People's Republic of China, in the Management Method of Clinical Application of Medical Technology, has controlled and managed medical technologies that limit their clinical application (involving major ethical issues; High risk, safety and effectiveness need to be verified; Scarce resources are needed). China Food and Drug Administration has specified the content and principles of the review of drug clinical trial programs conducted by the ethics committee in the Guiding Principles for Ethical Review of Drug Clinical Trials, aiming at ensuring the dignity, safety and rights of the subjects and enhancing public trust and support for drug clinical trials.

It can be seen that although China does not have relevant laws and policies about HET, corresponding ethical review regulations have been issued for biomedical research and human research. Clinical trials of drugs are also governed by ethical regulations. HET is in China often understood as the intervention in the cognition, emotion and physical ability of healthy subjects through biomedicine, drugs and emerging medical technology. In the documents found in

the national search for China, the protection or regulation of stakeholders and the hierarchical and classified management of various medical technologies and drugs are forward-looking avoidance of many ethical issues involved in HET, which cannot be ignored.

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Names and emails of persons who did the work (if different from above)	LIU Hongzuo
Your organisation	Dalian University of Technology
Your country (again)	China
Search conducted in which language	Chinese and English
Acknowledgements (any researcher who helped you to complete this task)	WANG Qian

TABLE 2: LIST OF ALL RELEVANT PROFESSIONAL ETHICS CODES

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments
HET	Ethical Review of Biomedical Research Involving Human Beings	http://www.nhfpc.gov.cn/fzs/s3576/201610/84b33b81d8e747eaaf048f68b174f829.shtml	2016	National Health Commission of the People's Republic of China	Researchers, practitioners	This method is applicable to all kinds of medical and health institutions at all levels to conduct ethical review of biomedical research involving human beings, including experimental research on new medical technologies or new medical products in human bodies, and may include HET.
HET	Convention on Professional Ethics of	http://www.cpa.org.cn/?do=info&cid=71335	2005	Chinese Pharmeceutical Association	Member of pharmaceuti	It is a convention used to regulate pharmaceutical practitioners.

	Members of China Pharmaceutical Association				cal association	
HET	Management Methods of Health Technology Assessment	http://www.cmda.net/glzd/5104.jhtml	2009	Chinese Medical Doctor Association	Researchers, Sponsor, policy makers	It is a systematic and comprehensive assessment of the technical characteristics, safety, effectiveness, economic characteristics and social adaptability (society, law, ethics, politics) of health technologies (including drugs and medical devices). It may involve HET.

TABLE 3: LIST OF ALL RELEVANT DOCUMENTS FROM NATIONAL ADVISORY/ETHICS GROUPS

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments
HET	Management Methods of Clinical Application of Medical Technology	http://www.nhfpc.gov.cn/mohyzs/s3585/200903/39511.shtml	2009	Ministry of Health of the People's Republic of China	Medical institutions and practitioners	Although there is no specific mention of HET, the restricted application medical technology, which involve serious ethical controversies, high-risks, unverified safety and effectiveness issues, as well as using scarce resources, such as, gene chip diagnosis, osteotomy and augmentation surgery etc,

						have been strictly controlled and regulated.
HET	Guiding Principles for Ethical Review of Drug Clinical Trials	http://www.zs-hospital.sh.cn/lcsy/101119.htm	2010	China Food and Drug Administration	Researchers, practitioners	It stipulates the content and principles of the ethical review of drug clinical trials by the ethics committee, aimed at guaranteeing the dignity, safety and rights of the subjects and enhancing public trust and support for drug clinical trials. The aspects related to drug enhancement in HET can be used for reference.
HET	Specification for Quality Management of Clinical Trials of Drugs	http://samr.cfda.gov.cn/WS01/CL1031/24473.html	2003	China Food and Drug Administration	Investigator, Sponsor, Monitor	Although it does not directly refer to HET, but clinical trials, human bioavailability or bioequivalence tests should be carried out in accordance with this code.
HET	Ethical Principles of Human Assisted Reproductive Technology and Human Sperm Bank	https://law.lawtime.cn/d647671652765.html	2003	Ministry of Health of the People's Republic of China	practitioners	It stipulates the ethical principles that human sperm bank should follow, involving genetic enhancement technology.
HET	Regulations on Management of Narcotic Drugs and Psychotropic Substances	http://www.nhfpc.gov.cn/mohzcfgs/pfg/200903/39556.shtml	2005	the State Council of the People's Republic of China	Researchers, practitioners, manufacturer	Although there is no direct mention of HET, it is stipulated that clinical trials of narcotic drugs and psychotropic substances of the first category should not be conducted on

						healthy subjects, indirectly related to HET.
HET	Interim Management Method of Human Genetic Resources	http://www.most.gov.cn/bszn/new/rlyc/wjxz/200512/t20051226_55327.htm	2005	Ministry of Science and Technology of the People's Republic of China	Researchers, policy makers	The collection, research, development, trading, export and exit of human genetic resources in China are regulated, which is indirectly related to the management of gene enhancement.
HET	Management Methods of Prenatal Diagnosis Technology	http://www.moh.gov.cn/mohzcfgs/s3577/200804/17612.shtml	2003	Ministry of Health of the People's Republic of China	Medical institutions and practitioners	Although it does not directly refer to HET, it is emphasized that prenatal diagnostic technologies could not be implemented for non-medical purposes. It indirectly relates to gene enhancement.

TABLE 4: LIST OF ALL RELEVANT GUIDANCE DOCUMENTS ON HOW TO WRITE RESEARCH ETHICS PROTOCOLS

Name of national REC	Title of document (original + English translation)	SIENNA area	URL	Stated audience	comments
Beijing Municipal Commission of Health and Family Planning	Interim Management Method of Human Research in Beijing	HET	http://www.bjchfp.gov.cn/zwgk/fgwj/gfxwj/201612/t20161221_203498.htm	Researchers, practitioners	Due to the fact that HET directly affects human body, the nine standards in the management methods that are not approved for human research are considered as reference.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET （1）

Document found via (national associations or Google or another database)	National advisory organisation (National Health Commission of the People's Republic of China's website)	
Title of document	Ethical Review of Biomedical Research Involving Human Beings	
Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	National Health Commission of the People's Republic of China	
Year the document was published (between 2005-2018)	2016	
Document saved in folder as		
Who is the stated audience	Researchers, practitioners	
Which definition of enhancement is used in the document?	No definitions are offered.	
Which forms of enhancement are described in the document?	The enhancement of people's physiology and psychology through biomedicine	
Which targets of enhancement are described (what is enhanced)?	Improvement of physical ability ,cognitive function, control of emotion/affect	
Which means/methods/tools of enhancement are described?	☑ Pharmacology ☑ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:

Which motivations/intentions of enhancement are described?	The improvement of physical and psychological ability	
Which life stage is addressed in the document?	☑ Adults ☑ Elderly ☑Minors (children and adolescents) ☐Prenatal	
Which context is addressed?	☑Private life ☑ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	When a new medical technology or a new medical product conducts experimental research on humans, it involves issues including subjects' dignity, autonomy, health and safety, justice and equality, as well as issues of conflicts of interest and social impacts	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The solutions are proposed, including setting up ethics committees, protecting subject's legal rights and interests, maintaining the dignity of the subjects, promoting standardized conduct of biomedical research. Six ethical principles should be followed in the ethical review, which are principles of informed consent, risk control, free charging and incentive, privacy protection, legal compensation, and special protection principle.	
Which format is used in the document (checklist, continuous text, other)?	Continuous text	
How is the document structured?	Chapters & sections	
Why is the document important/useful for your country?	This document issued by the national authoritative organisation. It has systematically and detailedly managed and supervised the biomedical research from the aspects of ethical committee, ethical review, informed consent, supervision and management, and legal liability. It has avoided the ethical problems involved, analyzed the risks and solved the problems in advance. It has great significance to the biomedical research in China.	

	It is the first time to regulate human biomedical research from the legislative perspective of national administrative regulations. All medical institutions engaging in biomedical research involving human beings are required to act as the subject of responsibility, and an ethics committee must be established to fully protect the subjects and ensure the quality of the research.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. Although this document does not directly refer to HET, it clearly states in the general provisions that "new medical technologies or new medical products' activities in human trials and studies" should comply with this document. In particular, the establishment standards of the ethics committee and the division of supervision have been explained in detail, and the interpretation of the six ethical principles has important value as reference.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET （2）

Document found via (national associations or Google or another database)	**National advisory organisation (Ministry of Health of the People's Republic of China's website)**
Title of document	Management Methods of Clinical Application of Medical Technology
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	Ministry of Health of the People's Republic of China
Year the document was published (between 2005-2018)	2009
Document saved in folder as	
Who is the stated audience	Medical institutions and practitioners
Which definition of enhancement is used in the document?	No definitions are offered.
Which forms of enhancement are described in the document?	Cosmetic enhancements
Which targets of enhancement are described (what is enhanced)?	Increase body height

Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☑Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Change appearance, increase body height	
Which life stage is addressed in the document?	☑ Adults ☐ Elderly ☑Minors (children and adolescents) ☐Prenatal	
Which context is addressed?	☐Private life ☑ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	The technology with high risk and unverified safety and effectiveness issues, and those need use scarce resources should be oversight.	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Before medical technologies that limit their clinical application is applied to clinic for the first time, the safety, along with the study, demonstration and ethical reviews of effective clinical trials must be conducted by the Ministry of Health organisation.	
Which format is used in the document (checklist, continuous text, other)?	Continuous text	
How is the document structured?	Chapters & sections	
Why is the document important/useful for your country?	Ministry of Health of the People's Republic of China is an authoritative national health institution. The classified management of medical technology can promote the development of medical science and medical technology, improve medical quality and ensure medical safety.	

Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. A way to enhance human technology is through clinical trials of biomedicine and medical technology. The management method of medical technology has reference value for it, In particular, this document management medical technology is conducted according to safety, effectiveness and the size of ethical issues involved.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET （3）

Document found via (national associations or Google or another database)	National advisory organisation (China Food and Drug Administration's website)	
Title of document	Guiding Principles for Ethical Review of Drug Clinical Trials	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	China Food and Drug Administration	
Year the document was published (between 2005-2018)	2010	
Document saved in folder as		
Who is the stated audience	Researchers, practitioners	
Which definition of enhancement is used in the document?	No definitions are offered.	
Which forms of enhancement are described in the document?	Enhancements through drugs.	
Which targets of enhancement are described (what is enhanced)?	Through the drug to achieve cognitive, emotional, physical enhancement	
Which means/methods/tools of enhancement are described?	☑ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering	☐ Other, please specify:

	☐ Prosthetics	
Which motivations/intentions of enhancement are described?	Through the drug to achieve cognitive, emotional, physical enhancement	
Which life stage is addressed in the document?	☑ Adults ☑ Elderly ☑Minors (children and adolescents) ☐Prenatal	
Which context is addressed?	☑Private life ☑ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	There are issues of risk and benefit, medical care and protection of the subjects, privacy and confidentiality, special protection for vulnerable groups, people with special diseases and people in specific areas.	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Evaluation of expected benefits: benefits to subjects and to society. The reasonableness of experimental risk and benefit is evaluated. Measures to ensure the confidentiality and safety of the subject's information. Where the trial is not likely to provide direct benefit to vulnerable subjects, the trial risk shall generally not be greater than the minimum risk unless the ethics committee agrees that the risk level may be slightly increased. When the subject cannot give full informed consent, he/she shall obtain the informed consent of his/her legal agent and, if possible, the consent of the subject himself/herself.	
Which format is used in the document (checklist, continuous text, other)?	Continuous text	
How is the document structured?	Chapters & sections	
Why is the document important/useful for your country?	The duties and requirements of the ethics committee are specified in detail. In article 28, chapter 5, the main content of the ethical review is provided, which covers a wide range of aspects and guarantees the quality of the ethical review.	

Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. Although this document does not directly refer to HET, the ethical review of drug clinical trials is very concrete. As HET inevitably involves the use of drugs, it can be used for reference to develop HET ethical review guidance.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET （4）

Document found via (national associations or Google or another database)	National advisory organisation (Policy and Regulation Department's website)	
Title of document	Regulations on Management of Narcotic Drugs and Psychotropic Substances	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	the State Council of the People's Republic of China	
Year the document was published (between 2005-2018)	2005	
Document saved in folder as		
Who is the stated audience	Researchers, practitioners, manufacturer	
Which definition of enhancement is used in the document?	No definitions are offered.	
Which forms of enhancement are described in the document?	Neuro enhancement	
Which targets of enhancement are described (what is enhanced)?	Cognitive skills, memory and emotion/affect	
Which means/methods/tools of enhancement are described?	☑Pharmacology ☑Neurotechnology ☐Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐genetic engineering ☐ Prosthetics	☐ Other, please specify:

Which motivations/intentions of enhancement are described?	Increased cognitive function, Improved memory, control of emotion/affect	
Which life stage is addressed in the document?	☑ Adults ☑ Elderly ☑ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☑Private life ☐ Employment ☑ Military ☐ Others:	
Which ethical challenges are addressed in the document?	The abuse of psychotropic drugs has caused or may cause serious harms for individuals and society.	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Article 13, Chapter 2 indicates that the clinical trials of narcotic drugs and class I psychotropic drugs should not be conducted by healthy subjects. There are detailed regulations on the cultivation, experimental research, production, marketing, use and storage of drugs. (e.g. Narcotic drugs and class I psychotropic drugs are not permitted to be sold. The second category of psychotropic drugs should be sold in prescribed dosage according to the prescription issued by medical practitioners and should be kept for 2 years for reference. It is prohibited to sell psychotropic drugs of category 2 in excess of dosage or without prescription. The second type of psychotropic drugs may not be sold to minors.)	
Which format is used in the document (checklist, continuous text, other)?	Continuous text	
How is the document structured?	Chapters & sections	
Why is the document important/useful for your country?	These regulations, formulated in accordance with the drug administration law and other relevant laws, strengthen the administration of narcotic drugs and psychotropic substances, ensure the legal, safe and rational use of narcotic drugs and psychotropic substances, and prevent their flow into illegal channels.	

Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. It is inevitable that the use of neuronal drugs will be involved in the process of neuronal enhancement. Drug abuse is likely to lead to addiction of healthy subjects and excessive dependence on neuronal drugs in both physical and psychological aspects. This document regulates drug abuse in various aspects and can serve as a regulation for HET.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET （5）

Document found via (national associations or Google or another database)	National advisory organisation (National Health Commission of the People's Republic of China's website)	
Title of document	Ethical Principles of Human Assisted Reproductive Technology and Human Sperm Bank	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	Ministry of Health of the People's Republic of China	
Year the document was published (between 2005-2018)	2003	
Document saved in folder as		
Who is the stated audience	practitioners	
Which definition of enhancement is used in the document?	No definitions are offered.	
Which forms of enhancement are described in the document?	Genetic enhancement	
Which targets of enhancement are described (what is enhanced)?	Genetic traits	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☑ genetic engineering ☐ Prosthetics	☐ Other, please specify:

Which motivations/intentions of enhancement are described?	Protect the health and rights of individuals, families and future generations of sperm donors and recipients, and safeguard social welfare.
Which life stage is addressed in the document?	☑ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal
Which context is addressed?	☑ Private life ☐ Employment ☐ Military ☐ Others:
Which ethical challenges are addressed in the document?	It leads to commercialization and the widening gap between rich and poor. Confidentiality and privacy issues.
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The ethical principle that human sperm bank should follow are proposed in the following details: the principle of benefiting donor-recipient; the principle of informed consent; the principle of protecting offspring; the principle of social public welfare; the principle of confidentiality; the principle of strictly preventing commercialization; and the principle of ethical supervision.
Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	Chapters & sections
Why is the document important/useful for your country?	This document promotes safe, effective and reasonable collection, preservation and supply of sperm from the human sperm bank, and protects the health and rights of the donor and recipient, family and offspring, as well as the social welfare.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. Human sperm banks involve gene enhancement technology, and the heated debate about parents wanting to "design babies" has led to the existence of "celebrity sperm banks" and a series of ethical controversies. The ethical principles that should be followed in this document have normative and guiding significance for gene enhancement technology.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET （6）

Document found via (national associations or Google or another database)	National advisory organisation (China Food and Drug Administration's website)	
Title of document	Specification for Quality Management of Clinical Trials of Drugs	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	China Food and Drug Administration	
Year the document was published (between 2005-2018)	2003	
Document saved in folder as		
Who is the stated audience	Investigator、Sponsor、Monitor	
Which definition of enhancement is used in the document?	No definitions are offered.	
Which forms of enhancement are described in the document?	To achieve some kind of enhancement through a drug	
Which targets of enhancement are described (what is enhanced)?	Improvement of cognition, emotion, physical ability, etc	
Which means/methods/tools of enhancement are described?	☑Pharmacology ☐ Neurotechnology ☐Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	To achieve an improvement of ability through drugs	
Which life stage is addressed in the document?	☑ Adults ☑ Elderly ☑Minors (children and adolescents)	

	☐Prenatal
Which context is addressed?	☑Private life ☑ Employment ☐ Military ☐ Others:
Which ethical challenges are addressed in the document?	Subjects' rights and interests
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The investigator or his/her designated representative must explain the details of the clinical trial to the subject and the subject should participate voluntarily; Confidentiality of personal data of the subject; Inform the subject of the potential benefits and risks. In case of related damages, the subject may receive treatment and corresponding compensation. To guarantee the subject's right of informed consent, as a subject, the child must obtain the informed consent of its legal guardian and sign the informed consent. When the child can make the decision to agree to participate in the study, he/she must also obtain his/her consent
Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	Chapters & sections
Why is the document important/useful for your country?	China Food and Drug Administration is an authoritative institution of the state. This specification is the standard for clinical trials. Clinical trials of all phases, human bioavailability or bioequivalence tests should be conducted in accordance with this code.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. HET directly affects human body, and it is particularly important to protect the rights and interests of subjects, especially minors. This document provides detailed policy guidelines for the protection of subject's rights and interests.

France

Following the research done on the state of the ethical debate on HET in France, it appears that the French scene on this topic is rather underdeveloped. Few recognised institutions in ethics have produced reports specifically dedicated to this topic. One noteworthy exception is the report by the National Ethics Consultative Committee for Life Sciences and Health (CCNE) which is a highly respected institution provided insights on ethics relating to life sciences and health: "Use of biomedical techniques for the 'neuro-enhancement' of the non-sick person: ethical stakes" from 2013. The second one mentioned in annex 1 only superficially tackles ethical aspects.

The question of HET is addressed in other documents that engage with the two other SIENNA's technology. For instance, the CERNA's report on the "ethics of research in robotics" has two pages on HET (pp. 38-40). The report by the Parliamentary Office (OPECST) "Toward a Controlled, Useful and Demystified AI" also touches on issues related to HET. It is also important to note that there has been some engagement with HET as part of the national consultation that took place in 2018 in relation to the revision of the bioethics law. Some points on HET appear in the Report published in June 2018 following this consultation (see the report in Table 3 by the CCNE on the General States on Bioethics). It is not included in the table above as it is quite weak, but it does point to the fact that there is an engagement of the French public on this question. Finally, the report by the CNIL on the connected body also touches on HET but only over 4 pages and remains very general, using a tone that is almost ironic, giving a sense of contempt toward those who support HET.

The research has therefore shown that there is a paucity of documents produced by recognised institutions that address specifically the ethics of HET. This means that the general debate on this technology in France is rather dominated by opinions held by groups or individuals that tend to lack scientific substance. There are some strong supporters of HET in France, such as the Dr Laurent Alexandre or the Transhumanist French Association15; however, the French population appears generally resistant to it. In any case, the discussion on this topic is rather polarised and filled up by naïvely enthusiastic views or dystopian perspectives.

The lack of rigorous scientific publications on the ethics of HET might be explained by the fact that this is not a field that, contrary to HG or AI&R, clearly falls within a scientific discipline. The academic sector in France being still quite strongly attached to disciplinary divisions, this might explain the reason why the issue of HET has not led to more research from recognised scientific and ethics groups. If the research produced by SIENNA shows that there is scientific and ethical value in addressing HET as a field on its own, there will be much work in France to develop this area of research. It would require the country to move away from the narrowly disciplinary approach that tends to dominate French research today in order to develop an interdisciplinary perspective making it possible to address the specific ethical issues that emerge from HET technologies.

[15] https://transhumanistes.com

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Names and emails of persons who did the work	Anaïs Rességuier anais.resseguier@sciencespo.fr
Your organisation	Sciences Po Paris
Your country (again)	France
Search conducted in which language	French
Acknowledgements (any researcher who helped you to complete this task)	Robert Gianni and Bernard Reber

TABLE 2: LIST OF ALL RELEVANT PROFESSIONAL ETHICS CODES

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments
Medical research in general	"Charte d'éthique de l'Institut Pasteur" "Pasteur Institute Ethics Charter"	https://www.pasteur.fr/fr/institut-pasteur/engagements	2012	Pasteur Institute	Researchers at Pasteur Institute	
Research in general	"Charte Nationale de Déontologie" "French National Charter for Research Integrity"	http://www.cnrs.fr/comets/spip.php?article183	2015	A consortium of research institutes	Researchers	

TABLE 3: LIST OF ALL RELEVANT DOCUMENTS FROM NATIONAL ADVISORY/ETHICS GROUPS

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments
Research in general	"Pratiquer une recherche intègre et responsable. Un guide" "Conducting honest and responsible research. A guide"	http://www.cnrs.fr/comets/IMG/pdf/pratiquer_une_recherche_integre_et_responsable_un_guide_05.12.2016.pdf	2016	National Centre for Scientific Research (CNRS) and the Conference of University Presidents (CPU)	Researchers in general	
Research in general	"Promouvoir une recherche intègre et responsable. Un guide" "Promoting honest and responsible research. A guide"	http://www.cnrs.fr/comets/IMG/pdf/guide_promouvoir_une_recherche_inte_gre_et_responsable_8septembre2014.pdf	2014	COMETS: Ethics Committee of the National Centre for Scientific Research (CNRS)	Researchers in general	
AI&R and HET	"Ethique de la recherche en robotique" "Ethics of research in robotics"	http://cerna-ethics-allistene.org/Publications+CERNA/	2014	CERNA: Research Ethics Board of Allistene, the Digital Sciences and Technologies Alliance	Researchers in AI & R and the general public	
AI&R and HET	"Pour une intelligence artificielle maîtrisée, utile et démystifiée" "Toward a Controlled, Useful and Demystified Artificial Intelligence"	http://www.senat.fr/rap/r16-464-1/r16-464-11.pdf	2017	OPECST: Parliamentary Office for the evaluation of scientific and technological choices	General public, policy makers, jurists, engineers and researchers	There is synthesis document in English of this report. I have also saved it in the folder.

HET	"Recours aux techniques biomédicales en vue de 'neuro-amélioration' chez la personne non-malade: enjeux éthiques" "Use of biomedical techniques for the 'neuro-enhancement' of the non-sick person: ethical stakes"	http://www.ccne-ethique.fr/fr/publications/recours-aux-techniques-biomedicales-en-vue-de-neuro-amelioration-chez-la-personne-non	2013	CCNE: National Ethics Consultative Committee for Life Sciences and Health	Health professionals, researchers, general public, policy makers	
HET	"L'homme augmenté. Notre Humanité en quête de sens" "Human enhancement. Our humanity in search for meaning"	https://www.fondation-mines-telecom.org/wp-content/uploads/2016/01/2015-CahierDeVeille-HommeAugmente.pdf	2015	Fondation Telecom	Researchers, funding bodies, and the general public.	
AIR and HET	"Le corps, nouvel objet connecté. Du quantified self à la M-santé: les nouveaux territoires de la mise en données du monde" "The body, new connected object. From the quantified self to mobile health: the new territories of the datafication of the world"	https://www.cnil.fr/sites/default/files/typo/document/CNIL_CAHIERS_IP2_WEB.pdf	2014	CNIL: National Commission Information Technologies and Liberties	Researchers, funding bodies, policy makers and the general public.	
HG, HET and AIR	"Rapport de synthèse du comité consultatif national d'éthique" "Synthesis report from the national consultative committee for life science and health"	https://etatsgenerauxdelabioethique.fr/blog/le-rapport-des-etats-generaux-de-la-bioethique-2018-est-en-ligne	2018	CCNE: National Ethics Consultative Committee for Life Sciences and Health	General public, policy makers, health professionals, researchers and lawyers	

HG, HET and AIR	“Intelligence artificielle et robotique” “Artificial intelligence and robotique”	https://etatsgeneraux delabioethique.fr/pages/intelligence-artificielle-et-robotisation	2018	National Ethics Consultative Committee for Life Sciences and Health (CCNE)	General public	

Name of national REC	Title of document (original + English translation)	Ethical issues addressed in which SIENNA area (HG, HET, AI&R)?	URL	Stated audience	comments
ANSM	"Courrier de demande d'autorisation d'une recherche impliquant la personne humaine mentionnée au 1° de l'article L. 1121-1 du code de la santé publique portant sur le médicament" "Request for authorising research involving the human person as mentionned in 1° of article L. 1121-1 of the public health code relating to drugs"	Concerns medical research in general	https://ansm.sante.fr/Mediatheque/Publications/Formulaires-et-demarches-Essais-cliniques	Researchers	
N/A	Rédaction d'un protocole médicamentaux Template for writing a medicinal research protocol	Concerns research on drugs	http://urcest.com/essais-cliniques/documents-essaiscliniques	Researchers in health research	
N/A	Rédaction d'un protocole pour un dispositif médicamenteux Template for writing a research protocol for a medicinal dispositive	Concerns research on drugs	http://urcest.com/essais-cliniques/documents-essaiscliniques	Researchers in health research	
INSERM	Instruction de remplissage du format du protocole Guide to complete the protocol template	Concerns medical research involving the human person	https://www.inserm.fr/professionnels-recherche/recherche-sur-personnes/soumission-	Researchers in health research	

			projets-impliquant-personne-humaine		
CNIL: National Commission Information Technologies and Liberties	MR-001 “Recherches dans le domaine de la santé avec recueil du consentement” “Research in the health area with consent”	Concerns medical research	https://www.cnil.fr/sites/default/files/atoms/files/mr-001.pdf	Researchers in health research	Concerns research that involve collection and management of private data as part of the research.
CNIL: National Commission Information Technologies and Liberties	“Demande d’autorisation d’un traitement de recherche dans le monde de la santé” “Request for authorising a research treatment in the health sector”	Concerns medical research	https://www.formulaires.modernisation.gouv.fr/gf/cerfa_10769.do	Researchers in health research	Concerns research that involve collection and management of private data as part of the research.
CERNI (Ethics Commitees for noninvasive research) at the University of Paris-Saclay	“Formulaire de soumission au CERNI”	Concerns medical research		Researchers in non invasive research at the University of Paris-Saclay	
CERNI (Ethics Commitees for noninvasive research) Grenoble Alpes	“Guide de soumission” “Submission guide”	Concerns medical research	http://www.grenoblecognition.fr/index.php/ethique/ethique-soumettre-un-dossier	Researchers in Grenoble area	Guide to proceed to the evaluation of research protocols in particular in relation to ethical aspects.

CERNI (Ethics Commitees for noninvasive research) of the Federal University of Toulouse	"Formulaire de soumission au CERNI" "CERNI application form"	Concerns medical research	http://www.univ-toulouse.fr/actualites/comite-d-ethique-de-recherche-cer EN version also available.	Researchers in non invasive research at the Federal University of Toulouse.	Guide to proceed to the evaluation of research protocols in particular in relation to ethical aspects.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET

Document found via (national associations or Google or another database)	Google
Title of document	"Recours aux techniques biomédicales en vue de 'neuro-amélioration' chez la personne non-malade: enjeux éthiques" "Use of biomedical techniques for the 'neuro-enhancement' of the non-sick person: ethical stakes"
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	CCNE: National Ethics Consultative Committee for Life Sciences and Health
Year the document was published (between 2005-2018)	2013
Document saved in folder as	HET_CCNE_2013_Recours aux techniques biomédicales en vue de « neuro-amélioration » chez la personne non malade- enjeux éthiques
Who is the stated audience	Not specified, but most likely: Health professionals, researchers, general public, policy makers
Which definition of enhancement is used in the document?	The first section of the document precisely problematizes the notion of "enhancement" by examining the distinction between the normal and the pathological.
Which forms of enhancement are described in the document?	It focuses on neuro-enhancement,

Which targets of enhancement are described (what is enhanced)?	Cognitive and psychological.	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☒ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Enhancement of cognitive capacity and well-being.	
Which life stage is addressed in the document?	☒ Adults ☒ Elderly ☒ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☒ Private life ☒ Employment ☒ Military ☐ Others:	
Which ethical challenges are addressed in the document?	risks and benefits of neuro-enhancement (on short and long terms) autonomy of the person in the decision to use these techniques or not, i.e. question of coercion questions of social justice and fair repartition of resources Questions related to the role of the doctors and of medicine in relation to these techniques More philosophical questions related to the sense of the self	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Scientific and technological background is presented as well as the state of the debate, primarily in relation to the distinction between the normal and the pathological. The document concludes with two series of recommendations: 1: concerning research, health, medicine and social protection:	

	to prevent use of these technologies for children, teenagers and vulnerable person considering the degree of doubts on these technologies. To engage in more qualitative and quantitative studies on these technologies To better informed the medical sector about them to prevent a distortion of health priorities 2: concerning the person and life in society. To recognise the pressures on freedom of choice in the use of these technologies in the current context characterised by competition and performance. To recognise the risk of a reduction of human complexity To recognise the importance of the sense of the self, a sense that cannot be reduced to its performance And more generally, the document identifies the need to pursue ethical vigilance on these questions.
Which format is used in the document (checklist, continuous text, other)?	Continuous text of 29 pages.
How is the document structured?	The document is divided in 5 sections including a concluding section providing recommendations.
Why is the document important/useful for your country?	It is important as it emanates from a highly recognised ethics group in France.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	It can be useful as it provides an in-depth exploration of neuro-enhancement and presents the view of the CCNE on the ethical challenges of this technology.

Document found via (national associations or Google or another database)	Google
Title of document	"L'homme augmenté. Notre Humanité en quête de sens" "Human enhancement. Our humanity in search for meaning"
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	Fondation Telecom

Year the document was published (between 2005-2018)	2015	
Document saved in folder as	HET_Telecom_2015_HommeAugmente	
Who is the stated audience	Not stated but most likely researchers, funding bodies, and the general public.	
Which definition of enhancement is used in the document?	Rather than defining enhancement it problematizes it around questions of normality and distinguishes it from other terms such as the “instrumented human”, the “connected human”, the “improved human”, etc.	
Which forms of enhancement are described in the document?	It covers a wide range of forms of enhancement.	
Which targets of enhancement are described (what is enhanced)?	It covers a wide range of enhancement’s targets.	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☒ Augmented reality ☒ tissue engineering ☒ genetic engineering ☒ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Various kinds.	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal Not specified	
Which context is addressed?	☒ Private life	

	☒ Employment ☐ Military ☐ Others:
Which ethical challenges are addressed in the document?	It only superficially mentions ethical aspects of HET, pointing to the need to develop the reflection on these.
How are the ethical issues addressed? Are solutions offered? If so, which ones?	See above
Which format is used in the document (checklist, continuous text, other)?	Continuous text with illustrations and boxes focusing on specific elements.
How is the document structured?	See above
Why is the document important/useful for your country?	See below
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	It might not be extremely useful for the development of SIENNA codes or frameworks; however, I have included it here as it presents the view of a French institution bringing together major French engineering schools and touches on questions of ethics.

Germany

There are different German national advisory groups, ethics groups and professional groups, which published recommendations or guidelines on HET which have influence on the public and political debate and partially on legal developments. The German Medical Association (Bundesärztekammer) and its central ethics committee (ZEKO) and the Office of Technology Assessment at the German Bundestag (TAB) published relevant recommendations and position papers or guidelines on research in HET, which had legal influence. The German Ethics Council (Deutscher Ethikrat), the working Group of Medical Ethics Committees in the Federal Republic of Germany (Arbeitskreis medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland), the German research foundation (DFG) and the national academy of sciences Leopoldina published recommendations which are important for the German debate and developments, although they have no direct legal influence. The same applies for documents published by HET specific professional organisations, e.g. the Association of German Aesthetic Plastic Surgeons, the German association for neurology or the national anti-doping agency of Germany (NADA).

We searched for professional ethics codes, documents from ethics and advisory groups and guidance documents on how to write research ethics protocols in the field of HET. The main challenge here was, that there are many documents published in Germany by single authors or groups of authors on all enhancement field (brain doping and doping in sports, neuro enhancement and life style drugs, plastic surgery etc.). Although these documents reflect single opinions and are (as described in the methodology for the X.3 tasks) irrelevant for the search here, since we are looking especially for recommendations from professional groups and ethics advisory bodies, not from single authors or rather unprofessional author groups. Another challenge was that there are many documents which describe the ethical, legal and social challenges of HET, but only a few documents which give guidance or entail recommendations.

The search for professional codes brought only two results: The national anti-doping code, developed by the national anti-doping agency (NADA) and a Code of Transparency for interaction with Healthcare Professionals and Healthcare Organisations, developed by the German Association FSA “Voluntary Self-regulation for the pharmaceutical industry” (“Freiwillige Selbstkontrolle für die Arzneimittelindustrie”). The Association of German Aesthetic Plastic Surgeons (VDÄPC) and the German Association for Neurology, which can be considered as professional organisations regarding enhancement, developed no relevant codes, guidelines or recommendations which include ELSI.

The search for national advisory and ethics groups dealing with HET was more effective. The German ethics council discussed the topic in various conferences and workshops and published relevant books, although guidelines, codes and recommendations on HET are missing yet. The German medical association published guidelines on ADHD and on the use of pharmaceuticals, which are in a broad sense relevant.

Very relevant is a document developed and published by the Office of Technology Assessment at the German Bundestag (TAB) in 2013 with the title “The Pharmacologically Improved Human”. This document is very broad and focuses on different forms of enhancement, although it gives an overview of potential

areas for required activities in the field of HET. Furthermore, a statement developed by the central ethics committee at the German Medical association (Bundesärztekammer) (ZEKO) published in 2009 on doping and medical ethos is quite interesting for the SIENNA work (see Table in annex 1).

Unfortunately, we were not able to find any guidance documents on research ethics protocols that address issues in HET specifically.

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Names and emails of persons who did the work (if different from above)	Lisa Tambornino, tambornino@eurecnet.eu Dirk Lanzerath, mailto:lanzerath@eurecnet.org
Your organisation	EUREC
Your country (again)	Germany
Search conducted in which language	German
Acknowledgements (any researcher who helped you to complete this task)	

TABLE 2: LIST OF ALL RELEVANT PROFESSIONAL ETHICS CODES

SIENNA area	Title of document (original + English translation)	URL	Year	organisation	stated audience	comments
HET	Nationaler Anti Doping Code National Anti Doping Code	https://www.nada.de/fileadmin/-DOWNLOADS-/Regelwerke/NADA-Code_2015.pdf	2005/2015 (revised version)	Nationale Anti Doping Agentur Deustchland National Anti Doping Germany	Athlets or other people working in the sports business	

HET	Transparenzkodex Code of Transparency for interaction with Healthcare Professionals and Healthcare Organisations	German: https://www.pharma-transparenz.de/fileadmin/Downloads/Pdf_s/Kodizes__Empfehlungen/FSA_Transparenzkodex_2015_Tabelle_Web.pdf English: http://www.pharma-transparency.eu/fileadmin/Downloads/Transparenzkodex_Englisch_Web.pdf	2013	Freiwillige Selbstkontrolle für die Arzneimittelindustrie e. V.“ (FSA)	all member companies of the FSA, as well as to their domestic subsidiaries	On 27 November 2013, the Association of Voluntary Self-Regulation for the Pharmaceutical Industry (FSA) adopted the FSA Transparency Code. According to the new Transparency Code, all future payments in kind by the pharmaceutical industry to physicians and other healthcare professionals are to be made public.
HG, HET, AI&R	Research Code of Conduct	https://verwaltung.uni-koeln.de/forschungsmanagement/content/e12474/e160886/018_Research_Code_of_Conduct_neu_D_ger.pdf		University of Cologne	researchers	Very broad. value based approach
HG, HET	Berufsordnung für Ärztinnen und Ärzte professional code for physicians	https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/MBO/MBO-AE.pdf (only German)	Version from 2018	Bundesärztekammer German Medical Association	physicians	Very broad

TABLE 3: LIST OF ALL RELEVANT DOCUMENTS FROM NATIONAL ADVISORY/ETHICS GROUPS AND PROFESSIONAL GROUPS

SIENNA area	Title of document (original + English translation)	URL	Year	organisation	Stated audience	comments
HG, HET, AI&R	Wissenschaftsfreiheit und Wissenschaftsverantwortung Empfehlungen zum Umgang mit sicherheitsrelevanter Forschung Scientific Freedom and Scientific Responsibility Recommendations for Handling Security-Relevant Research	http://www.dfg.de/download/pdf/dfg_im_profil/reden_stellungnahmen/2014/dfg-leopoldina_forschungsrisiken_de_en.pdf	2014	DFG German Research Foundation + Leopoldina	Professional organisations and universities, policy makers, researchers, public	Very broad "The recommendations offer assistance in answering ethical questions, thus contributing to defining standards and codes of conduct beyond statutory norms for scientists dealing with security-relevant research. "
HET, HG	Gendoping Wissenschaftliche Grundlagen – Einfallstore – Kontrolle Gene Doping Scientific Basis – Gateways – Monitoring	https://www.tab-beim-bundestag.de/de/pdf/publikationen/buecher/gerlinger-etal-2008-124.pdf English version: https://www.bundestag.de/blob/190958/8638bc0aa98521f057e22e5422	2008	Büro für Technikfolgenabschätzung beim Deutschen Bundestag (TAB) Office of Techology Asessment at the German Bundestag	professionals	

		59fe85/gene_doping-data.pdf				
HET	Stellungnahme. Ärztliche Behandlungen ohne Krankheitsbezug unter besonderer Berücksichtigung der ästhetischen Chirurgie Position paper. Medical treatments beyond disease under special consideration of aesthetic surgery	https://www.zentrale-ethikkommission.de/fileadmin/user_upload/downloads/pdf-Ordner/Zeko/Stellungnahme_aestethische_Chirurgie.pdf	2012	Zentrale Ethikkommission bei der Bundesärztekammer (ZEKO) Central Ethics Committee for Observance of Ethical Principles in Medicine and its Adjacent Fields of the German Medical Association (Bundesärztekammer)	Society, physicians	
HET	Stellungnahme. Position paper. Doping and medical ethics		2009	Zentrale Ethikkommission bei der Bundesärztekammer (ZEKO)		

				Central Ethics Committee for Observance of Ethical Principles in Medicine and its Adjacent Fields of the German Medical Association (Bundesärztekammer)		
HET	Der pharmakologisch verbesserte Mensch Leistungssteigernde Mittel als gesellschaftliche Herausforderung The Pharmacologically Improved Human. Performance-Enhancing Substances as a Social Challenge. Final Report	http://www.itas.kit.edu/pub/v/2012/sage12b.pdf english version: http://www.itas.kit.edu/pub/v/2013/sage13a.pdf	2013	Büro für Technikfolgenabschätzung beim Deutschen Bundestag (TAB) Office of Technology Assessment at the German Bundestag	Professionals, society, policy makers	
HET	Hirndoping. Die Position der Deutschen Hauptstelle für Suchtfragen e.V. (DHS) Doping of the brain. The position of the german centre for addiction issues	http://www.dhs.de/fileadmin/user_upload/pdf/news/2011-06-20_Positionspapier_Hirndoping.pdf	2011	Deutsche Hauptstelle für Suchtfragen German Centre for Addiction Issues	Society, polic makers	
HET	Die Verbesserung des Menschen - Tatsächliche und rechtliche	Book publication. no link available	2008	Deutsche Gesellschaft für Medizinrecht		

	Aspekte der wunscherfüllenden Medizin					
HET	Stellungnahme der Deutschen Gesellschaft für Kinder- und Jugendpsychiatrie, Psychosomatik und Psychotherapie (DGKJP) zum Barmer GEK Arztreport 2013 über die Häufigkeit von Diagnosen einer hyperkinetischen Störung und der Verordnung von Medikamenten zu ihrer Behandlung	http://www.zentrales-adhs-netz.de/fileadmin/ADHS/Newsletter/DGKJP_-_Stellungnahme_Arztreport_13.pdf	2013	Deutsche Gesellschaft für Kinder- und Jugendpsychiatrie, Psychosomatik und Psychotherapie (DGKJP)	Policy makers, health sector	
HET	Stellungnahme zur Aufmerksamkeitsdefizit- / Hyperaktivitätsstörung (ADHS) Statement on ADHD	https://www.zentrales-adhs-netz.de/fileadmin/ADHS/%C3%9Cber_das_Netz/Grundlagen/B%C3%84K/Bundesaerztekammer_2005_ADHS_Stellungnahme_kurz_1_.pdf	2005	Bundesärztekammer German Medical Association	Policy makers, society	

HET	Empfehlungen der Deutschen Gesellschaft für soziale Psychiatrie zu ADHS, Retalin, Psychopharmaka Recommendations of the German Society for Social Psychiatry on ADHD, Retalin, Psychotropic drugs	https://www.dgsp-ev.de/fileadmin/user_files/dgsp/pdfs/Flyer_Infoblatt_KuFo-Programme_Broschueren/Brosch.Generation_krankgeschr..pdf	2013	Deutsche Gesellschaft für soziale Psychiatrie German Society for Social Psychiatry	Society, professionals, policy makers	
HET	Medikamente – schädlicher Gebrauch und Abhängigkeit Leitfaden für die ärztliche Praxis Pharmaceuticals – harmful use and addiction. A guide for medical practice	https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/LeitfadenMedAbhaengigkeit.pdf	2007	Bundesärztekammer German medical association	Society, professionals, policy makers	

TABLE 4: LIST OF ALL RELEVANT GUIDANCE DOCUMENTS ON HOW TO WRITE RESEARCH ETHICS PROTOCOLS

Name of national REC	Title of document (original + English translation)	SIENNA area	URL	stated audience	comments
Ethics committee of the German Society for Nursing Science	Fragen zur ethischen Reflexion Guidance for ethical reflexion	all	https://dg-pflegewissenschaft.de/wp-content/uploads/2017/05/FragenEthReflexion.pdf	researchers	Very broad

Arbeitskreis Medizinischer Ethikkommissionen in der Bundesrepublik Deutschland e.V. (AMEK) Working group of medical ethics committees in Germany	Checkliste für die Probandeninformation zur Erlangung der Einwilligung in die wissenschaftliche Verwendung von Blut- bzw. Gewebeproben Checklist for getting informed consent for studys with blood or tissue samples	HG	https://www.uni-due.de/imperia/md/content/ethikkomission/berufsrecht_checkliste_probandeninformation.pdf	researchers	
	Checkliste: Erforderliche Antragsunterlagen für Studien nach AMG Checklist: Required application documents for studies according to AMG	HET, HG	https://www.uniklinik-freiburg.de/fileadmin/mediapool/10_andere/ethikkommission/sonstiges/checklisteamg.doc	researchers	
	Mustertext zur Information und Einwilligung in die Verwendung von Biomaterialien und zugehöriger Daten in Biobanken Template	HG	https://www.ak-med-ethik-komm.de/docs/MustertextBiobanken.docx https://www.ak-med-ethik-komm.de/docs/Template-for-informed-consent.docx	researchers	

	For informed consent concerning the donation, storage, and utilization of biological materials as well as collecting, processing, and usage of (related) data in biobanks				
	Mustertext zur Information und Einwilligung bei einer optionalen zusätzlichen Sammlung von Biomaterialien anlässlich einer klinischen Arzneimittelprüfung zur Nutzung außerhalb des Prüfplans Template for information and consent to an optional additional collection of biomaterials for a clinical proving out of schedule	HG	https://www.ak-med-ethik-komm.de/docs/PharmakogenetikalsZusatzzuAMG.docx		
	Recommendation For the Assessment of Research-related Human Biobanks by Ethics Committees	HG	https://www.ak-med-ethik-komm.de/docs/Recommendations2016_draft2016_09_07.pdf	For Ethics Committee members	

TABLE 6: MOST RELEVANT DOCUMENTS IN HET

Document found via (national associations or Google or another database)	Google
Title of document	The Pharmacologically Improved Human Performance-Enhancing Substances as a Social Challenge
Kind of document (PEC, NAEG, GDREC)	National advisory group
Document developed by whom (organisation, profession)?	Office of Technology Assessment by the German Bundestag (TAB)
Year the document was published (between 2005-2018)	2013
Document saved in folder as	TAB-Enhancement-NAEG
Who is the stated audience	"In order better to assess the present and medium-term societal and political significance of the topic »Enhancement«, the Committee on Education, Research and Technology Assessment (Ausschuss für Bildung, Forschung und Technikfolgenabschätzung) of the German Bundestag commissioned the Office of Technology Assessment at the German Bundestag (Büro für TechnikfolgenAbschätzung beim Deutschen Bundestag, TAB) to undertake a technology assessment project on the topic »Pharmacological and technical interventions to improve performance – prospects for more widespread use in medicine and everyday life« (»Enhancement«). The final report of this project focuses on developments to date and plausible projections of trends in the use of (psychotropic) medicines for performance enhancement in working and everyday life." (p13)
Which definition of enhancement is used in the document?	The used definition of enhancement is explained in chapter 5 of the document about "Use of the term ENHANCEMENT" (pp. 42, 43) "… the term »enhancement« is used to mean very different things. On the one hand it is used in a very broad sense to refer to, among other things, any one of a multitude of technical and biomedical interventions intended to influence and mold the human body in a given way. On the other hand, a substantial part of the specialist and public debate refers in particular, via the terms

	»cognitive enhancement« and »neuroenhancement«, to enhancement (or »improvement«) of the intellectual or mental capacities of humans as distinct from enhancement of physical abilities…"	
Which forms of enhancement are described in the document?	Neuro-enhancement, cognitive enhancement, doping of the brain, pharmacological enhancement	
Which targets of enhancement are described (what is enhanced)?	Improvement of human abilities	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☒ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?		
Which life stage is addressed in the document?	☒ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☒ Private life ☒ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	Concerns about the future of human nature Enhancement as part of medicalization process	

	Boundaries between health, illness, improvement Effects on social pressure and self-determination From health care to health market
How are the ethical issues addressed? Are solutions offered? If so, which ones?	With regard to research the question arises as to what investigational questions and objections are significant enough to be supported by public funding. With regard to regulation, it must be investigated whether the available statutory regulations and their procedural and institutional implementation appear appropriate. With regard to the current use of putative performance-enhancing agents, there is a need for unbiased consumer information, public healthcare, and workplace health and safety measures. With regard to the future debate, it must be asked whether and how social debate and opinion formation can be actively promoted.
Which format is used in the document (checklist, continuous text, other)?	Continues text
How is the document structured?	
Why is the document important/useful for your country?	
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	

Greece

There is not much research on HET in Greece. The search results only in one Code of Medical Ethics and consent to aesthetic surgery and two Opinions on HET by the National Committee on Bioethics. Apart from the aesthetic surgery, the other themes of enhancement remain mostly unknown in Greece.

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Names and emails of persons who did the work	Maria Bottis
Your organisation	Ionian University
Your country	Greece
Search conducted in which language	Greek and English
Acknowledgements	Fereniki Panagopoulou

TABLE 2: LIST OF ALL RELEVANT PROFESSIONAL ETHICS CODES and OF ALL RELEVANT DOCUMENTS FROM NATIONAL ADVISORY/ETHICS GROUPS

Note: Only the first three documents are PECs.

SIENNA area	Title of document	URL	Year	Author/ Organisation	Stated audience	Comments
HG, HET	Κώδικας Ιατρικής Δεοντολογίας (Code of Medical Ethics)	https://www.lawspot.gr/nomikes-plirofories/nomothesia/nomos-3418-2005	2015 (latest version)	Greek Parliament (The Parliament codified medical ethics rules also as a statute)	Physician, Nurses, general public, policy makers	This is a code on medical ethics, whichhas been ratified also by law. The code makes reference to the possible amendment to the human genome, which is expressly forbidden, except for particular purposes, under art. 34 of the Code, par. 1 and 2.

						Also, the Code deals with consent to plastic surgery.
HG, HET	Code of Ethics for the Medically Assisted Reproduction Κώδικας Δεοντολογίας Ιατρικώς Υποβοηθούμενης Αναπαραγωγής	http://eaiya.gov.gr/wp-content/uploads/2016/12/KODIKASSITE.pdf	2017	National Committee for the Medically Assisted Reproduction Εθνική Επιτροπή για την Ιατρικά Υποβοηθούμενη Αναπαραγωγή/ The Greek Parliament /Βουλή των Ελλήνων	Physician, Geneticists, researchers, policy makers, general public	This Code covers the ethical rules on medically assisted reproduction. It is also a statue voted by the Greek Parliament.
HET	'Enhancement' of human characteristics-effect upon cognitive and mental human condition, Opinion Γνώμη, ΄Βελτίωση' ανθρώπινων χαρακτηριστικών και επίδραση στην πνευματική και ψυχική κατάσταση του ανθρώπου	http://www.bioethics.gr/index.php/el/gnomes/530-b-e	2013	National Bioethics Commission Εθνική Επιτροπή Βιοηθικής	Physicians, Geneticists, General public and policy-makers	Opinion on HET and its effect upon the cognitive and mental human condition
HET	Report, Enhancement of human characteristics, effect upon cognitive	http://www.bioethics.gr/index.php/el/gnomes/530-b-e	2018	National Bioethics Commission	Physicians, Geneticists, Policy-makers and the general public	Report on HET and its effect upon the cognitive and mental human condition

	and metal human condition, Έκθεση, ΄Βελτίωση' ανθρώπινων χαρακτηριστικών και επίδραση στην πνευματική και ψυχική κατάσταση του ανθρώπου	http://www.bioethics.gr/images/pdf/GNOMES/REPORT_HET_COGNITIVE_AND_MENTAL_FINAL_GR.pdf				
HET	Opinion, 'Enhancement' of human characteristics, natural traits, Βελτίωση' χαρακτηριστικών του ανθρώπου-φυσικά χαρακτηριστικά, Γνώμη	http://www.bioethics.gr/ind'ex.php/el/gnomes/107-beltiosh-anthropou http://www.bioethics.gr/images/pdf/GNOMES/OPINION-Human%20enhancement%20-Physical%20FINAL%20GR.pdf	2013	National Bioethics Commission ΕθνικήΕπιτροπή Βιοηθικής	Physicians, Plastic surgeons, Policy-makers and the general public	An Opinion on the enhancement of natural human traits with plastic surgery and other methods
HET	Report, 'Enhancement' of human characteristics, natural traits,'Βελτίωση' χαρακτηριστικών του ανθρώπου-φυσικά χαρακτηριστικά- Έκθεση	http://www.bioethics.gr/index.php/gnomes/107-beltiosh-anthropou http://www.bioethics.gr/images/pdf/GNOMES/REPORT-Human%20enhancement-Physical%20FINAL%20GR.pdf	2013	National Bioethics Commission Εθνική Επιτροπή Βιοηθικής	Physicians, Geneticists, Policy-makers and the general public	A Report on the enhancement of natural human traits with plastic surgery and other methods

HET	Opinion, Informed Consent in the patient/doctor relationship, Γνώμη-Συναίνεση στη σχέση Ιατρού-Ασθενούς	file:///C:/Users/user/Desktop/informed_consent_opinion_report_gr.pdf	2010	National Bioethics Committee/ Εθνική Επιτροπή Βιοηθικής Physicians, general public, policy makers		The Opinion does not refer to consent in plastic surgery expressly, but it applies also in this case
HET	Report, Informed Consent in the patient/doctor relationship, Έκθεση, Συναίνεση στη σχέση Ιατρού-ασθενούς	file:///C:/Users/user/Desktop/informed_consent_opinion_report_gr.pdf	2010	National Bioethics Committee/ Εθνική Επιτροπή Βιοηθικής Physicians, general public, policy makers		The Report does not refer to plastic surgery expressly, but it applies also in this case

TABLE 6: MOST RELEVANT DOCUMENTS IN HET

Document found via (national associations or Google or another database)	National Committee of Bioethics database
Title of document	Opinion on the 'Enhancement' of human characteristics-natural characteristics
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	National Committee of Bioethics
Year the document was published (between 2005-2018)	2013

Document saved in folder as		
Who is the stated audience	Not stated	
Which definition of enhancement is used in the document?	The document does not contain a definition of enhancement.	
Which forms of enhancement are described in the document?	Aesthetic plastic surgery, face transplants, enhancement of corporal abilities, drugs, sports and enhancement, military	
Which targets of enhancement are described (what is enhanced)?		
Which means/methods/tools of enhancement are described?	Pharmacology Neurotechnology Cosmetic surgery Prosthetics	Genetic/genomic engineering
Which motivations/intentions of enhancement are described?	They are not really described, but it follows from the document that the motivations/intentions are the betterment of the human image and strength.	
Which life stage is addressed in the document?	Adults	
Which context is addressed?	Private life Military Others: sports	
Which ethical challenges are addressed in the document?	Personal autonomy to change one's image, stemming from the right to personality. Protection of individual will to belong to a particular sex. Informed consent to surgery Protection of a vulnerable patient suffering from a mental disorder (Body Dysmorphic Disorder) Personal autonomy to enhance one's strength Protecting the health of athletes Consent of a soldier in enhancement in the military	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	HET is seen in principle as a valid purpose. Aesthetic surgery is accepted, unless the patient suffers from diseases such as Body Dysmorphic Disorder or the purpose of the surgery is to help a criminal become	

	unrecognizable. The conditions of a valid informed consent in aesthetic surgery are more strict. The Committee suggests that a Code of Ethics in Aesthetic Surgery be compiled. The Committee lays down the terms of a valid enhancement of physical characteristics such as strength, skill, speed, punctuality in moving etc. The use of artificial 'drugs' etc must be severely controlled in this case by the authorities and the person recommending the use bears responsibility. Third parties in the domain of sports must be protected against doping, as well as athletes who use these drugs.
Which format is used in the document (checklist, continuous text, other)?	Continuous text.
How is the document structured?	Chapters and paragraphs.
Why is the document important/useful for your country?	The document is the only authoritative text on HET in relation to bodily characteristics.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	The document is useful, as it deals with the centre of one of SIENNA main themes, HET.

Document found via (national associations or Google or another database)	National Committee of Bioethics database
Title of document	Opinion on the 'Enhancement' of human characteristics-effects upon the cognitive and mental condition
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	National Committee of Bioethics
Year the document was published (between 2005-2018)	2013
Document saved in folder as	
Who is the stated audience	Not stated
Which definition of enhancement is used in the document?	The document does not contain a definition of enhancement.
Which forms of enhancement are described in the document?	Use of drugs, use of antidepressants, nicotine, caffeine etc, electromagnetic signs, (for the future) genetic intervention on genes connected to mental functions, interaction of a computer with the human brain

Which targets of enhancement are described (what is enhanced)?	Mental function, memory, attention, emotional status	
Which means/methods/tools of enhancement are described?	Pharmacology Neurotechnology	Genetic/genomic engineering
Which motivations/intentions of enhancement are described?	They are not really described, but it follows from the document that the motivations/intentions are the betterment of the human cognitive and mental status of a person.	
Which life stage is addressed in the document?	Adults	
Which context is addressed?	Private life	
Which ethical challenges are addressed in the document?	Personal autonomy to change one's emotional/mental/cognitive status, stemming from the right to personality. Protection of cognitive and mental health Protection of children Right to personality	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	HET is seen in principle as a valid purpose. However, the Committee notes that we do not have yet any conclusive evidence of the risks and benefits of HET methods such as the use of particular drugs etc from science. The use of these methods for non therapeutic purposes is declared unacceptable for children. Informed consent remains crucial. The Greek authorities must control the way drugs not subject to prescription are presented to the Greek public (what information is offered along with them etc).People who recommend these drugs are responsible for their use. Research bodies must engage in further important research on this matter with the support of the Ministry of Health. It remains in doubt whether the prescription of non prescriptable drugs in this case falls within medical duties under the Code of Medical Ethics of 2005.	
Which format is used in the document (checklist, continuous text, other)?	Continuous text.	
How is the document structured?	Chapters and paragraphs.	
Why is the document important/useful for your country?	The document is the only authoritative text on HET in relation to cognitive and mental human functions.	

Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	The document is useful, as it deals with the centre of one of SIENNA main themes, HET.

Document found via (national associations or Google or another database)	Google	
Title of document	Code of Medical Ethics	
Kind of document (PEC, NAEG, GDREC)	PEC/The Greek Parliament	
Document developed by whom (organisation, profession)?	The Greek Parliament	
Year the document was published (between 2005-2018)	2005	
Document saved in folder as		
Who is the stated audience	Not stated	
Which definition of enhancement is used in the document?	The document does not contain a definition of enhancement.	
Which forms of enhancement are described in the document?	The document refers generally to medical ethics and incorporates the principles of integrity, obligations by the physicians to patients (alleviate pain etc), protection of human dignity and life, informed consent, trust, respect, protection of health of the patient.	
Which targets of enhancement are described (what is enhanced)?	The document does not describe forms of enhancement.	
Which means/methods/tools of enhancement are described?	The document does not describe methods of enhancement.	
Which motivations/intentions of enhancement are described?	Not described.	
Which life stage is addressed in the document?	Adults and minors	

Which context is addressed?	Private life Right to health, integrity dignity
Which ethical challenges are addressed in the document?	Personal autonomy Protection of cognitive and mental health Protection of children Right to personality
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The Code of Medical Ethics intensifies the spectrum of the obligation to inform the patient especially in the case of aesthetic plastic surgery. (Art. 11 par. 3) (this intensification is valid also for transplants).
Which format is used in the document (checklist, continuous text, other)?	Continuous text.
How is the document structured?	Chapters and paragraphs.
Why is the document important/useful for your country?	The document is the only ethical and legal text mandating the wider obligation to inform a patient before aesthetic plastic surgery, considered non therapeutic in nature, but in essence, enhancement.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	The document is useful, as it also deals with the centre of one of SIENNA main themes, HET.

Netherlands

As HET covers a wide range of disciplines there is not one single professional organisation which covers it all. The search for professional organisations which professional ethical codes are linked to HET was mainly focussed on medical organisations, neurology, psychology and orthopaedic and cosmetic surgery. None of the PECs found specifically addressed HET or any other deviation from therapy or healing. The lack of HET within these PECs is however troubling and these professional organisations and the government should include ethical aspects concerning HET in PECs. As technologies begin to become accessible to the public, it is important for the code of conduct for physicians and medical devices to include guidelines concerning HET, which is not yet present. With time and the increasing popularity of HET, it might be of great significance to set up new umbrella organisations covering the field of HET. The need for the codes created by the SIENNA project is of the essence for the Netherlands.

The search for national advisory/ethical groups was more successful. The main contributors for policy recommendations are the Rathenau Institute and the Centrum voor Ethiek en Gezondheid (The Netherlands Centre for Ethics and Health). They both had specific advisory reports which were written for the government and policy-makers to use. Together, the reports managed to cover most of the different areas within HET and thus give a representative overview of HET guidelines for policy-making and the public debate in the Netherlands. The reports on Wish-fulfilling medicine and nanotechnology don't focus on HET as a core but are useful adjacent topics which provide a different approach and view on HET which could be useful for the SIENNA ethical codes and protocols. Other reports cover policy recommendations for each HET specifically and cover legal recommendations and recommendations on grounds of justice and national security within the Netherlands.

Unfortunately, the search was not able to find any guidance documents on research ethics protocols that address issues in HET.

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Names and emails of persons who did the work (if different from above)	Tanne Ditzel (t.f.ditzel@student.utwente.nl)
Your organisation	University of Twente (NL)
Your country (again)	The Netherlands
Search conducted in which language	Dutch / English
Acknowledgements (any researcher who helped you to complete this task)	

TABLE 2: LIST OF ALL RELEVANT PROFESSIONAL ETHICS CODES

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments
HET	Gedragscode Medische hulpmiddelen 2018 / Code of Conduct Medical Devices 2018	http://www.gmh.nu/images/Gedragscode_GMH_-_english_January_2018.pdf	2018	Gedragscode medische hulpmiddelen (GMH)	Developers medical devices and healthcare professionals	Do not explicitly state HET
HET	NMSBA Ethische Code / Ethical code of conduct	http://www.nmsba.com/ethics/nl	2018	Neuromarketing Science & Business Association (NMSBA)	Practitioners/members	Do not explicitly state HET
HET	De orthopedisch chirurg en de medische industrie	https://www.orthopeden.org/downloads/8/gedragscode-industrie.pdf	2012	Nederlandse Orthopaedische Vereniging (NOV)	Practitioners/members	Do not mention HET
HET	Gedragsregels voor artsen / ethical code of conduct for physicians	https://www.knmg.nl/advies-richtlijnen/dossiers/gedragsregels-van-artsen.html	2013	Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst (KNMG)	Practitioners/members	Do not mention HET

TABLE 3: LIST OF ALL RELEVANT DOCUMENTS FROM NATIONAL ADVISORY/ETHICS GROUPS

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments

HET	Maakbare mens (manufacturable human being)	https://www.ceg.nl/uploads/publicatiedb/maakbare.pdf	2003	Centrum voor Ethiek en Gezondheid (CEG)	Policy-makers, politicians, professionals, clients	
HET	Wensgeneeskunde (wish-fulfilling medicine)	https://www.ceg.nl/uploads/publicaties/Wensgeneeskunde.pdf	2015	Centrum voor Ethiek en Gezondheid (CEG)	Policy-makers, politicians	
HET	Geslachtscellen uit HET lab (reproductive cells from the lab)	https://www.ceg.nl/uploads/publicaties/WEB_103726_Signalement_CEG_Gametogenese.pdf	2017	Centrum voor Ethiek en Gezondheid (CEG)	Policy-makers, politicians	
HET	Leven als een bouwpakket (life as a construction box)	https://www.rathenau.nl/sites/default/files/Leven_als_bouwpakket.pdf	2009	Rathenau Institute	General public and policy-makers	
HET	Van vergeetpil tot robotpak (between forgetting drug and robotsuit)	https://www.rathenau.nl/sites/default/files/Van_vergeetpil_tot_robotpak_-_Rathenau_Instituut.pdf	2011	Rathenau Institute	General public and policy-makers	
HET	Goed beter betwist (Good, better, questionable)	https://www.rathenau.nl/sites/default/files/Rathenau_Goed_Beter_betwist.pdf	2012	Rathenau Institute	Policy-makers, politicians, general public	
HET	Tien lessen voor een nanodialoog (Ten lessons for the nanodialogue)	https://www.leefmilieu.nl/sites/www3.leefmilieu.nl/files/imported/pdf_s/2008-07_Tien_lessen_voor_een_nanodialoog.pdf	2008	Rathenau Institute	Policy-makers, politicians,	

					general public	

TABLE 6: MOST RELEVANT DOCUMENTS IN HET

Document 1

Document found via (national associations or Google or another database)	National advisory organisation (Centrum voor Ethiek en Gezondheid website)	
Title of document	Maakbare mens (manufacturable human being)	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	Centrum voor Ethiek en Gezondheid (CEG)	
Year the document was published (between 2005-2018)	2003	
Document saved in folder as	signalering ethiek en Gezondheid, CGZ, maakbare mens, 2003	
Who is the stated audience	Policy-makers, politicians, professionals, clients	
Which definition of enhancement is used in the document?	Applying genetic, medical or pharmaceutical knowledge in order to enhance the human capabilities and characteristics. Such as aesthetics, performance, and character traits.	
Which forms of enhancement are described in the document?	Cosmetic surgery, pharmaceuticals, longevity, genetical modification, affective, embryo selection	
Which targets of enhancement are described (what is enhanced)?	Aesthetics, cognition, mood, personality, confidence, sex	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☒ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering	☐ Other, please specify:

	☐ Prosthetics	
Which motivations/intentions of enhancement are described?	increased confidence, living up to the (western) beauty standards	
Which life stage is addressed in the document?	☒ Adults ☒ Elderly ☒ Minors (children and adolescents) ☒ Prenatal	
Which context is addressed?	☒ Private life ☐ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	Autonomy, raising the bar of standards, social pressure, identity, equality, health risks,	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Non-concrete solutions are offered. They claim that the government should provide the following: adequate counselling, protection of individual well-being, protect public goods and societal equality.	
Which format is used in the document (checklist, continuous text, other)?	Continuous text	
How is the document structured?	Introduction, societal developments, moral considerations, impactions for the government, conclusions and recommendations.	
Why is the document important/useful for your country?	It is one of the few with guidelines for the government, not coming from the Rathenau Institute.	
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	yes, it is a bit outdated and does not give concrete recommendations, however, it is one of the few to be found in the Netherlands.	

Document 2

Document found via (national associations or Google or another database)	National advisory organisation (Centrum voor Ethiek en Gezondheid website)	
Title of document	Wensgeneeskunde (wish-fulfilling medicine)	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	Centrum voor Ethiek en Gezondheid (CEG)	
Year the document was published (between 2005-2018)	2015	
Document saved in folder as	Wensgeneeskunde, CGZ, HET, 2015	
Who is the stated audience	Policy-makers, politicians	
Which definition of enhancement is used in the document?	Modifying the human body with biomedical technology with the intention to improve the human being. HET overlaps with; "wish-fulfilling medicine will be understood as doctors and other health professionals using medical means (medical technology, drugs etc.) in a medical setting to fulfil the explicitly stated, prima facie non-medical wish of a patient"	
Which forms of enhancement are described in the document?	Cosmetic surgery, pharmaceuticals, fertility, general wish-fulling medicine	
Which targets of enhancement are described (what is enhanced)?	Aesthetics, fertility	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☒ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	The patient's wishes, aesthetics, precautions.	

Which life stage is addressed in the document?	☒ Adults ☒ Elderly ☒ Minors (children and adolescents) ☐ Prenatal
Which context is addressed?	☒ Private life ☐ Employment ☐ Military ☐ Others:
Which ethical challenges are addressed in the document?	Autonomy of doctors, against nature, undesirable medicalizing, equality, will wish-fulfilling medicine rule out normal medicine? freedom of choice, responsibility
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The government should hold back and only interfere if the medicine has exceeded the ethical boundaries or causes harm to the population. The government also has the responsibility to inform the public and provide transparency.
Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	Introduction, definition, regulating frameworks; professional, legal and financial, ethical questions, consequences, conclusion and recommmendation
Why is the document important/useful for your country?	It takes a different approach to HET by looking at as wish-fulfilling medicine, states the professional legal and financial frameworks
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, It takes a different approach to HET by looking at as wish-fulfilling medicine, states the professional legal and financial frameworks

Document 3

Document found via (national associations or Google or another database)	National advisory organisation (Centrum voor Ethiek en Gezondheid website)

Title of document	Geslachtscellen uit HET lab (reproductive cells from the lab)	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	Centrum voor Ethiek en Gezondheid (CEG)	
Year the document was published (between 2005-2018)	2017	
Document saved in folder as	Geslachtscellen uit HET lab, CGZ, HET, 2017	
Who is the stated audience	Policy-makers, politicians	
Which definition of enhancement is used in the document?	Modifying the human body with biomedical technology with the intention to improve the human being. HET overlaps with wish-fulfilling medicine will be understood as doctors and other health professionals using medical means (medical technology, drugs etc.) in a medical setting to fulfil the explicitly stated, prima facie non-medical wish of a patient (	
Which forms of enhancement are described in the document?	in vitro gametogenesis (IVG)	
Which targets of enhancement are described (what is enhanced)?	reproductive	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Reproduction, fertility	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☒ Prenatal	

Which context is addressed?	☒ Private life ☐ Employment ☐ Military ☐ Others:
Which ethical challenges are addressed in the document?	Dignity, the well-being of the unborn child and infertile couples, the importance of genetic heritage, identity, health risks
How are the ethical issues addressed? Are solutions offered? If so, which ones?	It raises questions which are to be reflected by doctors, politicians and policy-makers. No real solutions are offered.
Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	Introduction, IVG for reproduction and legal situation in the Netherlands, applied IVG, ethical considerations, conclusion
Why is the document important/useful for your country?	It sketches a good image of the current legal situation in the Netherlands and how the IVG technology fits into this situation.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, It sketches a good image of the current legal situation in the Netherlands and how the IVG technology fits into this situation.

Document 4

Document found via (national associations or Google or another database)	National advisory organisation (Rathenau institution website)
Title of document	Leven als een bouwpakket (life as a construction box)
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	Rathenau institution
Year the document was published (between 2005-2018)	2009

Document saved in folder as	Leven als bouwpakket, Rathenau Institute, HET, 2009	
Who is the stated audience	General public and policy-makers	
Which definition of enhancement is used in the document?	Enhancing the characteristics of the human body and mind	
Which forms of enhancement are described in the document?	Cognitive, moral, longevity	
Which targets of enhancement are described (what is enhanced)?	Cognitive, moral, longevity	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☒ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☒ Other, please specify: Ambient intelligence, Persuasive technologies, Molucal medicine, Synthetic biology
Which motivations/intentions of enhancement are described?	Increasing lifespan, and cognitive abilities	
Which life stage is addressed in the document?	☒ Adults ☐ Elderly ☒ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☒ Private life ☒ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	Freedom, equality, the right of exclusion, justice, responsibility, sustainability of humans, social vs technological logic	

How are the ethical issues addressed? Are solutions offered? If so, which ones?	No concrete solutions, it serves as a thinking tool for scientists, policymaker, politicians and interested civilians to think about the social meaning and of this new technological wave.
Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	Introduction, brain-computer interface, persuasive technology/ambient intelligence, molecular medicine and synthetic biology, implications for policy and government
Why is the document important/useful for your country?	it has sections specific on different HET and their implications on policymaking.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, it has sections on specific different HET and their implications on policymaking.

Document 5

Document found via (national associations or Google or another database)	National advisory organisation (Rathenau institution website)
Title of document	Van vergeetpil tot robotpak (between forgetting drug and robot suit)
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	Rathenau institution
Year the document was published (between 2005-2018)	2011
Document saved in folder as	Van vergeetpil tot robotpak, Rathenau Institute, HET, 2011
Who is the stated audience	General public and policy-makers
Which definition of enhancement is used in the document?	Technology which enhances the human being, becoming more human than normal positively or negatively.
Which forms of enhancement are described in the document?	Physical, Cognitive, Affective, Moral

Which targets of enhancement are described (what is enhanced)?	Cognitive abilities, safety, choices, mood, physical abilities	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☒ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☒ Prosthetics	☒ Other, please specify: Surveillance/persuasive technology nanotechnology
Which motivations/intentions of enhancement are described?	Increasing cognitive abilities, abilities to show empathy, physical abilities, adapting characteristic traits such as devotion to tasks, carefulness, shutting down moral feelings within soldiers, activating pleasure feelings etc.	
Which life stage is addressed in the document?	☒ Adults ☒ Elderly ☒ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☒ Private life ☒ Employment ☒ Military ☒ Others: medical, education	
Which ethical challenges are addressed in the document?	Justice, responsibility, autonomy, equality, dignity, social duty, individual freedom,	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	It must be transparent if a human being has had HET technologies applied to him.	
Which format is used in the document (checklist, continuous text, other)?	Continuous text, interviews	
How is the document structured?	The scientific view of psychopharmacology, neurotechnology, robotics and ICT on the possibilities of HET in national justice and security, then these topics are reviewed one by one in which ethicists provide the ethical	

	dilemmas for individual and collective purposes, interviews are provided with professional in the fields, conclusions are made by analyzing the previous sections,
Why is the document important/useful for your country?	It is a very versatile report very specific on the 4 HET and the only one found in the literature search which focusses specifically on justice and national security
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, It is a very versatile report very specific on the 4 HET and the only one found in the literature search which focusses specifically on justice and national security

Document 6

Document found via (national associations or Google or another database)	National advisory organisation (Rathenau institution website)
Title of document	Goed beter betwist (Good, better, questionable)
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	Rathenau institution
Year the document was published (between 2005-2018)	2012
Document saved in folder as	Goed beter betwist, Rathenau Insitute, HET, 2012
Who is the stated audience	General public and policy-makers, politicians
Which definition of enhancement is used in the document?	Using biomedical technology to improve the abilities of healthy people.
Which forms of enhancement are described in the document?	Physical Cognitive Affective Cosmetic Longevity Moral
Which targets of enhancement are described (what is enhanced)?	Cognition, concentration, empathy, mood, physical capabilities, aesthetics, lifespan

Which means/methods/tools of enhancement are described?	☒ Pharmacology ☒ Neurotechnology ☒ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering ☒ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Enhancing ones physical cognitive and aesthetic capabilities, also to live a longer life and to have better control on mood and empathy.	
Which life stage is addressed in the document?	☒ Adults ☒ Elderly ☒ Minors (children and adolescents) ☒ Prenatal	
Which context is addressed?	☒ Private life ☒ Employment ☒ Military ☒ Others: medical, education	
Which ethical challenges are addressed in the document?	Safety of technologies, equality, individual freedom, religious concerns, social or work-related pressure, human nature, transparency,	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The publication does not offer clear cute solutions, it, however, shows how the public opinion is shaped in the Netherlands on these ethical questions.	
Which format is used in the document (checklist, continuous text, other)?	Continuous text	
How is the document structured?	It starts off with a summary of the report, then the conclusions and found recommendations, then the definition of HET, the opinion group studies, an international literature study on opinions on HET	
Why is the document important/useful for your country?	It is the first and only study on the public opinion of HET in the Netherlands.	

Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, it is the first and only study on the public opinion of HET in the Netherlands and gives clear point to point policy recommendations on grounds of these studies.

Document 7

Document found via (national associations or Google or another database)	National advisory organisation (Rathenau institution website)	
Title of document	Tien lessen voor een nanodialoog (Ten lessons for the nanodialogue)	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	Rathenau Institute	
Year the document was published (between 2005-2018)	2008	
Document saved in folder as	Tien lessen voor een nanodialoog, Rathenau Insitute, HET, 2008	
Who is the stated audience	Policy-makers, politicians, the general public	
Which definition of enhancement is used in the document?	Not the prevention or therapy but concerning the enhancement of healthy people and overcome the natural disabilities.	
Which forms of enhancement are described in the document?	General/moral	
Which targets of enhancement are described (what is enhanced)?	General/morality	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☒ Other, please specify: nanotechnology

Which motivations/intentions of enhancement are described?	Increasing human abilities in all groups possible with nanotechnology and the merge of NBCI	
Which life stage is addressed in the document?	☒ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☒ Private life ☒ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	Safety risks for humans and nature, privacy, desirability,	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	There are 10 recommendations given towards the government to provide a guideline to stir the nano dialog, some include how to handle the ethical questions.	
Which format is used in the document (checklist, continuous text, other)?	Continuous text, 10 stated points	
How is the document structured?	Introduction, summary of 10 lessons, early signalling of societal questions, societal organisations in the Netherlands, foreign societal organisations, research into the public and their opinion, the ten lessons as recommendations.	
Why is the document important/useful for your country?	Even though this document is not specific to HET it provides guidelines which also can be used for HET as this is one of the possible applications of nanotechnology.	
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, Even though this document is not specific to HET it provides guidelines which also can be used for HET as this is one of the possible applications of nanotechnology.	

Document 8

Document found via (national associations or Google or another database)	Google	
Title of document	Gedragscode medische hulpmiddelen (Code of Conduct Medical Devices)	
Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	Gedragscode medische hulpmiddelen (GMH)	
Year the document was published (between 2005-2018)	2018	
Document saved in folder as	Code of Conduct Medical Devices, GMH, HET, 2018	
Who is the stated audience	Developers medical devices and healthcare professionals	
Which definition of enhancement is used in the document?	N/A: Document does not directly address enhancement, thus does not define it, but does discuss adjacent issues	
Which forms of enhancement are described in the document?	Non specifically, but any enhancement which is in need of a medical device is covered by this code of conduct (BCI, brain and organ implants, wearables, prosthetics, RFID-chips etc)	
Which targets of enhancement are described (what is enhanced)?	general	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☒ Neurotechnology ☒ Cosmetic surgery ☒ Augmented reality ☒ tissue engineering ☐ genetic engineering ☒ Prosthetics	☐ Other, please specify: All which can use medical devices
Which motivations/intentions of enhancement are described?		
Which life stage is addressed in the document?	☒ Adults ☒ Elderly	

	☒ Minors (children and adolescents) ☐ Prenatal
Which context is addressed?	☒ Private life ☒ Employment ☒ Military ☐ Others:
Which ethical challenges are addressed in the document?	Improper practice, Legitimate Foundations, documentation, Accountability/Transparency
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Provide guidelines on how to deal with these issues
Which format is used in the document (checklist, continuous text, other)?	Bullet points
How is the document structured?	Introduction, general principles, the articles, notes explaining some articles.
Why is the document important/useful for your country?	It is the general code of conduct used within the medical field when it comes to medical devices
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, as many HET are medical devices it gives a good example for guidelines

Document 9

Document found via (national associations or Google or another database)	Google
Title of document	Gedragsregels voor artsen / ethical code of conduct for physicians
Kind of document (PEC, NAEG, GDREC)	PEC
Document developed by whom (organisation, profession)?	Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst (KNMG)

Year the document was published (between 2005-2018)	2013	
Document saved in folder as	Gedragsregels voor artsen, KNMG, HET, 2013	
Who is the stated audience	Practitioners/members	
Which definition of enhancement is used in the document?	N/A: Document does not directly address enhancement, thus does not define it, but does discuss adjacent issues	
Which forms of enhancement are described in the document?	-	
Which targets of enhancement are described (what is enhanced)?	Public health	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☒ Other, please specify: general
Which motivations/intentions of enhancement are described?	Increasing public health and well-being	
Which life stage is addressed in the document?	☒ Adults ☒ Elderly ☒ Minors (children and adolescents) ☒ Prenatal	
Which context is addressed?	☒ Private life ☐ Employment ☐ Military ☐ Others:	

Which ethical challenges are addressed in the document?	Health risks, relationship physician and patient, responsibility, privacy,
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Provide guidelines on how to deal with these issues
Which format is used in the document (checklist, continuous text, other)?	Bullet point
How is the document structured?	General, physician in relation to the patient, to other caretakers, to scientific research, publicity, businesses, public health and well-being
Why is the document important/useful for your country?	It is the general code of conduct for all physicians in the Netherlands
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, as many HET will have to deal with physicians and their code of conduct. It seems troubling that HET is not mentioned in any form in these codes of conducts. Regulations in the physician's allowability to apply HET must be included in these kinds of codes.

Poland

In Poland there is no HET professional organisation, nor HET ethics code. A Polish Transhumanist Association[16] exists, however it has adopted no codes or guidelines.
The Code of Ethics of the Polish Society of Plastic, Reconstructive and Aesthetic Surgery is the document that could be considered in some way HET-adjacent. However, it makes no clear indication of HET, but focuses on principles of professional conduct.
The general Code of Medical Ethics mentions the issue of doping in sports and states it should be considered unethical.
There are no HET-relevant documents on writing ethical codes and no policy statements regarding HET domains have been issued.

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Your organisation	Helsinki Foundation for Human Rights
Your country	Poland
Search conducted in which language	Polish

TABLE 2: LIST OF ALL RELEVANT PROFESSIONAL ETHICS CODES

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments
HG HET (art 75, only in the context	Kodeks Etyki Lekarskiej (The Code of Medical Ethics)	https://www.nil.org.pl/dokumenty/kodeks-etyki-lekarskiej	1991	Krajowy Zjazd Lekarzy (General Medical Assembly)	Medical profession	Art. 3[17] Art. 29[18] Art. 38.3[19]

[16] http://www.psth.pl/
[17] The doctor shall always carry out their duties irrespective of the genetic heritage of the patient.
[18] The doctor and people cooperating with them are obliged to protect the confidentiality of information contained in the genetic material of patients and their families.
[19] The doctor is obliged to familiarize patients with the possibilities of modern medical genetics as well as diagnostics and pre-birth therapy. By providing the above information, the physician is required to inform them about the risks associated with conducting pre-birth tests.

of sports and doping)						Chapter II b Human Genome [20] Art. 75[21]
HET (?)	Kodeks Etyki Polskiego Towarzystwa Chirurgii Plastycznej, Rekonstrukcyjnej I Estetycznej (Code of Ethics of the Polish Society of Plastic, Reconstructive and Aesthetic Surgery)	http://www.ptchprie.pl/kodeks_etyczny.html	n/a	Polskie Towarzystwo Chirurgii Plastycznej, Rekonstrukcyjnej i Estetycznej (Polish Society of Plastic, Reconstructive and Aesthetic Surgery)	professionals	

TABLE 4: LIST OF ALL RELEVANT GUIDANCE DOCUMENTS ON HOW TO WRITE RESEARCH ETHICS PROTOCOLS

Please note: these are examples of recommendations published by some of the local RECs. Not all 54 RECs have been looked at. Because the documents are not technology specific, it was not possible to carry out analysis referred to in Step 3 of the work plan.

Name of national REC	Title of document	Ethical issues addressed in	URL	Stated audience	comments

[20] 1. A physician is not allowed to discriminate people on the basis of their genetic heritage.
2. A physician participating in procedures (badaniach) aimed at identifying whether a person is a carrier of a generic disease or is susceptible to a genetic condition, may carry it out only for health purposes or scientific research related to them, after obtaining the consent of the patient and allowing them genetic consultation.
3. A doctor may intervene in the human genome only for preventive or therapeutic purposes in accordance with Article 46 of the Code of Medical Ethics.
4. A physican cannot participate in activities aimed at causing heritable genetic changes in humans.

[21] The doctor may not use doping products or methods for non-medical purposes. The use of products and methods recognized as doping in people practicing sports is unethical.

	(original + English translation)	which SIENNA area (HG, HET, AI&R)?			
Bioethics Committee by the Warsaw Chamber of Physicians	Regulamin Komisji Bioetycznej Rules of proceeding of a the bioethics committee (REC) by the Warsaw Chamber of Physicians	n/a (non-specific)	https://izba-lekarska.pl/wp-content/uploads/2015/03/Regulamin-Komisji-Bioetycznej.pdf	Researchers submitting the application.	Rules of proceeding the REC contain a form that has to be filled by the applicant. However there is no guidance on how to write a research ethics protocol
Bioethics Committee by the Warsaw Medical University	(Information on required documents)	n/a (non-specific)	https://komisja-bioetyczna.wum.edu.pl/content/szczeg%C3%B3%C5%82owe-informacje-oraz-wzory-dokument%C3%B3w	Researchers submitting the application.	REC provides information on what information should be given to participants and an example of an informed consent form.
Bioethics Committee by the Copernicus University in Toruń	(Bioethics Committee - Remarks on the most common formal mistakes	n/a	https://www.cm.umk.pl/aktualnosci-2/2-collegium-medicum/165-komisja-bioetyczna.html https://www.cm.umk.pl/aktualnosci-2/2-collegium-		REC provides information on the „most common formal mistakes", and are related to e.g. recruitment of participants, the use of medical data in research or on biological material.

Uniwersytet Mikołaja Kopernika w Toruniu	made when filling in applications)		medicum/561-komisja-bioetyczna-uwagi-odnosnie-najczestszych-bledow-formalnych-popelnianych-przy-wypelnianiu-wnioskow.html		

TABLE 6: MOST RELEVANT DOCUMENTS IN HET

Document found via (national associations or Google or another database)	National association (General Medical Assembly)
Title of document	The Code of Medical Ethics
Kind of document (PEC, NAEG, GDREC)	PEC
Document developed by whom (organisation, profession)?	Profession (medical doctors)
Year the document was published (between 2005-2018)	1991 but still in force
Document saved in folder as	1. Kodeks-Etyki-Lekarskiej+NIL+medical ethics+1991
Who is the stated audience	Medical professionals
Which definition of enhancement is used in the document?	n/a
Which forms of enhancement are described in the document?	Some reference to doping in sports
Which targets of enhancement are described (what is enhanced)?	n/a

Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☒ Other, please specify: doping in sports
Which motivations/intentions of enhancement are described?	The use of doping in sports	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal NS	
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☒ Others: sports	
Which ethical challenges are addressed in the document?	Doping in sports	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	According to the code "the doctor may not use doping products or methods for non-medical purposes. The use of products and methods recognized as doping in people practicing sports is unethical."	
Which format is used in the document (checklist, continuous text, other)?	Articles	
How is the document structured?	Code, consisting of 78 articles	
Why is the document important/useful for your country?	It is the key document concerning medical ethics, there are no specific documents that would address HET issues directly.	

Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	n/a

Document found via (national associations or Google or another database)	National association	
Title of document	Code of Ethics of the Polish Society of Plastic, Reconstructive and Aesthetic Surgery	
Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	Profession (professional association)	
Year the document was published (between 2005-2018)	n/a	
Document saved in folder as	2. Code of Ethics+cosmetic surgery	
Who is the stated audience	Professionals	
Which definition of enhancement is used in the document?	n/a	
Which forms of enhancement are described in the document?	Aesthetic surgery	
Which targets of enhancement are described (what is enhanced)?	n/a	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☒ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☒ Other, please specify

Which motivations/intentions of enhancement are described?	The document does not address the question of enhancement per se, but in the broader context. It provides general ethical principles that should be respected,
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal NS
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☐ Others NS
Which ethical challenges are addressed in the document?	General ethical issues faced by physicians, not related specifically to HET.
How are the ethical issues addressed? Are solutions offered? If so, which ones?	n/a
Which format is used in the document (checklist, continuous text, other)?	Introduction and 14 points
How is the document structured?	Introduction and 14 points
Why is the document important/useful for your country?	It is one of the very few national documents that could be said to address ethical issues related to HET.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	n/a

South Africa

In South Africa not much work has been done with regard to the development of professional codes and/or guidance documents from RECs about any of the forms of HET considered in SIENNA. For instance, although the national ethics code does include some discussion of genetics research, it does not cover genetic enhancement and the use of CRISPR-Cas9. Local ethics guidelines (for local ethics committees) pertinent to genetic or other enhancement are not existent.

Alternative sources (newspaper articles, scientific papers, blogs etc) showed that there is a scarcity of discussion about enhancement. There are some sources that talk about the potential for genetic enhancement, and there are some that talk about pharmacological enhancement, but these draw on or expand the same kind of arguments that are forwarded in international literature on these topics; i.e. the discussions of ethical challenges are premised largely on international thinking, and are not expanded to or considered in the South African context specifically.

Importantly, and similar for the other three topical areas, the primary ethical issues brought to the fore are about justice in terms of equal access and reduction of socio-economic inequality. The concern is that a) the use of some of these technologies could be designed to remedy health problems of the rich, not of the poor, and that this would be unfair and undesirable; b) that it would be more desirable to use these technologies to explicitly address inequality and poverty. Another concern is that some forms of enhancement (e.g. pharmacological) would be unsafe in the long term.

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Names and emails of persons who did the work (if different from above)	Jantina de Vries
Your organisation	University of Cape Town
Your country (again)	South Africa
Search conducted in which language	English
Acknowledgements (any researcher who helped you to complete this task)	

TABLE 6: MOST RELEVANT DOCUMENTS IN HET

Document found via (national associations or Google or another database)	Google

Title of document	Science: Gene editing tool takes laboratories by storm – but there are ethical concerns	
Kind of document (PEC, NAEG, GDREC)	Newspaper article	
Document developed by whom (organisation, profession)?	Marelise van der Merwe, Daily Maverick	
Year the document was published (between 2005-2018)	2015	
Document saved in folder as	https://www.dailymaverick.co.za/article/2015-08-04-science-gene-editing-tool-takes-laboratories-by-storm-but-there-are-ethical-concerns/	
Who is the stated audience	General public	
Which definition of enhancement is used in the document?	Not defined; article talks about Crisp-Cas9/Gene editing	
Which forms of enhancement are described in the document?	Gene editing in general, not specifically applied to any one condition	
Which targets of enhancement are described (what is enhanced)?		
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	The duality between 'good use' (e.g. for therapeutic use) and nefarious purposes (but no example given) is described. Also discussed is the risk in taking Crisp-Cas9 technology to the clinic too soon, with potential harmful side-effects later.	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal Not specified	

Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☐ Others: not specific (but mostly related to health)
Which ethical challenges are addressed in the document?	See above
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Not addressed, just raised
Which format is used in the document (checklist, continuous text, other)?	article
How is the document structured?	
Why is the document important/useful for your country?	Sort of
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Not really

Document found via (national associations or Google or another database)	Google
Title of document	CRISPR-Cas: Revolutionising genome engineering
Kind of document (PEC, NAEG, GDREC)	Scientific article
Document developed by whom (organisation, profession)?	S. Nicholson and M. Pepper
Year the document was published (between 2005-2018)	2016
Document saved in folder as	http://www.samj.org.za/index.php/samj/article/view/11061/7588
Who is the stated audience	Readers of the South African Medical Journal

Which definition of enhancement is used in the document?	Genetic enhancement is a precise and predictable process by which an organism's genome may be permanently altered or repaired.	
Which forms of enhancement are described in the document?	Genetic enhancement	
Which targets of enhancement are described (what is enhanced)?		
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Therapeutic (i.e. health-related)	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal Not specified	
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☒ Others: Health context	
Which ethical challenges are addressed in the document?	The following ethical issues are identified: What will be the ultimate consequences of gene editing on the evolution of the human race? Should germline engineering be permitted or should only somatic cell engineering be allowed? How to use this technology to increase equality and not inequality	

How are the ethical issues addressed? Are solutions offered? If so, which ones?	No solutions proposed
Which format is used in the document (checklist, continuous text, other)?	Article
How is the document structured?	Article
Why is the document important/useful for your country?	Somewhat
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	No

Document found via (national associations or Google or another database)	Search on the website of the South African Academy of Sciences (ASSAF)
Title of document	Can we predict the ultimate consequences of gene editing on the evolution of the human race?
Kind of document (PEC, NAEG, GDREC)	Web article
Document developed by whom (organisation, profession)?	Developed by Assaf
Year the document was published (between 2005-2018)	2018
Document saved in folder as	https://www.assaf.org.za/index.php/news/468-does-genome-editing-mean-progress-or-peril-for-the-future-of-human-health
Who is the stated audience	People who read the Assaf website and the Assaf membership
Which definition of enhancement is used in the document?	Genetic enhancement (not defined)
Which forms of enhancement are described in the document?	Genetic enhancement for therapeutic and agricultural purposes
Which targets of enhancement are described (what is enhanced)?	Crops and people

Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	To augment food supplies and to treat or prevent diseases	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal Not specified	
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☒ Others: Health and agriculture	
Which ethical challenges are addressed in the document?	Safety, equality, need for public education and awareness creation, harnessing the potential of the technology to reduce inequality and contribute to the health of the poor	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	No solutions offered	
Which format is used in the document (checklist, continuous text, other)?	Article	
How is the document structured?	Article	
Why is the document important/useful for your country?	Somewhat	

Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Not really

Document found via (national associations or Google or another database)	Assaf website search for 'gene editing'	
Title of document	The Regulatory Implications of New Breeding Techniques	
Kind of document (PEC, NAEG, GDREC)	Report	
Document developed by whom (organisation, profession)?	A joint report by the SA Department of Science and Technology and the South African Academy for Sciences (Assaf)	
Year the document was published (between 2005-2018)	2017	
Document saved in folder as	http://research.assaf.org.za/bitstream/handle/20.500.11911/29/2017_%20assaf_newbreedingtechniques.pdf?sequence=5&isAllowed=y	
Who is the stated audience	The agricultural and science communities in South Africa	
Which definition of enhancement is used in the document?		
Which forms of enhancement are described in the document?	Different aspects of genetic modification, gene editing and traditional plant breeding are discussed	
Which targets of enhancement are described (what is enhanced)?	Crops and animals for food production and breeding	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering ☐ Prosthetics	☐ Other, please specify:

Which motivations/intentions of enhancement are described?	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal Plants and crops are considered
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☐ Others: Agriculture
Which ethical challenges are addressed in the document?	Many of the challenges discussed are copied from an article published in the US, but these ones have been added: Preparedness of the regulatory framework to deal with new technologies and approval processes; Environmental safety and risks to the health of humans and animals; Fair distribution and risks of 'developing countries' missing out on the development of these technologies, meaning downstream access may be impaired.
How are the ethical issues addressed? Are solutions offered? If so, which ones?	No solutions offered; report outlines the challenges
Which format is used in the document (checklist, continuous text, other)?	
How is the document structured?	report
Why is the document important/useful for your country?	Yes
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes insofar as it extends to agriculture and food production

Document found via (national associations or Google or another database)	Google	
Title of document	Cognitive enhancement: a brief overview	
Kind of document (PEC, NAEG, GDREC)	Scientific article	
Document developed by whom (organisation, profession)?	K. Outhoff in the journal South African Family Practice	
Year the document was published (between 2005-2018)	2016	
Document saved in folder as	https://www.ajol.info/index.php/safp/article/viewFile/132181/121779	
Who is the stated audience	Academic audience	
Which definition of enhancement is used in the document?	Pharmacological enhancement is the non-medical use of illicit or prescription drugs to improve cognitive function or to combat the effects of tiredness and stress	
Which forms of enhancement are described in the document?	See above	
Which targets of enhancement are described (what is enhanced)?	Use of Modafinil, Methylfenidate	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	To improve performance particular by medical doctors	
Which life stage is addressed in the document?	☒ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal	

Which context is addressed?	☒ Private life ☒ Employment ☐ Military ☐ Others:
Which ethical challenges are addressed in the document?	Primarily the challenge addressed is the risk of medical doctors using pharmacological substances to stay awake and manage impossible workloads, resulting in an increased error rate, and also possibly having long-term health effects.
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Issues are not addressed, just raised. Also, article is very generic and does not offer insight into the nature of this challenge in South Africa.
Which format is used in the document (checklist, continuous text, other)?	Article
How is the document structured?	
Why is the document important/useful for your country?	Somewhat
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Not specific to SA, quite generic. But a real challenge in South Africa is the absolute overburdening of professionals, including academics and clinicians. Our healthcare system is getting increasingly resource-deprived with a growing and ageing population of which about 30% is HIV-infected. Many clinicians are struggling with burnout (not in the least because of compassion fatigue and the impossibility of dealing with the abject poverty of so many people in this country), and it wouldn't surprise me if many clinicians turn to drugs to help performance.

Document found via (national associations or Google or another database)	Google
Title of document	Human genetic engineering and social justice in South Africa: Moltmann and human dignity
Kind of document (PEC, NAEG, GDREC)	Scientific article
Document developed by whom (organisation, profession)?	M. Kotze in the Acta Theologica

Year the document was published (between 2005-2018)	2016	
Document saved in folder as	http://www.scielo.org.za/scielo.php?script=sci_arttext&pid=S1015-87582016000100005	
Who is the stated audience	Not stated	
Which definition of enhancement is used in the document?	Not defined	
Which forms of enhancement are described in the document?		
Which targets of enhancement are described (what is enhanced)?	Genetic enhancement (Crispr-Cas9 I presume) of humans	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?		
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal Not defined but including adults and children and even unborn	
Which context is addressed?	☒ Private life ☐ Employment ☐ Military ☐ Others:	

Which ethical challenges are addressed in the document?	Issues of access between rich and poor, with technologies being used by the rich to gain a competitive/cognitive/wellbeing advantage over the poor. Sideline issue is the concern that this could lead to exploitation of the poor by the rich. Challenge is "exacerbating of existing social divides, segregation and inequalities" but these divisions are not caused by the availability of enhancement technologies; technologies may make these more manifest or obvious.
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Issues are raised but not addressed
Which format is used in the document (checklist, continuous text, other)?	Article
How is the document structured?	
Why is the document important/useful for your country?	Somewhat, but it further emphasises that one of the primary concerns relating to the use of technologies for HET relates to issues of justice. Specifically, concerns relate to issues of access and threats of further widening the income inequality gap in the country
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	As an academic article it could be a useful reference

Document found via (national associations or Google or another database)	Google
Title of document	Moral perspectives on stimulant use by healthy students
Kind of document (PEC, NAEG, GDREC)	Article
Document developed by whom (organisation, profession)?	C Verster and A van Niekerk in the South African Medical Journal
Year the document was published (between 2005-2018)	2012
Document saved in folder as	http://www.samj.org.za/index.php/samj/article/view/6090/4733
Who is the stated audience	Not specified
Which definition of enhancement is used in the document?	

Which forms of enhancement are described in the document?	Pharmacological enhancement (cognitive enhancement)	
Which targets of enhancement are described (what is enhanced)?		
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	To increase cognitive performance	
Which life stage is addressed in the document?	☒ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☒ Private life ☐ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	The article sets out the range of ethical considerations relating to students' use of drugs to increase performance. These are rather universal and not specific to the South African context. Specifically, it sets out the following concerns: "• Using cognitive enhancement is a form of cheating, and it allows users an unfair advantage. • It is dishonest and detracts from the user as role-model for others. • The problem of indirect coercion – the belief that everybody else is taking these drugs and that I will be left behind if I do not. • The argument that stimulants are dangerous – both because of direct physiological side-effects and the possibility that they are habit	

	forming. • If enhancement is not regulated or even banned outright, it will inevitably result in an eventual unknown future 'post-human' being, an unnatural entity with the expected potential to harm, abuse or suppress those who have not been exposed to the enhancement therapies" (pg 909)
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Issues described not addressed
Which format is used in the document (checklist, continuous text, other)?	Article
How is the document structured?	
Why is the document important/useful for your country?	Not specifically
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	As a South African article it could be a useful reference.

Spain

In Spain there are no codes or guidance documents on HET because the professions most related to these technologies (doctors, pharmacists, bio-engineers etc.) maintain as a sole professional objective the therapy or the complement of it. The search in Google with the suggested words, but in Spanish, and with different combinations of these (along with other words added as "bio-enhancement" or "domestic surgery") has been unsuccessful. There has also been no success in finding research ethics protocols when visiting the websites of the National Association of Research Ethics Committees, the Network of Ethics Committees of Universities and Research Centres in Spain, and the Spanish Medicines and Health Products Authority. It could be concluded, therefore, that in Spain everything is to be done in the field of ethical regulation of professional behaviour and of researching in new technologies for HET.

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Names and emails of persons who did the work (if different from above)	FRANCISCO LARA Javier Valls flara@ugr.es; jvalls@ugr.es
Your organisation	University of Granada
Your country (again)	Spain
Search conducted in which language	Spanish
Acknowledgements (any researcher who helped you to complete this task)	

No relevant documents were found (see summary above)

Sweden

We analysed four documents (potentially) relevant to HET. Two of them are issued by professional organisations of dentists and pharmacists and contain rather general recommendations and principles for these two groups of professionals (see annex 1, section 5.10). None of these two documents addressed the issue of enhancement explicitly. Yet, explicitly some recommendations and principles outlined may be relevant to enhancement practices within these two professions.

SMER – the Swedish National Council on Medical Ethics, which is a parliamentary advisory body to the government issued guidelines on cosmetic interventions and “brain doping” (see Annex 1, section 5.10). Both documents refer to the issue of enhancement. The reports firstly shortly introduce the topic, report on foreign relevant documents, comment on it, and express SMERs own opinion/comments on the topics. These two documents contain recommendations, some specific, other less specific on the related topic (for example, in the document on brain doping: “Research results in this area should be interpreted and communicated with visibility to avoid a "hype" around possible effects of the methods.”) and Swedish perspective on them, which may be somehow relevant or important to take into account when designing the SIENNA guidelines. Notably, SMER issues various types of documents/recommendations. The documents studied herein seem to have the form of a report, and their main function does not seem to be to give recommendations and change/influence the practices/legislations, but rather to point out ethical problems and shortly discuss them.

Overall, there are very few ethics guidance documents for HET in Sweden (including no specific mention for ethics research protocols). There seems to have been an initiative to "start" addressing it by the national ethics advisory body, but nothing directly explicit to HET from professional organisations. And, even what is presented by the SMER is still more reflective than normative; that being said, depending on what is found in other countries, we may still want to refer to these for the SIENNA framework.

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Names and emails of persons who did the work (if different from above)	HC Howard, Emilia Niemiec, Caroline Gallant, and Cornelia Tandre Heidi.howard@crb.uu.se
Your organisation	Uppsala University
Your country (again)	SWEDEN
Search conducted in which language	Swedish and English
Acknowledgements (any researcher who helped you to complete this task)	NA

TABLE 2: LIST OF ALL RELEVANT PROFESSIONAL ETHICS CODES (all three fields)

SIENNA area	Title of document	URL	Year	Author/organisation	Stated audience	Comments
HET/AI/RO	Hederskodex (Honorary codex)	https://www.sverigesingenjorer.se/Om-forbundet/Sa-tycker-vi/hederskodex/		Sveriges ingenjörer	Ingenjörer	Meta level guidance for engineers
HET	Etiska riktlinjer för farmaceuter (Ethical guidelines for farmaceuts)	https://www.sverigesfarmaceuter.se/globalassets/2-dokument/kanslirelaterat/styrelse-fortroendevalda--	2013	Sveriges farmaceuter	Farmaceuts	For pharmacists, general guidelines. http://www.sverigesapoteksforening.se/wp-content/uploads/Etisk-plattform-

		rs/ovriga-engagerade/etikradet/etiska-riktlinjer-sveriges-farmaceuter.pdf				apoteksbranschen.pdf made for the members of Sveriges Apoteksförening Note that there is a smaller subset in a doc that is not now accessible since They're editing their webpage so none of their documents are available for the moment.
HET	Etiska riktlinjer (Ethical guidelines)	https://tandlakarforbundet.se/app/uploads/2017/01/etiska-riktlinjer-skrift.pdf	2014	Tandläkarförbundet	Dentists	Dentists' ethical code could

TABLE 3: LIST OF ALL RELEVANT DOCUMENTS FROM NATIONAL ADVISORY/ETHICS GROUPS

SIENNA area	Title of document	URL	Year	Author/organisation	Stated audience	Comments
HET		http://www.smer.se/wp-content/uploads/2017/11/Smer-kommenterar-Kosmetiska-ingrepp-etiska-aspekter.pdf	2017	SMER		Cosmetic interventions are various invasive therapies, such as surgical procedures or injections, aimed at changing a person's appearance for aesthetic reasons. Today there is no uniform regulation about this type of treatment in Sweden and the individual protection is weak. This comment draws attention to ethical problems that arise in connection with the

						rapidly expanding spread and use of invasive cosmetic treatments.

TABLE 4: LIST OF ALL RELEVANT GUIDANCE DOCUMENTS ON HOW TO WRITE RESEARCH ETHICS PROTOCOLS (all three fields)

SIENNA area	Title of document	URL	Name of national REC	Stated audience	Comments
HG + All types with humans	Vägledning till ansökan (Guidance for application)	https://www.epn.se/media/2469/vaegledning-till-ansokan.docx https://www.epn.se/start/	Etikprövningsnämnderna	Researchers	There is one part called "Redogör för om insamlat biologiskt material kommer att förvaras i en biobank" so it should apply to HG. For all research involving humans
All	Vägledning till forskningsplan/ forskningsprotokoll (program) (Guidance for research plan/research protocol (program))	https://www.epn.se/media/1103/v_gledning_till_forskningsplan.pdf https://www.epn.se/start/	Etikprövningsnämnderna	Researchers	could be relevant as a complement, but very brief and mostly about the research protocol application, not the ethics per se
all	Vägledning till forskningspersonsinformation (Guidance for research	https://www.epn.se/media/2573/vaegledning-till-forskningspersonsinformationgdpr-med-korrigeringar.pdf https://www.epn.se/start/	Etikprövningsnämnderna	Researchers	Guide to research professionals information. Useful for information needed to recruit human subjects u

	person information)				
HG/Biomed professions	Yrkesetiska koder	https://www.vardforbundet.se/rad-och-stod/regelverket-i-varden/etik/yrkesetiska-koder/	Vårdförbundet	See ->	Vårdförbundet is a union for nurses, midwives, biomedical scientists and radiology nurses. PECs for all the professions can be found at their websites.
ALL	Nationella etiknätverket (KI)	https://ki.se/lime/etik-i-praktiken		Researchers and other stakeholders in research	A They have some good links on their website,like the mapping of all regional ethics groups for example. They also make documents where they collect new articles, laws e.t.c. about ethics (e.g. https://ki.se/sites/default/files/2017/11/02/omvarldsbevakning_varen_2017.pdf) No ethical guidelines.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET[22]

Table 6.1

Document found via (national associations or Google or another database)		
Title of document	Etiska riktlinjer för farmaceuter Ethical guidelines for pharmacists	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	the Ethics Council established by the Swedish Federation of Swedish Medicines (Utarbetade av Etikrådet och fastställda av Förbundsstyrelsen i Sveriges Farmaceuter)	
Year the document was published (between 2005-2018)	2013	
Document saved in folder as	etiska-riktlinjer-sveriges-farmaceuter.pdf	
Who is the stated audience		
Which definition of enhancement is used in the document?	no definition, it doesn't explicitly refer to enhancement	
Which forms of enhancement are described in the document?	no enhancement described	
Which targets of enhancement are described (what is enhanced)?	no enhancement described	
Which means/methods/tools of enhancement are described?	x Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering	☐ Other, please specify:

[22] Please note that the quotes included in these tables are based on translations obtained using Google Translate software, which were then refined by the authors. Yet, they may not always precisely reflect the content of the documents; they are rather indicative of their content.

	☐ Prosthetics	
Which motivations/intentions ofenhancement are described?	-	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal it doesn't say	
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☐ Others: not specified	
Which ethical challenges are addressed in the document?	Please see below	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	"The six ethical guidelines for pharmacists are based on the basic principles of biomedical ethics, which summarize the ethical core of a variety of normative documents of the above kind: ● Goodness principle: strive to do good, to prevent and reduce suffering. ● Human dignity principle: not to harm or kill, respect all people's equal value and human rights. ● Autonomy principle: respect others' right to privacy and self-determination). ● Justice principle: Equal cases should be treated equally, distributing goods fairly." (Olika yrken…) (these principles are further described in the text) "1: The pharmacist has the health of the individual and well-being as the primary goal. 2: The pharmacist respects the individual's self-determination, values and intrinsic value. 3: The pharmacist respects the integrity of the individual.	

	4: The pharmacist gives every attention no matter who the person is 5: The pharmacist works in accordance with proven experience as well as upholding his professional skills to provide individuals such as healthcare 6: The pharmacist collaborates with colleagues, healthcare professionals and other players in the pharmaceutical market to cure or alleviate ill health and to promote health." ●" In the case of pharmacist's decision on prioritization, the needs of individual individuals for drug treatment should be ruling." (Vid farmaceutens beslut…)
Which format is used in the document (checklist, continuous text, other)?	6 chapters organized around 6 recommendations (see above)
How is the document structured?	see above
Why is the document important/useful for your country?	It outlines the ethical principles which should guide the practice fo pharmaceutics
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Potentially yes, it shows what are the principles for pharmacy. The principles can be discussed in the context of enhancement to see whether there are any enhancement issues not addressed here.

Table 6.2

Document found via (national associations or Google or another database)	
Title of document	Etiska riktlinjer (Ethical guidelines)
Kind of document (PEC, NAEG, GDREC)	
Document developed by whom (organisation, profession)?	The Swedish Dental Association (Sveriges Tandläkarförbund)
Year the document was published (between 2005-2018)	2014

Document saved in folder as	etiska-riktlinjer-skrift.pdf	
Who is the stated audience		
Which definition of enhancement is used in the document?	no definition	
Which forms of enhancement are described in the document?	not present	
Which targets of enhancement are described (what is enhanced)?	-	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	x Other, please specify: dental practice
Which motivations/intentions of enhancement are described?	-	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal not specified, relevant to all	
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☐ Others: not specified, relevant to all	

Which ethical challenges are addressed in the document?	See below
How are the ethical issues addressed? Are solutions offered? If so, which ones?	"The ethical guidelines focus on the relationship between dentists and patients and assume a humanistic view of humanity. They are based on three primary principles in health care: 1) The principle of autonomy that the dentist should protect the right to self-determination and integrity, 2) the principle of care, which is a combination of the principle of goodness and non-harm, which means that the dentist should strive to do good and prevent and reduce suffering as well as 3) The principle of justice, which means that all people should be treated equally in care." (p.4) 1st "In his occupation, the dentist should be guided by human love and honesty and respond to the patient with empathy, consideration and respect. The primary goal is to be patient's health and wellbeing." 2nd "The dentist should conduct his activities in accordance with science and proven experience, constantly following developments in healthcare, widening their occupational knowledge and, as best knowledge and judgment, contribute both to scientific development and to the public's awareness of it." 3rd "The dental practitioner may not exercise his authority so that it violates the patient's right to decide on himself." 4."The dentist's approach to the patient should be based on the principle of equal value of humans and must not be affected by conditions that are unfavorable to care." 5th "The dentist should then be motivated to use other expertise and

	meet the reasonable wishes of the patient or relative to obtain a new assessment." 6th "The dentist has a duty of confidentiality regarding the patient's information that emerges during the professional practice and should take into account the patient's right to privacy." 7th "The dental practitioner must not be affected by an unfair acquisition request and shall carry out that examination and propose the treatment that appears to be justified." Eighth "The dental practitioner should respect his interests without departing from the interests of the patient colleagues and other carers' work and integrity." 9th "The dentist is to market himself, his profession and the profession in a correct, factual and respectful manner." (p 6-7)
Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	9 chapters organized around 9 recommendations
Why is the document important/useful for your country?	It is issued by national professional organisation and outlines the principles that should guide the practice of dentists in the country.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Potentially, these guidelines may apply also to enhancement uses of dental practice.

Table 6.3

Document found via (national associations or Google or another database)	
Title of document	Brain doping – cognitive performance enhancement in healthy people (Hjärndoping–kognitiv prestationshöjning hos friska personer)

Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	SMER - the Swedish National Council on Medical Ethics. SMER is a parliamentary advisory body to the government, which is at the forefront task to illuminate medical-ethical issues from an overall social perspective (Statens medicinsk-etiska råd, Smer, är ett parlamentariskt sammansatt rådgivande organ till regeringen, som har till främsta uppgift att belysa medicinsk-etiska frågor ur ett övergripande samhällsperspektiv)
Year the document was published (between 2005-2018)	2014
Document saved in folder as	Smer-kommenterar-hjärndoping.pdf
Who is the stated audience	Not specified
Which definition of enhancement is used in the document?	"This document deals with the use of various biomedical methods in purpose of enhancing mental / cognitive functions. The methods have in common that they affect the brain function and that they have developed within the medical research as potential treatment methods for different neurological or mental condition (in English: biomedical neuroenhancement, or short: enhancement)."
Which forms of enhancement are described in the document?	Brain doping
Which targets of enhancement are described (what is enhanced)?	Mental/cognitive functions, memory effects, con- centration, problem solving, mood and social cognition
Which means/methods/tools of enhancement are described?	x Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering

	☐ genetic engineering ☐ Prosthetics X Other, please specify: Medical technics • non-invasive brain stimulation, e.g. transcranial magnet stimulation (TMS) • "neurofeedback": using EEG or magnetic camera survey looks patient brain activity on one monitor and learn to self-regulate this • invasive brain stimulation, deep brain stimulation (DBS)
Which motivations/intentions of enhancement are described?	memory effects, con-centration, problem solving, mood and social cognition
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal Not specified
Which context is addressed?	xPrivate life ☐ Employment X Military ☐ Others:

Which ethical challenges are addressed in the document?	The document discusses a French document and says that SMER (the authors) agree with it. Pages 2 and 3: Definition of normality, and changes to what is perceived normal Unpredictable, or very small effects of brain doping and associated risks, unknown long term risks/benefits, and side effects The usage of brain doping may cause that some will be under pressure to use it (directly or indirectly), due to the competitiveness in our society; parents may impose use of brain doping on their children. Social justice – potential to widen the gap between poor and wealthy
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The document discusses a French document and says that SMER (the authors) agree with it. Page 3: "Due to uncertain risk-benefit balance as well as known risks for addicted children, young judgments and vulnerable individuals powerful advised against using brain doping. • Research results in this area should interpreted and communicated with visibility to avoid a "hype" around possible effects of the methods. • Studies and long-term observations about the methods are desirable, especially around them newer technologies. It is needed to be able to evaluate risks and to know needs to be able to establish guidelines and rules on how to get the methods used. • A greater awareness of the phenomenon needed. This is especially true of doctors like will meet patients who have been affected by side effects to have used the methods, or want to preparations printed. • About cognition increase at healthy people would be incorporated into it traditional health care is available there is a high risk of displacement effects. This could lead to one unfair distribution of public resources. • Those who use the methods often claim that it is their own free choice to do so. However, the phenomenon can largely managed by a competitive society climate that drives individuals to seek to improve their performance on one almost compelling way.

	• In the long run, the phenomenon could lead to an unfair society with one small, privileged upper class who has once again, methods for cognition increase. • There is a risk that the methods can be abused and used for to force or manipulate people. • One should remember one's personality is complex and can not measured or evaluated solely from the outside abilities and achievements. “
Which format is used in the document (checklist, continuous text, other)?	Short paragraphs, bullets points
How is the document structured?	Short introduction; summary of the position of French Council; comments of SMER (i.e. the authors of the report)
Why is the document important/useful for your country?	
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, underlines what is important from Swedish perspective

Table 6.4

Document found via (national associations or Google or another database)	
Title of document	Smer comments - Cosmetic interventions - ethical aspect (Smer kommenterar – Kosmetiska ingrepp etiska aspekter)
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	SMER (Statens medicinsk-etiska råd) - the Swedish National Council on Medical Ethics
Year the document was published (between 2005-2018)	2017
Document saved in folder as	Smer-kommenterar-Kosmetiska-ingrepp-etiska-aspekter.pdf

Who is the stated audience	-	
Which definition of enhancement is used in the document?	"Cosmetic interventions are used in this document intended as a collective term for surgical and other invasive treatments such as: • aims to change a person's appearance of mainly aesthetic reasons, in front of functional or medical motives, • performed in a medical environment or in an environment that perceives as "medical" and • Not usually publicly funded." (p2 and3)	
Which forms of enhancement are described in the document?	Cosmetic surgery	
Which targets of enhancement are described (what is enhanced)?		
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology X Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Aesthetic reasons	
Which life stage is addressed in the document?	x Adults ☐ Elderly X Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	X Private life ☐ Employment	

	☐ Military ☐ Others:
Which ethical challenges are addressed in the document?	Mentioned: Difficulty to distinguish medical and aesthetic reasons (p.1) Mentioned: self-determination, informed consent, medical and social risks, safety Lack of adequate legislation “To perform a cosmetic treatment for to change or manage their appearance can be up-lived as a valuable opportunity. But it also means a risk of injury and can also have negative consequences in a further social perspective, points out the Nuffield Council. The Nuffield Coucil emphasizes that the social and economic pressure can make individuals that they feel that they have to change their appearance to adapt to current / market led appearance level. Cosmetic intervention becomes not just a matter of personal choice. That more people feel anxiety or anxiety in order not to live up to special appearance, and the influence on mental health n it can cause, is a potential public health concern, the NCB believes. Social expectations and ideal people are encouraged to strive is not always ethically neutral. Several cosmetic interventions reflect and support the prevailing standards of gender, age, disability and race, for example, women do not show their "real age" or that it is "finer" with a whiter skin. These normative beliefs can eventually strengthen existing unequal similarities in society, NCB points out. Teenagers may be particularly sensitive to the impact, the availability of cosmetic interventions raises particular ethical problems.

	According to the Nuffield Council, the beauty industry both utilizes and generates specific appearance ideal. Cosmetic interventions are then presented as "solutions" to those designed outreach problems. According to the Nuffield Council, it is also problematic that cosmetic interventions are often offered in environments which is perceived as medical, which from the user's / patient's page introduces trust end of business, for example what smiling professionalism and integrity. This risks hiding the fact that it is a commercial activities where the patient is a customer, and not about a care situation that is based on patient needs. The NCB puts forward an ethical key issue that cosmetic surgery is offered in a commercially driven industry and marketed intensive social contexts There is widespread concern and dissatisfaction over their own appearance. The NCB therefore advocates an ethical approach that focuses on the broader social context. One proposes an ethical policy as contains measures to promote a more ethical practice both considering the demand side ie how people encouraged to consider cosmetic interventions and when it comes to supply side, ie how and what the circumstances of these treatments offered. In addition, the NCB emphasizes that better data is needed about the use of different types of cosmetic surgery, and more research to improve the knowledge base.”
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The document summarizes recommendations of the Nuffield Council here: “Marketing industry agencies should oppose advertising which can cause a social pressure what applies to body ideals. - Social media, including Facebook, Instagram, Snapchat, Twitter and YouTube, should work together to maintain independent research on

	how social media can help to minimize worry about appearance and look- then adjust to the results. - The authority of Ofcom (the British equivalent to audit radio and television committees) should consider the need for guidance about what appearance ideals as read in conjunction with so-called "makeovers" in TV where different types of cosmetic in-grip included. - Commission for Gender Equality and human rights should develop one specific guidance on appearance discrimination based on current rules ring. - The Ministry of Education should ensure that the curriculum includes evidence-based knowledge of body and mind so that all children and young people have access to this knowledge. - App shops should not sell games as is about cosmetic surgery and which is aimed at children. The largest suppliers of cosmetic surgery should cooperate to finance quality information to users. They should also develop a code for good Practices for how to provide cosmetic treatments. - Professional associations and Practitioners should work together to ensure that all surgeons perform cosmetic surgery is certified - The Public Health Authority should initiate a campaign aimed at potential users of cosmetic surgery with the aim of paying attention them on the importance of not hiring professional practitioners like is not quality assured. Ministry of Health and Medicine The sub-authority should require robustness proof of both safety and efficiency as regards products used for cosmetic purposes (like fillers and implants) before being used market.

	- The Ministry of Health should propose legislation foundation so fillers become prescription exists. - Children and adolescents under 18 years of age should unable to access invasive cosmetic surgery, other than in band with medical care”
Which format is used in the document (checklist, continuous text, other)?	Some continuous text, also rather short paragraphs and bullet points
How is the document structured?	Introduction; summary of Nuffield Council; comments of the SMER(reports’ authors)
Why is the document important/useful for your country?	
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes

UK

There are no professional organisations specifically focussed on 'human enhancement' per se in the UK. The organisations identified have various missions, focuses and significance.

Following the prescribed methodology, the research identified eight relevant codes of such organisations (covering ethical aspects) (of which we examined four in detail) that are relevant to HET.23 The Codes deal with a variety of specific topics such as emerging science and bioethics, health technology, pharmaceuticals, prosthetics and orthotics, cosmetic/plastic surgery, and medicines (and their advertisement).

The examined Codes cover a broad range of ethical principles (depending on the topic). E.g., acceptable use of medical terminology, accuracy of information, acknowledgment, clear and respectful communications, confidentiality, continuity of care, data privacy and protection, equity of service provision, equivalence, patient autonomy and welfare, personal and professional integrity and competence, proper documentation and record keeping, quality, reflection and consent, respect for patients, safe and effective use of health technology, separation (not misusing interactions between industry and healthcare organisations), transparency and truthfulness (e.g., regarding medicinal advertisement).

The identified nine NAEG documents (of which we examined three in detail) have been issued by organisations such as General Medical Council, College of Optometrists, the National Health Service (NHS), the British Standards Institution (BSI) and national associations and the Royal Academies. Some of the documents have a general focus (i.e., GMC Guidance) but some are more specific (e.g. apply to prescribing medicine, or plastic surgery, or cognitive enhancing drugs) and target a range of audiences.

In our search for guidance on writing research ethics protocols, we found no guidance specific to 'human enhancement' issued by NRECs. However, we found some guidance (see annex 1, 5.11) issued by various national bodies on writing research ethics protocols at the national level some of which might apply to researchers in HET. There is general and discipline-specific institutional guidance on research ethics protocols and templates but these are not specific to 'human enhancement'.24

[23] This was a limited, non-exhaustive search.

[24] E.g., Lancaster University, "How to write a research protocol", Undated. http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/onlinehandbook/how_to_write_a_research_protocol/ ; University of Portsmouth, "Application for Ethics Review – Staff and Postgraduate Students", Undated. http://www2.port.ac.uk/research/ethics/

The Codes do not provide a definition of 'enhancement', though some terms such as 'cosmetic surgery' were defined. Two of the three analysed NAEG documents defined 'human enhancement' and 'cognitive enhancement/neuro-enhancement'.

There is no comprehensive guidance on the full spectrum/or all forms of HET; whether this might be produced in the future is not clear given the nature of the topic (some aspects of HET are well-regulated already, others less so) and the fluid and fast-changing nature of HET (from traditional methods to more sophisticated methods such as genome editing). The 2012 report on HET and the Future of Work saw the greatest challenge as being cognition-enhancing drugs and called for a "rigorous consideration of the complex ethical and social impacts of human enhancement in the workplace".25

Intro: This document presents the results of the UK country research for HET professional ethics codes, guidance documents from national advisory/ethics groups. It has five tables: 1. Individual and country information, 2. List of relevant professional ethics codes (PECs), 3. List of all relevant documents from national advisory/ethics groups (NAEGs) 4. List of relevant guidance documents on how to write research ethics protocols (GDREPs) and 5. Most relevant documents in HET – analysis. This is followed by a summary.

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Names and emails of persons who did the work (if different from above)	Rowena Rodrigues rowena.rodrigues@trilateralresearch.com David Wright david.wright@trilateralresearch.com
Your organisation	Trilateral Research Ltd
Your country (again)	UK
Search conducted in which language	English
Acknowledgements (any researcher who helped you to complete this task)	-

[25] https://acmedsci.ac.uk/file-download/35266-135228646747.pdf

TABLE 2: LIST OF ALL RELEVANT PROFESSIONAL ETHICS CODES

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments
HET	Code of Ethical Business Practice	http://www.abhicodeofpractice.org.uk	2018	Association of British Healthcare Industries (ABHI)	Members of the ABHI (non-members can also sign up)	
HET	Code of Practice for the Pharmaceutical Industry	http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf	2016	Association of the British Pharmaceutical Industry (ABPI)	Pharmaceutical industry	The Code applies to the promotion of medicines to members of the UK health professions and to other relevant decision makers.
HET	Ethical Code The Ethical Code and Professional Conduct for Prosthetists, Orthotists, Associates and Affiliates	https://www.bapo.com/Framework/ResourceManagement/GetResourceObject.aspx?ResourceID=7507719d-4e75-4f06-b5b8-bb464dfdf4cd	Updated 2016 (2009)	British Association of Prosthetists and Orthotists (BAPO)	Prosthetists, orthotists, associates and affiliate members.	
HET	Professional Standards for Cosmetic Surgery	https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/service-standards/cosmetic-surgery/professional-standards-for-cosmetic-surgery/	2016	Royal College of Surgeons	Doctors who offer cosmetic interventions, surgery	

HET	Code of conduct	https://baaps.org.uk/login.aspx?ReturnUrl=%2fmembers%2fcode_of_conduct.aspx	2013	British Association of Aesthetic Plastic Surgeons (BAAPS)	Members of BAAPS	
HET	Code of Practice	http://www.bapras.org.uk/docs/default-source/BAPRAS-Position-Statements/code_of_practice_2013_v4.pdf?sfvrsn=2	2013	British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS)	Members of BAPRAS	
HET	PAGB Professional Code for Medicines	https://www.pagb.co.uk/codes-guidance/professional-code/	Undated	PAGB (the Proprietary Association of Great Britain)	Member companies (over-the-counter medicines advertisers)	
HET	PAGB Consumer Code for Medicines	https://www.pagb.co.uk/codes-guidance/consumer-code/	Undated	PAGB (the Proprietary Association of Great Britain)	Member companies (over-the-counter medicines advertisers)	Applies to advertising materials aimed at consumers and those persons who may legitimately purchase medicines on behalf of another consumer.

TABLE 3: LIST OF ALL RELEVANT DOCUMENTS FROM NATIONAL ADVISORY/ETHICS GROUPS

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments

HET	Ethical guidance for doctors	https://www.gmc-uk.org/ethical-guidance	Living document	General Medical Council (GMC)	Doctors	
HET	Guidance for doctors who offer cosmetic interventions	https://www.gmc-uk.org/-/media/documents/guidance-for-doctors-who-offer-cosmetic-interventions-210316_pdf-65254111.pdf	2016	General Medical Council (GMC)	All doctors who offer cosmetic interventions.	
HET	Good practice in prescribing and managing medicines and devices	https://www.gmc-uk.org/-/media/documents/Prescribing_guidance.pdf_59055247.pdf	2013	General Medical Council (GMC)	Doctors	
HET	Cognitive enhancing drugs and the workplace	https://www.bma.org.uk/advice/employment/occupational-health/cognitive-enhancing-drugs	2015	British Medical Association	Occupational physicians and others who care for patients who work	Includes practice based recommendations
HET	HET and the future of work	https://acmedsci.ac.uk/file-download/35266-135228646747.pdf	2012	Academy of Medical Sciences, the British Academy, the Royal Academy of Engineering and the Royal Society.	Policy-makers, researchers in science and engineering, experts in the social sciences and humanities, research funders, industry, investors and publics, both within the UK and internationally.	
HET	Information for Commissioners of Plastic Surgery Services Referrals and Guidelines in Plastic Surgery	http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/information-for-commissioners-of-plastic-	Not clear	NHS Modernisation Agency's Action on Plastic Surgery	Commissioners of plastic surgery services	Covers principles and mentions 'consent'. Came up when we looked for

		surgery-services.pdf?sfvrsn=2				'augmentation' 'guidance' 'UK'.
HET	Oncoplastic Breast Reconstruction: Guidelines for Best Practice	http://www.bapras.org.uk/docs/default-source/commissioning-and-policy/final-oncoplastic-guidelines---healthcare-professionals.pdf?sfvrsn=0	2012	Association of Breast Surgery & British Association of Plastic, Reconstructive and Aesthetic Surgeons	Clinical teams across the country and patients treated.	Covers aspects such as 'consent', 'safety'.
HET	Guidance for Professional Practice	https://guidance.college-optometrists.org/home/	2017	The College of Optometrists	Optometrists, owners practitioner, partner, employee, locum, or pre-registration optometrist, students	Covers aspects such as safety, quality, trust, consent.
HET	BSI PAS 277: 2015 Health and wellness apps. Quality criteria across the life cycle. Code of practice	https://shop.bsigroup.com/ProductDetail?pid=000000000030303880	2015	The British Standards Institution (BSI)	App developers, health care professionals selecting apps to recommend, providers, charities, and community organisations commissioning bespoke apps.	

TABLE 4: LIST OF RELEVANT GUIDANCE DOCUMENTS ON HOW TO WRITE RESEARCH ETHICS PROTOCOLS

Name of national REC (**please note not all below listed	**Title of document (original + English translation)**	**Ethical issues addressed in which SIENNA area (HG, HET, AI&R)?**	**URL**	**Stated audience**	**comments**

are NRECs as defined)					
National Health Research Authority	Protocol guidance and template for use in a Clinical Trial of an Investigational Medicinal Product (CTIMP)	Not HET specific but could apply.	https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/	Clinical trial researchers	Includes ethical and regulatory considerations
National Health Research Authority	Protocol guidance and template for use in qualitative research	Not HET specific but could apply.	https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/	Researchers developing protocols	Includes ethical and regulatory considerations
Economic and Social Research Council (ESRC)	Ethics review application forms and protocols	Not HET specific but could apply.	https://esrc.ukri.org/funding/guidance-for-applicants/research-ethics/useful-resources/ethics-review-application-forms-and-protocols/	Researchers	Suggests research proposals, including student proposals, submitted for review to a REC should include the information it recommends
Social Research Association (SRA)	Ethical Guidelines	Not HET specific but could apply.	http://the-sra.org.uk/wp-content/uploads/ethics03.pdf	Social research community	Covers standard protocols for checking ethical considerations including a protocol checklist
Scottish Government	Social Research Ethics	Not HET specific but could apply.	http://www.gov.scot/Topics/Research/About/Social-Research/Guidance-for-Contractors/Ethical-Sensitivity-Check	Scottish Government researchers	Includes a social research ethics checklist & privacy impact assessment template

	Guidance and Sensitivity checklist			and social research contractors	

TABLE 5: MOST RELEVANT DOCUMENTS IN HET - ANALYSIS

Document found via (national associations or Google or another database)	Google	
Title of document	Code of ethical business practice	
Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	Association of British Healthcare Industries (ABHI)	
Year the document was published (between 2005-2018)	2018 (updated)	
Document saved in folder as	ABHI_Code of ethical business practice_2018	
Who is the stated audience	Members of the ABHI (non-members can also sign up)	
Which definition of enhancement is used in the document?	-	
Which forms of enhancement are described in the document?	Mentions innovative medical devices, technologies and in vitro diagnostics	
Which targets of enhancement are described (what is enhanced)?	-	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	-	

Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal Not specified
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☒ Others: safe and effective use of medical technologies
Which ethical challenges are addressed in the document?	The Code sets out specific policies on: Quality & Regulatory Compliance Interactions with Healthcare Professionals Advertising & Promotion Unlawful Payments & Practices Competition/Antitrust & Procurement Laws Export Controls & Sanctions Data Privacy Compliance & Enforcement
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Guidance is provided.
Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	It starts with an Introduction (covering key Legislation, aims and Principles of the Code, interpreting the Code, administering the Code and implementation and Transition Period). PART 1 covers guidelines on the interactions with healthcare professionals and healthcare organisations. PART 2 covers guidelines on advertisements and promotions addressed solely or primarily to healthcare professionals. PART 3 covers complaints principles, procedure & panel constitution. PART 4 includes a glossary and definitions.
Why is the document important/useful for your country?	It sets standards for ethical behaviour and to govern ethical promotion and sales practices in the medical devices industry in the UK (“the Industry”). Its website provides illustrative summaries of complaints.

Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. It has a good structure, dedicated website and complaints adjudication process.

Document found via (national associations or Google or another database)	Association of the British Pharmaceutical Industry (ABPI) website	
Title of document	Code of Practice for the Pharmaceutical Industry	
Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	Association of the British Pharmaceutical Industry (ABPI)	
Year the document was published (between 2005-2018)	2016	
Document saved in folder as	ABPI_Code of Practice_2018	
Who is the stated audience	Pharmaceutical industry	
Which definition of enhancement is used in the document?	-	
Which forms of enhancement are described in the document?	-	
Which targets of enhancement are described (what is enhanced)?	-	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:

Which motivations/intentions of enhancement are described?	-
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal Not specified
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☐ Others: Pharmaceutical industry
Which ethical challenges are addressed in the document?	The Code covers, inter alia, aspects that present ethical issues such as, appropriate use of medicines, discredit to, and reduction of confidence in, the industry, marketing authorisations, prescribing information, disparaging references, high standards, format, suitability and causing offence, sponsorship, provision of reprints and the use of quotations, distribution of material, disguised promotion, clinical trials and non - interventional studies of marketed medicines, inducements and inappropriate payments, relationships and contracts with certain organisations , transfers of value to health professionals and healthcare organisations etc.
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Detailed guidance is provided on the above aspects.
Which format is used in the document (checklist, continuous text, other)?	Continuous (numbered) text
How is the document structured?	The document has an Introduction, 29 clauses, a section on the Code administering body, i.e., the Prescription Medicines Code of Practice Authority (PMCPA), a section on the Constitution and Procedure, Guidelines on Company Procedures Relating to the Code Of Practice, List of Legislation, other Codes & Guidelines and an Index.
Why is the document important/useful for your country?	Yes.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. In additon to the above, the Code is well-formulated, it makes a connection with other Codes and legislation and is available in interactive format and PDF.

Document found via (national associations or Google or another database)	British Association of Prosthetists and Orthotists (BAPO) website	
Title of document	Ethical Code: The Ethical Code and Professional Conduct for Prosthetists, Orthotists, Associates and Affiliates	
Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	British Association of Prosthetists and Orthotists (BAPO)	
Year the document was published (between 2005-2018)	Updated 2016 (2009)	
Document saved in folder as	BAPO_Ethical code_2016	
Who is the stated audience	Prosthetists, orthotists, associates and affiliate members.	
Which definition of enhancement is used in the document?	-	
Which forms of enhancement are described in the document?	-	
Which targets of enhancement are described (what is enhanced)?	-	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☒ Prosthetics	☒ Other, please specify: Orthototics
Which motivations/intentions of enhancement are described?	-	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly	

	☐ Minors (children and adolescents) ☐ Prenatal Not specified ('patient' is mentioned)
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☒ Others: Patient welfare
Which ethical challenges are addressed in the document?	Patient autonomy and welfare, services to patients, personal and professional integrity , professional competence and standards
How are the ethical issues addressed? Are solutions offered? If so, which ones?	For each of the above, requirements/duties of care are prescribed.
Which format is used in the document (checklist, continuous text, other)?	Continuous (numbered) text
How is the document structured?	Opening remarks 1.Introduction 2.Patient Autonomy and Welfare 3. Services to Patients 4. Personal and Professional Integrity 5. Professional Competence and Standards
Why is the document important/useful for your country?	It provides a set of principles that apply to prosthetists, orthotists, associates and affiliate members and is a public statement of the values and principles used in promoting and maintaining high standards of professional behaviour. (BAPO Code) The Code is well-recognised in the field.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes, from the prosthetics/orthotics point of view.

Document found via (national associations or Google or another database)	Royal College of Surgeons (RCS) website
Title of document	Professional Standards for Cosmetic Surgery

Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	Royal College of Surgeons (RCS)	
Year the document was published (between 2005-2018)	2016	
Document saved in folder as	RCS_Professional Standards for Cosmetic Surgery_2016	
Who is the stated audience	Doctors who offer cosmetic interventions, surgery	
Which definition of enhancement is used in the document?		
Which forms of enhancement are described in the document?	Cosmetic surgery	
Which targets of enhancement are described (what is enhanced)?	Body, physical appearance	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☒ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	-	
Which life stage is addressed in the document?	☒ Adults (and adults with incapacity) ☐ Elderly ☒ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☒ Private life ☐ Employment ☐ Military	

	☒ Others: Might apply otherwise as well
Which ethical challenges are addressed in the document?	The guidance addresses key areas of risk identified for cosmetic surgery including communication, consent, professional behaviours, safety (in quality, practice, environment), and dealing with the psychologically vulnerable patient.
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The document presents surgery-specific principles alongside the generic GMC statements, which apply to all cosmetic treatments. The content has been organised thematically but the paragraph numbers of the GMC document have been kept.
Which format is used in the document (checklist, continuous text, other)?	Continuous (numbered) text.
How is the document structured?	Introduction How to use this document 1. Knowledge, skills and performance 2. Safety and quality 3. Communication, partnership and teamwork 4. Maintaining trust References
Why is the document important/useful for your country?	This guidance supplements the broad principles set out in the GMC Guidance for Doctors Who Offer Cosmetic Interventions (GMC, 2016) for the needs of invasive cosmetic surgery. It should be read in conjunction with the GMC document.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. The principles of this guidance underpin cosmetic surgery certification and set standards of good practice for all surgeons who perform cosmetic surgery. The guidance addresses key areas of risk identified for cosmetic surgery including communication, consent, professional behaviours and dealing with the psychologically vulnerable patient.

Document found via (national associations or Google or another database)	General Medical Council website
Title of document	Ethical guidance for doctors (including Guidance for doctors who offer cosmetic interventions)
Kind of document (PEC, NAEG, GDREC)	NAEG

Document developed by whom (organisation, profession)?	General Medical Council	
Year the document was published (between 2005-2018)	Undated/various dates for various parts	
Document saved in folder as	GMC_Ethical guidance for doctors	
Who is the stated audience	Doctors working in the UK	
Which definition of enhancement is used in the document?		
Which forms of enhancement are described in the document?	Drugs, medicines, cosmetic interventions	
Which targets of enhancement are described (what is enhanced)?	Body	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☒ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	-	
Which life stage is addressed in the document?	☒ Adults (and adults with incapacity) ☒ Elderly ☒ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☒ Others: Not sure how to answer this question	

Which ethical challenges are addressed in the document?	E.g., Confidentiality, consent and shared decision-making, candour and raising concerns, leadership and managenent, prescribing, children and young people, care at the end of life, maintaining professionalism, cosmetic interventions, research.
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Detailed guidance is provided.
Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	Sections.
Why is the document important/useful for your country?	Key guidance. The GMC's role is to "protect patients and improve medical education and practice across the UK" and this guidance sets the standards doctors need to follow throughout their careers to ensure the safety of patients, and the public's confidence in doctors is not risked.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. It might be useful to consult to see how it is structured and covers a variety of topics.

Document found via (national associations or Google or another database)	British Medical Association website
Title of document	Cognitive enhancing drugs and the workplace
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	British Medical Association
Year the document was published (between 2005-2018)	2015
Document saved in folder as	BMA_cognitive-enhancing-drugs-and-the-workplace-v2-Aug2015pdf
Who is the stated audience	Occupational physicians and others who care for patients who work
Which definition of enhancement is used in the document?	Cognitive enhancement or neuro-enhancement is the use by individuals of traditional, scientific or medical technologies to augment cognitive abilities.
Which forms of enhancement are described in the document?	Cognitive enhancement, neuro-enhancement, pharmacological cognitive enhancement, non-pharmacological modalities of enhancing cognition

Which targets of enhancement are described (what is enhanced)?	cognitive abilities, cognitive functioning, cognitive powers	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☒ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	to augment cognitive abilities to improve cognitive functioning in those suffering from specific medical disorders. to aid memory and concentration to protect or enhance their cognitive powers	
Which life stage is addressed in the document?	☒ Adults (and adults with incapacity) ☒ Elderly ☒ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☐ Private life ☒ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	Efficacy and safety of use, unrealistic user expectations	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Some solutions are suggested. It also includes a set of practice based recommendations for occupational physicians and others who care for patients who work.	
Which format is used in the document (checklist, continuous text, other)?	Continuous text	
How is the document structured?	Contents Executive summary	

	Chapter 1 – Cognitive enhancement Chapter 2 – Prescribed use of pharmacological cognitive enhancers Chapter 3 – Use of pharmacological cognitive enhancers by healthy individuals Chapter 4 – Legal aspects Chapter 5 – Practice based recommendations References
Why is the document important/useful for your country?	It includes a set of practice based recommendations for occupational physicians and others who care for patients who work.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Potentially, since it is one of the documents covering enhancement, per se.

Document found via (national associations or Google or another database)	Royal Society database
Title of document	HET and the future of work
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	Academy of Medical Sciences, the British Academy, the Royal Academy of Engineering and the Royal Society.
Year the document was published (between 2005-2018)	2012
Document saved in folder as	AMS_BA_RAE_RS_HET and future of work_2012
Who is the stated audience	Policy-makers, researchers in science and engineering, experts in the social sciences and humanities, research funders, industry, investors and publics, both within the UK and internationally.
Which definition of enhancement is used in the document?	The term 'HET' encompasses a range of approaches that may be used to improve aspects of human function (e.g. memory, hearing, mobility). This may either be for the purpose of restoring an impaired function to previous or average levels, or to raise function to a level considered to be 'beyond the norm' for humans. Its working definition includes all forms of enhancement that directly alter the individual, but excludes the wider environment, i.e. alterations to the environment itself that enhance human interactions with it.

Which forms of enhancement are described in the document?	Cognitive enhancement, physical enhancement, sensory enhancement, visual enhancement, cosmetic enhancement, nutrition and performance enhancement, collective enhancement etc	
Which targets of enhancement are described (what is enhanced)?	Mental faculties such as memory Abilities (auditory, mobility and limb function) Cells	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☒ Neurotechnology ☒ Cosmetic surgery ☒ Augmented reality ☒ tissue engineering ☒ genetic engineering ☒ Prosthetics	☒ Other, please specify:
Which motivations/intentions of enhancement are described?	To restore or improve human performance, overcome the current limits of one's human body.	
Which life stage is addressed in the document?	☒ Adults (and adults with incapacity) ☒ Elderly ☒ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☐ Private life ☒ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	Potential harms (to young people, from malfunctions, overehancement), fairness, coercion and disability (fairness and equity, coercion and freedom, disability and normality.	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The issues listed above are discussed. The report's Chapter 5 discusses possible implications for the future of work and society. Potential policy and regulatory implications are considered in Chapter 6.	
Which format is used in the document (checklist, continuous text, other)?	Continuous text	

How is the document structured?	Chapter 1 introduces the topic. Chapters 2 and 3 explore the science and engineering developments that could give rise to physical and cognitive enhancement. Opportunities and challenges relating to investment and commercialisation are outlined in Chapter 4. Chapter 5 discusses possible implications for the future of work and society. Potential policy and regulatory implications are considered in Chapter 6.
Why is the document important/useful for your country?	The report outlines selected developments from across science and engineering that could enable both cognitive and physical enhancement, although it is not exhaustive. Given that there is currently little debate about the use of enhancements at work or an academic research base to draw upon, the report highlights possible implications of such use, which are likely to be complex, and to identify potential areas for debate. This is the first time that four academies have combined their expertise to consider the policy implications of developments in a diverse range of research fields. The report captures the themes and questions that emerged from small policy-focused workshop on 7 March 2012, which brought together policy-makers with leading experts from across engineering, science, social science, the humanities and industry (note, it does not necessarily represent the views of the four host academies).
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes. For reasons stated above.

USA

Even though a large portion of the academic literature on HET continues to emerge from American institutes few professional organisations/societies have addressed the topic in terms of ethical codes or guidelines. Regarding official government institutions, the NIH (National Institute of Health) includes institutes and centres that may be expected to produce minor research on HET or research that could be considered HET-adjacent in the near future, such as via the National Institute on Aging (NIA) or the National Institute of Biomedical Imaging and Bioengineering (NIBIB), such that one might expect to find, if nothing else, positions on some HET issues within NIH departments. However, the results of the study failed to discover documents from any NIH institutes specifically focused on HET ELSI. The National Centre for Complementary and Integrative Health (NCCIH) currently includes a page on what they call sexual enhancements, but this is geared toward consumers/individuals and does not focus on research ethics or technological guidance.

Professional groups for medical fields that are expected to include HET options in the future currently make no clear indication about HET (generally) in their ethical codes. However, a few groups have issued policy statements regarding some HET domains, including a statement on performance-enhancing drugs

issued by AAOS (the American Academy/Association of Orthopaedic Surgeons) and detailed position statements from the American Academy of Neurology on neuro-enhancement for adults and paediatric patients in separate documents. The President's Council on Bioethics during former President George W. Bush and Barack Obama's administrations both released insightful documents acknowledging enhancement in part (focused on neurotechnology's during Obama's tenure) or whole (the report, Beyond Therapy, from Bush's administration covers virtually every topic that was discussed at the time). Unfortunately, at this time there is no existing President's Council on Bioethics, making it unclear when further work of this kind may emerge from such a group.

Whilst searching for relevant material on HET, the study failed to uncover any relevant documents on writing ethical codes that specifically address HET issues. Few relevant documents were found overall, demonstrating that even in the United States the subject has yet to take root at a policy/regulatory level. Existing enhancement technologies (performance-enhancing drugs, cosmetic surgery, limited cognitive enhancement options) have been acknowledged by the most relevant bodies (i.e., the American Academy of Neurology for cognitive enhancement), but it appears there are few official policy documents that offer anything more than recommendations for addressing emerging issues.

Challenges for this study included a limitation on time for the search task, meaning it is possible some important documents may have been missed due to the large number of organisations in the United States of America. As this report was not intended to provide a systematic overview on the topic, the results succeed in displaying a useful snapshot of the regulatory & policy landscape regarding HET in the USA; namely, the extensive amount of gaps on the subject.

TABLE 1: INDIVIDUAL AND COUNTRY INFORMATION

Names and emails of persons who did the work (if different from above)	Sean R. Jensen (s.r.jensen@utwente.nl)
Your organisation	University of Twente (NL)
Your country (again)	United States of America
Search conducted in which language	American English
Acknowledgements (any researcher who helped you to complete this task)	Dr. Valerie Racine, Western New England University (valerie.racine@wne.edu); Dr. Collin O'Neil, Lehman College CUNY (collin.oneil@lehman.cuny.edu)

TABLE 2: LIST OF ALL RELEVANT PROFESSIONAL ETHICS CODES (only HET)

SIENNA area	Title of document	URL	Year	Author/organisation	Stated audience	comments
HET	Code of Medical Ethics: Chapter 7: Opinions on Research & Innovation	https://www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-7%20.pdf	2016	American Medical Association	Practitioners/members	Does not explicitly address enhancement, but discusses adjacent areas
HET	Code of Ethics	https://www.cosmeticsurgery.org/page/CodeofEthics	2018	American Academy of Cosmetic Surgeons	Academy members	Very general
HET	Code of Ethics	https://www.americanboardcosmeticsurgery.org/about-abcs/code-of-ethics/	2018	American Board of Cosmetic Surgery	Members	General; board issues licenses for cosmetic surgeons

HET	Code of Ethics	https://www.ambrdfcs.org/code-ethics	2018	American Board of Facial Cosmetic Surgery	Members	General; board issues licenses for cosmetic surgeons
HET	Code of Ethics	http://www.apa.org/ethics/code/ethics-code-2017.pdf	2017	American Psychological Association	Members	Thorough, but no direct guidelines for HET
HET	Code of Professional Conduct	https://www.aan.com/siteassets/home-page/footer/membership-and-support/member-resources/professionalism--disciplinary-program/09codeofprofssionalconduct_ft.pdf	2009	American Academy of Neurology	Practitioners/members	General; does not offer any specific guidelines for HET
HET	Code of Medical Ethics and Professionalism for Orthopaedic Surgeons	https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/ethics/Code%20of%20Ethics%202013%20color%20logo.pdf	1988; most recent version: 2011	American Academy/Association of Orthopaedic Surgeons	Practitioners/members	Explicitly forbids (as unethical) prescribing "substances for the sole purpose of enhancing athletic performance" (VII.B)

TABLE 3: LIST OF ALL RELEVANT DOCUMENTS FROM NATIONAL ADVISORY/ETHICS GROUPS (only HET)

SIENNA area	Title of document (original + English translation)	URL	Year	Author/organisation	Stated audience	comments

HET	Responding to requests from adult patients for neuroenhancements. Guidance of the Ethics, Law and Humanities Committee	http://n.neurology.org/content/early/2009/09/23/WNL.0b013e3181beecfe.full-text.pdf	2009; revised 2013	American Academy of Neurology: Ethics, Law and Humanities Committee	Practitioners	Direct guideline; determines neuroenhancement ought to fit same category as cosmetic surgery: non-obligatory, not prohibited. Report does not offer guidance for children.
HET	Position Statement: Performance Enhancing Drugs	https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/position/1102%20Performance%20Enhancing%20Drugs.pdf	1991; revised 2012	American Academy/Association of Orthopaedic Surgeons	Practitioners	Direct guideline forbidding prescription of IPED for enhancement purposes.
HET	Position Statement: Innovation and New Technologies in Orthopaedic Surgery	https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/position/1185%20Innovation%20and%20New%20Technologies%20in%20Orthopaedic%20Surgery.pdf	2015	American Academy/Association of Orthopaedic Surgeons	Practitioners	Does not directly refer to HET, but encourages practitioners to ensure new innovations are properly understood w/ solid scientific basis, which may include HET
HET	Position Statement: Use of Emerging	https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/position/1187_Use%20of%20Emerging%20Biologic%20Therapies.pdf	2017	American Academy/Association of Orthopaedic Surgeons	Practitioners	Does not directly refer to HET, but acknowledges need for patient education and consent in new

	Biologic Therapies					therapies which may straddle therapy/enhancement distinction
HET	Beyond Therapy: Biotechnology and the Pursuit of Happiness	https://repository.library.georgetown.edu/bitstream/handle/10822/559341/beyond_therapy_final_webcorrected.pdf?sequence=1&isAllowed=y	2003	President's Council on Bioethics	Researchers, practitioners, policy makers	Exhaustive document weighing ethical issues, but offering no definite policy guidelines, only recommendations
HET	Gray Matters: Topics at the Intersection of Neuroscience, Ethics, and Society (vol. 2)	https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/GrayMatter_V2_508.pdf	2015	President's Council on Bioethics	Researchers, practitioners, policy makers	Provides recommendations on neuro-enhancement, including need for research and further guidance.
HET	Pediatric neuroenhancement: Ethical, legal, social, and neurodevelopmental implications	http://n.neurology.org/content/80/13/1251	2013	William D. Graf, Saskia K. Nagel, Leon G. Epstein, Geoffrey Miller, Ruth Nass, Dan Larriviere for the American Academy of Neurology (published in Neurology)	Practitioners	Advances position against neuroenhancement for paediatric patients, and recommends against neuroenhancement for nearly autonomous adolescents based on social, developmental and professional integrity issues.

HET	Therapeutic Use Exemption Policy	https://www.usada.org/wp-content/uploads/tue_policy.pdf	2018	U.S. Anti-Doping Agency	Athletes, coaches	Provides rules for athletes/coaches to apply for exemptions to anti-doping regulations in professional competition.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET (1 / 7)

Document found via (national associations or Google or another database)	Google
Title of document	Code of Medical Ethics: Chapter 7: Opinions on Research & Innovation
Kind of document (PEC, NAEG, GDREC)	PEC
Document developed by whom (organisation, profession)?	American Medical Association (AMA)
Year the document was published (between 2005-2018)	Most recent: 2016
Document saved in folder as	CodeofMedicalEthicsChapter7OpinionsonResearchandInnovation-AMA-HET-2016.pdf
Who is the stated audience	physicians
Which definition of enhancement is used in the document?	N/A: Document does not directly address enhancement, thus does not define it, but does discuss adjacent issues
Which forms of enhancement are described in the document?	Genetic engineering
Which targets of enhancement are described (what is enhanced)?	Genetic traits

Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☒ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?		
Which life stage is addressed in the document?	☒ Adults ☐ Elderly ☐ Minors (children and adolescents) ☒ Prenatal	
Which context is addressed?	☒ Private life ☐ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	Unpredictable effects of germ-line genetic engineering	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Issues are raised as reasons to forbid the practice of HET in this domain	
Which format is used in the document (checklist, continuous text, other)?	Continuous text & bullet points	
How is the document structured?	Chapter, section, subsection	
Why is the document important/useful for your country?	The AMA is one of the largest medical institutions in the country	

Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes; demonstrates few HET issues are addressed even by a large, highly-esteemed medical institution in the USA, and also demonstrates the issue that is addressed is explicitly forbidden (genetic enhancement).

TABLE 6: MOST RELEVANT DOCUMENTS IN HET (2 / 7)

Document found via (national associations or Google or another database)	Google	
Title of document	Responding to requests from adult patients for neuroenhancements. Guidance of the Ethics, Law and Humanities Committee	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	American Academy of Neurology's Guidance of the Ethics, Law and Humanities Committee	
Year the document was published (between 2005-2018)	2009	
Document saved in folder as	RespondingToRequestsFromAdultPatientsForNeuroenhancements-AAN-HET-2009	
Who is the stated audience	Physicians	
Which definition of enhancement is used in the document?	Neuroenhancement is described as "prescribing medications to normal adults for the purpose of augmenting their normal cognitive or affective function" (p2).	
Which forms of enhancement are described in the document?	Neuro/cognitive enhancement	
Which targets of enhancement are described (what is enhanced)?	Cognitive skills, memory	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☒ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering	☐ Other, please specify:

	☐ Prosthetics	
Which motivations/intentions of enhancement are described?	Increase of memory or cognitive skills	
Which life stage is addressed in the document?	☒ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☐ Others:	
Which ethical challenges are addressed in the document?	Authority for off-label prescribing, beneficience & nonmaleficence, respect for autonomy, conflicts of interest	
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Issues are described and discussed. Solution offered is that physicians prescribing medications "have no obligation to do so and may ethically refuse to do so. Neurologists must exercise their clinical and ethical judgment to decide whether to prescribe medications for neuroenhancement. It is ethically permissible for neurologists to prescribe such therapies, provided that they adhere to well-known bioethical principles of respect for autonomy, beneficence, and nonmaleficence" (p6).	
Which format is used in the document (checklist, continuous text, other)?	Continuous text	
How is the document structured?	Medical report with introduction, methods, & sections describing issues and positions	
Why is the document important/useful for your country?	It is one of very few documents offering official guidelines on an HET issue for practicing physicians published by a professional organisation.	
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes; document offers insight into current policy on neuroenhancement for adults.	

TABLE 6: MOST RELEVANT DOCUMENTS IN HET (3 / 7)

Document found via (national associations or Google or another database)	Google	
Title of document	Gray Matters: Topics at the Intersection of Neuroscience, Ethics, and Society (vol. 2)	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	Presidential Commission for the Study of Bioethical Issues	
Year the document was published (between 2005-2018)	2015	
Document saved in folder as	GrayMatterVolume2-PCoB-HET-2015	
Who is the stated audience	President of the United States; other policy-makers; public	
Which definition of enhancement is used in the document?	Cognitive enhancement is defined as "interventions such as pharmaceuticals, technological devices, and surgeries that improve abilities to think, feel, and remember" (p36)	
Which forms of enhancement are described in the document?	Cognitive, affective, cosmetic	
Which targets of enhancement are described (what is enhanced)?	Memory, cognitive function, control of emotion/affect	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☒ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Cosmetic & augmentation/enhancement of abilities	

Which life stage is addressed in the document?	☒ Adults ☐ Elderly ☒ Minors (children and adolescents) ☐ Prenatal
Which context is addressed?	☒ Private life ☒ Employment ☐ Military ☐ Others:
Which ethical challenges are addressed in the document?	Most issues discussed in 3.1 regarding cognitive enhancement are covered: methylphenidate, modafinil, DBS, etc., also including minor discussion of psychedelic drugs
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Issues are raised with citations to academic literature, often acknowledging lack of policy/guidelines and suggesting a solution of "engag[ing] the public and all relevant stakeholders in a discussion about the ethics of novel neural modifiers" (p40).
Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	Chapters & sections
Why is the document important/useful for your country?	Document was issued by an official government body
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes; can be used as supporting text to confirm our research on neuro/cognitive enhancement, including where there are gaps.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET (4 / 7)

Document found via (national associations or Google or another database)	Google
Title of document	Ethical Principles of Psychologists and Code of Conduct

Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	American Psychological Association (APA)	
Year the document was published (between 2005-2018)	2016	
Document saved in folder as	CodeofEthics-APA-HET-2018	
Who is the stated audience	Practitioners	
Which definition of enhancement is used in the document?	Enhancement is not discussed directly.	
Which forms of enhancement are described in the document?	N/A (see above)	
Which targets of enhancement are described (what is enhanced)?	N/A (see above)	
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	N/A (see above)	
Which life stage is addressed in the document?	☒ Adults ☒ Elderly ☒ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☒ Private life ☐ Employment ☐ Military	

	☒ Others: Patient & Research Subject
Which ethical challenges are addressed in the document?	General ethical principles are described, then codes are established for dealing with ethical violations, standards of professional integrity, responsibilities, etc.
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Issues are broad, i.e. "Conflicts between ethics and organisational demands" (p4), with text establishing the association's stance on how to resolve the issues (i.e., it is stated "Under no circumstances may [the association's] standard be used to justify or defend violating human rights" in relation to organisational ethics conflicts (p4).)
Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	Sections with subsections
Why is the document important/useful for your country?	APA is a large, influential institution dealing with a science that we expect will need to address HET issues in the near future.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	The complete lack of material about enhancement in this document demonstrates there is a significant gap in ethical codes for professional associations regarding emerging technologies.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET (5 / 7)

Document found via (national associations or Google or another database)	Google	
Title of document	Code of Medical Ethics and Professionalism for Orthopaedic Surgeons	
Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	American Academy of Orthopaedic Surgeons & American Association of Orthopaedic Surgeons	
Year the document was published (between 2005-2018)	2011 (most recent revision; originally adopted in 1988)	
Document saved in folder as	CoMedEthProfessionalismforOrthopaedicSurgeons-AAOS-HET-2011.pdf	
Who is the stated audience	Practitioners	
Which definition of enhancement is used in the document?	Enhancement is not defined in the document.	
Which forms of enhancement are described in the document?	Physical enhancement	
Which targets of enhancement are described (what is enhanced)?	Substances for enhancing athletic performance	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☒ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Athletic performance	
Which life stage is addressed in the document?	☒ Adults ☐ Elderly ☐ Minors (children and adolescents)	

	☐ Prenatal
Which context is addressed?	☒ Private life ☐ Employment ☐ Military ☐ Others:
Which ethical challenges are addressed in the document?	Although the issues are not elaborated upon, VII. B. identifies that it is "unethical to prescribe substances for the sole purpose of enhancing athletic performance," (p5) and III. E. states "Except when inconsistent with applicable law, orthopaedic surgeons have a right to dispense medication, products, assistive devices, orthopaedic appliances, and similar related patient-care items [. . .] as long as their doing so provides a convenience or an accommodation to the patient without taking financial advantage of the patient" (p3).
How are the ethical issues addressed? Are solutions offered? If so, which ones?	Enhancement, as long as it is the sole outcome, is expressly forbidden. Otherwise, enhancement is not directly discussed.
Which format is used in the document (checklist, continuous text, other)?	List divided into paragraphs
How is the document structured?	As a list
Why is the document important/useful for your country?	The AAOS is a major association in the United States with wide influence.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	This document demonstrates areas where ethical lapses have already been identified (i.e. abuse by professional athletes) is acknowledged. However, other still-emerging technologies, such as prosthetic devices with enhancement potential, are not discussed.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET (6 / 7)

Document found via (national associations or Google or another database)	Consortium member
Title of document	Pediatric neuroenhancement: Ethical, legal, social, and neurodevelopmental implications.
Kind of document (PEC, NAEG, GDREC)	NAEG

Document developed by whom (organisation, profession)?	American Academy of Neurology: William D. Graf, Saskia K. Nagel, Leon G. Epstein, Geoffrey Miller, Ruth Nass, Dan Larriviere	
Year the document was published (between 2005-2018)	2013	
Document saved in folder as	PediatricNeuroenhancement-Neurology-HET-2013	
Who is the stated audience	Practitioners, parents	
Which definition of enhancement is used in the document?	"Neuroenhancement is the use of prescription medication by healthy persons for the purpose of augmenting normal cognitive or affective function" (p1).	
Which forms of enhancement are described in the document?	Neuroenhancement	
Which targets of enhancement are described (what is enhanced)?	Cognitive or affective function	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☒ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Enhancement of cognitive function in children and adolescents	
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☒ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☒ Private life ☐ Employment ☐ Military ☐ Others:	

Which ethical challenges are addressed in the document?	"the special fiduciary roles and obligations of the physician within doctor-child-parent relationships" and "physicians asked to prescribe pharmacologic neuroenhancement drugs for presumably healthy children and adolescents" (p2)
How are the ethical issues addressed? Are solutions offered? If so, which ones?	The issues are discussed at length, considering trends of use, development of pharmacological drugs, and more. The authors find "Physicians have the authority and the obligation to refuse requests for inappropriate treatment" (p6) and "at the present time that neuroenhancement in legally and developmentally non-autonomous children and adolescents is not justifiable. In nearly autonomous adolescents, the fiduciary obligation of the physician may be weaker, but the prescription of neuroenhancement is inadvisable because of numerous social and neurodevelopmental issues (p8).
Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	Position paper
Why is the document important/useful for your country?	The AAN is a large and highly influential academy in the United States.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes; this is a rare document from a NAEG that directly addresses an ethical issue about HET and provides clear recommendations with a justification.

TABLE 6: MOST RELEVANT DOCUMENTS IN HET (7 / 7)

Document found via (national associations or Google or another database)	Correspondence with contributor
Title of document	Therapeutic Use Exemption Policy
Kind of document (PEC, NAEG, GDREC)	NAEG
Document developed by whom (organisation, profession)?	U.S. Anti-doping Agency
Year the document was published (between 2005-2018)	2018

Document saved in folder as	TherapeuticUseExemptionPolicy-USADA-HET-2018.pdf	
Who is the stated audience	Athletes, coaches & practitioners	
Which definition of enhancement is used in the document?	The term enhancement is used, but HET is not explicitly defined in the document.	
Which forms of enhancement are described in the document?	Enhancement of performance beyond an individual's normal state of health	
Which targets of enhancement are described (what is enhanced)?	Athletic enhancement	
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☐ Other, please specify:
Which motivations/intentions of enhancement are described?	Enhancement of physical abilities for athletic performance	
Which life stage is addressed in the document?	☒ Adults ☐ Elderly ☐ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☒ Others: Professional sports	
Which ethical challenges are addressed in the document?	Exemption from anti-doping policy for therapeutic purposes, i.e. enhancement as a side-effect of a treatment.	

How are the ethical issues addressed? Are solutions offered? If so, which ones?	Rules are provided for athletes & coaches to follow for documenting possible enhancement as a side-effect of a treatment that would otherwise exempt the athlete from professional competition based on wider guidelines from the U.S. Anti-doping Agency.
Which format is used in the document (checklist, continuous text, other)?	Continuous text with some listing
How is the document structured?	Policy document
Why is the document important/useful for your country?	The U.S. Anti-doping Agency's policies are followed by many national sports leagues.
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	Yes; it is useful to see how an agency that oversees competitive violations that are often due to the use of HET pharmaceuticals discusses therapeutic use of substances that may also result in enhancement.

Annex 2: Report of the international search

The international search for relevant international documents (including European level) was conducted by EUREC with the following criteria:

We searched via Google and directly by looking at professional organisations websites. We looked at the first 25 results and only at documents from a formal body/recognized group or organisation or advisory bodies. The time period covered in the search was 1990's to current. The search terms used in the search were:

- "enhancement" or "human enhancement" or "neuro-enhancement" or "human augmentation" AND "recommendations" or "points to consider" or "guidelines" or "guidance" or "code" or "policy" AND "European" "international"
- "lifestyle drugs" or "biohacking" or "non-therapeutic" or "beyond therapy" or "physical performance enhancement" or "image and performance enhancing drugs" or "nootropics" or "smart-drugs" or "designer drugs"

The search was carried out only in English and used the following inclusion/exclusion criteria:

- Ethics or ELSI had to be in it (but it could be more applied).
- Anything that did not address ethical aspects (i.e., was in the nature of practical standard operating procedures) was excluded.
- Articles written by individual authors who are not part of an official /recognised group/professional organisation/advisory body were excluded (unless commissioned by the relevant body/group/authority).

All the documents found were saved on SharePoint (SIENNA project shared space) as PDF documents with the document author, title and year.

TABLE 1: LIST OF ALL RELEVANT PROFESSIONAL ETHICS CODES

SIENNA area	Title of document	URL	Year	Author/organisation	Stated audience	comments
HET	World Anti-Doping Code	https://www.wada-ama.org/sites/default/files/resources/files/wada_anti-doping_code_2018_english_final.pdf	2015 with 2018 amendments	World Anti-Doping Agency	Signatories especially, athletes, sports clubs, sports federations, etc.	

HET	International Convention against Doping in Sport	http://portal.unesco.org/en/ev.php-URL_ID=31037&URL_DO=DO_TOPIC&URL_SECTION=201.html	2005	UNESCO	Signatories	
HET	International Olympic Committee Anti-Doping Rules applicable to the Olympic Winter Games PyeongChang 2018	https://www.wada-ama.org/sites/default/files/resources/files/ioc_adr_pyeongchang_2018_20180125_en.pdf	2018	International Olympic Committe	Any Person belonging in any capacity whatsoever to the Olympic Movement	
HET	ISAPS Code of Ethics	https://www.isaps.org/medical-professionals/code-of-ethics/	No date	International Society of Aesthetic Plastic Surgery	professionals	Very general

TABLE 2: LIST OF ALL RELEVANT DOCUMENTS FROM INTERNATIONAL ADVISORY/ETHICS GROUPS (IAEGs)

SIENNA area	Title of document	URL	Year	Author/organisation	Stated audience	comments
HET	HET Study	https://www.itas.kit.edu/downloads/etag_coua09a.pdf	2009	Science and Technology Options Assessment STOA of the European Parliament	EU legislators, parliament	
HET	HET. Scientific, Ethical and Theological Aspects from a European Perspective	http://www.ceceurope.org/wp-content/uploads/2015/07/CEC-Bookonline.pdf	2012	Church and Society Commission of the Conference of European	Experts in bioethical issues (especially HET) and the interested public	

				Churches (Publisher)		
HET	HET – A Discussion Document	http://www.ceceurope.org/wp-content/uploads/2015/12/Human_Enhancement_March_10.pdf	2009	Conference of European Churches (CEC), Church & Society Commission, Working Group on Bioethics and Biotechnology	Presented at CEC Lyon Assembly	
HET	Better Humans? The politics of human enhancement and life extension	https://www.demos.co.uk/files/betterhumansweb.pdf	2006	Demos (publisher)	policy-makers, companies, public service providers and social entrepreneurs	
HET	The non-medical use of prescription drugs Policy direction issues. Discussion paper	https://www.unodc.org/documents/drug-prevention-and-treatment/nonmedical-use-prescription-drugs.pdf	2011	United Nations Office on Drugs and Crime	Governments, policy-makers	Mention of lifestyle drugs, no special policies for them
HET	Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality	http://www.euro.who.int/__data/assets/pdf_file/0008/98432/E83015.pdf	2004	European Observatory on Health Systems and Policies Series	health policy makers and advisers in Europe, academics and students in the field of health policy	
HET, HG	Guidelines for the Appropriate Risk Governance of Synthetic Biology	https://www.irgc.org/IMG/pdf/irgc_SB_final_07jan_web.pdf	2010	International Risk Governance Council	Policy makers	Only implicit relevance for HET

HET	Ethical aspects of ICT implants in the human body	http://ec.europa.eu/archives/bepa/european-group-ethics/docs/avis20_en.pdf	2005	European Group on Ethics in Science and new Technologies (EGE)	Society, scientists, professionals, policy makers	
HET	Ethical aspects arising from doping in sports	http://ec.europa.eu/archives/bepa/european-group-ethics/docs/avis14_en.pdf	1999			

MOST RELEVANT DOCUMENTS FOUND IN THE INTERNATIONAL SEARCH FOR HET

Document found via	Google	
Title of document	Word Anti-Doping Code	
Kind of document (PEC, NAEG, GDREC)	PEC	
Document developed by whom (organisation, profession)?	World Anti-Doping Agency	
Year the document was published (between 2005-2018)	2005 with 2018 amendments	
Document saved in folder as		
Who is the stated audience	Athletes, society	
Which definition of enhancement is used in the document?		
Which forms of enhancement are described in the document?	Doping Enhancement of sports performance	
Which targets of enhancement are described (what is enhanced)?		
Which means/methods/tools of enhancement are described?	☐ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality	☒ Other, please specify:

	☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	Doping, enhancement of sport performance with drugs and other performing enhancing substances
Which motivations/intentions of enhancement are described?		
Which life stage is addressed in the document?	☒ Adults ☐ Elderly ☒ Minors (children and adolescents) ☐ Prenatal	
Which context is addressed?	☒ Private life ☒ Employment ☐ Military ☒ Others: everyone doing sports professional	
Which ethical challenges are addressed in the document?	"To fight doping by promoting the spirit of sport, the Code requires each Anti-Doping Organisation to develop and implement education and prevention programs for Athletes, including youth, and Athlete Support Personnel." (p. 14)	
How are the ethical issues addressed? Are solutions offered? If so, which ones?		
Which format is used in the document (checklist, continuous text, other)?	Continuous text	
How is the document structured?		
Why is the document important/useful for your country?		
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.		

Document found via (national associations or Google or another database)	Google	
Title of document	The non-medical use of prescription drugs Policy direction issues	
Kind of document (PEC, NAEG, GDREC)	NAEG	
Document developed by whom (organisation, profession)?	United Nations Office on Drug and Crime (UNODC)	
Year the document was published (between 2005-2018)	2011	
Document saved in folder as		
Who is the stated audience	Governments, policy-makers, society	
Which definition of enhancement is used in the document?	Not specified. Document is very general	
Which forms of enhancement are described in the document?		
Which targets of enhancement are described (what is enhanced)?		
Which means/methods/tools of enhancement are described?	☒ Pharmacology ☐ Neurotechnology ☐ Cosmetic surgery ☐ Augmented reality ☐ tissue engineering ☐ genetic engineering ☐ Prosthetics	☒ Other, please specify: Lifestyle drugs
Which motivations/intentions of enhancement are described?		
Which life stage is addressed in the document?	☐ Adults ☐ Elderly ☐ Minors (children and adolescents)	

	☐ Prenatal
Which context is addressed?	☐ Private life ☐ Employment ☐ Military ☐ Others:
Which ethical challenges are addressed in the document? **How are the ethical issues addressed? Are solutions offered? If so, which ones?**	• Collecting basic epidemiological data, on an ongoing basis, regarding the extent and patterns of non-medical use of prescription drugs and their consequences; • Establishing a medication management system that ensures that medication is available to those who need it, while monitoring for and preventing possible diversion at all different levels: production, storage, health-care (prescribing physicians and pharmacists), patients, and the Internet; • Raising awareness among policymakers and clinicians, parents, young people, and • teachers; • Training health-care professionals on an ongoing basis on how to prevent, recognize and manage the non-medical use of prescription drugs and related consequences; • Taking an official stance by addressing the issue of non-medical use of controlled prescription drugs directly in drugs legislation; • Researching whether and how to tailor prevention and treatment efforts for the non-medical use of prescription drugs; • Researching how to treat polysubstance users and those with a co-morbid illness; • Doing further research on the risk and protective factors for the non-medical use of prescription drugs, with particular attention to specific risk populations, such as young people, women, older adults and health professionals; • Providing clear guidelines to physicians on good practices for prescribing the use of strong psychoactive medication, including both initiation and time limits; • Using systems of supervised daily dosing for strong psychoactive medication when appropriate; • Providing incentives for medical practitioners to not overprescribe strong psychoactive medication; • Providing disincentives for the overprescription of strong psychoactive medication. (P. 47-48)

Which format is used in the document (checklist, continuous text, other)?	Continuous text
How is the document structured?	
Why is the document important/useful for your country?	
Is the document useful for the development of the SIENNA codes and other ethical frameworks? If yes, please explain.	

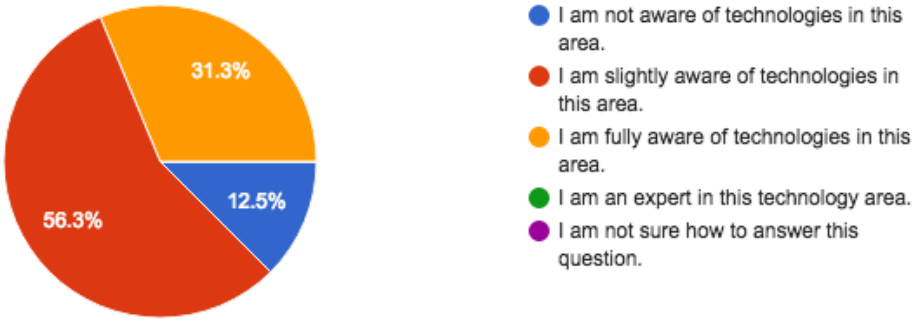
Annex 3: Online Survey – questions and answers

The online survey was developed for all three SIENNA areas, therefore questions are asked not only regarding AI&R, but also regarding Human Genomics and Human Enhancement. The responses were stripped from identifying information.

Questions and answers

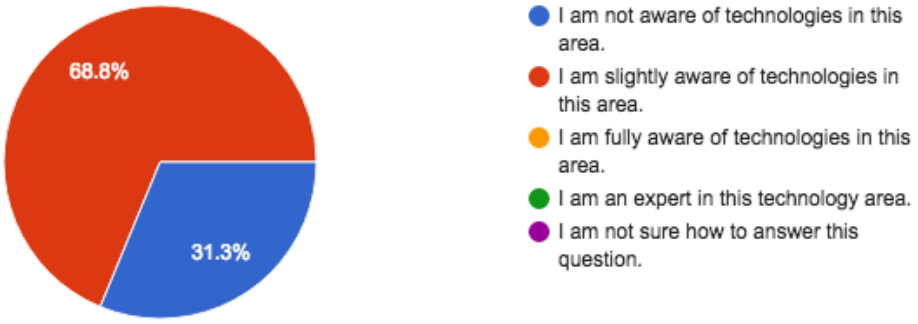
With respect to Human Genomics, to what extent are you aware of technologies in this area?

16 responses



With respect to Human Enhancement, to what extent are you aware of technologies in this area?

16 responses

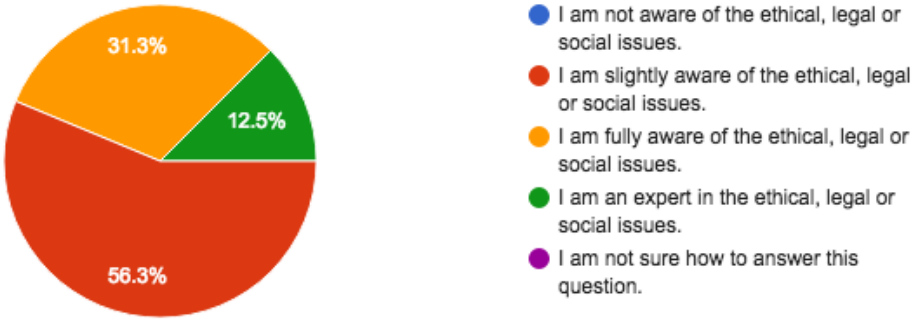


With respect to Artificial Intelligence and Robotics to what extent are you aware of technologies in this area?

16 responses

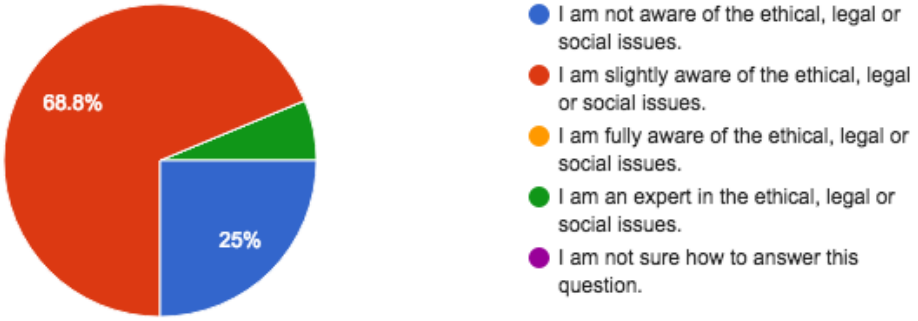
How aware are you of the ethical, legal and social issues relating to Human Genomics?

16 responses



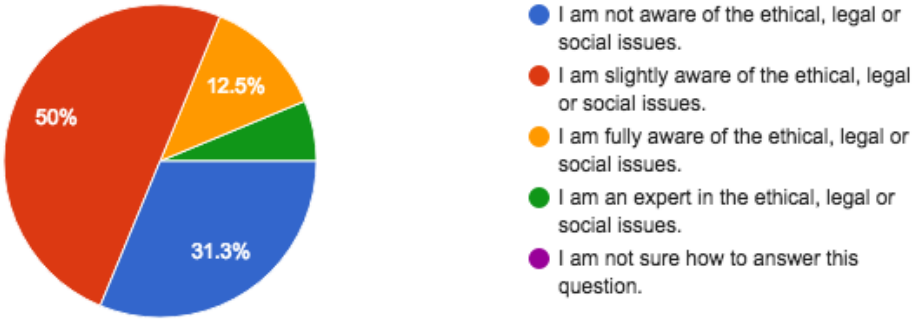
How aware are you of the ethical, legal and social issues relating to Human Enhancement?

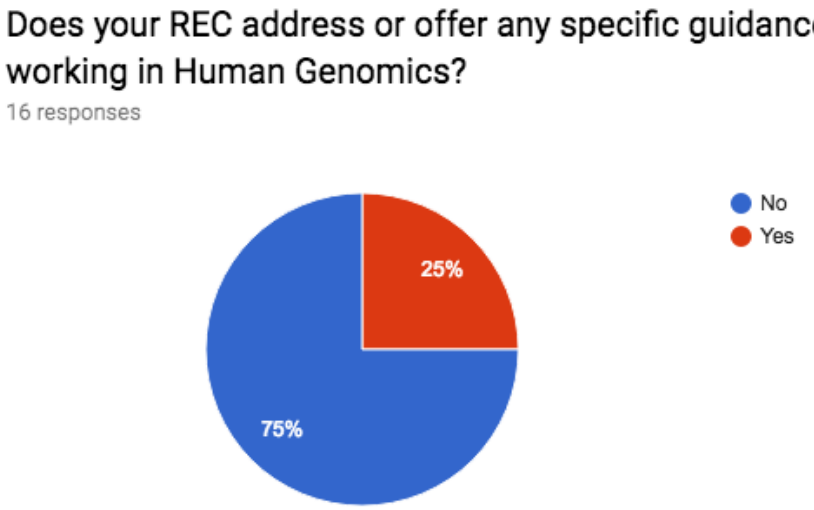
16 responses



How aware are you of the ethical, legal and social issues relating to Artificial Intelligence and Robotics?

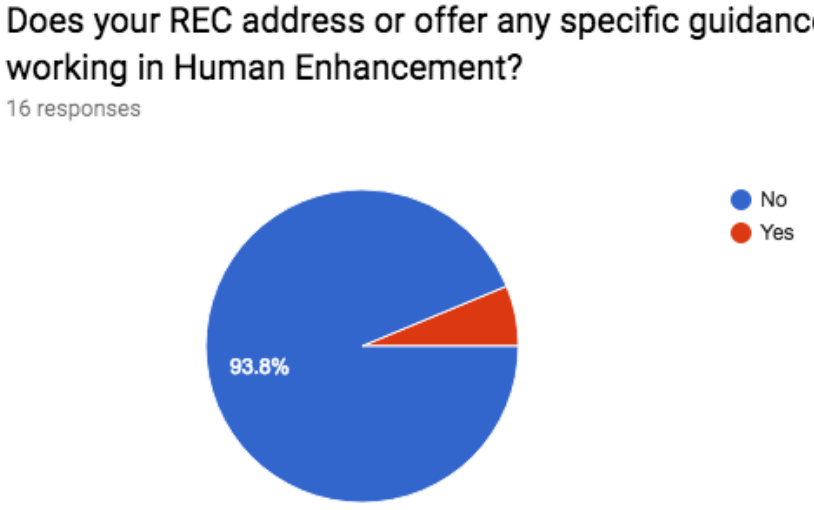
16 responses





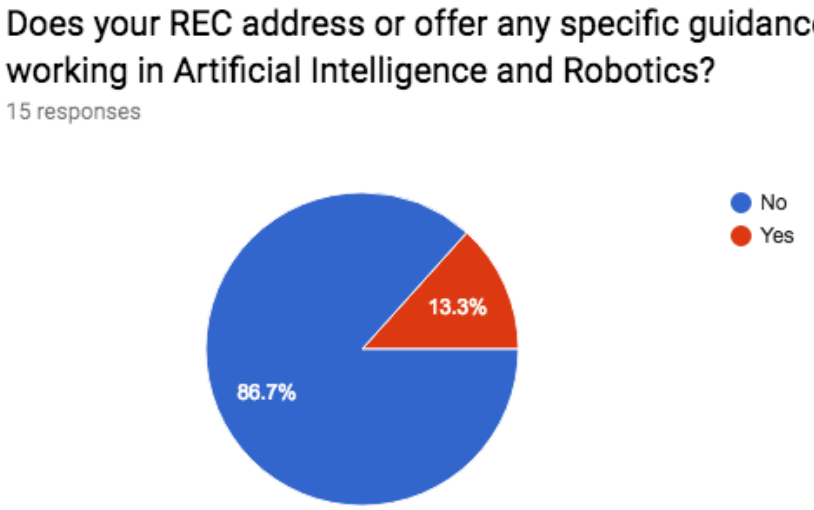
If yes, please provide links and/or information here: 4 responses

- The question is ambiguous as any REC has the responsibility to assess protocols on HG. Yet it does not necessarily require to draft specific guidance documents as there are already some available and the general principles of research ethics apply in any case which means that specific guidance documents may not be needed.
- we approve all medical research projects
- http://www.nvk.dk/~/media/NVK/Dokumenter/Guidelines-on-Genomics-Research.pdf?la=da
- Management of Incidental Findings in projects involving whole-genome sequencing (http://www.cner.lu/en-gb/procedures/incidentalfindings.aspx)



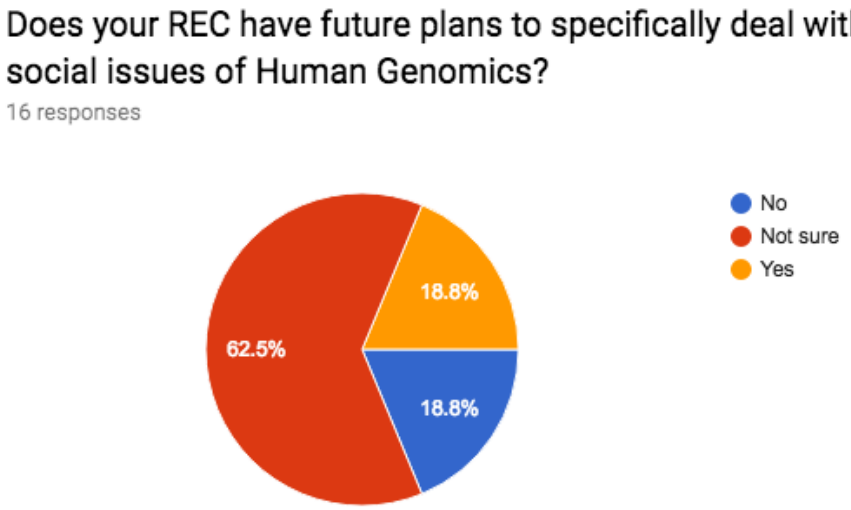
If yes, please provide links and/or information here:2 responses

- The question is ambiguous as any REC has the responsibility to assess protocols on "HET" (whether they are identified as such or not). Yet it does not necessarily require to draft specific guidance documents as there are already some available and the general principles of research ethics apply in any case which means that specific guidance documents may not be needed. In addition, HET is as such a confusing concept as it implies that the research is actually enhancing human while some would argue that such technological enhancement may well be an impoverishment of mankind in a philosophical viewpoint. Innovation does not always equals progress.
- we have not received applications for this yet



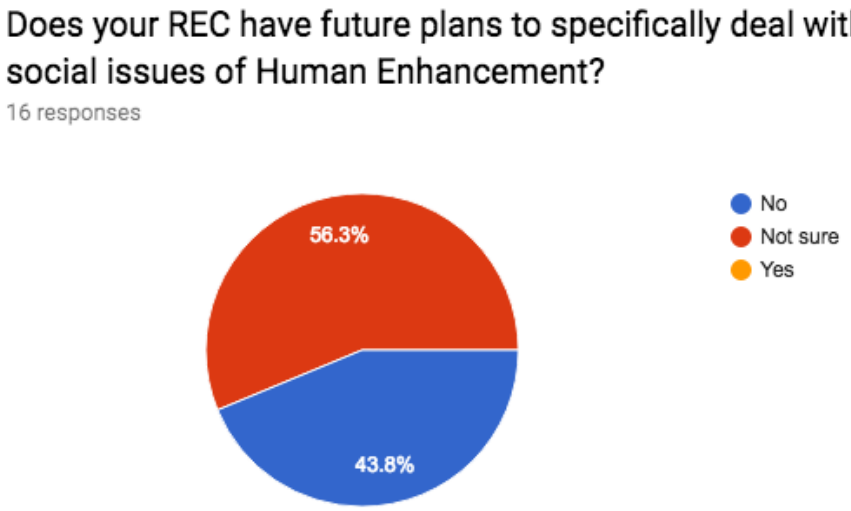
If yes, please provide links and/or information here: 2 responses

- The question is ambiguous as any REC has the responsibility to assess protocols on AI and Robotics. Yet it does not necessarily require to draft specific guidance documents as there are already some available and the general principles of research ethics apply in any case which means that specific guidance documents may not be needed.
- when the projects use real patient data



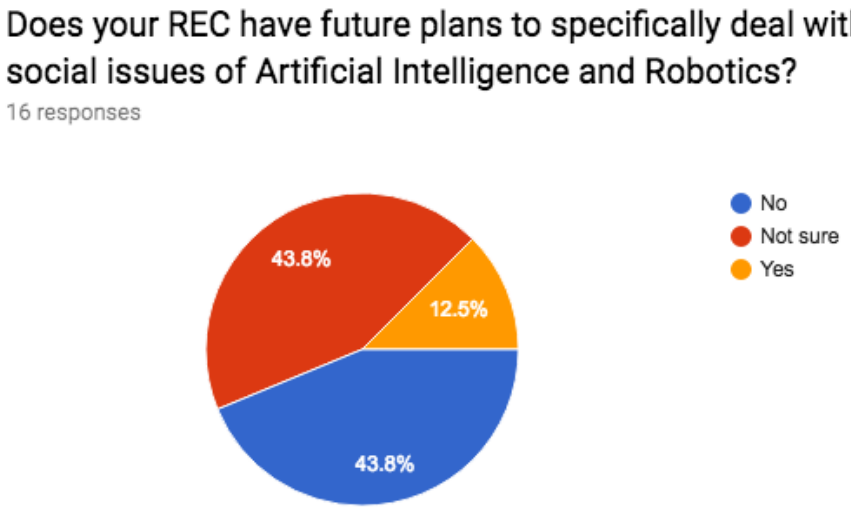
If yes, please specify here: 3 responses

- RECs normally have limited control on the researches submitted to them. The region around the lake Leman (aka Lake of Geneva) presents itself as the health valley. This is therefore likely that there will be increased research activities in this field. The REC will then adapt itself to this evolution (see remarks above).
- we have published guidelines
- We plan to help researchers to balance health needs and risks of high expectations, exploitation



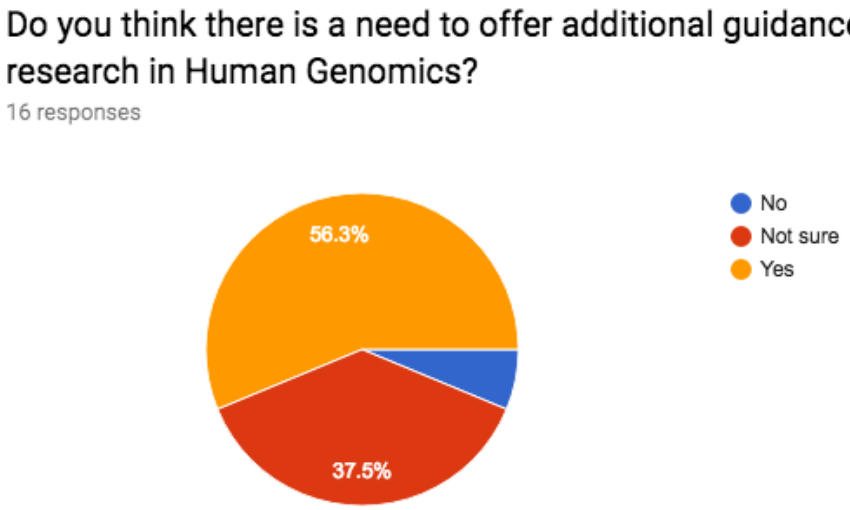
If yes, please specify here: 1 response

- It all depends on what is meant by HET. Advance research is done on exoskeleton and repairing brain damages. There is also a lot of activities around doping. This is therefore likely that there will more activities in this field in the future (see remark on HG).



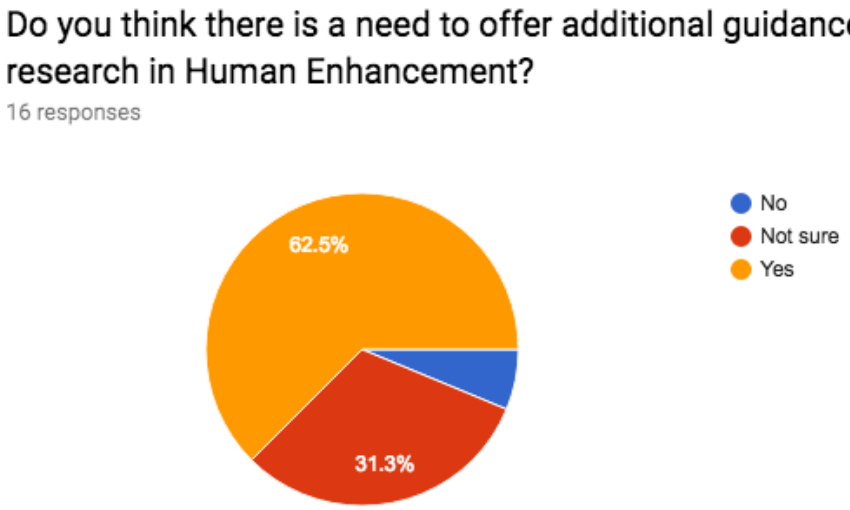
If yes, please specify here:3 responses

- RECs normally have limited control on the researches submitted to them. The region around the lake Leman (aka Lake of Geneva) presents itself as the health valley. This is therefore likely that there will be increased research activities in this field. The REC will then adapt itself to this evolution (see remarks above).
- swissethics is organising a symposium, specifically designed for members of the Swiss ethics committees, on ethical, legal and social issues of artificial intelligence, in Zurich on November 13, 2018. Link to the Agenda: https://swissethics.ch/doc/swissethics/fortbildung/2018/181113_Fortbildung_swissethics.pdf
- Topics like data protection and validation of research are more important in big data;



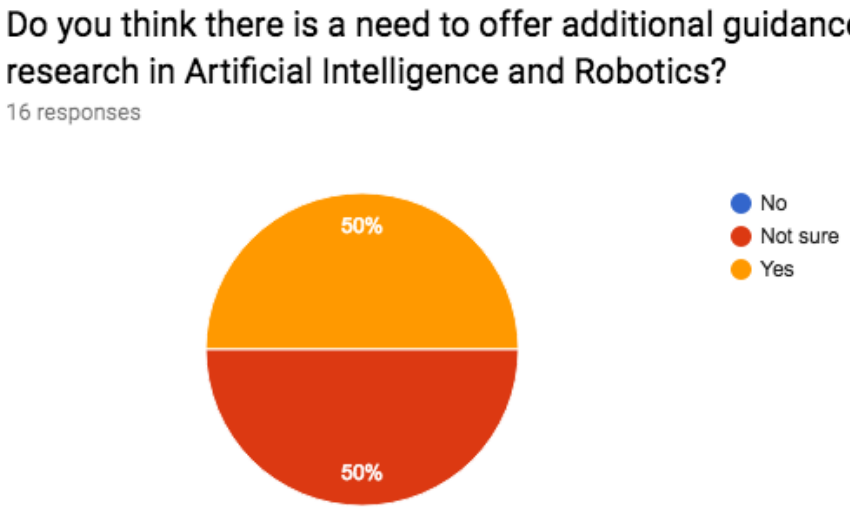
If yes, please specify here: 4 responses

- As recent (and past) history, most abuses do not happen due to a lack of norms but rather a lack of consideration for them and their underlying principles. Producing more norms has been a trend in research ethics and regulation since WWII. As Jay Katz said in 1969: "The proliferation of such codes testifies to the difficulty of promulgating a set of rules that does not immediately raise more questions than it answers. At this stage of our confusion, it is unlikely that codes will resolve many of the problems, though they may serve a useful function later. Even the much endorsed Declaration of Helsinki – praised, perhaps, because it is the newest and therefore the least examined – will create problems for those who wish to implement it". There has been limited progress in raising the ethical mentality within research institutions. Of course, this would be less lucrative for ethics centres as the industry and others are less likely to finance virtues behaviour rather than workshops and other publications.
- There is a need for the informed consent in this field
- risk management, realistic expectations
- Ethically difficult issue with rapid development



If yes, please specify here:5 responses

- Not only the same remarks apply than for HG, but the very concept of "HET" is at best confusing, at worst the entry door to totalitarism. The very idea that humans need to be enhanced is worrying, especially if you refer to the previous time in history when similar proposals were formulated and, even worst, tested. As Hans Jonas said in 1969 (again), ""“Let us not forget that progress is an optional goal, not an unconditional commitment, and that its tempo in particular, compulsive as it may become, has nothing sacred about it”. The best guidance in fact would be to explain to researchers why "human enhancement" should be banned as a concept.
- a guide for REC members regarding the ethical concerns such research projects may raise and possible approaches to deal with them could be useful
- The knowledge about these issues and their development is scarce. Identifying the ethical problems they pose is the first step
- risk Management, use and abuse,
- It is necceary to draw a line between ehancement and mere addiction to anything new

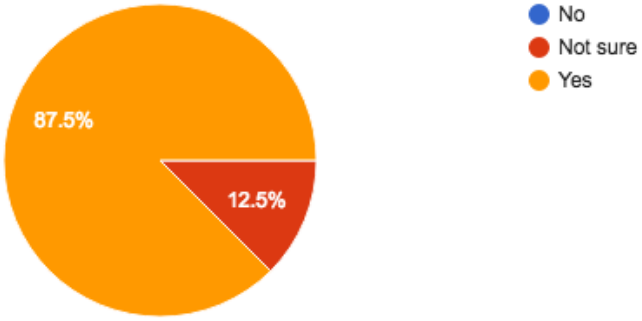


If yes, please specify here:5 responses

- see remarks on HG
- a guide for REC members regarding the ethical concerns such research projects may raise and possible approaches to deal with them could be useful
- The knowledge about these issues and their development is scarce. Identifying the ethical problems they pose is the first step
- consequences of automated decision support
- Quite dangerous research with unpredictable progress

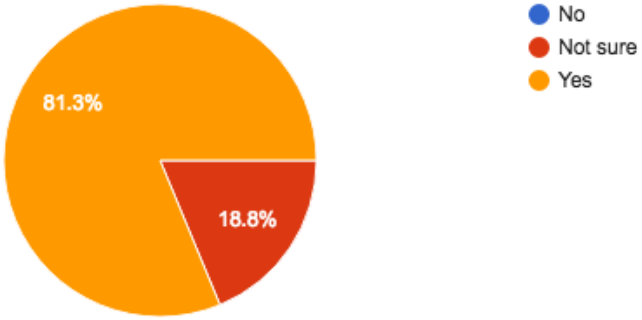
Do you think there is a need to offer additional education and training for REC members to learn more about ethi...nd social issues in Human Genomics?

16 responses



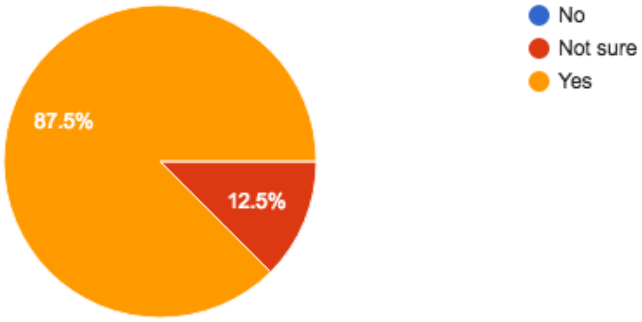
Do you think there is a need to offer additional education and training for REC members to learn more about eth...ocial issues in Human Enhancement?

16 responses



Do you think there is a need to offer additional education and training for REC members to learn more about ethica...Artificial Intelligence and Robotics?

16 responses



What do you think are the most pressing needs/challenges facing RECs in Europe today? (open question) 12 responses

- As Adam Smith shrewdly pointed out in 1775: “A degree can pretend to give security for nothing but the science of the graduate; and even for that it can give but a very slender security. For his good sense and discretion, qualities not discoverable by an academical examination, it can give no security at all”. promoting training of researchers and RECs' members is certainly a priority, but one can notice that such training does not offer much protection to research participants if its is not followed by a truly ethical evaluation of research with the aim to protect human participants before all other priorities. Instead of training, it seems time to educate all actors in the field that the rules they have learned actually apply to them and that they are morally and legally responsible to implement them.
- GDPR and open data
- In my opinion one of the major challenges is what happens in certain online communities of patients in which we assisted to two new phenomena: Lay crowdsourcing expertise and Patient Led Research. This bottom up kind of patient empowerment put in question the ethics regulation system.
- 1. lack of resources to adapt to new EU legal requirements; 2. fast advances in big data and genetic research; 3. lack of free international training offered to new REC members
- Do the RECs need to rethink the way they review the research projects to cope with the recent , and soon to come, changes in the EU legislations (CTR, MDR, IVDR)? Paediatric research, Data protection in an international research setting, New technologies: CAR-T cell therapy, CRISPR, AI and robots.
- Training
- The most pressing needs concern HG and artificial intelligence
    - Training in emerging technologies and associated ethical issues
    - Resources for administration
    - Communication with RECs in other institutions and jurisdictions/regions.
- In my opinion, the major challenges for Italian RECs in this moment are to keep their independence and to assure reliable evaluations despite short timelines. Certainly, another important general need is to be updated with respect to new technologies and related ELSI
- there is no common legal base; there is no common social consent about "what is possible" and "what should be avoided"
- Lack of communication among RECs across Europe; theoretical background is gradually vanishing; education of members sharply differs in different countries.

If you have any other comments/suggestions/feedback which might help us, please specify here:4 responses

- The main difficulty in dealing with the latest innovation in biomedical progress is to confuse the technical enhancement they provide with a human one. Going back to the principles should always be the easiest solution. Yet, the scientific community and those expected to guide them in their action often prefer to create new rules to accommodate the so-called progress that industry, the market and the States are hoping for.
- I think that there are many new subjects that challenge the ethics regulation in force that's the need to reflect on these new issues is URGENT there not many expert that we have to set up meetings , workshops with the people that work in these domains
- n/a
- These methods will probably change the classical clinical trials, including biostatistical concepts, regulatory aspects, research methodology and social attitudes