D5.6: Recommendations for the enhancement of the existing legal frameworks for genomics, human enhancement, and AI and robotics

[WP5 – The consortium's proposals]

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Abstract

This report identifies potential changes needed in the existing legal and human rights frameworks (international, EU and national) that might be necessary or desirable to create an environment in which the SIENNA proposals for ethical human genetics and genomics, human enhancement technologies and AI and robotics could be implemented most effectively. It also includes recommendations to improve enforcement and promote the uptake and effectiveness of the existing legislation in these fields. The desired or necessary changes advanced are specified in the report along with related actions, actors responsible for implementing them, their priority levels, implementation challenges and how these could be addressed. The report also discusses the interrelations between ethics and law from the perspective of policymakers.

Document history

Version	Date	Description	Reason for change	Distribution
V1.0	6.07.2020	First draft		D 5.6 contributors and reviewers
V2.0	30.07.2020	Final version	Address feedback and comments from partners and reviewers.	SIENNA partners, European Commission

Information in this report that may influence other SIENNA tasks

Linked task	Points of relevance
Task 6.2: Adapt and exploit methods	Task 6.2 draws on the results included here (to analyse the possibilities for the general application of our approach for legal and human rights analysis, with reference to other types of future and emerging technologies).
Task 6.4: Obtain buy-in for SIENNA proposals from EU and international institutions	Task 6.4 will disseminate and/or exploit the recommendations advanced here through liaising with organisations at the international, EU or national levels to obtain buy-in for them.

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Executive summary

In order to ensure that human rights and other important societal values are respected, ethics and human rights standards need to be taken on board in the development and use of the emerging technologies, such as human genetics and genomics, human enhancement technologies and artificial intelligence and robotics. Ethical guidelines and practices and adequate legal frameworks are important measures to achieve this goal.

This report identifies **potential changes needed in the existing legal and human rights frameworks** (international, EU and national) that might be **necessary or desirable to create an environment in which the SIENNA proposals for ethical human genetics and genomics, human enhancement technologies and artificial intelligence (AI) and robotics could be implemented most effectively**. It also includes recommendations to improve enforcement and promote the uptake of the existing legislation in these fields.

Chapter 1 outlines the objectives of the report and its background (how it draws on the previous results of the project), and its scope and limitations. It also presents the general approach and methods, including information on **consultation with stakeholders** via webinars and emails, and engaging with policy makers through **participating in public consultations**.

Since the general aim of this report is to give recommendations on changes in the *legal* frameworks that would create a supportive environment for SIENNA *ethical* proposals, Chapter 2 contains introductory remarks on the **relations between ethics and law** and on **measures to enhance regulation**. It observes how from the perspective of a regulator, the complex interplay between law and ethics presents itself as a practical question. Given the risks of "ethics washing", we outline the roles ethics and law may play in the governance of new technologies, and how in general law can relate to ethical criteria. Further, we underline that regulators have at their disposal a number of tools for governance beyond command and control regulation and we stress the importance of evaluating existing frameworks.

The report next presents our key recommendations to enhance the legal frameworks for human genetics and genomics (chapter 3), human enhancement technologies (chapter 4) and AI and robotics (chapter 5), respectively. They identify **required legal changes** and specify **actions** needed to be taken, **responsibility, priority levels** and the **associated challenges**.

Chapter 3 discusses recommendations for **human genetics and genomics** and begins by explaining the principles that steer potential changes in this field at three levels. At the international level, it explores issues related to strengthening compliance with existing instruments through their interpretation and promoting their further uptake, improving dialogues with stakeholders, as well as enhancing the right to science in human genetics and genomics. With regard to the EU law, it outlines, e.g., specific actions required for effective enforcement of existing law and enhancing it through revisions to resolve fragmentation and uncertainties, also referring to the EU's scientific aspirations in this area, and to the proposed idea of the European Health Union. It notes also the responsibilities of the national legal

orders to ensure that their commitments in human genetics are followed, including ensuring that the laws are capable of responding to scientific advances and securing effective oversight and enforcement.

Chapter 4, which covers **human enhancement technologies** (HET), takes as a starting point the societal values identified in the SIENNA ethical analysis[1] as being among the most affected by HET. It outlines some potential changes needed in the legal frameworks to address these challenges, focusing on existing HET and these ones that are to be expected in near future and in context of which regulatory gaps and grey zones have been identified. Adopting 'systemic case-by-case approach'[2] to human enhancement (HE), it provides recommendations for regulators at the international, EU and national levels in regard to ensuring safety of HE devices and safety of HE procedures, privacy and data protection (including in the context of brain data), and safeguarding informed consent in HE procedures. It also discusses actions related to addressing misleading advertising and risks of discrimination, especially in the workplace context, and emphasises a need for a model of technology assessment of HET that is not limited to medical risks.

Chapter 5, which relates to **AI and robotics**, covers proposals to enhance legal frameworks at three levels – international, EU and national. It seeks to create new and/or promote existing avenues/mechanisms for ethical AI and robotics, actionable enforcement of existing laws and effective redress for human rights impacts. While some required changes are specific to a given level, we have also identified some shared recommendations. Between the international and EU-levels, common change ambitions include clarifying and/or expanding the scope of key concepts to cover new technological challenges and addressing discrimination gaps. Common EU and national level change ambitions include increasing the reliability and security of AI and robotics products and services; making them respectful of EU values (applicable to Member States), fundamental rights and freedoms and reducing mass and disproportionate surveillance of individuals designed into or perpetuated by AI and robotics products, services and systems.

The report **conclusions** (Chapter 6) present observations common to all three studied technological areas. Making the governance of the three technological fields more compliant with human rights and ethical values is a multi-layered and continuous task that requires simultaneous actions at different levels, with diverse tools and the involvement of a wide range of actors. There is no silver bullet regulatory solution. It is important to **rely on the existing frameworks**, which may need to be **supplemented with interpretive guidance**, and to use capacity of the monitoring mechanisms that are already in place, with **better enforcement**. But we **also** should not turn away from **new (or revised) measures.** These new or revised measures may be **particularly important when we need to introduce stronger protection and/or introduce clear red lines on what is not permissible**. They are also needed – especially looking beyond the most urgent actions – when new legal categories, expended scope of application and novel procedures or bodies may provide a more optimal way forward.

[1] Jensen, Sean, et. al, SIENNA D3.1 State-of-the-art review, WP3 - Human Enhancement, 2018, https://www.sienna-project.eu/digitalAssets/788/c_788666-l_1-k_d3.1sotahet.pdf; Kühler, Micheal, Nils-Frederic Wagner, Philip Brey, SIENNA D3.7: Proposal for an ethical framework for human enhancement, 2020.
[2] Science and Technology Options Assessment (STOA), Human Enhancement. Study, Brussels, 2009.

Key take-aways

For **human genetics and genomics,**

- At the **international level**, the key take-away is that a human genetics and genomics treaty is necessary to overcome the existing challenges and fulfil responsibilities towards future generations. Although SIENNA acknowledges the difficulty in agreeing on several important principles relating to the HGGT, the state of the art of the technologies on the one hand and the need for further developments, on the other hand, require it to be addressed as an urgent priority of the UN. Additionally, there is a need to continue clarifying how the existing human rights norms respond to the specific questions in the area of genetics of genomics, including new and emerging technologies in the field and their applications.
- At the **EU level**, key take-away is the need to remove hurdles associated with regulatory fragmentation and approach to the governance of human genetic and genomic technologies. As a longer-term objective, SIENNA has identified and shed light into the avenues to ensure better potential to exploit the area of human genetics and genomics to further the EU objectives, in particular those relating to research and technological development, including if the European Health Union is advanced.
- At the **national level**, key take-away is the urgent need to revisit comprehensiveness, oversight, and enforcement strategies of the national legal frameworks and their capability to adequately respond to the scientific advances in the area of human genetics and genomics.

For **human enhancement technologies,**

- The key take-away at the **international level** is that there is a need for more interpretative guidance on how international law relates to HE challenges. Considering the diversity of HET and the low level of institutionalisation of the field, a regulatory approach that seeks to address all the relevant issues in one legal instrument might not the best way to start. A more incremental building of understanding and consensus with a number of legal instruments may be more helpful at this stage.
- At the **EU level**, the key take-away is that the EU should take up a more leading role in data protection in the HE context, especially with regard to the challenges associated with the brain data. Moreover, product safety legislation in the HE context may require further scrutiny (following some positive steps already taken in this area).
- The key take-away at the **national level** is that national legislator should review and monitor how their respective legislation responds to the HE challenges and ensure that these responses are in line with the general human rights protection commitments.

For **AI and robotics**,

- At the **international-level,** the key take-away is the need to *clarify how the existing human rights framework applies to AI/robotics* (e.g., via creating new specific rules). While adoption of a new human rights treaty for AI and robotics is a low priority fraught with difficulties, changes to existing relevant laws that protect certain values underlying human rights may be desirable and more feasible.

- At the **EU-level,** the key take-away is the *urgency to ensure consistency and a harmonised approach across the European Union* and *establish common governance standards* to address AI and robotics ethical and human rights-related risks while recognising that *flexibility and sector and/or use specificity regulation are critical***.** It is also *not opportune to pursue, at this time, the creation of a specific legal status for autonomous systems*
- At the **national-level,** the key take-away is to ensure that any *changes in legislation are fit for purpose and in accordance with the country's international obligations, especially with regards to human rights and fundamental values*. There is also need for *legal clarity and guidance*.

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List of acronyms/abbreviations

Abbreviation	Explanation
AI	Artificial intelligence
AI HLEG	High-Level Expert Group on Artificial Intelligence
ASEAN	Association of Southeast Asian Nations
AU	African Union
BCI	Brain-computer interface
BBMRI-ERIC	Biobanking and BioMolecular resources Research Infrastructure (European research infrastructure for biobanking).
CAT	Committee against Torture (UN)
CCW	Convention on Certain Conventional Weapons
CERD	Committee on the Elimination of Racial Discrimination (UN)
CESCR	Committee on Economic, Social and Cultural Rights (UN)
CFREU	Charter of Fundamental Rights of the European Union
CJEU	Court of Justice of the European Union

Abbreviation	Explanation
Clinical Trials Regulation	Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC
CMW	Committee on Migrant Workers (UN)
CoE	Council of Europe
CPT	European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CoE)
CRC	Committee on the Rights of the Child (UN)
CRPD	Committee on the Rights of Persons with Disabilities (UN)
D	Deliverable
DH-BIO	Committee on Bioethics (CoE)
EC	European Commission
ECHR	European Convention on Human Rights
ECSR	European Committee of Social Rights
ECtHR	European Court of Human Rights
EDPB	European Data Protection Board
ELSI	Ethical, legal, social issues
EP	European Parliament
EU	European Union
FRA	Fundamental Rights Agency
GDPR	General Data Protection Regulation
HE	Human enhancement
HET	Human enhancement technologies
HGGT	Human genetic and genomic technologies
HRC	Human Rights Committee (UN)
HRIA	Human Rights Impact Assessment
IBC	International Bioethics Committee
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICT	Information and Communications Technology
IGBC	Intergovernmental Bioethics Committee
ILO	International Labour Organization
***In Vitro* Diagnostic Medical Devices Regulation**	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
LARs	Lethal autonomous robotics
LAWS	Lethal autonomous weapons
Medical Devices Regulation	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
NAP	National Action Plan
NHRIs	National Human Rights Institutions

Abbreviation	Explanation
OAS	Organization of American States
OECD	Organisation for Economic Co-operation and Development
OHCHR	Office of the High Commissioner for Human Rights (UN)
Patients' Rights Directive	Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare
RFID	Radio-Frequency Identification
RRI	Responsible Research and Innovation
SR	Special Representative (UN)
STOA	Science and Technology Options Assessment Panel of the European Parliament
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
UDHR	Universal Declaration of Human Rights
UN	United Nations
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNGA	UN General Assembly
UNGP	UN Guiding Principles on Business and Human Rights
UNICRI	United Nations Interregional Crime and Justice Research Institute
UPR	Universal Periodic Review
v.	versus
WIPO	World Intellectual Property Organization
WP	Work Package

Table 1: List of acronyms/abbreviations

Glossary of terms

Term	Explanation
Artificial intelligence	The science and engineering of machines with capabilities that are considered intelligent (i.e., intelligent by the standard of *human* intelligence).
Autonomy	The value of a person's ability to decide and act on her own authentic desires and preferences, without being unduly influenced, coerced or manipulated by others.
Command and control regulation	Regulation by the state through the use of legal rules backed by (often criminal) sanction.[3]
Ethics by design	The systematic inclusion of ethical guidelines, recommendations and considerations into design and development processes.
Hard law	Authoritative rules backed by coercive force exercised at the national level by a legitimately constituted (democratic) nation-state and

[3] Black, Julia, "Critical reflections on regulation", *Australian Journal of Legal Philosophy,* vol. 27, no. 1, 2002, p. 2.

Term	Explanation
	constituted in the supranational context by binding commitments voluntarily entered into between sovereign states (typified by public international law).[4]
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.
Law	Encompasses both hard law and soft law
Regulation	The intentional use of authority to affect behaviour of a different party according to set standards. Law is one of the institutions for purposively attempting to shape behaviour and social outcomes, but there may be other means, including the market, social norms, and technology itself. Regulation can also mean a species of hard law, e.g., a type of EU legal act with a direct effect defined by Article 288 of the Treaty on the Functioning of the European Union[5] or, in some instances, a legal act adopted at the national level.
Regulatory bodies	Bodies that exercise regulatory or supervisory powers. E.g., regulatory agencies, watchdogs, commissions.
Robotics	The field of science and engineering that deals with the design, construction, operation, and application of robots.
Soft law	Normative, non-binding instruments emanating from law-making bodies including resolutions, recommendations, guidelines, communications, notices etc. (public, top-down instruments). The lack of binding force is the main feature distinguishing soft from hard law.[6]

Table 2: Glossary of terms

[4] Brownsword, Roger, Eloise Scotford and Karen Yeung, "Law, Regulation and Technology: The Field, Frame, and Focal Questions", in Roger Brownsword, Eloise Scotford and Karen Yeung (eds.), *The Oxford Handbook of Law, Regulation and Technology*, Oxford University Press, Oxford, 2017, pp. 3-40.

[5] According to this provision, "To exercise the Union's competences, the institutions shall adopt regulations, directives, decisions, recommendations and opinions. A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States. A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods. A decision shall be binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them. Recommendations and opinions shall have no binding force."

[6] Goncales, Maria Eduarda, and Maria Ines Gameiro, "Hard Law, Soft Law and Self-regulation: Seeking Better Governance for Science and Technology in the EU", Working paper, 2011. https://www.researchgate.net/publication/272351073_Hard_Law_Soft_Law_and_Self-regulation_Seeking_Better_Governance_for_Science_and_Technology_in_the_EU

1. Introduction

1.1 Background and objectives

In order to ensure that human rights and other important societal values are respected, ethics and human rights standards need to be taken on board in the development and use of the emerging technologies, such as human genetics and genomics, human enhancement technologies and artificial intelligence and robotics. Ethical guidelines and practices and adequate legal frameworks are important measures to achieve this goal. These are the basic normative presuppositions of this report, which presents recommendations for the enhancement of the existing legal frameworks for genomics, human enhancement, and AI and robotics.

This report has been developed within the SIENNA project, a European Horizon 2020-funded project[7] on the ethical, legal and social dimensions of three technological areas: human genetics and genomics, human enhancement technologies and artificial intelligence and robotics. The project has conducted extensive analysis of ethical and legal aspects of these technological areas, reviewed their present and expected applications, socio-economic impacts and analysed key concepts and demarcations of the fields, and performed studies on the public awareness and acceptance of these areas and of their current coverage by research ethics committees and in ethical codes. Moreover, the project has also proposed general ethical frameworks for the three fields.[8]

Based on the results of the SIENNA analysis, particularly drawing on the research on legal developments and approaches to specific legal issues and human rights challenges related to the three studied domains, this report identifies potential changes needed in the existing legal and human rights frameworks (international, EU and national) that might be necessary or desirable to create an environment in which the SIENNA ethical proposals could be implemented most effectively. At the moment of writing of this report, the SIENNA ethical recommendations are still in development, therefore SIENNA legal and ethical proposals go hand in hand. This report includes also recommendations on improving the enforcement or promoting the uptake of the existing legislation.

1.2 Approach and methods

The general methods and approaches for analysing international, regional and national laws were presented in the SIENNA Handbook.[9] This report follows the outlined combination of doctrinal, functional, and law-in-context methods used already in the SIENNA legal analysis, but this time with

[7] https://www.sienna-project.eu

[8] More information about the SIENNA work that this report builds upon are presented in the chapters 3, 4 and 5, for each of the technological fields. The SIENNA reports may be found here: https://www.sienna-project.eu/publications/.

[9] Rodrigues, Rowena, Stearns Broadhead et. al., *SIENNA D1.: The consortium's methodological handbook,* 2018, pp. 35-45;
https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5ba68b5a2&appId=PPGMS

prescriptive and specific aim of identifying potential changes needed in the legal frameworks and possible policy actions. The research drew upon the legal analysis carried out in the SIENNA Tasks 2.2, 3.2 and 4.2 and included a further supportive review of academic, policy and legal developments related to the three technological areas.

Along with desktop research, the task involved consultations with stakeholders. Preliminary outlines of changes needed in the legal frameworks, possible actions and associated challenges were presented to and discussed with academics, policy makers, regulators and other experts in three SIENNA webinars (one for each investigated technology area). The webinars were held on 17 June 2020.[10] The webinar participants received in advance discussion papers (one per topic) for their inputs.[11] Based on the feedback received in the webinars discussions and through individual mails to the webinars presenters, the recommendations were revised and are presented in this report (chapters 3, 4 and 5). When a consulted person provided explicit consent, their contribution has been acknowledged in this report by using their name, in other cases, we have indicated inputs without personal information as agreed with the stakeholders consulted.[12] We are very grateful to all the participants in the webinars for discussions and their valuable feedback; also to those who communicated via email.

As a way of further engaging with policymakers on our recommendations, SIENNA participated in the public consultation on the European Commission White Paper on AI,[13] and provided (jointly with the SHERPA project[14]) feedback on the European Parliament Committee on Legal Affairs Draft report with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies (2020/2012(INL).[15]

The three technology areas studied in SIENNA are substantially different in many aspects. They significantly differ in terms of their level of maturity and institutionalisation (both with regard to stages of development of legal frameworks and general policy debates), degree of controversy, type of

[10] The speakers for the webinars were: Rowena Rodrigues (Trilateral Research) for the AI and robotics webinar, Santa Slokenberga (Uppsala University) for the human genomics and genetics webinar and Konrad Siemaszko (Helsinki Foundation for Human Rights) for the human enhancement webinar. All three webinars were organised with help of the SIENNA communications team: Josepine Fernow and Anna Holm (Uppsala University). Open invitations to the webinars were distributed by emails and shared through social media.

[11] The discussion papers were the initial drafts of the chapters 3, 4 and 5.

[12] Choice left to the webinar leader was not been treated as an explicit consent.

[13] Siemaszko, Konrad, Rowena Rodrigues, Anaïs Rességuier, Javier Valls Prieto, *SIENNA Submission to the Consultation on the White Paper on Artificial Intelligence*, 13 June 2020, https://www.sienna-project.eu/digitalAssets/885/c_885056-l_1-k_sienna_white-paper-consultation_13.06.2020.pdf

[14] For more on SHERPA (Shaping the ethical dimensions of smart information systems (SIS) – a European perspective) – an EU-funded project that analyses how artificial intelligence and big data analytics impact ethics and human rights, see: https://www.project-sherpa.eu/

[15] Rodrigues, Rowena, Nicole Santiago, Anaïs Rességuier, Bernd Stahl, Konrad Siemaszko, Stéphanie Laulhé Shaelou, *Joint SHERPA and SIENNA Commentary on the European Parliament Committee on Legal Affairs Draft report with recommendations to the Commission on a framework of ethical aspects of artificial intelligence, robotics and related technologies (2020/2012(INL),* 22.05.2020, https://www.sienna-project.eu/digitalAssets/883/c_883282-l_1-k_feedback-from-the-sienna-sherpa-projects_ep_ai-regulation_final_22-may.pdf

research and application domains, as well as their impacts.[16] This led us to adopt partially different approaches to the ethical and legal analysis that was conducted in the project thus far and to the different nature of the project's proposed general ethical frameworks. In this report, which relates to all three domains, we have attempted to strike a balance between a consistent approach and flexibility required by the specifics of each field.

The analyses of the three areas shared common goals: identifying potential changes needed in legal frameworks at the international, EU and national levels (with a particular focus on the EU level), presenting potential recommendations to policy makers and outlining challenges related to the enhancement of the legal frameworks in a given area. However, taking into account among others different level of institutionalisation of the fields, the presentation of recommendations for of AI and robotics and human genetics and genomics are organised along the lines of legal orders, while in case of HET, recommendations are first divided and discussed along the lines of impacts on societal values and then, in the chapter conclusions, summarised in tables corresponding to the thee legal orders. As part of the joint methodology, in all the areas we have specified additional information. First, primary body, agency or organisation that is best placed to enable the change and carry out the specific action (marked as 'responsibility', which should not be understood as excluding other relevant organisations from carrying out the action). Secondly, we have indicated priority levels of the actions (i.e., how quickly they should be taken), with four categories: level 1 (urgent; action is needed within the next 12 months), level 2 (high; action needs to be taken within next 2 years), level 3 (medium, action needs to be taken within next 3-5 years), level 4 (low; action needs to be taken within next 5-10 years). The priority levels were awarded taking into account the state of the art in the technological area, particularly the gaps identified in the legal analysis and relevant policy developments. [17] Finally, we have also outlined some change implementation challenges, understood as obstacles or hurdles to the implementing the specific actions to bring about the change.[18]

1.3 Structure of the report

Chapter 2 shortly presents introductory remarks on the relations between ethical and legal frameworks, how law may relate to ethical guidelines and discusses some of the regulatory possibilities in the area of new technologies. Chapters 3, 4 and 5 outline the desired changes in the legal frameworks and our recommendations for each of the investigated technological fields: human genomics and genetics technologies, HET and AI and robotics, respectively. Chapter 6 presents general conclusions for all three domains.

1.4 Scope and limitations

The scope of the report is pre-defined by the SIENNA project Grant Agreement Description of Action. While we have referred to the three levels of legal frameworks (international, EU and national), we have paid particular attention to the EU-level, in accordance with the objective of this task in the

[16] Rodrigues, Rowena, Stearns Broadhead et. al., op. cit., 2018, p. 38.
[17] Priority level awarded reflects the views of the SIENNA researchers' based on their research and as at time of writing (June-July 2020).
[18] This approach was proposed by Trilateral Research.

project. In addition, with regard to the international level, we have focused primarily on the Council of Europe and the United Nations systems.

Given the time constraints and vastness of each of the topics covered (and all the more when combined in one report), the presented changes that are needed in the legal frameworks and recommendations are not be understood as exhaustive, or covering all desirable actions. Moreover, for the same reasons, it was not possible to examine every recommended action in great detail and they may rather serve as basis for policymakers and regulators for a continued in-depth research and discussion in the indicated areas.

2. Ethics, law and enhancing the legal frameworks – introductory clarifications

This report identifies potential changes needed to enhance the *legal* frameworks in the three studied fields that might be beneficial to support SIENNA *ethical* proposals. Therefore before outlining specific areas for potential changes and actions, this chapter briefly presents some introductory clarifications that are relevant to achieve this objective.

Relations between ethics and law are complex, multi-dimensional and reciprocal. The two domains are particularly interrelated in communities that are politically and legally committed to respect human rights – as is Europe, through the EU, CoE and through respective constitutional regimes of their member states.[19] As Brownsword points out, "in a community of rights, the discourses of ethics and of regulation are regarded as both contiguous and continuous. Debates about the ethics of rights flow straight into the regulatory consciousness; and regulatory reflection on rights flows back into ethical debate."[20]

Far from being only a topic of legal philosophy, questions about relations between ethics and law are part of the very practical challenges that regulators face when seeking to modify behaviours of actors in a given field. As noted perhaps most famously by Lawrence Lessig, affecting behaviour directly by law is only one of the options that regulators have at their disposal – law may also channel behaviour indirectly by regulating social norms (as well as by regulating the market or the design of the technology itself).[21] All four modalities of regulations interact with each other and in practice a regulator always uses a mix of direct and indirect strategies.[22] Connections between law and social norms (and with other modalities) are therefore also a *practical* problem of a regulator seeking an 'optimal mix' of the regulatory tools.[23]

[19] Rodrigues, Rowena, Stearns Broadhead et. al., op. cit., 2018, p. 37.
[20] Brownsword, Roger, "Regulating the Life Sciences, Pluralism, and the Limits of Deliberative Democracy", *Singapore Academy of Law Journal*, vol. 22, no. special ed. 2, 2010, p. 818.
[21] Lessig, Lawrence, "The Law of the Horse: What Cyberlaw Might Teach", *Harvard Law Review,* vol. 113, no. 2, 1999, pp. 501-546.
[22] Ibid, p. 513
[23] Ibid.

The interplay between law and ethics has been a long-standing question in the fields of human genetics and genomics. It is also an important issue in the context of HET. As Van Der Burg states, "there is probably no other field in which law and ethics are so strongly intertwined as in biomedicine"[24]. However, it is with reference to AI and robotics that the interrelation between the two domains recently has sparked the most heated debate. In the last years, ethical aspects of AI technologies have been widely covered in popular debates in media, documents with sets of ethical principles for AI have proliferated around the world[25] and the industry itself has actively engaged to various degrees with the ethics discourse. Commentators have warned that beside many genuine, well-needed and helpful concerns and initiatives, in some cases the ethics discourse may be instrumentalised and abused in a phenomenon sometimes referred as "ethics washing". Although there is no set, precise definition of this term, it is usually used to describe a practice of making specious claims of upholding to ethical values in order to lobby for voluntary self-regulation in place of binding norms (or to postpone their adoption, to water down a biding regulation or its enforcement).[26] It is doubtful whether such soft measures would be sufficient, among others due to lack of external accountability and absence of effective enforcement mechanisms (including sanctions and redress).[27] These doubts are further justified by drawing lessons from the history of internet regulation[28] and because many actors that currently develop and deploy AI have, in the words of Paul Nemitz, "already demonstrated that they cannot be trusted to pursue public interest on a grand scale without the hard hand of the law".[29]

These abusive instances of co-optation of ethics rhetoric in bad faith by no means should deter from continuing genuine ethical work – both law and ethics have their role in a governance of emerging technologies. Ethics may provide guidance that goes beyond what is required by law (it is not possible,

[24] Van Der Burg, Wibren, "Law and Bioethics" in Helga Kuhse and Peter Singer (eds.), *A Companion to Bioethics,* 2009, Blackwell, Singapore, p. 61.
[25] Fjeld, Jessica, Nele Achten, Hannah Hilligoss, Adam Nagy, and Madhulika Srikumar, *Principled Artificial Intelligence: Mapping Consensus in Ethical and Rights-based Approaches to Principles for AI*, Berkman Klein Center for Internet & Society, Cambridge, 2020.
[26] Wagner, Ben, "Ethics as an escape from regulation: From ethics-washing to ethics-shopping" in Emre Bayamliogl, Irina Baraliuc, Liisa Albertha, Wilhelmina Janssens, Mireille Hildebrandt (eds.), *Being profiling. Cogitas ergo sum*, 2018, pp. 1-7; Metzinger, Thomas "EU guidelines: Ethics washing made in Europe.", *Tagesspiegel ,* 2019, https://www.tagesspiegel.de/politik/eu-guidelines-ethics-washing-made-ineurope/24195496.html; Wagner, Ben and Sylvie Delacroix, "Constructing a Mutually Supportive Interface between Ethics and Regulation", *Corporate Social Responsibility (CSR) eJournal,* 2019, http://dx.doi.org/10.2139/ssrn.3404179; Floridi, Luciano, "Translating Principles into Practices of Digital Ethics: Five Risks of Being Unethical", *Philosophy and Technology,* vol. 32,2019, pp. 185–193.
[27] Nemitz, Paul, "Constitutional democracy and technology in the age of artificial intelligence", *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Science*s, vol. 376, no. 2133, October 2018; Mittelstadt, Brent, "Principles alone cannot guarantee ethical AI", *Nature Machine Intelligence*, vol. no. 7, 2019.
[28] Black, Julia and Andrew Murray, "Regulating AI and Machine Learning: Setting the Regulatory Agenda", *European journal of law and technology*, vol. 10, 2019.
[29] Nemitz, Paul, op. cit., 2018, p. 8.

nor desirable to enshrine in legislation everything that is relevant from ethical perspective[30]). For instance, in the context of responsible research and innovation (RRI), it has been observed that "RRI predisposes societal actors to voluntarily assume an early and shared responsibility for research and innovation processes *beyond merely abiding by duties or complying with rules*" (emphasis added).[31] "Going beyond what is required by law" should not be only understood as, for example, imposing more demanding obligations (in terms of specific dos and don'ts), but also as providing a broader framework for a moral reflection and a deeper understanding of stakes at a given situation.[32] Furthermore, ethics can also precede law – frame/inspire or advise its adopting, amending or abolishing. Ethics may also help in interpretation of existing law, clarify the content of existing legal norms (especially in communities that are constitutionally founded upon the commitment to human rights, democracy and the rule of law).

Our concern in this report is primarily with the opposite direction of this interrelation, that is: how legal frameworks may support ethical guidelines. In Brey et al., three general ways in which policies and law can relate to ethical criteria were identified: they can "explicitly institute, promote or require ethics guidelines, procedures, or bodies; they can have a focus on upholding certain moral values or principles without explicitly identifying them as ethical (e.g., well-being, privacy, fairness, sustainability, civil rights); and they either explicitly or implicitly take on board ethical considerations in broader social and economic policies" [33]. These three ways will be shortly elaborated below.

1. Law explicitly instituting, promoting or requiring ethics guidelines, procedures, or bodies

Explicit references to ethics is not the most common of the three identified measures, but its role is increasing at the national and EU levels, especially since the 1990s.[34] This trend has been sometimes described as "ethicalization" of law[35] or "institutionalization of ethics".[36] As Markus Frischhut noticed,

[30] Data Ethics Commission of the Federal Government, *Opinion of the Data Ethics,* Berlin, 2019, pp.41-41; Van Der Burg, Wibren, op. cit., 2009, p. 63.
[31] Arnaldi, Simone, Guido Gorgoni, Elena Pariotti, "Responsible research and innovation between "New Governance" and fundamental rights" in Robert Gianni, John Pearson, Bernard Reber (eds.), *Responsible Research and Innovation From Concepts to Practices,* Routledge, Abingdon, 2019, p. 159.
[32] On ethical guidelines that do not have a purpose to "prescribe specific do's and don'ts", but rather serve as an "invitation to moral reflection or stakeholder engagement concerning morally controversial topics", see Brey, Philip et al., op. cit., 2020, pp. 10-11; for further discussion of this point in the context of new technologies, see also: Bietti, Elettra, "From ethics washing to ethics bashing: a view on tech ethics from within moral philosophy", in *Proceedings of the 2020 Conference on Fairness, Accountability, and Transparency (FAT* '20*), New York Association for Computing Machinery, 2020.
[33] Brey, Philip et al., op. cit., 2020, p. 22. Although the cited report relates to AI and robotics, these remarks are also valid for other fields.
[34] Frischhut, Markus, *The Ethical Spirit of EU Law*, Springer, Cham, 2019, pp. 1-3.
[35] Ibid.; Wilms, Hans Christian, "The Assumption of Scientific Responsibility by Ethical Codes – An European Dilemma of Fundamental Rights" in: Jeroen van den Hoven, Neelke Doorn, Tsjalling Swierstra, Bert-Jaap Koops, Henny Romijnf (eds.) *Responsible Innovation 1*, Springer, Dordrecht, 2014, p. 94.
[36] Tallacchini, Mariachiara, "Governing by Values. EU Ethics: Soft Tool, Hard Effects"*, Minerva,* vol. 47, 2009, pp. 281-30; Ruggiu, Daniele, "A Rights-Based Model of Governance: The Case of Human Enhancement and the Role of Ethics in Europe", in Kornelia Konrad, Christopher Coenen, Anne Dijkstra, Colin Milburn and Harro van Lente

such an explicit referencing may occur in a number of ways, including the following: (1) ethics can serve as a supportive argument (e.g., in a Directive Recital); (2) law can institute an ethics committee (or a similar body) or require an ethical review to be conducted by such a body; (3) law may introduce an ethical code of conduct (or other ethical guidelines), encourage adoption of them or refer to existing ones (e.g., require adherence to it in public funded projects); (4) ethical criteria may be incorporated in legislation, as part of legal obligations or prohibitions, with content determined in the relevant document itself or left as a broad, undetermined clause.[37]

2. Law focussing on upholding certain moral values or principles without explicitly identifying them as ethical

This category includes an enormously broad range of legislative measures (although it would be wrong to assume that it covers law as whole – there are provisions adopted more on pragmatic grounds, without an ethical purpose, at least in focus). Human rights legislation as a "normative anchor point" of legal frameworks in Europe, [38] constitutes a crucial type here, but relevant examples include also health and safety frameworks (product, occupational and others), anti-discrimination legislation, data protection, consumer protection, environment law and many, many others.

3. Law explicitly or implicitly taking on board ethical considerations in broader social and economic policies

These more indirect regulatory actions may be particularly relevant where wider social or economic issues are either underlying sources of other ethical concerns or constitute their broader consequences. For instance, the issue of algorithmic discrimination may be addressed by requiring the use of data sets that are sufficiently representative,[39] and by wider social and economic policies that may affect systemic roots of marginalization and oppression.[40] Similarly, privacy concerns may be addressed not only by general privacy protection requirements and data protection framework and

(eds.), *Shaping Emerging Technologies: Governance, Innovation, Discourse*, IOS Press / AKA, Berlin, 2013, p. 104.

[37] Frischhut, Markus, op. cit., 2019, pp. 64-79. Markus Frischhut analyses EU law using 8 categories that have been partly modified in this report to adapt them for the discussed context, for instances the category "references only as an argument against interference from the EU" was omitted here, while some other categories were joined for simplification.

[38] Ruggiu, Daniele, "Anchoring European Governance: Two versions of Responsible Research and Innovation and EU Fundamental Rights as 'Normative Anchor Points", *Nanoethics*, vol.9, no. 3, 2015 pp. 217–235; Schomberg, Rene, "The Quest for the 'Right' Impacts of Science and Technology: A Framework for Responsible Research and Innovation", in Jeroen van den Hoven, Neelke Doorn, Tsjalling Swierstra, Bert-Jaap Koops, Henny Romijnf (eds.), *Responsible Innovation 1*, Springer, Dordrecht, 2014, pp. 33-53; Leenes, Ronald, Erica Palmerini, Bert-Jaap Koops, Andrea Bertolini, Pericle Salvini, and Federica Lucivero, "Regulatory challenges of robotics: some guidelines for addressing legal and ethical issues", *Law, Innovation and Technology,* vol. 9, no. 1, 2017, p.30.

[39] European Commission, White paper On Artificial Intelligence - A European approach to excellence and trust, COM(2020) 65, February 2020, p. 19.

[40] Gangadharan, Seeta Peña, Jędrzej Niklas, "Decentering technology in discourse on discrimination, Information", *Communication & Society*, vol.22, no. 7, 2019, pp. 882-899.

online privacy legislation, but also indirectly through competition law confronting the dominant market position of technological giants (e.g. restricting dominant market players access to datasets).[41]

Whichever combination of the three ways of relating to ethical guidelines a policymaker chooses, two further distinctions need to be taken into account.

First, a regulator has a number of types of tools of governance at their disposal in all of the three outlined cases. These types of tools are often presented in form of a pyramid or a scale, starting with allowing a 'pure' self-regulation as a baseline (e.g., self-regulation by a company or an industry), continuing with many facets of co-regulation (different forms of interactions between public and non-public actors in a governance framework), up to a command and control regulation[42] with different sanctions.[43]

Secondly, adopting new legal instruments (even understood broadly, including amendments, delegated acts, etc.) is not the only possible action of a regulator – it is also crucial to consider relying on the existing legal frameworks, with their appropriate implementation or enforcement. Therefore, in many cases, a key step for a regulator is it to evaluate the regulation already in place, in order to assess whether there is indeed a regulatory gap or rather a given issue may be addressed by existing general principles, a broader uptake of a legal instrument or by its improved enforcement. This is especially important in the area of new technologies, where there is a particular risk of what Leenes describes as a 'flawed law syndrome' – a tendency to jump too quickly to conclusion that with a new technology, the current legal framework are obsolete and there is a need for a new law.[44] The problem is not only that following this type of reasoning may lead to unnecessary efforts – it may also open door for a regulatory capture by industry actors lobbying for a special, more favourable treatment, instead of a 'standard' enforcement of the existing legislation.[45]

The following chapters of the report present recommendations that include a broad range of the above outlined types of regulatory dimensions, tools and actions: explicit references to ethical frameworks, non-explicit legal changes with a focus of upholding to ethical values, broader economic or social

[41] Vezzoso, Simonetta, "All happy families area alike: The EDPS' bridges between competition and privacy", *Market and Competition Law Review,* vol. 4, no. 1, 2020, pp. 41-67.
[42] 'Command and control' regulation is a traditional, top-down form of regulation, defined by Julia Black as "Regulation by the state through the use of legal rules backed by (often criminal) sanctions", Black, Julia, "Critical reflections on regulation", *Australian Journal of Legal Philosophy,* vol. 27, no. 1, 2002, p. 2. According to Robert Baldwin, Martin Cave and Martin Lodge, "the essence of command and control (C & C) regulation is the exercise of influence by imposing standards backed by criminal sanctions", Baldwin, Robert, Martin Cave, Martin Lodge, *Understanding Regulation. Theory, Strategy, and Practice*, Oxford University Press, 2012, p. 106.
[43] Ayres, Ian, John Braithwaite, *Responsive Regulation: Transcending the Deregulation,* Oxford University Press, Oxford, 1992; Cave, Jonathan, Chris Marsden, and Steve Simmons, *Options for and Effectiveness of Internet Self- and Co-Regulation,* Santa Monica, RAND Corporation, 2008, https://www.rand.org/pubs/technical_reports/TR566.html
[44] Leenes, Ronald, "Regulating New Technologies in Times of Change" in Reins, Leonie (ed.), *Regulating New Technologies in Uncertain Times Regulating New Technologies in Uncertain Times,* Springer, The Hague, 2019, p. 6.
[45] Ibid.

policies, co-regulation and command-and-control regulation, as well as adopting new legal instruments and evaluating the existing frameworks and improving their enforcement.

3. Enhancing the legal frameworks for human genetics and genomics

3.1. Introduction

3.1.1 Background and purpose

As part of SIENNA work on ethical, legal and social issues (ELSI) in human genomics,[46] in 2018-2019 the legal requirements relevant for human (genetics and) genomics in and outside the EU were examined. Key findings were presented in Deliverable 2.2 (D2.2).[47] Based on those findings, further work that has been carried out within SIENNA Work Package 2,[48] as well as key legal, policy and scholarly developments in the field, this chapter presents potential changes that are needed in the existing legal frameworks at the international, EU and national level that might be necessary or desirable to create an environment in which SIENNA proposals for ethical and human-rights respectful human genetics and genomics applications (i.e., Human Genetics and Genomics Code, Task 5.2) could be implemented most effectively.

3.1.2 Approach and delimitations

Our proposals are informed by the following key considerations:

- The aspiration to further the right to enjoy the benefits of scientific progress and its applications as outlined in Article 15(1)(b) of the International Covenant on Economic, Social and Cultural Rights (ICESCR)[49] and in a different wording affirmed in Article 27(1) of the Universal Declaration of Human Rights (UDHR), hereinafter jointly referred to as 'the right to science';
- The EU's interest in strengthening the European Research Area under Article 176 of the Treaty on the Functioning of the European Union (TFEU) and research as a means to further EU's global competitiveness, whilst ensuring adequate protection to human rights (in accordance with Article 51, Charter of Fundamental Rights of the European Union, CFREU) and high level of human health (in accordance with Article 168(1) TFEU) in respective policies.

[46] https://www.sienna-project.eu/genomics/legal-aspects/
[47] Slokenberga, Santa et al., *SIENNA D2.2 Analysis of the legal and human rights requirements for genomics in and outside the EU*, 2019, https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5c2e1586f&appId=PPGMS.
[48] https://www.sienna-project.eu/genomics/
[49] E.g. Committee on Economic, Social and Cultural Rights, General Comment No. 25 (2020) on Science and Economic, Social and Cultural Rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights), E/C.12/2020/1.

In developing the SIENNA proposals for human genetics and genomics at the international level, we focussed exclusively on two international legal orders, the UN and its agencies (UNESCO and WHO), as well as the CoE, and the competencies enshrined in the treaties and declarations under which bodies established in these legal orders operate. However, in so far as the proposals relate to commonly shared human rights, they are of relevance to other human rights legal orders that have been at the core of SIENNA work in D2.2 (in particular ASEAN, AU, OAS), and could also inform the work of OECD. Likewise, proposals that are for the national levels could be of relevance to the EU Member States and third countries alike. Although other stakeholders, such as professional organisations and civil society has not been the focus of this task, their engagement is crucial for the implementation of the SIENNA proposals.

In our analysis for human genetics and genomics technologies (HGGT), due to the delimitations of previous SIENNA WP 2 tasks we have not focused on questions relating to intellectual property. However, a greater understanding of how intellectual property interplays with the right to science is necessary. We cannot exclude that it could have bearing on SIENNA proposals.

The proposals presented in this document are based on the principles that steer potential changes and are developed in collaboration with SIENNA Task 5.2 (responsible for developing Human Genetics and Genomics Code). The proposals have been developed in consultation with experts and stakeholders who participated in the SIENNA webinar on 17 June 2020 (for details see section 1.2 in this report). Key points that were discussed in the webinar and subsequent email correspondence include:

- Enhancing research in the fields relevant for HGGT;
- Account for the low and medium-income countries;
- Considering whether “right to genetic data” also extends to other omics data;
- Rights of relatives to access genetic data about another person;
- Protection of integrity and dignity in light of the scientific advances;
- Public participation.

Following the webinar minor changes have been made, except for the proposal relating to the right to gen(omic) data which was re-conceptualized and re-targeted to include not only the international level but also the EU level.

3.2 Principles that steer potential changes

The area of human genetics and genomics is already extensively regulated through hard and soft law measures. Additionally, professional organizations have adopted standards, consensus positions, and other documents that seek to shape professional activities relating to research and application of HGGT. Nonetheless, as SIENNA WP2 has shown, gaps in the current frameworks also emerge.[50]

SIENNA proposals for ethical and human-rights respectful HGGT applications do not require an immediate introduction of conceptually new international human rights or fundamental rights in the EU legal order. However, in D2.2 we have identified an emerging trend that could necessitate such a

[50] See Slokenberga, Santa et al., op. cit., 2019, chapter 7 and 8.

right (*right to gen(omic) data)*,[51] that has such rights as the right to science, right to health and prohibition of stigmatization and discrimination, as well as the right to education as its inherent elements. Likewise, it triggers the protection of privacy and integrity and mandates accounting for the familial nature of this information.[52]

Aside from the proposal regarding the right to gen(omic) data, which requires introducing a conceptually new right and is an aspiration that could be fulfilled in a long-term, SIENNA proposals rest on the following pillars:

1) Existing human rights as a starting point in shaping legal responses to new and emerging HGGT, e.g., for safeguarding the rights of individuals and protecting from unethical and illegal scientific experimentation as well as for creating a framework and preconditions for furthering the right to enjoy the benefits of scientific progress and its applications;[53]
2) A necessity for effective regulatory responses to new and emerging HGGT, including for non-health application;
3) Ethics as an integral and continuous reflective part of the conduct of science and clinical practice;
4) The necessity to carry out continuous work on the interplay of scientific advances, ethics and human rights;[54]
5) Enhanced research and development in the field, achieved through ensuring the necessary preconditions for furthering research and innovation and reducing regulatory hurdles and unnecessary fragmentation;
6) Consolidation and, in so far as possible, alignment of rules, in order to reduce fragmentation, provide clarity, application of better regulation principles and the like, including adequate engagement and dialogue with the stakeholders, including members of the society;[55]
7) The necessity for awareness, accounting for globalization and health tourism, and aspiration to overcome regulatory fragmentation;[56]
8) The necessity to ensure that benefits from advances in human genetics and genomics are made available to all.[57]

[51] As personalized medicine advances, SIENNA researchers have identified that this right could become a means to further the right to the highest attainable standard of health. This relates to earlier discussions of genetic passports/passes, see e.g. Baranov, Vladislav S., Baranova E.V., Ivaschenko T.E., Aseev M.V, *Human Genome and Predisposition Genes. Introduction into Predictive Medicine*, Intermedica, Saint-Petersburg, 2000, p. 63, later also Baranov, Vladislav S., "Genome paths: a way to personalized and predictive medicine", *Acta Naturae,* vol. 1 no. 3, 2009, pp. 70-80. David W. Wood has suggested expanding genomic data to omic data.

[52] One webinar participant has drawn attention to the UK case law in the field and importance, should proposal for the human right to (gen)omic data be furthered. See English High Court decision in ABC v St Georges Health Trust (2020).

[53] As experts and stakeholders have highlighted and in line with conclusions of SIENNA 2.7, considerable ethical dilemmas in accessing *early* and/or controversial treatments for potential individual or specific patient group benefit.

[54] SIENNA HGGT webinar participants raised this point.

[55] SIENNA HGGT webinar participants, including David W. Wood raised this point.

[56] SIENNA HGGT webinar participants raised this point.

[57] SIENNA HGGT webinar participants raised this point.

3.3 International level changes

The UN and its agencies as well as the CoE have made several notable contributions in responding to the challenges that genetic and genomic technologies present to human rights. However, in SIENNA D2.2 we identified several gaps that could become hurdles in uptake and effective implementation of SIENNA proposals for ethical and human-rights respectful HGGT applications.

At the core of SIENNA proposals for HGGT the international level are the following key considerations.

- An international treaty[58] that addresses *inter alia* data sharing for scientific research and human genome modification, as well as introduces a right to (gen)omic information. Introduction of a new right requires considerable agreement about the purpose, content obligations as well as implications, and might face different hurdles than questions of data sharing and genome modification. Stakeholders have argued that more effective regulation could be achieved through a bottom-up approach and a better dialogue with the stakeholders, including society.[59]
- Each legal order and actor therein that have adopted several hard or soft law instruments relevant to the area of human genetics and genomics should review whether the respective instruments are comprehensive enough and appropriate to tackle present-day challenges that scientific advances present, as well as whether and to what extent they are responsive to emerging technologies, and whether they have adequate oversight and enforcement mechanisms. This requires ensuring availability of adequate scientific/technical expertise. While at the principle level, these frameworks often are comprehensive, their responsiveness to the new and emerging technologies has appeared to be limited.[60] Where possible, any revision of these instruments should consider more effective regulation and elimination of unnecessary fragmentation.
- Through interpretative avenues, guidance shall be provided on how the existing human rights tackle challenges that new and emerging HGGT present, including such considerations as altering the content of the right to the highest attainable standard of health, impact on integrity, and dignity.[61]
- Where relevant, external accountability of national legal orders should be requested in complying with their obligations, e.g., through established reporting systems. This requires introducing questions relating to HGGT and human rights in compliance reviews.

[58] See in that regard also a call from International Bioethics Committee on a treaty for genome editing, see UNESCO International Bioethics Committee (IBC), Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights, SHS/YES/IBC-22/15/2 REV.2, Paris 2015.
[59] This includes considerations shared by stakeholders in the SIENNA HGGT webinar, including those made by David W. Wood.
[60] In that regard, see also UNESCO International Bioethics Committee (IBC), Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights, SHS/YES/IBC-22/15/2 REV.2, Paris 2015.
[61] This includes considerations shared by stakeholders in the SIENNA webinar, including, those made by David W. Wood.

- Avenues to further the right to enjoy the benefits of scientific progress and its applications in human genetics and genomics should be established and explicitly linked to other rights; knowledge should be furthered and made available.

The table below, "International level potential changes, actions, and challenges for HGGT" presents the changes that are necessary/desired for creating a platform in which SIENNA proposals can effectively be operationalised, specifies the action that is required and assigns responsibility and priority level, as well as identifies potential challenges (obstacles or hurdles) that could hinder the proposed changes. The change implementation challenges are not exhaustive; they should be perceived as examples of potential obstacles or hurdles.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
Strengthen compliance	Address human rights challenges relating to human genetics and genomics in the interpretation of existing human rights instruments (General Comments, statements, treaty follow-ups, and recommendations to the sates)	UN Treaty monitoring bodies (e.g. HRC; CESCR; CAT; CRPD; CRC). CoE (Secretary General, Parliamentary Assembly, Committee of Ministers, CTP, ECSR)	1	Lack of expertise/ awareness of genetics issues. Getting consensus on core issues to address; getting consensus on joint interpretation and thereby position on the issue. Political will, internal priorities and resources.
Further uptake	Continue promoting uptake of the existing instruments specifically addressing human genetics and genomics	UNESCO IBC (UNESCO) IGBC (UNESCO) CoE (Parliamentary Assembly, Committee of Ministers)	1	Political will, internal priorities, resources. Reluctance to engage by the national legal orders and civil society.
Disseminate knowledge	Continue to provide interpretative guidance regarding how existing frameworks respond to new and emerging HGGT	UNESCO IBC (UNESCO)	1	Political will, internal priorities and pre-set procedures, resources, expertise.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
		IGBC (UNESCO) CoE (DH-BIO, Parliamentary Assembly, Committee of Ministers, CTP, ECSR)		
Enhance the right to science in human genetics and genomics	Greater emphasis in explaining the right to science needs to be placed on new and emerging HGGT, without precluding a joint action on new and emerging technologies. In overseeing compliance with the ICESCR, particular attention on this right and HGGT need to be given	CESCR	1	General comment on the right to science has recently been adopted. Concerns over HGGT had been raised inter alia by the members of SIENNA consortium,[62] but the final version addresses HGGT only vaguely.[63] The reasons for doing that, as well as internal priorities, will, and resources, as well as the overall nature of the general comments could hinder addressing them expressly.
Enhance human rights frameworks to address challenges that HGGT presents	Adopt a human rights treaty for human genetics and genomics (either separately or as part of a re-regulation strategy). Key areas focus genomic data and scientific research, genome modifications), right to (gen)omic data, and	UN General Assembly	1	Different approaches to fundamental questions at the core of challenges that HGGT presents and valid arguments to retain the differences; time and other resource constraints; adding to already complicated HGGT governance and human rights landscape. Proposals touch upon civil and political, as well as social/economic/cultural rights. The full realization of the right to genomic data could demand resources.

[62] See Submission of Scholars in Biomedicine at Swedish Universities, 5 October 2018, https://www.ohchr.org/Documents/HRBodies/CESCR/Discussions/2018/SwedishsScholars.pdf. See also a follow-up Draft General Comment on Article 15, Recommendations to the Committee on Economic, Social and Cultural Rights from scholars in medical law and bioethics from Swedish universities, https://www.ohchr.org/Documents/HRBodies/CESCR/Discussions/2020/DGC_Science/MedicalLawBioethicsScholarsSweden.pdf.

[63] Committee on Economic, Social and Cultural Rights, General Comment No. 25 (2020) on Science and Economic, Social and Cultural Rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights), E/C.12/2020/1.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
	associated rights (incl. prohibition of discrimination, right to health, right to education)			
Enhance dialogues	Revisit the effectiveness and implementation of strategies to consult stakeholders, including the public, for any new proposals	UNESCO, UN Treaty monitoring bodies (e.g. HRC; CESCR; CAT; CRPD; CRC). CoE (Secretary General, Parliamentary Assembly, Committee of Ministers, DH-Bio)[64]	2	Political will, resources.
Enhance the right to science in human genomics	Review such rights as the right to the highest attainable standard, continued legitimacy of the existing restrictions on the use of technology and implications relating to any potential changes	UNESCO CoE	3	Political will, difficulty to reach agreement on sensitive issues.
Enhance human rights frameworks to address challenges that HGGT presents	Consolidate existing regulatory instruments	UNESCO CoE	3	Prima facie functionality of the already adopted approaches; sentimental value of the existing instruments, lack of political will to re-regulate the area.
Enhance the right	Set up mechanisms that further research	WHO (Health Assembly,	4	Political will, internal priorities, resources.

[64] Arguably, the most recent document in that regard is the Committee on Bioethics (DH-BIO), *Guide to Public Debate on Human Rights and Biomedicine,* Strasbourg, 12.03.2020. https://rm.coe.int/inf-2018-11-guide-deb-with-appendix-final-e/16809ce63c. See Lwoff, Laurence, "New Technologies, New Challenges for Human Rights? The Work of the Council of Europe", *European Journal of Health Law,* vol. 27, no. 3, 2020, pp 335-344.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
to science in human genomics	and ensure ethical oversight of HGGT at all stages	Executive Board, Secretariat)		

Table 3: International level potential changes, actions, and challenges for HGGT

3.4 EU level changes

Several of the EU secondary law frameworks apply to HGGT, as well as fundamental rights protection mechanisms in so far as HGGT are regulated under the EU law. Key secondary laws[65] are in the areas of *clinical trials* and *advanced therapy medicinal products* (gene therapy), *data protection* (genetic data), *in vitro diagnostic medical devices* (genetic, genomic analysis), *medical devices* (e.g., ultrasound technology). However, their capability to respond to challenges that the HGGT present is constrained to the existing contexts in which these legal instruments operate and their object and purpose, and the legal basis on which they were adopted. In our work, several gaps have been identified that could become hurdles in uptake and effective implementation of SIENNA proposals for ethical and human-rights respectful HGGT applications.

As a result of our analysis, we have found that different legal frameworks pose different challenges. While, e.g., medical devices framework shows a greater capability of dealing with non-medical applications, the same cannot be said about *in vitro* diagnostic medical devices.

There are several ways in which challenges relating to HGGT could be addressed at the EU-level. SIENNA proposals rest on the following strategic approaches, which could have a complementary effect.

- Interpretation avenue. The current gaps (and risks of gaps) that human HGGT present (e.g., limited scope of application of norms regulating gene therapy,[66] *in vitro* diagnostic medical

[65] In our work, we have focused on the newest legal instruments in the field (Clinical Trials Regulation, Medical Devices Regulation, and *In Vitro* Diagnostic Medical Devices Regulation) although they are not being applied yet.

[66] Definition of gene therapy medicinal product is enshrined in Annex I of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 OJ L 324, 10.12.2007, p. 121–137. It states Gene therapy medicinal product means a biological medicinal product which has the following characteristics: (a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; (b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence. Gene therapy medicinal products shall not include vaccines against infectious diseases. See an approach that the CJEU took in regard to medicinal products more generally, Court of Justice of the European Union, C-358/13, D. and G., 10.07.2014

devices as a result of which non-medical applications remain uncovered;[67] the vagueness of ethics requirements[68]) need to be further reviewed and interpretative strategies need to be crafted for overcoming them. This avenue is constrained to the limits within which the current legal frameworks operate and it may prove an inadequate approach in ensuring a comprehensive HGGT governance at the EU level.

- Legislation avenue. Another way is to adopt a more comprehensive approach to the regulation of HGGT through a specific legislative act or re-regulation of the field taking existing frameworks as a base and strive towards elimination of unnecessary fragmentation within the EU.[69] Human genetics and genomics trigger questions relating to the shared competence areas between the EU and its Member States, therefore, in addition to selecting appropriate legal basis, principles of proportionality and subsidiarity are of paramount importance, as well as risks of opposition from the Member States for expansion of the field. Any proposals should be taken with the Member States on board for the changes. Similar hurdles could also emerge in strengthening the area of ethics.
- Legislative avenue. A distinction needs to be drawn between recasting of the existing frameworks in shaping a technology-specific legislative measure and recasting the current frameworks through expanding their scopes. Acknowledging the importance of contexts in which the different HGGT operate, SIENNA perceives the latter as a more feasible option. Disregarding that, genetics and genomics legal instrument that coordinates the area, as well as stronger guidance on the interpretation and application of CFREU could be seen as a tool to further human rights compliance.
- Legislation avenue. SIENNA supports the ongoing work in reshaping health data governance and eliminating fragmentation that is a hurdle for EU internal[70] and external data sharing;[71] consequently also an obstacle to medical care relating to genetic data (e.g., in rare disease cases) and scientific research.
- If (following Covid-19 pandemic) the European Health Union is furthered and the EU will *expressis verbis* claim greater health competences, the introduction of the right to gen(omic)

[67] See Article 2(2) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU OJ L 117, 5.5.2017, p. 176–332

[68] All three key instruments (Clinical Trials Regulation; Medical Devices Regulation; *In Vitro* Diagnostic Medical Devices Regulation) leave it at the discretion of the national legal orders.

[69] From the perspective of EU competences, claim based on Article 114 TFEU coupled with a high level of human health could be made. We are hesitant as for relying on Article 168.1 as a separate legal basis (cf. Patient's Rights Directive). See Theodore Konstadinides, "The Competences of the Union", in Robert Schütze and Takis Tridimas (eds.), *Oxford Principles of European Union Law*, OUP, 2018, pp.191-220.

[70] In that regard, see analysis on the implementation of Article 89 GDPR across Europe in Slokenberga, Santa, Tzortzatou, Olga, Reichel, Jane (eds.), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe*, Springer International Publishing, 2020.

[71] See Soini, Sirpa, "The GDPR, secondary research purposes and global data sharing—one-wheel too many", *European Journal of Human Genetics,* vol. 28, no. 694, 2020. Concerning states in Africa, see Slokenberga, Santa, Jane Reichel, Rachel Niringiye, Talishiea Croxton, Carmen Swanepoel, June Okal, "EU data transfer rules and African legal realities: is data exchange for biobank research realistic?", *International Data Privacy Law*, vol. 9, no 1, February 2019, pp. 30–48, and Slokenberga, Santa, "Biobanking and data transfer between the EU and Cape Verde, Mauritius, Morocco, Senegal, and Tunisia: adequacy considerations and Convention 108", *International Data Privacy Law*, 2020.

information should be considered. Unlike the international legal orders, the EU has the advantage of furthering genomics competence also as part of the professional requirements of healthcare personnel.[72] We also see the potential to strengthen patients' rights protection in so far as these rights anchor in the common constitutional traditions of the Member States and content of the CFREU. Additionally, in that regard also the fundamental right to data protection in the EU legal order could be used as platform to further the right to gen(omic) data.

- The area of HGGT presents considerable research and innovation, and commercialization potential. The EU already has taken considerable steps in furthering genetics and genomics advances, e.g. through extensive resources allocation for research, Biobanking and BioMolecular Resources Research Infrastructure (BBMRI-ERIC).[73] However, a comprehensive approach to HGGT is missing. Measures to enhance human genetics and genomics as part of the EU's scientific aspirations could be made through strategic and targeted steps (e.g., establishment of an EU actor for biomedical research). Examples could be an action based on Article 352 TFEU or Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC).[74]

The EU has strategies to enhance stakeholder participation in the Commission's work, including legislative proposals adopted by the Commission.[75] As detailed analysis of the effectiveness of this strategy is not part of SIENNA work, we refrain from any proposals in that regard.

In line with the joint methodological approach outlined above in the section 1.2, the table below, "EU-level potential changes, actions, and challenges for HGGT" presents the changes that are necessary/desired for creating a platform in which SIENNA proposals can effectively be operationalised, specifies the action that is required and assigns responsibility and priority level, as well as identifies potential challenges (obstacles or hurdles) that could hinder the proposed changes.

[72] For an excellent insight in the fragmented regulatory landscape, see Purnhagen, Kai, Anniek De Ruijter, Mark L. Flear, Tamara K. Hervey, & Alexia Herwig, "More Competences than You Knew? The Web of Health Competence for European Union Action in Response to the COVID-19 Outbreak", *European Journal of Risk Regulation*, vol. 11 no. 2, 2020, pp. 297-306.

[73] BBMRI-ERIC is a European research infrastructure for biobanking, see https://www.bbmri-eric.eu/

[74] Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC), OJ L 206, 8.8.2009. A comprehensive insight in European Health Area can be expected in autumn 2020, see https://www.cambridge.org/core/journals/european-journal-of-risk-regulation/call-for-papers.

[75] See https://ec.europa.eu/social/main.jsp?catId=1192&langId=en.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
Effective enforcement of existing law	Interpretation and oversight of the current secondary law framework	Committees/ boards established under the respective frameworks European Commission	1[76]	Internal priorities, resources, disagreements at the interpretative level regarding the boundaries of EU law (CJEU competence, Article 19 TEU). Discretion of the European Commission under Article 258 TFEU, and consequently tolerance of existing discrepancies.
Effective enforcement of existing law and enhancement of the legal frameworks through revision	Address ethics in regard to HGGT in a more stringent and consistent way	European Commission, Parliament, Council, Member States	2	Already now, ethics is part of the requirements in some areas, e.g., clinical trials, studies relating to *in vitro* diagnostic medical devices. Stronger emphasis on ethics monitoring is necessary, as well as ethics as an integral part of health technology assessment should be furthered. These areas could be said to be of high sensitivity to the national legal orders, and consequently present hurdles for EU level actions.
Effective enforcement of existing law and enhancement of the legal frameworks through revision	Resolve fragmentation and uncertainties regarding genetic data protection; remove obstacles to sharing of the data	European Commission, Parliament, Council, Member States	2	Fragmentation in the field relates to difficulties in reaching an agreement when developing the GDPR. The risk of facing similar hurdles emerges.
Coordinate the existing legal responses through knowledge bases	Continuous and comprehensible guidance on how the law regulates human genetics and genomics (cross-sectorial perspective)	European Commission	2	Policy priority, resource allocation.
Enhance human genomics as part of EU's	Set up and support an EU actor for (bio)medical research	European Commission	3	Policy priority, resource allocation.

[76] From the moment the respective bodies fully operate under respective secondary laws.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
scientific aspirations				
Enhance the legal frameworks through revision	Regulate non-medical application of HGGT through reshaping existing frameworks	European Commission, Parliament, Council, Member States	4	Several of the key frameworks have been recently revised; reluctance of the Member States to agree on EU-level legislation; differing stakeholder interests.
Enhance human genomics through European Health Union	Streamline questions relating to HGGT and human genome in the area.	European Commission	4	Reluctance from the Member States to have treaty change and limited self-determination in the area of health care and other areas the proposal touches upon. EU's awareness of the reluctance, and consequently omission to act.
Enhance human genomics through European Health Union	Consider establishing a right to gen(omic) data	European Commission	4	Reluctance from the Member States to have treaty change and limited self-determination in the area of health care and other areas the proposal touches upon. EU's awareness of the reluctance, and consequently omission to act.

Table 4: EU-level potential changes, actions, and challenges for HGGT

3.5 National level changes

SIENNA D2.2 identified that the national legal orders respond to HGGT in some way. However, the scope of application of these laws could be limited to tackling medical application only, or parts of it. While we cannot preclude that some national legal orders have made deliberate choices, for others the lack of responsiveness relates to the fact that the laws are outdated. They also create uncertainties of oversight and effective enforcement. These could become hurdles in the uptake and effective implementation of SIENNA proposals for ethical and human-rights respectful HGGT applications.

The following actions at the national level are of importance for enhancing the human rights compliant application of HGGT.

- Revision and amendments of the existing laws where they are identified as inadequate.
- Re-assessment of necessity to maintain individualized approaches where harmonisation exists (e.g., values and other important reasons underpinning them).

- The necessity to consider whether and how stakeholders are consulted, including the public, quality of regulatory changes is ensured.[77]
- Compliance enhancing and effective enforcement of existing laws.
- Competence and capacity building.

The table below, "National level potential changes, actions, and challenges for HGGT", presents the changes that are necessary/desired for creating a platform in which SIENNA proposals can effectively be operationalized, specifies the action that is required and assigns responsibility and priority level, as well as identifies potential challenges (obstacles or hurdles) that could hinder the proposed changes.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
Effective compliance and enforcement of existing laws	Review compliance enhancing strategies (e.g. accurateness and accessibility of information about legal requirements) and regulatory enforcement measures regularly	National governments (including competent authorities)	1	Resources, priorities, political will.
Enhancement of the existing laws	Where national laws are inadequate to tackle the challenges that HGGT presents, relevant amendments to the existing laws or new laws should be proposed. Principles for better regulation should be followed, including enhancing stakeholder consultation[78]	National governments (including competent authorities), national parliaments	2	Resources, priorities, political will introduce changes, technical capacity and knowledge.
Enhancement of the existing laws	Streamline genetics and genomics in research and development, and medical care	National governments (including competent authorities)	2	Resources, priorities, political will.
Enhancement of the existing laws	Where national laws are based on EU law measures, assess the necessity for individualised legal frameworks to reduce fragmentation of the field	National government, national parliaments	3	Member States might have good reasons for upholding current approaches. Therefore, only greater harmonization could heal fragmentation.

[77] This includes considerations shared by stakeholders in the SIENNA webinar, including, those made by David W. Wood.
[78] This includes considerations shared by stakeholders in the SIENNA webinar, including, those made by David W. Wood.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
Enhancement of competence and capacity	Designate an authority responsible for human genetics and genomics and allocate resources	National governments, national parliaments	3	Resources, priorities, political will.

Table 5: National level potential changes, actions, and challenges for HGGT

3.6 Conclusions

Steps need to be taken to enhance the existing legal frameworks in responding to the challenges that HGGT present. The existing human genetics and genomics specific instruments at the international level, such as those of the UNESCO and CoE, provide considerable human rights guidance in the area of human genomics. Uptake of principles set in the respective frameworks should be furthered. Nonetheless, they also present limitations, which should be tackled without fear to revise these instruments.

An international human rights treaty in the area of human genomics might be an ambition that is desirable to further the right to science and associated rights and simultaneously ensure adequate protection from the misuse of science, and prevention of bioethics and bio-law *paradises* for scientific research. However, it is an aspiration that difficult to achieve, which is in part related to different and conflicting stands on fundamental questions. Nonetheless, SIENNA believes that considerable effects can be achieved through effective enforcement of the existing human rights norms, for example, the existing treaty monitoring bodies could require human rights compliance regarding HGGT. They could guide in their general comments on how HGGTs challenge the respective rights (e.g., freedom from unethical and illegal scientific experimentation), what measures are expected for the realization of the right (e.g. the right to health). This could offer the advantage of strengthening a human-rights based approach to the governance of human genetics and genomics. At the same time, such an approach is prone to delivering fragmentation that the existing human rights principles allow (e.g., differing understanding of human dignity, balancing of competing rights and interests). Appropriate steps in that regard shall need to be taken at the EU and national levels.

The EU has the potential to exploit its commitment to guarantee a high level of protection of health and further the EU internal market in the non-health application of HGGT. Some challenges can be overcome through interpretation, but the risk of an incomplete framework remains. Therefore, where relevant, SIENNA has called for secondary law revisions, albeit without an attempt to create a genomics-specific secondary law. This choice has been made, in part, due to the different nature of HGGT and broader areas to which these technologies belong (e.g., *in vitro* diagnostic medical devices; medicinal products). Should the European Health Union be developed, considerable room for strengthening patients' rights emerges. Further inquiries will be needed as the area starts shaping in determining the key steps that need to be taken for the full realization of HGGT in the area of health.

In addition to the international and EU levels, it is the responsibility of the national legal orders to ensure that their commitments in the area of human genomics are followed, including ensuring that the laws are capable of responding to scientific advances and securing effective oversight and enforcement. Periodic revisions of the existing laws, e.g., as in France,[79] could be taken as a role-model that could be adapted to the internal peculiarities of each of the national legal orders. It is also their responsibility as part of the current commitments under the right to science and the right to health to ensure that the benefits of HGGT can be enjoyed and risks are addressed.

4. Enhancing the legal frameworks for human enhancement technologies

4.1. Introduction

This chapter outlines some of the potential changes needed in the existing legal frameworks (international, EU and national) that might be necessary or desirable to create an environment in which the SIENNA ethical proposals for human enhancement technologies (HET) could be implemented most effectively. It is based on the results of SIENNA analysis of the legal and human rights requirements for HET,[80] studies of their ethical aspects[81] and the proposal for an ethical framework for HET[82], along with further analysis of relevant academic, policy and legal developments.

We first explain the scope and limitations of this chapter and present particular challenges connected to improving legal frameworks for HET, together with some ways of addressing them. Then, we discuss potential changes and recommendations in the legal frameworks, organised along the lines of some of the societal values that have been identified as being among the most likely to be affected by HET in the previous SIENNA analysis and that were further elaborated upon in the SIENNA proposal for an ethical framework for HET. In the conclusions, the changes and recommendations are summarised in three tables, corresponding to the discussed legal orders, and supplemented with information about their indicative level of priority and possible challenges related to their implementations.

[79] See Slokenberga, Santa et al. op. cit., 2019.
[80] Warso, Zuzanna, et al., *SIENNA D3.2: Analysis of the legal and human rights requirements for Human Enhancement Technologies in and outside the EU*, 2019, https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5c2e15872&appId=PPGMS
[81] Jensen, Sean, et al., *SIENNA D3.4: Ethical Analysis of Human Enhancement Technologies*, 2019, https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5cf2e83d0&appId=PPGMS; Jensen, Sean, et. al, *SIENNA D3.1 State-of-the-art review, WP3 - Human Enhancement,* 2018, https://www.sienna-project.eu/digitalAssets/788/c_788666-l_1-k_d3.1sotahet.pdf.
[82] Kühler, Micheal, Nils-Frederic Wagner, Philip Brey, *SIENNA D3.7: Proposal for an ethical framework for human enhancement,* 2020.

4.1.1 Scope and limitations

In SIENNA, human enhancement is defined as a "modification aimed at improving human performance and brought about by science-based and/or technology-based interventions in or on the human body."[83] This section does not cover issues related to genetic enhancement, as these questions are addressed in chapter 3, neither the issues specific for the use of AI in HET (as AI in general is discussed in chapter 5). It also does not relate to military applications of HET, since military applications are in general outside the scope of the SIENNA proposals.

One of the purpose of the legal recommendations within SIENNA project is to propose changes that would support the project's ethical proposals. Therefore in this chapter we take as a starting point the societal values that were identified in the SIENNA ethical analysis as being among the most affected by HET[84] and we seek to outline some potential changes needed in the legal frameworks to address related challenges. Neither the challenges nor the potential changes needed to address them are to be understood as exhaustive.

In order to develop the most useful recommendations, we focussed on the existing HET and their developments that are plausible in the near future. For the same reason, we paid particular attention to the current and emerging challenges, trying to avoid "multi-factorial speculations about potential scenarios"[85] about the (distant) future HET that often haunt this field. The choice of HET expected in the near future was primarily based upon the extensive state-of-the art review conducted within the SIENNA project.[86] Although attempts to predict technological developments always entail risks of mistakes and it is important to adopt a precautionary approach,[87] it also vital to prioritise policy proposals on less far-ranging visions.[88] This approach should not be understood as undermining the role of broader debates, but only as setting the focus of this chapter.

[83] Jensen, Sean, et. al, op. cit., 2018 p. 12.

[84] Jensen, Sean, et al., op. cit., 2018, p. 62; Kühler, Micheal, Nils-Frederic Wagner, Philip Brey, op. cit., 2020, pp.23-24. Both these report provide the following list of values that are often affected by HET and raise ethical issues: autonomy; dignity; equality; fairness; health and safety; peace; privacy; respect for human life and solidarity. This list was partly modified for the purpose of this report because of the time constraints, and the following other reasons. First, issues related to impacts on peace have been omitted, because military domains are not within the main scope of SIENNA proposals. Secondly, the related issues of equality, fairness, solidarity as well dignity and respect for human life (the two latter were discussed in previous SIENNA reports in the context of treatment with equal respect) have been addressed together under the heading of "equality" (as a simplification caused by time constraints, which should not be understood as treating these terms as synonymous). On the other hand, the issues of privacy were further extended to explicitly include also related questions of data protection.

[85] Jensen, Sean, et al., op. cit. 2019, p. 129.

[86] Jensen, Sean, et al., op. cit., 2018, p. 26-28.

[87] As suggested also by David W. Wood in the SIENNA HET webinar, 17.06.2020.

[88] For a similar approach, see: Science and Technology Options Assessment (STOA), Human Enhancement. Study, Brussels, 2009, as well as: Goold, Imogen, "The legal aspects of cognitive enhancement", in Ruud ter Meulen, Ahmed Mohammed and Wayne Hall (eds.), *Rethinking Cognitive Enhancement*, Oxford University Press, Oxford, 2017, p. 270.

Among the existing and emerging HET, we pay particular attention to areas where potential regulatory gaps or grey zones have been identified. For that reason, this chapter refers more to human enhancement (HE) devices (such as neuromodulatory devices, brain-computer interference systems, implants etc.) and procedures (e.g., body modifications through surgeries) rather than to pharmaceuticals. Though the latter are also already in use, there are in general currently strictly regulated by the International Drug Control Regime (and national laws following it).[89] Although this regime has been heavily criticised[90] and proposals of alternative (or supplementary) regulatory models in the HET context have been put forward,[91] this area remains a heavily disputed debate that this chapter has no ambition to resolve.

4.1.2 Challenges in improving the legal frameworks for HET

Improving legal frameworks is never an easy task, but there is a number of challenges that make it particularly difficult in the context of HET. This section will briefly outline three of them and propose some ways of addressing these difficulties.

First, the definition of human enhancement remains a highly debated issue, with recurring challenges of drawing distinctions between common, yet highly problematic demarcations in the HET debates, such as 'treatment v. enhancement', 'therapeutic v. non-therapeutic', 'medical v. non-medical', 'normal v. better-than-normal' or 'natural v. artificial'.[92] These conceptual hurdles are not purely theoretical – they make it difficult to define the field of potential legal interventions. This challenge may be addressed by focusing on more 'core' types of HET, while acknowledging that certain more shadow areas will remain.[93]

Secondly, human enhancement does not refer to a specific technology or application, but rather to a very diversified and wide field of procedures and goods that share a certain type of purpose.[94] For the reasons of this diversity, it is not necessarily advisable to adopt a high-level, general policy towards the whole field (such as a general 'pro-enhancement approach' or a general 'restrictive approach'), but rather a 'systemic case-by-case approach', with due consideration of both benefits and risks they may entail for important societal values.[95] Adopting such case-by-case approach means, among others, that

[89] Warso, Zuzanna, et al., op. cit., pp. 14-15.
[90] Bublitz, Jan-Christoph, "Drugs, Enhancements, and Rights: Ten Points for Lawmakers to Consider", in Fabrice Jotterand and Velko Dubljević (eds.), *Cognitive Enhancement: Ethical and Policy Implications in International Perspectives*, Oxford University Press, New York, 2016, pp. 309-328.
[91] Dubljević, Veljko, "Prohibition or Coffee Shops: Regulation of Amphetamine and Methylphenidate for Enhancement Use by Healthy Adults", *The American Journal of Bioethics*, vol. 13, no. 7, June 2013, pp. 23-33.
[92] Jensen, Sean, et al., op. cit., 2018, pp. 14-16; Warso, Zuzanna, et al., op. cit., p. 75.
[93] For more information on defining the field, see: Jensen, Sean, et al., op. cit., 2018, pp., 12-25. Examples of 'core' types of HET include, among others, neurostimulation devices used for non-medical purposes, RFID or NFC (near- field communication) implanted chips or pharmaceutical cognitive enhancers. 'Penumbra' HET may include intelligent personal assistants (see discussion in Jensen, Sean, et al., op. cit., 2018, p. 13) or wearables.
[94] Kühler, Micheal, Nils-Frederic Wagner, Philip Brey, op. cit.,2020, p.7.
[95] These options are based on the five policy options identified in STOA, op. cit., Brussels, 2009, pp. 144-149; see also: Coenen, Christopher, Mirjam Schuijff, Martijntje Smits, "The politics of human enhancement and the European Union", in Julian Savulescu, Ruud ter Meulen, Guy Kahane (eds.), *Enhancing Human Capacities*,

this chapter dismisses a complete rejection of HET as such, which sometimes relies on the view that HET are 'incompatible with human dignity', because they 'alter human nature' or because they commodify and/or commercialise the human body.[96] Providing more extensive arguments for dismissing this viewpoint is beyond the scope of this report, but it should be noted that this perspective rests upon a highly problematic notion of a 'human nature' and, in addition, upon a presumption that it is wrong to alter it;[97] this viewpoint is also based upon a specific, conservative understanding of human dignity as constraint (rather than as empowerment).[98]

Thirdly, human enhancement remains a highly controversial topic, in the sense that both academic literature and the general public is deeply divided with many moral positions regarding it, as indicated by SIENNA ethics literature review[99] and SIENNA survey among 11,000 people worldwide.[100] There is no common stance in regard to many questions even on a high-level. This contrasts sharply with artificial intelligence field, where despite heated disputes on many specific issues, general guidelines that have been recently adopted around the world show a remarkable convergence on a general level.[101] The situation is also different in the area of human genomics and genetics, where many controversies remain, but in some important aspects agreements have been reached.[102] In case of HET field, many of its issues still await further democratic deliberation. Acknowledging this, recommendations at this stage do not necessarily have to provide definite legal solutions, but may rather indicate areas of needed changes and possible directions.

4.2. Potential changes and recommendations

This section discusses some of potential changes in legal frameworks that might be needed with regard to four general societal values that are likely to be affected by HET, based on SIENNA research: (1) health and safety; (2) privacy and data protection; (3) autonomy and (4) equality.[103] It presents also some recommendations with respect to an overarching issue of (5) technology assessment.[104] As explained above in the section 4.1.2., due to the diversity of HET procedures and goods, the discussed

Wiley-Blackwell, 2011, pp. 531-532. For a call for case-by-case approach, see also Brownsword, Roger, "Regulating Human Enhancement: Things Can Only Get Better?", *Law, Innovation and Technology*, vol. 1, issue 1, 2009, 125-152.

[96] For discussion of these objections, see: Brownsword, Roger, op. cit., 2009, pp. 132-133.

[97] STOA, op. cit., Brussels, 2009, p. 144.

[98] Brownsword, Roger, "Five Principles for the Regulation of Human Enhancement", *Asian Bioethics Review*, vol. 4 no. 4, 2012, pp. 351-352.

[99] Jensen, Sean, et al., op. cit. 2019.

[100] Prudhomme, Maria, et. al. *SIENNA 3.5: Public views on human enhancement technologies in 11 EU and non-EU countries*, 2019.

[101] Brey, Philip, et. al, *Sienna D4.7: An Ethical framework for the development and use of AI and robotics technologies,* 2020, p. 10.

[102] As institutionalised among others in the UNESCO Universal Declaration on the Human Genome and Human Rights.

[103] These values belong to the list of values identified as being among the most affected by HET in: Jensen, Sean, et al., op. cit., 2018, p. 62; Kühler, Micheal, Nils-Frederic Wagner, Philip Brey, op. cit., 2020, pp.23-24, see discussion in footnote 83.

[104] Warso, Zuzanna, et al., op. cit., p. 61.

potential changes do not refer to a general acceptability of HET as such, as this chapter follows a 'systemic case-by-case approach'.

4.2.1 Health and safety

Risks to health and safety constitute one of the crucial concerns about many of the existing and emerging HET. Broadly speaking, safety concerns may be addressed by products safety regulation, which is aimed at ensuring that products placed on the market meet adequate safety requirements and by regulating how these technologies are used (for example who may use them in terms of age or training, whether their use has to be accompanied with provision of relevant information about the risks etc.).[105] We discuss them in turn.

4.2.1.1 Product safety

Currently in the EU legal framework, many devices marketed for enhancement purposes have to meet only basic product safety requirements, even if technically they are the same products that, when marketed for medical purposes, must undergo rigorous pre-market assessment.[106] With adoption of the new Medical Devices Regulation,[107] this situation will change, as the legal regime applicable to medical devices will be extended to a closed-list group of types of devices that are marketed for non-medical purposes, but are similar to medical devices in terms of functioning and risk profile.[108] The list includes among others "products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts, with the exception of tattooing products and piercings" [109] and "equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the

[105] Warso, Zuzanna, et al., op. cit., p. 52.
[106] Warso, Zuzanna, et al., op. cit., pp. 37-38; Maslen, Hannah, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu, "The Regulation of Cognitive Enhancement Devices: Extending the Medical Model", *Journal of Law and the Biosciences*, Volume 1, Issue 1, March 2014, pp. 68–93; Baldwin, Thomas D. et al., *Novel Neurotechnologies: Intervening in the Brain*, Nuffield Council on Bioethics, London, 2013, p. 178. This does not mean that there are no safety requirements applicable to them. As any product they would fall under the scope of the Directive 2001/95/EC on general product safety and, depending on their features, other safety legislations, such as Low Voltage Directive (Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits) or Radio Equipment Directive (Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC). Moreover, as noted by a participant in the SIENNA HET webinar (17.06.2020), European Product Liability Directive is also relevant for protecting the HET users safety. Although all these instruments can contribute to ensuring trust and safety in HET products, they cannot be equated with the safety oversight framework envisaged in the medical devises legislation.
[107] European Parliament and the Council, Regulation (EU) 2017/745 of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017. The Medical Devices Regulation was supposed to go into effect on 26 May 2020, but the date of application was postponed until May 2021.
[108] European Parliament and the Council, Medical Devices Regulation, recital 12.
[109] Ibid, Annex XVI.

cranium to modify neuronal activity in the brain".[110] This change increases safety of users of these types of HE devices and responds to a number of important calls for such an extension.[111] However, the current version of the list is limited only to seven types of devices and primarily focuses on devices with aesthetic purposes. It does not include some of enhancement products that have been described as also entailing health risks[112] and, taking into account the expending market of some devices, the selection may quickly become outdated.[113] **It is crucial that the European Commission, empowered to adopt delegated acts to amend the list, strives to keep the list up to date with technological and societal developments, based on expertise from all relevant fields.[114]**

Many HET pose **safety challenges that go beyond purely physical risks** (e.g., mechanical or electrical).[115] For instance, brain-computer interface (BCI) systems or ICT implants may entail **cybersecurity threats**, such malicious external attacks disrupting the functioning of devices, data breaches or risks resulting from losses of connectivity.[116] Moreover, some HET may also have **adverse impacts on mental health.**[117] These types of risks have been indicated for instance in the context of the use of chip implants for employees, as they could generate feeling of being constantly monitored and therefore increase their levels of stress and anxiety. [118] **These safety risks should not be overlooked** and the assessment should not be restricted to purely physical risks.

In general, the current EU product safety framework, to a certain level, recognises this extended concept of safety.[119] For instance, the Medical Devices Regulation envisages requirements on the IT security measures, including protection against unauthorised access and measures with respect to

[110] Ibid.
[111] Maslen, Hannah, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu, op. cit., 2014; Baldwin, Thomas D. et al, op. cit., Nuffield Council on Bioethics, 2013, p. 179.
[112] For instance there has been discussion whether neurofeedback equipment should be also regulated in a stricter way – The Parliamentary Office of Science and Technology, *Brain Computer Interfaces,* London, 2020, p. 4; Maslen, Hannah, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu, op. cit., 2014; STOA, *Making Perfect Life: European Governance Challenges in 21st Century Bio-engineering,* Brussels, 2012, pp. 115-125.
[113] Palmerini, Erica, "A legal perspective on body implants for therapy and enhancement", *International Review of Law, Computers & Technology*, vol. 29, issue 2-3, 2015, pp. 232.
[114] Ibid.
[115] On the extended concept of safety in AI context, see**:** European Commission, *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics*, Brussels, 19.2.2020.
[116] Warso, Zuzanna, et al., op. cit., p. 18; Kreitmair, Karola V., "Dimensions of Ethical Direct-to-Consumer Neurotechnologies", *AJOB Neuroscience*, vol. 10, no. 4, 2019, pp. 152-166.
[117] Jensen, Sean, et al., op. cit., 2018, p. 49.
[118] Graveling, Richard, Thomas Winski, Ken Dixon, *The Use of Chip Implants for Workers*. *Study for the European Parliament's Committee on Employment and Social Affairs*, Brussels, 2018, p. 27; Firfiray, Shainaz, *Microchip implants are threatening workers' rights,* 2018, https://warwick.ac.uk/newsandevents/knowledgecentre/business/work/microchipping/.
[119] European Commission, *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics*, Brussels, 19.2.2020, p. 6.

safety of the connections,[120] while the Cybersecurity Act establishes a voluntary cybersecurity certification framework for ICT products, services and processes.[121] Furthermore and looking also beyond the EU context, cybercrimes are already criminalised by the CoE Convention on Cybercrime ('Budapest Convention', the only binding international instrument on this issue, open for signature also for non-CoE member states),[122] the EU Directive on attacks against information systems[123] and national criminal laws. To what extent, however, cyber-attacks against HET would be covered by this legislation, have been subject to a debate.[124]

However, on a closer examination the existing legal frameworks present some potential loopholes in the extended safety context. The Medical Devices Regulation (and its IT security requirements) covers only limited number of types of HE devices – for example BCI systems without an intended medical purpose that do not modify neuronal activity in the brain, but only scan this activity, would not fall under the scope of this regulation.[125] Furthermore, due to the closed connectedness of some enhancement devices to a human body (and often to the brain), the harms inflicted by cybercrimes could have far greater effects on human health than attacks on traditional computers.[126] Hence it could be also questioned whether the voluntary cybersecurity certification framework provides adequate protection in these cases and whether the existing criminal provisions provide proportionate responses to these challenges.

The challenges related to the extended safety risks could be addressed by a number of regulatory options and at different levels. A consideration could be given to extending the scope of the Medical Devices Regulations to more enhancement devices. Besides, the specific cybersecurity risks could be dealt with in a standalone act (for instance, for HET that are not similar in terms of functioning and risk profile to the medical devices, but that pose particular risks due to their close connections to human body and/or to the brain) or by an amendment to the Cybersecurity Act (according to the Cybersecurity Act, the Commission will regularly assess whether a specific cybersecurity certificate scheme is to be

[120] European Parliament and the Council, Medical Devices Regulation, Annex I, par. 17.4. See also Medical Device Coordination Group, *Guidance on Cybersecurity for medical devices*, December 2019, https://ec.europa.eu/docsroom/documents/38941/attachments/1/translations/en/renditions/native.
[121] European Parliament and the Council, Regulation (EU) 2019/881 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act), OJ L 151, 7.6.2019,
[122] Council of Europe Convention on Cybercrime, 23.11.2001, Treaty No.185.
[123] European Parliament and the Council, Directive 2013/40/EU of 12 August 2013 on attacks against information systems and replacing Council Framework Decision 2005/222/JHA,OJ L 218, 14.8.2013.
[124] Gasson, Mark N., and Bert-Jaap Koops, "Attacking Human Implants: A New Generation of Cybercrime", *Law, Innovation and Technology*, vol. 5, issue 2, 2013, pp. 248-277 (arguing that that cyber-attacks against HET will be covered by this legislation); for a different assessment of the Budapest Convention, see: Ienca, Marcello, James Scheibner, "What is neurohacking? Defining the conceptual, ethical and legal boundaries" in Bárd, Imre and Elisabeth Hildt (eds.), *Ethical Dimensions of Commercial and DIY Neurotechnologies*, Elsevier, Cambridge,2020, 8., p. 213-216
[125] Pizzetti, Federico Gustavo, "Brain-Computer Interfaces and the Protection of the Fundamental Rights of the Vulnerable Persons", in: Antonio D'Aloia, Maria Chiara Errigo (eds.), *Neuroscience and Law: Complicated Crossings and New Perspectives,* Springer International Publishing, 2020, p. 304.
[126] Gasson, Mark N., and Bert-Jaap Koops, op. cit., p. 276, Kreitmair, Karola V, op. cit., p. 157.

made mandatory[127]). Furthermore, a direct recognition that a cyber-attack on a device connected to a human body (implants, prosthesis, BCI etc.) constitutes an aggravating circumstance for a cybercrime could be also contemplated. This could be addressed in the context of the CoE Convention on Cybercrime (e.g., through an additional Guidance Note[128] or an additional protocol[129]), the EU Cybercrime framework[130] or the national criminal legislation. What is more, explicit provisions in respect of mental health implications of certain HETs could be further analysed for the sake of better protection through an increased legal certainty.[131]

4.2.1.2 Safety of procedures

Regulations relevant for enhancement procedures (such as plastic surgery, use of enhancement devices, implanting human microchips) are primarily found at the national level.[132] The regulatory landscape in this sphere is diversified and the comparative legal analysis conducted in SIENNA identified the existence of certain grey zones, where it is "unclear which standards of care apply and where accountability gaps may occur", what may entail serious safety risks for person participating in an enhancement procedure.[133] This challenge is becoming increasingly important, as there is a growing market of consumer enhancement devices (such as direct-to-consumer brain stimulation technologies or BCI systems[134] or implants implanted in e.g., piercing studios[135]). Some of these HET do not incur serious safety risks when used under adequate supervision, but may present significant threats to

[127] Article 56(3) of the Cybersecurity Act. The first such assessment will be carried out by the end of 2023, and later assessments will take place at least every two years thereafter. The Cybersecurity Act also defines first priority sectors to be assessed by the Commission: the sectors listed in Annex II to Directive 2016/1148, that is: energy, transport, banking, financial market infrastructures, health sector, drinking water supply and distribution, and digital infrastructure.

[128] Guidance Notes are issued by Cybercrime Convention Committee, which represents the State Parties to the Budapest Convention on Cybercrime – Cybercrime Convention Committee*, T-Cy Guidance Notes,* Strasbourg, 2017, http://rm.coe.int/doc/09000016806f9471.

[129] In a more indirect way, this was proposed by Hans Frank, CoE Parliamentary Assembly Member of Parliament, in his Report *Increasing co-operation against cyberterrorism and other large-scale attacks on the Intern*et, 08 June 2015, paras. 2.5.-2.6.

[130] The directive on attacks against information system already includes certain general categories of aggravating circumstances, that could be extended – article 9(3)-(5) of the Directive 2013/40/EU of the European Parliament and of the Council of 12 August 2013 on attacks against information systems and replacing Council Framework Decision 2005/222/JHA OJ L 218, 14.8.2013.

[131] Such a proposal was put forward in the AI context in European Commission, *Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics*, Brussels, 19.2.2020.

[132]Warso, Zuzanna, et al., op. cit.,2019, p. 43.

[133] Ibid., p. 62.

[134] Maslen, Hannah, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu, op. cit., 2014; Wexler, Anna, "A pragmatic analysis of the regulation of consumer transcranial direct current stimulation (TDCS) devices in the United States", *Journal of law and the biosciences* vol. 2,3, Oct. 2015, pp. 669-696; Ienca, Marcello, Pim Haselager, Ezekiel, Emanuel, "Brain leaks and consumer neurotechnology", *Nature Biotechnology,* vol. 36, 1 October 2018, pp. 805–810.

[135] Bárd, Imre, "Tailoring reality—The ethics of DIY and consumer sensory enhancement", in Imre Bárd, Elisabeth Hildt (eds.), op. cit., 2020, pp. 93-125.

health if self-administrated in an inappropriate way or if provided as a service by a person who lacks necessary skills.[136]

The **measures aimed at ensuring safety of human enhancement procedures** could include:

- allowing HE services to be carried out only by an authorised person with appropriate training (skills); [137]
- imposing an obligation on persons carrying out HE procedures to have measures in place providing sufficient financial coverage for any potential liability;[138]
- imposing an obligation on persons carrying out HE procedures to gather information from the clients about their health and suitability for the procedure;[139]
- imposing an obligation on persons carrying out HE procedures to perform them in a technically-correct way, according to professional standards and safety requirements;[140]
- prohibiting HE services that put one's life in imminent danger or cause a serious injury;[141]
- introducing minimum age requirement for participating in HE procedures;[142]
- introducing a criminal sanction for cases in which an untrained person carries out HE procedure intended for adults on children.[143]

Further analysis is required to determine whether regulating HE procedures lies within the EU competences, in line with the principles of proportionality and subsidiarity. One may argue that the EU powers are very limited in this sphere, as the organisation and delivery of health services remain within the competence of the Member States.[144] Moreover, the Court of Justice of the European Union (CJEU) held that "the health and life of humans rank foremost among the assets or interests protected by [Art. 36 TFEU]" and "it is for the Member States, within limits imposed by the Treaty, to decide what degree of protection they wish to assure".[145] Consequently, while Medical Devices Regulation sets up safety and performance requirements also for certain types of enhancement devices, it clearly stipulates that it does not affect national laws concerning the organisation, delivery or financing of health services and medical care, such as the requirement that only certain health professionals may use certain devices.[146] Some authors, however, have noted that the divergent national laws on enhancement procedures may have adverse effects on the functioning of the internal market and thus

[136] Baldwin, Thomas D. et al, op. cit., Nuffield Council on Bioethics, 2013, pp. 174-180 ; STOA, op. cit. 2012; De Ridder, Dirk, Sven Vanneste and Farah Focquaert, "Outstanding questions concerning the regulation of cognitive enhancement devices", *Journal of Law and the Biosciences*, vol. 1, issue 3, September 2014, pp. 316-321.
[137] Warso, Zuzanna, et al., op. cit.,2019, p. 62.
[138] Warso, Zuzanna, et al., op. cit.,2019.
[139] Warso, Zuzanna, et al., op. cit.,2019.
[140] Warso, Zuzanna, et al., op. cit.,2019.
[141] Warso, Zuzanna, et al., op. cit.,2019.
[142] De Ridder, Dirk, Sven Vanneste and Farah Focquaert, op. cit., 2014, pp. 316-321.
[143] Maslen, Hannah, Thomas Douglas, Roi Cohen Kadosh, Neil Levy and Julian Savulescu, op. cit., 2014.
[144] Article 168 (7) of the Treaty on the Functioning of the European Union.
[145] Court of Justice of the European Union, *Deutscher Apothekerverband v 0800 DocMorris NV*, C-322/01, 11 December 2003, para. 103.
[146] European Parliament and the Council, Medical Devices Regulation, Article 1 (15).

the EU could introduce a common approach.[147] A line of reasoning similar to the latter opinion has contributed to introducing limited requirements on procedures accompanying genetic testing in the EU In-vitro Medical Devices Regulation (not without some controversies, though[148]).

Alternatively or additionally, the recommended safety measures could be implemented on the national or international level. Within the latter, the CoE Convention on Human Rights and Biomedicine (the Oviedo Convention) could be of particular importance here.[149] While in some of the Oviedo Convention provisions there is a clear distinction between health purposes and other purposes,[150] other provisions leave more space for diverse interpretation, including the articles that could be particularly important to guarantee safety of enhancement procedures, such as the requirement that any intervention in the health field must be carried out in accordance with relevant professional standards (article 4).[151] In order to ascertain that they also cover non-therapeutic interventions, further guidance – perhaps through an additional protocol on the interventions for enhancement purposes or recommendations issued by the Committee of Ministers – could be considered.

4.2.2 Privacy and data protection

As many HET – such as BCI systems, wearable devices, ICT implants – may process personal data and privacy and data protection have been recognised as one the key societal values that may be affected. These concerns are aggravated by the fact that data processed by HET frequently relate to human

[147] Palmerini, Erica, et. al, *RoboLaw D6.2: Guidelines on Regulating Robotics,* 22.09.2014, http://www.robolaw.eu/RoboLaw_files/documents/robolaw_d6.2_guidelinesregulatingrobotics_20140922.pdf pp. 209-210.

[148] Kalokairinou, Louiza, Heidi C Howard, Santa Slokenberga et al. "Legislation of direct-to-consumer genetic testing in Europe: a fragmented regulatory landscape", *Journal of community genetics* vol. 9, no. 2, 2018, pp. 117-132.

[149] Ruggiu, Daniele, "Implementing a responsible, research and innovation framework for human enhancement according to human rights: the right to bodily integrity and the rise of 'enhanced societies'", *Law, Innovation and Technology*, vol. 10, no. 1, 2018, pp. 91-92.

[150] Article 13 of the Oviedo Convention states that any intervention which aims to modify the human genome must be carried out for preventive, diagnostic or therapeutic purposes, while article 12 prohibits carrying out of predictive tests for reasons other than health or scientific research linked to health purposes.

[151] The Oviedo Convention explanatory report explains that "*The term "intervention" must be understood here in a broad sense; it covers all medical acts, in particular interventions performed for the purpose of preventive care, diagnosis, treatment or rehabilitation or in a research context*" – Secretary General of the Council of Europe, *Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Oviedo, 4.04.1997, I. European Treaty Series - No. 164. The meaning of the expression "intervention in the health field" used in the Oviedo Convention was also analysed in the Explanatory Memorandum to the CoE Committee of Ministers Recommendation Rec(1999)4 on principles concerning the legal protection of incapable adults, where it was explained that it should be understood as "*any act performed professionally on a person for reasons of health. It includes, in particular, interventions for the purposes of preventive care, diagnosis, treatment, rehabilitation or research."* See also: Whittall, Hugh, Laura Palazzani, Michael Fuchs and André Gazsó, *Emerging Technologies and Human Rights. International Conference organised by the Committee on Bioethics (DH-BIO) of the Council of Europe under the auspices of the Belgian Chairmanship of the Committee of Ministers. Report prepared by the Conference's rapporteurs to the Committee on bioethics,* Strasbourg 2015, p. 8.

physiological processes and especially because they may often include information on brain activity. It is this latter form of data (sometimes described also as "neurodata"[152] or "brain data"[153]) that particularly has led to questions whether the existing European privacy and data protection frameworks remain well-suited to address challenges of certain HET.[154] Firstly, although the EU General Data Protection Regulation (GDPR)[155] and the CoE Modernised Convention for the Protection of Individuals with Regard to the Processing of Personal Data (Convention 108)[156] recognise that there are certain categories of data that require an enhanced protection, brain data is not explicitly included in their (exhaustive) lists of sensitive data.[157] It is not clear whether brain data could always qualify as belonging to the existing special categories, such as health data, when used for enhancement purposes.[158] Moreover, it has been also argued that brain data may be even regarded as "more sensitive" than the sensitive data under the current data protection law and that the data protection framework is not constructed to deal with such a level of intimacy – and hence a new approach needs to be considered.[159]

Having regard to the above, **European data protection law should be reviewed to assess whether in its current form it is suitable to adequately protect brain data in the context of HET**. If the answer is negative, it should be examined whether it could be amended (e.g., by adding brain data to the list of

[152] Hallinan, Dara, Philip Schütz, Michael Friedewald, Paul de Hert, "Neurodata and Neuroprivacy: Data Protection Outdated?", *Surveillance and Society,* vol. 12, no. 1, 2014, pp. 55-72.
[153] Rainey, Stephen, Jan Christoph Bublitz, Hannah Maslen, Hannah Thornton, "Data as a Cross-Cutting Dimension of Ethical Importance in Direct-to-Consumer Neurotechnologies", *AJOB Neuroscience*, vol. 10, no. 4, 2019, pp. 180-182; Ienca, Marcello, Pim Haselager, Ezekiel, Emanuel, op. cit., 2018.
[154] Hallinan, Dara, Philip Schütz, Michael Friedewald, Paul de Hert, op. cit. 2014; Rainey, Stephen, Jan Christoph Bublitz, Hannah Maslen , Hannah Thornton, op. cit. 2019.
[155] European Parliament and the Council, Regulation (EU) 2016/679 of 27.04.2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
[156] Council of Europe, Modernised Convention for the Protection of Individuals with Regard to the Processing of Personal Data, 128th Session of the Committee of Ministers, May 2018.
[157] Article 9 and article 6, respectively.
[158]Rainey, Stephen, Jan Christoph Bublitz, Hannah Maslen, Hannah Thornton, op. cit. 2019; Hallinan, Dara, Philip Schütz, Michael Friedewald, Paul de Hert, op. cit. 2014. For an argument that at least some forms of brain data would fall under the existing categories of sensitive data, see also: Garstka, Krzysztof, "From Cyberpunk to Regulation – Digitised Memories as Personal and Sensitive Data within the EU Data Protection Law", *Journal of Intellectual Property, Information Technology and Electronic Commerce Law (JIPITEC*), vol. 8, no. 4, 2017, pp. 1-13.
[159] Ibid; STOA, op. cit., 2012, p. 38; Edwards, Sarah J. L., "Protecting privacy interests in brain images: the limits of consent", in Sarah D. Richmond, Geraint Rees, and Sarah J. L. Edwards*, I Know What You're Thinking: brain imaging and mental privacy*, OUP Oxford, 2012; Ligthart, Sjors L. T. J., "Coercive neuroimaging, criminal law, and privacy: a European perspective", *Journal of Law and the Biosciences*, vol. 6, no. 1, October 2019, pp. 289–309; Latini, Sara, *To the edge of data protection: How brain information can push the boundaries of sensitivity,* Tilburg University, 2018. On the need to recognise a new right to mental privacy, see also Ienca, Marcello, and Roberto Andorno, "Towards new human rights in the age of neuroscience and neurotechnology", *Life Sciences, Society and Policy,* vol. 13, no. 5, 2017, pp. 1-27 and (for critical remarks on this idea): Ligthart, Sjors, Thomas Douglas, Christoph Bublitz, et al., "Forensic Brain-Reading and Mental Privacy in European Human Rights Law: Foundations and Challenges", *Neuroethics* , 2020, 1-13.

sensitive data, similarly to genetic data) or whether a new legal framework is needed to address privacy risks it incurs. The EU might be in best position to address these challenges, with its strong competences to legislate on data protection measures[160] and having in mind that divergent national laws on privacy protection with regard to enhancement neurotechnologies could impede functioning of the internal market. The assessment of the applicability of the current EU data protection framework could be conducted under the auspices of the European Data Protection Board (EDPB) and the European Commission. If, following the review, it were judged to be sufficient in its current form, EDPB Opinion or Guidelines on this topic would be helpful. Further discussion and guidance on the international level could also be beneficial, especially within the Council of Europe system (e.g., by the Consultative Committee of the Convention 108 or the Committee of Bioethics – the latter already made plans in this area[161]) or within the OECD (which recently already has adopted a soft law act explicitly referring to the protection of personal brain data[162] and will now provide practical guidance on its adoption[163]).

Beyond brain data issues, particular privacy concerns were expressed also in regard to the use of **microchips for workers** (e.g., RFID, Radio-Frequency Identification, chips).[164] Due to the inherent power imbalance in the employment relationship and to the constant presence of a microchip in a human body (in contrast to, for example, a badge), consideration should be given whether the current data protection framework provides sufficient safeguards against abuses. Although a proportionate regulatory answer should take into account scope and nature of data collected, risk-mitigation measures adopted by the employer etc., an outright prohibition of at least the most intrusive cases should be contemplated.[165] The criteria for a permissible workplace surveillance set out it the European Court of Human Rights (ECtHR) Grand Chamber judgement *Bărbulescu v Romania* could be used, *mutatis mutandis,* as a starting point for a possible regulatory intervention.[166] It should be also

[160] Article 16 TFEU.
[161] According to its *Strategic Action Plan,* the Committee on Bioethics (DH-BIO) is planning to assess by 2023 "the relevance and sufficiency of the existing human rights framework to address the issues raised by the applications of neurotechnologies", including with regard to privacy. It will analyse whether there is a need to consider "new human rights pertaining to cognitive liberty, mental privacy, and mental integrity and psychological continuity". Council of Europe Committee on Bioethics, *Strategic Action Plan on Human Rights and Technologies in Biomedicine(2020-2025),* November 2019, https://rm.coe.int/strategic-action-plan-final-e/16809c3af1. See also, Lwoff, Laurence, op. cit., 2020.
[162] The OECD Council, Recommendation on Responsible Innovation in Neurotechnology, OECD/LEGAL/0457, adopted on 11.12.2019.
[163] Winickoff, David, Garden Herman, *New Frontiers of the Mind: Enabling responsible innovation in neurotechnology,* 19.12.2019, https://www.oecd-forum.org/users/338762-david-winickoff/posts/57641-new-frontiers-of-the-mind-enabling-responsible-innovation-in-neurotechnology
[164] Graveling Richard, Thomas Winski, Ken Dixon, op. cit., 2018.
[165] Laws limiting the use of human microchip in the employment area were adopted in some states in the United States – Wasbin, Joshua Z., "Examining the Legality of Employee Microchipping Under the Lens of the Transhumanistic Proactionary Principle", *Washington University Jurisprudence Review* , vol. 11, no. 2, 2019, pp. 401-425.
[166] ECtHR (Grand Chamber), *Bărbulescu v. Romania*, 61496/08, 05.09.2017; Graveling Richard, Thomas Winski, Ken Dixon, op. cit., 2018, pp. 21-22.

reviewed, to what extent labour law instruments could provide relevant and sufficient safeguards in this area.

Considering the EU competences in the data protection and its shared competences in some areas of labour law (including the field of working conditions and improvement of the working environment to protect workers' health and safety),[167] harmonised action in this area could be examined – especially if this phenomenon becomes more popular on the labour market.[168] In addition to national laws, International Labour Organisation (ILO) guidance would be beneficial. On every possible level of regulation, the involvement of social partners in the debate will be crucial.

4.2.3 Autonomy

With regard to autonomy (understood as "the value of a person's ability to decide and act on her own authentic desires and preferences, without being unduly influenced, coerced or manipulated by others"[169]) in the context of HET, the principle of **informed consent** is of special importance. A person undergoing an enhancement procedure should obtain clear and accurate information both about the expected benefits and the risks, possible adverse outcomes and possible complications that could arise from the procedure, including the long term effects.[170]

Legal frameworks for obtaining informed consent for enhancement procedures differ from country to country, where they exist (e.g., in the context of plastic surgery).[171] Moreover, in case of some applications, such as direct-to-consumer neurotechnologies, information duties may be currently fairly limited or lack clarity in scope. As noted above in the context of safety of enhancement procedures, further analysis is needed on whether the EU has competences to regulate in this area in line with the principles of subsidiarity and proportionality. It could be argued that these matters touch upon the organisation and delivery of health services, which remain within Member States competences. On the other hand, divergent national laws in this aspect may have an adverse impact on the functioning of the internal market and the high level protection of consumers. This could serve as a basis to consider introducing a requirement to provide relevant information on the nature, the significance and the implications of the enhancement procedure in the Medical Devices Regulation, with regard to some of devices used for enhancement listed in its Annex XVI – as it was introduced in the In-vitro Medical Devices Regulation in the context of genetic testing.[172] Besides adopting appropriate requirements on the informed consent for HET procedures on the national level (which seems the most likely option), it could be contemplated whether the safeguards envisaged in the CoE Oviedo Convention could not

[167] Article 153 TFEU.
[168] In 2017, a number RFID chip implants in humans was estimated as ranging from 3 000 to 10 000 worldwide (in and outside the workplace context) – Graveling Richard, Thomas Winski, Ken Dixon, op. cit., 2018, p. 15.
[169] Brey, Philip, et. al, op. cit., 2020, p. 22.
[170] Warso, Zuzanna, et al., op. cit., p. 62.
[171] Ibid., p. 52-53.
[172] European Parliament and the Council, Regulation (EU) 2017/746 of the of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, OJ L 117, article 4. On the background of introducing this provision, see: Kalokairinou, Louiza, Heidi C. Howard, Santa Slokenberga et al., op. cit., 2018.

serve as appropriate basis. Currently, the requirement for informed consent in the Convention refers to "any medical intervention in the medical field" (article 5).[173] An explicit recognition that this term covers also HE interventions may be considered.

Making informed choices about participating in an enhancement procedure can be also adversely affected by **misleading advertising,** which trivialises risks or makes false, overblown claims about benefits of a given HET. Misleading commercial practices – with regard to both goods and services – are already prohibited in the EU under the Unfair Commercial Practices Directive.[174] It has been reported that misleading marketing of HET occurs in the EU Member States (e.g., in the context of direct-to-consumer neuromodulatory devices),[175] therefore it should be examined whether this results from the lack of enforcement of the existing framework or there is a regulatory gap and advertising HET calls for a tailored legal response. Such an assessment could be done under the auspices of the European Commission, but action from the national consumer protection authorities could be also needed to improve enforcement and collect more data on the practice.

4.2.4 Equality

The principle of equal treatment may be potentially undermined by discrimination towards enhanced or non-enhanced persons.[176] Given the relatively limited effectiveness and limited popularity of existing HET, this issue may be more of a future challenge, but first claims of this type, for instance in the workplace environment, cannot be excluded in the near future. It should, therefore, be **examined whether being enhanced or not enhanced could be recognised as a protected characteristic** (i.e., characteristic that should not be considered relevant to the differential treatment[177]). Although this solution could be helpful to for example address the risks of employees being directly or indirectly coerced to enhance by their employers,[178] it entails some difficulties as well. One could argue that since deciding if a given intervention constitutes human enhancement is often problematic, prohibiting discrimination on this ground lacks necessary legal certainty. Although establishing one's status as being enhanced might by relatively less controversial in some cases (especially with regard to more permanent and concrete types, for example in cases of implants or advanced prosthetics), in other

[173] On this term, see also footnote no 150 in this report.
[174] European Parliament and the Council, Directive 2005/29/EC of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive'),OJ L 149, 11.6.2005.
[175] Baldwin, Thomas D. et al, op. cit., Nuffield Council on Bioethics, 2013, pp. 179-181; outside the EU, see also: Wexler, Anna, Robert Thibault, "Mind-Reading or Misleading? Assessing Direct-to-Consumer Electroencephalography (EEG) Devices Marketed for Wellness and Their Ethical and Regulatory Implications", *Journal of Cognitive Enhancement*, vol.3, 2018, pp. 131–137.
[176] Roosendaal, Arnold, "Implants and Human Rights, in Particular Bodily Integrity", in Mark N. Gasson, Eleni Kosta and Diana M. Bowman (eds.), *Human ICT Implants: Technical, Legal and Ethical Considerations*, Vol. 23 of Information Technology and Law, T.M.C. Asser Press, The Hague, 2012, p. 94; Jensen, Sean, et al., op. cit. 2019.
[177] European Union Agency for Fundamental Rights and Council of Europe, *Handbook on European non-discrimination law,* Luxembourg, 2018, p. 161.
[178] Jensen, Sean, et al., op. cit. 2019.

cases it presents serious conceptual difficulties (e.g., in the context of HET that have effects limited to a certain time, e.g., some pharmaceuticals).[179]

If these difficulties are surmountable and the concept of recognising being (non)enhanced as a protected characteristics is to be followed, it might be more likely to be developed within the Council of Europe system than at the EU-level. In general, the EU has competences to take action to combat discrimination only with regard to a closed list of discrimination grounds,[180] while the CoE is not restricted in this aspect. The CoE European Convention on Human Rights contains an open-ended prohibition of discrimination – it includes the category of 'other status'. While the idea of treating being (non)enhanced as a protected ground might seem problematic also because most protected categories are features that are considered as inherent, not being changeable (and undergoing enhancement is a personal choice)[181] – it should be noticed that the category of 'other statues' under the ECHR has been understood by the ECtHR as *not* being limited to "characteristics which are personal in the sense that they are innate or inherent".[182] Moreover, with regard to changeability, the Court held that "the prohibition of discrimination enshrined in Article 14 of the Convention is meaningful only if, in each particular case, the applicant's personal situation in relation to the criteria listed in that provision is taken into account exactly as it stands. To proceed otherwise in dismissing the victim's claims on the ground that he or she could have avoided the discrimination by altering one of the factors in question (…) would render Article 14 devoid of substance".[183] Key question for the ECtHR would be rather whether a different treatment because of being (non)enhanced has an objective and reasonable justification (legitimate aim) and whether the relationship between the employed means and the aim sought is proportionate.[184] Further within the CoE system, it may be also contemplated whether a prohibition of discrimination on the grounds of being enhanced or not could be added to the Oviedo Convention, in a similar way as the Convention already prohibits discrimination on the grounds of his or her genetic heritage (article 11).

4.2.5 Technology assessment

One of the overarching challenges of regulating HET is to use a model of technology assessment that would not be limited to medical risks, but that would also encompass the different societal and ethical impacts entailed by them.[185] The proposed EU Regulation on health technology assessment[186] to a certain extant may be seen as a step in this direction. The proposed framework envisages both clinical

[179] More on some difficulties connected to this idea, see Goold, Imogen, "The legal aspects of cognitive enhancement", in Ruud ter Meulen, Ahmed Mohammed and Wayne Hall (eds.), *Rethinking Cognitive Enhancement*, Oxford University Press, Oxford, 2017, pp. 263-267.
[180] Article 19 TFEU.
[181] A point raised by a participant in the SIENNA HET webinar, 17.06.2020.
[182] ECtHR (Grand Chamber), Carson and Others v. the United Kingdom, 26.03.2020, no 42184/05.
[183] ECtHR (Grand Chamber), Andrejeva v. Latvia , 18.02.2009, no 55707/00.
[184] ECtHR (Grand Chamber), Molla Sali v. Greece, 19.12.2018, no 20452/14, § 135.
[185] Warso, Zuzanna, et al., op. cit., p. 61.
[186] European Commission, Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU, COM/2018/051 final - 2018/018, Brussels, 31.1.2018.

and non-clinical assessment of health technologies, including ethical, organisational, social and legal aspects related to them – although the latter assessment is to remain within the competences of the Member States and the Commission will only support the voluntary cooperation between them and facilitate it via the Coordination Group. The proposed regulation covers the medical devices and medicinal products, as defined under the EU law, and therefore relates also to some types of HET. Having regard to many ethical, social and legal aspects of HET, it will be **crucial to keep HET impacts high on the agenda of non-clinical health technology assessment,**[187] especially taking into account the "risks of overemphasis on efficacy and cost-effectiveness issues".[188]

4.2.6 Conclusions

The three tables below summarise the identified legal changes and recommendations, in line with the joint methodological approach outlined in section 1.2. of this report. They list necessary and/or desired legal changes (and associate them with the societal values identified in the SIENNA ethical analysis), along with specific actions and information indicating who may be responsible for a given action. They also add information on indicative priority level, as well on the possible challenges related to its implementation.

International- level changes

Societal value	Necessary/desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
Health and safety	Ensure safety of HE products	Address cybersecurity threats through cybercrime instruments (assess to what extent current cybercrime framework would be sufficient for specific threats of some HET, especially connectedness to a human body; if needed, consider appropriate amendments or guidance documents).	CoE Cybercrime Convention Committee; CoE Committee of Ministers	2	Finding a balance between flexibility of a general framework and addressing peculiar threats; getting consensus.
	Ensure safety of HE procedures	Assess the relevance and sufficiency of the Oviedo Convention in this area; if needed: consider an additional protocol or	CoE Committee on Bioethics (DH-BIO), CoE Committee of Ministers	2	Getting consensus.

[187] Jensen, Sean, et. al, op. cit., 2018 p. 65.
[188] Banta, David, "What is technology assessment?", *International Journal of Technology Assessment in Health Care,* vol. 25 Suppl 1, 2009, p.9.

Societal value	Necessary/desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
		guiding recommendations.			
Privacy and data protection	Adequately protect information related to brain activity	Review data protection framework in the context of brain data. Consider adopting guidelines and/or, if needed, appropriate amendments (e.g. adding new category of sensitive data).	CoE Consultative Committee of the Convention 108	1	Many competing issues awaiting further review or guidelines; getting consensus on a potential amendment; resistance from a growing industry to new restrictions.
		Consider adopting new international soft law standards relating to brain data and mental privacy (building upon existing data protection and privacy frameworks).	UN Special Rapporteur on the right to privacy; CoE Parliamentary Assembly; CoE Committee for Ministers; CoE Committee of Bioethics (DH-BIO); OECD Working Party on Biotechnology, Nanotechnology and Converging Technologies	1	Getting consensus (where needed); resources.
	Address privacy threats related to the use microchip for workers	Asses the sufficiency of the data protection regulation; issue guidelines.	CoE Consultative Committee of the Convention 108 (for CoE).	3	Many competing issues awaiting further review or guidelines (resources).
		Review adequacy of protection envisaged in current labour law instruments vis-à-vis use of microchips for workers.	International Labour Organisation	3	Employers' resistance to enhance labour protection.
Autonomy	Safeguard informed consent in HE procedures	Assess the relevance and sufficiency of the Oviedo Convention in this area; if needed: consider an additional protocol or	CoE Committee on Bioethics (DH-BIO); CoE Committee of Ministers	2	Getting consensus

Societal value	Necessary/desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
		guiding recommendations			
Equality	Address the risk of discrimination of towards (non)enhanced persons, especially in the workplace context	Examine whether being enhanced or not could be recognised as a protected characteristic	CoE Committee of Bioethics (DH-BIO)	4	Conceptual difficulties that may undermine legal certainty; resistance to expand the scope of protected characteristics; getting consensus.
		Assess the sufficiency and relevance of the labour law safeguards to protect from the workplace pressure to enhance (including examining whether the risk of coercion could be addressed by more effective enforcement of existing frameworks or whether there is a regulatory gap)	International Labour Organisation	3	Resistance from employers; resources; getting consensus.

Table 6. International-level potential changes, actions, and challenges for HET

EU- level changes

Societal value	Necessary/desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
Health and safety	Ensure safety of HE devices	Keep the list of groups of devices without an intended medical purpose that are regulated under the Medical Devices Regulation up to date with technological and societal developments.	European Commission	2	Consensus on which HE devices are to be considered as similar to medical devices in terms of functioning and risk profile; resistance from the industry
		Address cybersecurity threats related to HE devices through product safety requirements (consider extending the	European Commission	2	Cybersecurity priorities set for more strategic network sectors;

Societal value	Necessary/desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
		scope of the Medical Devices Regulation to more types of HE devices; amending the Cybersecurity Act or adopting standalone legislation).			resistance from the industry
		Address cybersecurity threats through cybercrime legislation (assess to what extent current cybercrime framework would be sufficient for specific threats of some HET, especially connectedness to a human body; if needed, consider appropriate amendments or guidance documents).	European Commission	2	Finding a balance between flexibility of a general framework and addressing peculiar threats
		Address potential mental health impacts of some HET through product safety legislation.	European Commission	3	Resistance to addressing mental health in product safety legislation; Determining the scope of mental health impacts.
	Ensure safety of HE procedures	Assess whether the EU has the competences to legislate in this area, in line with the principles of subsidiarity and proportionality.	European Commission	2	Resistance from Member States
Privacy and data protection	Adequately protect information related to brain activity	Review data protection framework in the context of brain data. Consider adopting guidelines and/or, if needed, appropriate amendments (e.g. adding new category of sensitive data).	EDPB	1	Many competing issues awaiting further review or guidelines; getting consensus on a potential amendment; resistance from a growing industry to new restrictions.

Societal value	Necessary/desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
	Address privacy threats related to the use microchip for workers	Asses the sufficiency of the data protection regulation; issue guidelines.	EDPB	3	Many competing issues awaiting further review or guidelines (resources).
		If the use of microchip for workers becomes more popular on the European market, explore possibility of harmonised EU action addressing privacy threats.	European Commission	4	Employers' resistance to enhance labour protection;
Autonomy	Safeguard informed consent in HE procedures	Assess whether the EU has the competence to legislate in this area, in line with the principles of subsidiarity and proportionality.	European Commission	3	Resistance from Member States
	Address misleading advertising of HET	Improve enforcement of the existing unfair commercial practices framework.	European Commission	1	Getting resources
		Review the existing framework of Unfair Commercial Practices Directive to assess whether advertising HET calls for a tailored legal response	European Commission	2	Finding a balance between flexibility of a general framework and addressing peculiar threats; resources
	Establish or reinforce a model of technology assessment that would not be limited to medical risks, but that would also encompass the different societal and ethical impacts entailed by them[189]	Continue legislative work on EU Regulation on health technology assessment, which envisages also non-clinical assessment; keep HET high impacts high on the agenda of non-clinical health technology assessment.	European Commission, Council, European Parliament	1	Limited scope of the proposed Regulation (only some HET would be covered); Risk of divergence between Member States, who will be responsible for non-clinical assessment; resistance from (some) Member States

Table 7. EU-level potential changes, actions, and challenges for HET

[189] This change is not related to one particular societal value – it is an overarching issue, affecting all relevant societal values.

National-level changes

Societal value	Necessary/desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
Health and safety	Ensure safety of HE devices	Address cybersecurity threats through cybercrime legislation (assess to what extent current cybercrime framework would be sufficient for specific threats of some HET, especially connectedness to a human body; if needed, consider appropriate amendments or guidance documents).	National governments and parliaments	2	Finding a balance between flexibility of a general framework and addressing peculiar threats
	Ensure safety of HE procedures	Address gaps in regulatory framework relevant for safety of enhancement procedures.	National governments and parliaments	1	Finding a proportionate answer for different types of HE procedures
Privacy and data protection		Review adequacy of protection envisaged in current labour law instruments vis-à-vis use of microchips for workers.	National governments and parliaments	3	Employers' resistance to enhance labour protection
Autonomy	Safeguard informed consent in HE procedures	Address gaps and grey zones in national legal frameworks	National governments and parliaments	1	Finding a proportionate solutions for different types of HE procedures
	Address misleading advertising of HET	Improve enforcement of the existing unfair commercial practices framework	National consumer protection authorities	1	Getting resources
Equality		Assess the sufficiency and relevance of the labour law safeguards to protect from the workplace pressure to enhance (including examining whether the risk of coercion could be addressed by more effective enforcement of	National governments and parliaments;	3	Resistance from employers; resources

Societal value	Necessary/desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
		existing frameworks or whether there is a regulatory gap)			
	Establish or reinforce a model of technology assessment that would not be limited to medical risks, but that would also encompass the different societal and ethical impacts entailed by them[190]	Keep HET high impacts high on the agenda of non-clinical health technology assessment within the framework of the proposed EU Regulation on health technology assessment and/or within the relevant national frameworks	National governments and parliaments	1	Limited scope of the proposed Regulation (only some HET would be covered); avoiding overemphasis of efficacy and economical cost - effectiveness aspects

Table 8. National-level potential changes, actions, and challenges for HET

However disputed the term itself may be,[191] some applications of what we qualify as HET already entail certain risks for a number of societal values and human rights, which may intensify with the developments in the field. Taking into account the diversity of these technologies and their implications, a regulatory approach that has an ambition to address all the relevant issues in one legal instrument might not the best way to start, neither would be a general supportive or restrictive approach to all HET as such. At the same time, the general category of HE may be very helpful to draw attention to the regulatory grey zones in which many of its applications fell, especially when a regulation was created having in mind only medical/therapeutic purposes of a given product or an action.

With regard to the international legal order, taking into account low level of institutionalisation of the field, soft law instruments may be considered as a way of incremental building of understanding and consensus. As they may be adopted faster (compared to binding treaties, at least), they may be also better suited for areas where lack of clarity about their developments may call for a more flexible approach.[192] Some promising steps have been identified above, such as the OECD work in the area of

[190] This change is not related to one particular societal value – it is an overarching issue, affecting all relevant societal values.

[191] SIENNA definition of human enhancement technologies and boundaries of the field were among the most heavily discussed issues during the SIENNA HET webinar on 17 June 2020.

[192] Garden, Hermann, David E. Winickoff, Nina Maria Frahm and Sebastian Pfotenhauer, "Responsible innovation in neurotechnology enterprises", *OECD Science, Technology and Industry Working Papers 2019/5.* p. 29

neurotechnology[193] or the CoE Committee of Bioethics (DH-BIO) plans to go in this direction.[194] However, there is definitely room for more interpretative guidance on how high-level international law relates to HE challenges. This includes, among other, relevant guidance to instruments protecting the right to privacy, protecting against discrimination or cybercrime threats, as well as in in the area of biomedical safeguards of informed consent, the right to moral and physical integrity or the requirement to carry out inventions in accordance with relevant professional standards. While the challenge of reaching consensus (or a majority) between States may appear also in the context of certain soft law instruments (such as resolutions of collective bodies), in others, such as reports of UN Special Rapporteurs, this is not the case and building specific standards may begin with these types of soft law.

The speculative tone of some of discussions surrounding HET should not divert policymakers' attention from the fact that there are areas that may require more urgent action – and not only with soft law instruments. These include, among others, addressing gaps in adequate protection of safety of persons undergoing HE procedures and challenges related to processing brain data, especially considering growing market of consumer neurotechnologies.

The EU, with its world-leading role in the data protection, should take up a more guiding role in privacy and data protection in the HE context, especially with regard to the challenges associated with the brain data. A growing number on HE products and services circulating in the EU market also calls for a closer examination of the EU regulatory framework and its enforcement, including vis-à-vis the practice of misleading advertising. While the adoption of the new Medical Devices Regulation may be perceived as indication of a step in the right direction, the product safety legislation in the HE context may require further scrutiny and being open to the broader concept of safety (going beyond the physical risks). Inclusion of the non-health assessment within the proposed EU Regulation on health technology assessment may be understood as sign of acknowledging the need for broader evaluation that also takes on board the ethical and social aspects. However, its effects – should it be eventually adopted – remain to be seen.

National legal frameworks remain an important point of reference for the regulation of HE impacts, both because of the lack of clear guidance in many cases on the international and EU level, and because in some areas the EU competences to legislate may be subject to a debate (as in regulation of HE procedures). This puts a particular burden on the national legislators to review and monitor how their respective legislation responds to the HE challenges and that these responses are in line with the general human rights protection commitments – what leads again to the need for further guidance on the international level.

All three legal regimes should not be seen in isolation, but as dynamically affecting each other. Though this is true for almost every subject of regulation, it may be particularly important to remember that

[193] The OECD Council, Recommendation on Responsible Innovation in Neurotechnology, OECD/LEGAL/0457, adopted on 11.12.2019

[194] Council of Europe Committee on Bioethics, *Strategic Action Plan on Human Rights and Technologies in Biomedicine(2020-2025),* November 2019, https://rm.coe.int/strategic-action-plan-final-e/16809c3af1

in the context of the developing field of HET, in order to rely on all levels when responding to new challenges and to see the different levels as mutually supportive.

5. Enhancing the legal frameworks for AI and robotics

5.1. Introduction

In 2018-2019, SIENNA carried out research on legal developments and approaches to specific legal issues and human rights challenges related to AI and robotics at the international, EU and national level (12 countries, EU and non-EU).[195] Based on this research which analysed both general and specific legal issues of AI and robotics, views expressed in the SIENNA citizen panels carried out in five countries,[196] and current academic, policy and regulatory developments, this section identifies potential changes necessary and/or desirable in the existing legal and human rights frameworks (international, EU and national) **to create an environment in which the SIENNA proposals for ethical and human-rights respectful AI and robotics could be implemented most effectively.**

The SIENNA proposals for ethical and human-rights respectful AI and robotics include a *Multi-stakeholder Strategy for Ethical AI and Robotics* and a *Framework for Ethics by Design*. At the time of submitting this report to the European Commission in July 2020, these proposals were still in development. The *Multi-stakeholder Strategy* has three key elements: (1) identification of relevant actors, (2) identification of methods that these actors can use to contribute to ethical AI & robotics, and (3) proposal of ways in which these methods can be made available to these actors and ways to motivate them to use them.[197] The *Framework for Ethics by Design* aims to help AI and robotics developers include ethical requirements in a systematic and comprehensive manner in the design and development process.[198] Policies, laws and regulation can "explicitly institute, promote or require ethics guidelines, procedures, or bodies; they can have a focus on upholding certain moral values or principles without explicitly identifying them as ethical (e.g., well-being, privacy, fairness, sustainability, civil rights); and they either explicitly or implicitly take on board ethical considerations in broader social and economic policies."[199] This section supports this by identifying actionable measures.

[195] Rodrigues, Rowena et al., *SIENNA D4.2 Analysis of the legal and human rights requirements for Artificial Intelligence and Robotics in and outside the EU*, 2019,. https://www.sienna-project.eu/robotics/legal-aspects/
[196] SIENNA/Kantar Public, "D4.6: Qualitative research exploring public attitudes to AI and robotics", 31 August 2019.
[197] Brey, Philip et al., op. cit., 2020.
[198] Ibid.
[199] Ibid.

Structure, approach and method including scope and limitations

This first section focusses on changes at the international level, followed by those at the EU-level and national levels. A range of necessary and/or desired legal changes are identified, along with the specific actions, responsibilities[200], indicative priority levels[201] and change implementation challenges[202] as indicators for policy-makers and regulators and as a baseline for further in-depth research in the area.[203] The specific approaches are outlined in each sub-section.

5.2. International level changes

At the international level, various actions are under consideration and being taken, e.g., at the United Nations[204] and Council of Europe[205], to address legal issues and impacts of AI and robotics. The table below presents necessary and/or desired legal changes, along with specific actions, responsibilities, indicative priority levels and change implementation challenges based on the legal analysis carried out in Task 4.2[206] of SIENNA and a supportive, limited literature review (that looked at international policy documentation at the UN, including UNESCO, WIPO, ILO, and Council of Europe) to extract the most currently relevant ones that create the environment needed for the SIENNA proposals to flourish. The priority levels awarded reflect the views of the SIENNA researchers' based on their research at time of writing (June-July 2020).

Some of the proposed changes have been repeated many times but benefit from re-stating. Urgent priority actions have been identified at this level:

[200] Responsibility refers to the primary body/agency/organisation best placed to enable the change and carry out the specific action but does not exclude other relevant organisations from carrying out the action.
[201] Priority level 1 is urgent and for action within the next 12 months, 2 is high and to be actioned within next 2 years, 3 is medium and to be actioned within 3-5 years, 4 is low and to be actioned within next 5-10 years.
[202] The change implementation challenges refer to the obstacles or hurdles to the implementing the specific actions to bring about the change.
[203] Given the limited scope of this task, it has not been possible to analyse each action in greater detail.
[204] The UN High Commissioners, Special Rapporteurs, and independent experts have produced reports on lethal autonomous robotics (LARs), the impact of assistive and robotics technology, artificial intelligence and automation on the human rights of older persons, and on ways to bridge the gender digital divide from a human rights perspective. The United Nations Interregional Crime and Justice Research Institute (UNICRI) center on AI and robotics is "committed to advancing understanding of AI, robotics and the broader ecosystem of related technologies, from the perspective of crime, justice and security, and to exploring their use for social good and contributing to a future free of violence and crime." See http://www.unicri.it/topics/ai_robotics/ UNESCO is under a two-year process to "elaborate the first global standard-setting instrument on ethics of artificial intelligence". https://en.unesco.org/artificial-intelligence/ethics (public consultation underway as of time of writing). See also UN General Assembly, "Road map for digital cooperation: implementation of the recommendations of the High-level Panel on Digital Cooperation", Report of the Secretary-General, 29 May 2020. https://undocs.org/A/74/821.
[205] See Council of Europe and Artificial Intelligence. https://www.coe.int/en/web/artificial-intelligence
[206] Rodrigues, Rowena et al., op. cit., 2019.

- Incorporate and/or adopt new interpretative language related to AI and robotics into revised general comments/recommendation for core human rights treaties and other relevant international legal instruments;
- Encourage UN Member States to explicitly expand the mandate of national human rights institutions (NHRIs) to address the impacts of AI and robotics on human rights;
- Adopt a Resolution banning lethal autonomous weapons systems (LAWS); include LAWS in the Convention on Certain Conventional Weapons (CCW); encourage wide adoption of risk mitigation measures;
- Prohibit AI-based racial profiling;
- Provide authoritative guidance and resources to enhance the quality of implementation to the UN Guiding Principles on Business and Human Rights (UNGPs);
- Encourage national governments to require AI patents[207] applicants to affirm applications do not violate core fundamental human rights.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
Clarify and/or articulate human rights frameworks and standards to address challenges and impacts of AI and robotics	Incorporate interpretative language related to AI and robotics into revised general comments/ recommendations for core human rights treaties and other relevant international legal instruments	Treaty Bodies (e.g., CERD; Human Rights Committee; CESCR; CAT; CRC; CMW); CoE	1	There are examples of process underway but getting consensus of strong language remains an issue.
	Adopt new interpretative language (general comments/recommendations) specifically addressing AI and robotics	Treaty Bodies (e.g., CERD; Human Rights Committee; Committee on Economic, Social and Cultural Rights; CAT; CRC; CMW); CoE	1	Getting consensus of strong language.
	Encourage UN Member States to explicitly expand the mandate of	UN OHCHR	1	Getting resources and States cooperation.

[207] This recommendation has been put forward based on stakeholder views and considering how intellectual property is often used to prevent or restrict access to information in the technological context. For AI in particular, this frustrates transparency and accountability which have been identified as key requirements for trustworthiness and societal acceptability. SIENNA looked at intellectual property issues of AI and robotics in D4.2 and studied in detail intellectual property issues related to works created by AI.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
	NHRIs to address the impacts of AI and robotics on human rights			
	Adopt a Resolution on the impacts of AI and Robotics on human rights	UN Human Rights Council	3	No global consensus.
	Adopt a new human rights treaty for AI and robotics	UNGA CoE	4	No global consensus Long process Concerns about adding to already complicated human rights landscape.
	Amend language of, or adopt Protocols to core human rights treaties to expressly address AI and robotics	UNGA CoE	4	No global consensus Long process Concerns about adding to already complicated human rights landscape.
Restrict the international proliferation of harmful AI and robotics applications; set clear rules on what is not permissible	Adopt a Resolution banning lethal autonomous weapons	UNGA; CoE	1	No global consensus (but maybe more likely if limited to specific issue) Long process Would likely be least common denominator.
	Include lethal autonomous weapons systems (LAWS) in the Convention on Certain Conventional Weapons (CCW). Encourage wide adoption of risk mitigation measures.	UN CCW Group of Experts	1	Difficult to get global consensus and will to adopt.
Clarify and/or expand scope of key concepts to cover new	Expand the interpretation of 'torture' in line with new challenges and capabilities arising in	UN Committee Against Torture (CAT)	2	Resistance to expanding the traditional interpretation.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
technological challenges	relation to emerging technologies including AI and robotics			
	Clarify whether (and how) human rights apply to robotics (which may require a new definition of 'human')	UN OHCHR, HRC	3	Difficult to get global consensus.
	Further clarify, consider and develop the normative and operational framework on emerging technologies in LAWS	UN CCW Group of Experts	3	Difficult to get global consensus.
Support the adoption and use of ethical standards	Adopt standard-setting framework on the ethics of AI and/or robotics	UNESCO	3	No global consensus Long process 'Ethics' are not a legal framework so less useful Risk of competing priorities.
Address discrimination	Prohibit AI-based racial profiling	UNGA CoE	1	No global consensus (but maybe more likely if limited to specific issue) Long process Would likely be least common denominator
More directly connect innovation with fundamental human rights	Encourage national governments to require AI patents applicants to affirm applications do not violate core fundamental human rights	WIPO	1	Likely lack of will power; Getting resources and cooperation from States in face of likely extreme push-back from industry Unclear how would apply to open source.
Boost international coordination and implement supportive measures	Provide authoritative guidance and resources to enhance the quality of implementation to the UNGPs	UN OHCHR (B-Tech Project)	1	Getting consensus of strong language.
	Create a Special Representative (SR) for AI and Robotics, or	UN Secretary-General	2	Getting the right resources and access.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
	explicitly incorporate issues related to AI and robotics into the mandate of the SR on human rights and transnational corporations and other business enterprises			
	Create new Special Procedure (Working Group or Special Rapporteur) for AI and robotics	UN OHCHR; CoE PACE	2	Getting the right resources and access.
	Review the impact of AI and robotics on labour and adopt necessary policy/convention/ Recommendation	ILO	2	Getting resources and consensus
Create new and/or promote existing mechanisms for actionable enforcement	Require Member States to report on the impacts of AI and robotics and invite comments from CSOs during Universal Periodic Review (UPR)	UN Human Rights Council	1	Getting resources and States' meaningful cooperation.
	Request existing Special Procedures to investigate and report on impacts of AI and robotics related to their mandates; invite individual complaints and issue opinions on violations of human rights related to AI and robotics	UN OHCHR	1	Getting resources and States' meaningful cooperation.
	Accept complaints (under existing complaints mechanisms) related to AI and robotics	UN Human Rights Council	2	Need clear guidance on treaty language before HRC can analyse complaints.

Table 9: International-level potential changes, actions, and challenges for AI and robotics

While we do indicate one specific action to "Adopt a new human rights treaty for AI and robotics", this we see as low priority and being fraught with difficulties – the key takeaway is that we do not need a NEW international-level human rights framework specially dedicated to AI and robotics. However, we

do need to clarify how the existing human rights framework applies to AI/robotics. This may require creating new specific rules, but that shouldn't be confused with the need to totally re-invent the wheel. Some stakeholders are not convinced there are changes needed directly in human rights instruments, and see more of a benefit in changes to related laws that protect certain values underlying human rights (e.g., in product liability and data protection).[208]

The identified challenges identified at this level could be overcome in various ways. Changes should be made only where and to the extent necessary after well-considered gaps analysis or impact assessments of the human rights frameworks. Developed guidance issued should be clear, coherent and comprehensive. Global consensus could be supported via greater public dialogue, reduction in finger-pointing, targeted diplomacy efforts, and inclusiveness. Political buy-in could be gained through advocacy, dissemination of results, sharing of information and case studies. Resistance to expanding traditional interpretations of concepts could be overcome via education and awareness efforts. Alongside allocating big budgets to technology development, the need of the hour is to also push the policy and legislative agenda forward on research into ethical and human-rights respectful technology, and the adoption of tools to consider the ethical and human rights issues early-on in the design and development process.

5.3. EU-level changes

Generally, existing EU legal frameworks (human rights, data protection, product liability and safety) are fully applicable (in principle)[209] and should be able to cope with the challenges posed by AI and robotics and other emerging technologies. However, various gaps have been identified for addressing based on our research[210] and work in policy[211] and academia.

As of July 2020, there are many actions being taken at the EU-level that are relevant to consider.[212] For example, the European Commission published a *White Paper on Artificial Intelligence (AI)* on 19 February 2020[213] and an accompanying Report on the safety and liability framework.[214] This was open

[208] Feedback from industry expert.
[209] European Commission, White paper On Artificial Intelligence - A European approach to excellence and trust, COM(2020) 65, February 2020.
[210] Rodrigues, Rowena et al., op. cit., 2019.
[211] See e.g., European Commission EASME, DG GROW, *Artificial intelligence – critical industrial applications, Report on current policy measures and policy opportunities,* April 2020. https://op.europa.eu/en/publication-detail/-/publication/fe5a340a-93fb-11ea-aac4-01aa75ed71a1/language-en; High-Level Expert Group on Artificial Intelligence (AI HLEG), *Policy and investment recommendations for trustworthy Artificial Intelligence,* 2019. https://ec.europa.eu/digital-single-market/en/news/policy-and-investment-recommendations-trustworthy-artificial-intelligence
[212] Previous work has been identified and as relevant analysed in SIENNA D4.2.
[213] European Commission, White paper On Artificial Intelligence - A European approach to excellence and trust, COM(2020) 65, February 2020. SIENNA has considered this draft in the preparation of this report along with the HLEG Policy recommendations and responded to the public consultation on this. See https://www.sienna-project.eu/digitalAssets/885/c_885056-l_1-k_sienna_white-paper-consultation_13.06.2020.pdf.
[214] European Commission, Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics, COM(2020) 64, February 2020.

for public consultation till 14 June 2020.[215] In the European Parliament, the Legal Affairs (JURI) committee discussed in May 2020 three draft reports on artificial intelligence: the draft report on AI civil liability,[216] the draft report on AI ethical framework,[217] and the draft report on intellectual property rights for the development of artificial intelligence technologies.[218] Other reports related to AI are also in progress, e.g., a report from the Committee on Civil Liberties, Justice and Home Affairs (LIBE) on Artificial intelligence in criminal law[219] and a report from the Committee on Culture and Education (CULT) on the use of AI in education, culture and the audiovisual sector.[220] In December 2020, the EU Fundamental Rights Agency (FRA) will deliver its report on 'AI and big data – fundamental rights in the digital age'.[221]

The table below presents some of the key changes necessary and/or desired along with the specific actions required, responsibilities, indicative priority levels and change implementation challenges. These changes were identified based on the legal analysis carried out in Task 4.2 of SIENNA and a supportive, limited literature review (of policy documentation at the EU-level from the European Parliament, FRA, European Commission, AI HLEG, SIENNA and SHERPA projects). The priority levels awarded reflect the views of the SIENNA researchers' based on their research at time of writing (June-July 2020).

The identified urgent priority actions at the EU-level include the following: create a specific regulatory framework for AI and robotics products and service, measure/review adequacy of complaints redressal in companies deploying AI/robotics systems in the EU, explicit commitments and actions to reduce technological surveillance of individuals, prohibit AI-enabled large-scale scoring of individuals, AI-based racial profiling by default and where used, enforce strict controls. These priorities are already in some measure being considered at the EU-level. But much more remains to be done.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
Ensure consistency and a harmonised approach across the Union and	Create a specific regulatory framework for AI and robotics products and services	European Commission	1	Proposed framework is not aligned with EU societal values and existing legislation.

[215] The SIENNA response to the consultation is documented at: https://www.sienna-project.eu/digitalAssets/885/c_885056-l_1-k_sienna_white-paper-consultation_13.06.2020.pdf
[216] European Parliament, draft report on AI civil liability (rapporteur Axel Voss, EPP, Germany), 2020/2014(INL),
[217] European Parliament, draft report on AI ethical framework (rapporteur Ibán García del Blanco, S&D, Spain) 2020/2012(INL). SIENNA and SHERPA jointly provided feedback to the Rapporteurs of this report on 22 May 2020, Rodrigues, Rowena, Nicole Santiago, Anaïs Rességuier, Bernd Stahl, Konrad Siemaszko, Stéphanie Laulhé Shaelou, op. Cit., 2020.
[218] European Parliament, draft report on intellectual property rights for the development of artificial intelligence technologies (rapporteur Stéphane Séjourné, Renew, France), 2020/2015(INI).
[219] (2020/20165 (INI))
[220] (2020/2017(INI)).
[221] https://fra.europa.eu/en/news-and-events/fra-calendar-2020

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
establish common governance standards to address AI and robotics risks				Not flexible to technical progress and becomes redundant during its development itself. Failure to get agreement on the regulatory framework.
	Create/designate a European Agency for Artificial Intelligence	European Commission	2	Political will. Overlap of/conflict of remit and relationship with sectoral regulators.
	Set up framework for cooperation of national competent authorities via network of national authorities, as well as sectorial networks and regulatory authorities, at national and EU level.	European Commission	2	Political will. Appropriate modelling of the framework. Engaging stakeholders.
Increase reliability, security of AI and robotics products and services and make them respectful of European values and rules	Encourage the use of ethical impact assessment, 'ethics by design' and human rights impact assessments (HRIAs) and include provisions for them in the new regulatory framework for AI and/or emerging technologies. Reference it via amendments to existing legislation or in guidance documents as part of standard practice.	European Commission	3	Buy-in to the methodologies Advancement of the ethics by design methodology and its testing. Commitment to HRIAs.
	Use regulatory sandboxes to test the safe and effective use of AI and robotics technologies in real-world environment	All EU institutions	2	Proper design of the sandbox parameters. Embedding transparency in the design, operation and outcomes.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
	Set up a sector-specific conformity assessment/ certification schemes for high-medium risk products and services	European Commission	3	Determining the 'precise' scope of the conformity assessment.
	Establish criteria and conditions for conformity assessment/certification	European Commission	3	Getting agreement on and setting the criteria parameters and conditions based on EU standards
Clarification of key concepts	Set out/clearly and consistently define in legislation the scope of '*high-risk'* AI in existing or new legislation or via a Resolution or Opinion.	European Commission, European Parliament and the Council	2	Different institutional positions and sectoral challenges in defining this concept; changes and fluidity of AI and robotics system or application uses and unintended consequences.
	Provide interpretative and evolving guidance on risky AI and robotics applications	European Data Protection Board	2	Fluidity and agreement on what is 'risky'.
	Further clarify the definition of 'product' in the Product Liability Directive to address the complexity of emerging technologies	EC, Expert Group on Liability and New Technologies – New Technologies Formation	2	Whether seen as able to widely impact EU product liability law across Europe.
Enhanced protection of vulnerable populations, especially the poor and children	Expand the list of vulnerable groups to include children, elderly, people with disabilities, disfavoured or 'excluded' people, minorities, inhabitants of poor countries, and social welfare recipients.	European Commission	2	Resistance to mainstreaming the vulnerability discussion. Pressures (implicit or institutional) to disregard vulnerabilities. Competing priorities to push/deploy use of AI and robotics within these groups.
	Amend the European Pillar of Social Rights (EPSR) in one or more of the following ways: (a) Include a new principle on protection of the poor and redress from technological harms, (b)	European Commission	3	Getting buy-in for the amendment and the new principle from social partners, including civil society organisations. As stated in a CoE study, "social rights have been

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
	update its general content to reflect concerns related to AI and robotics			hitherto virtually ignored".[222] There is a lack of enforceability of principles in absence of implementing measures.
Effective enforcement of existing laws	Mandate proper record keeping, information provision and auditing	European Commission	2	Resistance to systems tracking and verification.
	Add basis/develop further redress by design mechanisms	European Commission	3	Lack of good implementation models for such mechanisms, transparency and resistance.
	Assess/facilitate reporting on Member States implementation of EU AI and robotics regulatory framework/policies	European Parliament	4	Lack of data sharing and information provision from Member States
Access to justice and remedies for adverse human rights impacts	Measure/Review adequacy of complaints redressal in companies deploying AI/robotics systems in the EU	European Commission	1	Transparent reporting and information availability.
Prevention of regulatory capture	Investigate which regulations have and are likely to be vulnerable to regulatory capture, the connected institutional cultural factors, and what factors in the regulatory process enhance the influence of special interests.	European Parliament	3	Resistance from industry actors.
Reduction of mass and disproportionate surveillance of individuals	Explicit commitments and actions to reduce technological surveillance of individuals, e.g., ban/prohibit/pause biometric recognition technologies	European Parliament, European Commission	1	Conflict of interest with the drive to fund and adopt technologies that facilitate large-scale monitoring. Embedding of technologies in governance and politics.

[222] De Schutter, Olivier, "Study on the European Pillar of Social Rights and the role of the European Social Charter in the European Union legal order", Strasbourg, 2018, https://rm.coe.int/study-on-the-european-pillar-of-social-rights-and-the-role-of-the-esc-/1680903132

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
	facilitating mass surveillance, boost and/or create additional oversight mechanisms[223]			
Reduction of abuse in dominant market positions	Disempower such positions through fines or mandating that some activities must be blocked or paused as illegal and/or unlawful	European Commission	3	Challenges with ill-advised investigations and prosecutions on markets actors. Selecting appropriate targets for enforcement action.
Guarantee compensation for damage[224] caused by robots	Set up a general compensation fund to guarantee compensation if damage caused by a robot is not covered by insurance	European Commission	3	Underpinning by suitable legislation (e.g., Convention/Treaty/ Regulation/Directive on compensation). Maintaining clear coherence in the definition of compensation award and the scheme elements.
Fill product safety gaps	Address gaps in current product safety legislation i.e., General Product Safety Directive, Machinery Directive, the Radio- Equipment Directive and the New Legislative Framework.	European Commission	2	Ability to flexibility explicate the gaps without making legislation redundant for the future. Complexity of products, services and the value-chain.
	Reinforce requirements for manufacturers on instructions and warnings for users of AI and robotics products	European Commission	2	Applicability to diverse contexts. Warning formats and whether they have potential to cause more confusion.
	Require algorithm developers to disclose the design parameters and metadata of datasets where accidents occur	European Commission	2	Security, intellectual property and confidentiality conflicts.

[223] Oversight was repeatedly highlighted by the webinar participants as critical.
[224] The precise scope of this needs to be determined. This could refer to harms to property and/or persons but this needs to be researched further based on technological developments.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
	Additional obligations for manufacturers to ensure that they provide features to prevent upload of software that affects safety during the lifetime of the AI/robotics products.	European Parliament, Commission and the Council	2	Resistance to embed such obligations. In some cases, their lack of feasibility.
	Provide/Facilitate compensation for damage caused by products that are defective because of software or other digital features	European Parliament, Commission and the Council	2	Presence or creation of a general fund where such compensation is not available.
	Central EU registry of bad/defective (products that have harmed natural persons or property) algorithms/AI or robotics products and cases	European Commission	3	A legal basis will be required to identify/establish an overseeing European agency to maintain the register.
Address discrimination gaps	Prohibit AI-enabled large-scale scoring of individuals, AI-based racial profiling by default and where used, enforce strict controls	European Parliament, Commission and the Council	1	Political and industry resistance.
	Provide further clarification on when a certain practice breaches the prohibition of indirect discrimination[225].	Fundamental Rights Agency	2	Lack of case studies.
	Expand the scope of 'protected	European Parliament,	3	Disputed views of 'protected' characteristics and lack of agreement and/or consensus.

[225] The elements of indirect discrimination, according to the FRA Handbook are: a neutral rule, criterion or practice that affects a group defined by a 'protected ground' in a significantly more negative way by comparison to others in a similar situation. European Union Agency for Fundamental Rights, Council of Europe, *Handbook on European non-discrimination law*, 2010, p.29. https://fra.europa.eu/sites/default/files/fra_uploads/1510-fra-case-law-handbook_en.pdf. As pointed out by Borgesius, "indirect discrimination can remain hidden to both the organisation and the victim". Its "enforcement is difficult, however, and non-discrimination law has weaknesses". Borgesius, Zuiderveen, J. Frederik, "Strengthening legal protection against discrimination by algorithms and artificial intelligence," *The International Journal of Human Rights*, 2020, pp. 1-22. Therefore this clarification becomes vital.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
	characteristics'[226] to cover discrimination on other basis e.g., financial status.	Commission and the Council		

Table 10: EU-level potential changes, actions, and challenges for AI and robotics

In addition to the above, there is one issue that needs to be further highlighted – we recommend at the present time, that there is no EU-level pursuit of the creation of a specific legal status for autonomous systems (or electronic personhood). There are good reasons for this. As argued by Bryson, Diamantis and Grant,[227] "difficulties in holding "electronic persons" accountable[228] when they violate the rights of others outweigh the highly precarious moral interests that AI legal personhood might protect".[229] Pagallo, in the context of AI robots, also suggests to "i) in the mid term, skip any hypothesis of granting AI robots full legal personhood; (ii) take seriously into account the possibility of new forms of accountability and liability for the activities of AI robots in contracts and business law, e.g., new forms of legal agenthood in cases of complex distributed responsibility; and, (iii) test such new forms of accountability and liability through methods of legal experimentation." [230] Further, the issue of legal personhood is a national competence, politically and socially divisive, convoluted and has serious potential to cause conflict with fundamental rights and freedoms and the reduction of human responsibility for harms caused by AI and robots.

The key take-away is the urgency to ensure consistency and a harmonised approach across the European Union and establish common governance standards to address AI and robotics risks. Yet at the same time, we should recognise that flexibility and sector[231] and/or use specificity regulation are critical (along with national policy peculiarities) to consider given the nature of and development in AI and robotics along with the emergence of other new technologies. While the EU is significantly poised to become a regulatory lighthouse for AI and robotics, we underline the concern that was also raised in the SIENNA citizen panels (specially Germany) and by the webinar participants – i.e., the European

[226] See ibid, p 160.: Under the EU non-discrimination directives, the protected grounds are expressly fixed to: sex, racial or ethnic origin, age, disability, religion or belief and sexual orientation. Under the ECHR there is an open-ended list which may be developed on a case-by- case basis.
https://www.echr.coe.int/Documents/Handbook_non_discri_law_ENG.pdf

[227] Bryson, Joanna J., Mihailis E. Diamantis, & Thomas D. Grant, "Of, for, and by the people: the legal lacuna of synthetic persons", *Artificial Intelligence and Law, vol.* 25, 2017, pp. 273–291.

[228] Ibid. Bryson, Diamantis and Grant highlight how such legal personality could be abused as a shield from the consequences conduct by unscrupulous actors who hide behind such entities, which might be further aggravated if veil-piercing is frustrated. Also giving legal personality without consequent legal obligations would cause legal recourse issues.

[229] Bryson, Joanna J., Mihailis E. Diamantis, & Thomas D. Grant, "Of, for, and by the people: the legal lacuna of synthetic persons", *Artificial Intelligence and Law, vol.* 25, 2017, pp. 273–291.

[230] Pagallo, Ugo, "Vital, Sophia, and Co. - The Quest for the Legal Personhood of Robots." *Information* 9, 2018, p. 230.

[231] As pointed out by one participant of the AI and robotics SIENNA webinar (17 June 2020), sector-specific applications means it is difficult to create horizontal framework.

Union regulation of these technologies could potentially slow technological progress and ultimately lead to Europe being less competitive, particularly if the rest of the world continues to rapidly develop these technologies without similar regulation.[232] Given its implications, this needs further deliberation.

The challenges to creating and/or implementing actions at the EU-level are many, depending on the measure, the actor responsible and the timing of the action. What might help address these challenges is closer dialogues between the EU institutions (to align policy and positions as feasible to avoid message confusion), greater transparency in the regulation development and consultation process (to avoid regulatory capture), inclusive stakeholder dialogues and involvement in consultation (not perfunctory), increased parallel funding of research into addressing legal issues, getting regulators to talk to each other, and knowing and understanding when to not regulate (this also helps avoid regulatory capture).[233]

5.4. National level changes

At the national level, there is a great deal of interest in AI and robotics (evident in the development of national AI strategies[234]). But as our SIENNA research revealed, there are no major or significant amendments in legislation bearing on constitutional or human rights in direct response to AI and robotics developments reported in the countries we researched.[235] Existing laws and regulations which address such issues directly or indirectly may fail to take into account the creative uses and impacts of AI and robotics on individuals and society, and may thus not be sufficient or adequate (e.g., in accommodating issues of discrimination). Further, some calls for regulatory bodies were evident where the remit of existing bodies falls short.[236]

The table below presents some of the key changes necessary or desired, along with the specific actions required, responsibilities, indicative priority levels and change implementation challenges at the national level (based primarily on legal analysis carried out in Task 4.2 of SIENNA and a supportive, limited literature review covering policy and research documents[237] discussing national level changes to extract the most currently relevant ones). The priority levels awarded reflect the views of the SIENNA researchers' based on their research and at time of writing (June-July 2020).

At the national level, the urgent priority actions include the following: implement special protective measures to protect children, racial and religious minorities, political opposition and activists; prohibit

[232] SIENNA/Kantar Public, "D4.6: Qualitative research exploring public attitudes to AI and robotics", 31 August 2019.
[233] For discussion on regulatory prudence in AI and big data context, see Rodrigues, Rowena, Stephanie Laulhe Shaelou, "Regulatory options for AI and big data", SHERPA D3.3, December 2019, p. 68. https://dmu.figshare.com/articles/D3_3_Report_on_regulatory_options/11618211
[234] See OECD.AI Policy Observatory, *National AI policies & strategies.* https://oecd.ai/dashboards
[235] Brazil, China, France, Germany, Greece, Poland, Spain, Sweden, The Netherlands, South Africa, United Kingdom, the United States.
[236] See Rodrigues, Rowena et al., op. cit., 2019; also Rodrigues, Rowena, Stephanie Laulhe Shaelou, op. cit., December 2019. https://dmu.figshare.com/articles/D3_3_Report_on_regulatory_options/11618211
[237] Including various policy docs at the national, regional and international level and from SIENNA and SHERPA.

the use of automated facial recognition technology in public places and review its use[238]; carry out legal reviews to assess whether potential weapons systems based on emerging technologies in the area of LAWS would be prohibited by any rule of international law applicable to that State in all or some circumstances (CCW GoP) and explicit commitments to reduce technological surveillance of individuals. The identified urgent and high priority actions are already, to some extent, on policy and regulatory agendas, e.g., Automated Facial Recognition Technology (Moratorium and Review) Bill [HL] 2019-21 (Bill in second reading stage in UK Parliament)[239], but need further and wider uptake.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
Improved protection of fundamental rights and societal values	Implement special protective measures to protect children[240], racial and religious minorities, political opposition and activists.[241]	Parliament	1	Conflicts of interests with a 'majority' government priorities.
	Prohibit the use of automated facial recognition technology in public places and review its use	Parliament	1	Industry resistance and pre-existing roll out of technology.
	Set out procedures to carry out human rights impact assessments (HRIAs) for AI and robotics applications	Public authorities, NHRIs	2	Lack of buy-in and resources.
	Develop a national action plan (NAP) to identify existing relevant laws and policies, articulate desired policy goals/outcomes, and	Government	2	Lack of resources, lack of follow-through.

[238] Note that, for example, that, the ACM U.S. Technology Policy Committee (USTPC) has called for an "immediate suspension of the current and future private and governmental use of FR technologies in all circumstances known or reasonably foreseeable to be prejudicial to established human and legal rights" given its findings that "when rigorously evaluated, the technology too often produces results demonstrating clear bias based on ethnic, racial, gender, and other human characteristics recognizable by computer systems". The ACM U.S. Technology Policy Committee (USTPC), "Statement On Principles And Prerequisites For The Development, Evaluation And Use Of Unbiased Facial Recognition Technologies", 30 June 2020. https://www.acm.org/binaries/content/assets/public-policy/ustpc-facial-recognition-tech-statement.pdf

[239] https://services.parliament.uk/bills/2019-21/automatedfacialrecognitiontechnologymoratoriumandreview.html

[240] See https://www.unicef.org/innovation/media/10726/file/Executive%20Summary:%20Memorandum%20on%20Artificial%20Intelligence%20and%20Child%20Rights.pdf

[241] See https://www.accessnow.org/cms/assets/uploads/2018/11/AI-and-Human-Rights.pdf

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
	outline ways to achieve them			
	In-depth regulatory analysis/impact assessment of specific rights, e.g., non-discrimination, freedom of movement	Parliament, NHRIs	2	Lack of commitment to such analysis/impact assessment. Limitations in budget, legal support etc.
Make AI/robotics products and services reliable, secure and respectful of fundamental rights and freedoms	Procurement processes should support the AI and robotics products and services that facilitate high standards and particularly transparency[242]	Government to set requirements; public service procurers	1	Lack of focus and strategy Explicit commitments; lack of resources to monitor compliance.
	Use regulatory sandboxes to test the safe and effective use of AI and robotics technologies in real-world environment	National ICT ministries; digital agencies	3	Proper design of the sandbox parameters.
	Set up national regulator/advisory body to monitor developments/provide guidance/share best practice and **clarify** how existing laws apply to new technologies	Parliament	3	Political will and support, and statutory footing. Lack of funding. Scope of body already covered by existing regulators/overlaps.
	Revise old laws and/or create new liability law to address issues related to AI and robotics and new business models that will be created	Parliament	3	Political will and support. Not based or preceded by a regulatory impact assessment.

[242] As identified in the AI HLEG Guidance on Trustworthy AI, transparency *(including traceability, explainability and communication)* is a critical element. See AI HLEG*, Ethics Guidelines for Trustworthy AI,* 2019. https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai. The importance of 'explainability' in particular was re-iterated as part of the discussion paper feedback and in the webinar, as essential to identify potential problems.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
	Licensing requirements - grant a license for legitimate use and to do their best to prohibit misuse[243]	Intellectual property holders	3	Use by IP holders in licensing agreements.
Restrict the proliferation of harmful AI and robotics applications; set clear rules on what is not permissible	Carry out legal reviews to assess whether potential weapons systems based on emerging technologies in the area of LAWS would be prohibited by any rule of international law applicable to that State in all or some circumstances (CCW GoP)	States party to CCW	1	Resources and political support.
Effective enforcement of existing laws	Review regulatory enforcement measures on a regular basis	Parliament	2	Putting in place a new body/giving existing one the power and mandate to carry out effective review.
	Create effective and accessible complaints and redress mechanisms accessible to stakeholders where not present	Policy-makers, National supervisory bodies, regulators	2	Resources and funding.
	Make explicit in NHRIs mandate that they can investigate, report and have redress mechanism for abuses related to AI and robotics	Parliament	3	Lack of good implementation models for such mechanisms, transparency and resistance.
	Set up a register of algorithms used in government[244]	Government/ regulatory body	3	Requires the identification and establishment of the responsible agency for this, and cooperation of governmental departments.
Reduce mass and disproportionate surveillance of individuals by	Explicit commitments to reduce technological surveillance of individuals	Parliament	1	Conflict of interest with the drive to fund and adopt technologies that facilitate large-scale monitoring.

[243] Proposal from webinar participant. SIENNA AI and Robotics Webinar, 17 June 2020.
[244] For in-depth analysis of this, see Rodrigues, Rowena, Stephanie Laulhe Shaelou, op. cit., December 2019.

Necessary/ desired legal change	Specific action required	Responsibility	Priority level	Implementation challenges
public and private actors				Embedding of technologies in governance and politics.

Table 11: National-level potential changes, actions, and challenges for AI and robotics

One key take-away is to ensure that any changes in legislation are fit for purpose and in accordance with the country's international obligations, especially with regards to human rights and fundamental values. Another is the need for legal clarity and guidance. The national-level is also the point at which much more effective oversight and enforcement of laws is possible and this should be strongly ensured and reviewed continuously (especially to evaluate whether existing mechanisms are working or not and taking into account technological developments and deployments).

The actions required at the national level also come with their own challenges and these could be addressed by: putting specific legal issues of AI and robotics high on the policy agenda (for urgent addressing where not yet in the fore), inclusive and wide stakeholder consultations when assessing legal issues and/or need for regulation (also in particular paying attention to the public's views), not jumping the gun on new regulation but carefully assessing this in light of the country's international obligations and the national interest, using and/or requesting guidance from international or regional bodies on issues of common interest and given the transboundary nature of AI and robotics.

5.5 Conclusions

We need to make improvements and take steps to enhance legal frameworks for AI and robotics to ensure effective and robust protection of human rights[245], fundamental freedoms and ethical values (e.g., access, autonomy, dignity, equality, privacy, safety, security, transparency, trust, responsibility, well-being)[246] in the context of AI and robotics, either by maximising the use of existing legal frameworks and tools and/or developing new ones. Human rights and ethical frameworks and mechanisms should further underpin and inspire the governance of AI and robotics (and other new and emerging technologies). We caution, however, that ethics, must not be seen, promoted or used as the only mechanism to regulate AI and robotics. Further "using ethics to prevent the implementation of legal regulation that is actually necessary is a serious and worrying abuse and misuse of ethics".[247] Although ethics may help identify the new issues and challenges brought about

[245] See UN General Assembly, "Road map for digital cooperation: implementation of the recommendations of the High-level Panel on Digital Cooperation", Report of the Secretary-General, 29 May 2020. https://undocs.org/A/74/821. It calls on "Member States to place human rights at the centre of regulatory frameworks and legislation on the development and use of digital technologies".

[246] Jansen, Philip, Philip Brey et al., *SIENNA D4.4: Ethical Analysis of AI and Robotics Technologies"*, 2019. https://www.sienna-project.eu/digitalAssets/801/c_801912-l_1-k_d4.4_ethical-analysis--ai-and-r--with-acknowledgements.pdf

[247] Rességuier, Anaïs, Rowena Rodrigues, "AI ethics should not remain toothless! A call to bring back the teeth of ethics", *Big Data & Society*, July 2020. https://doi.org/10.1177/2053951720942541

by AI and robotics, and provide guidance on how to navigate them, it is necessary to put in place hard lines to regulate these technologies. Hence, the law must play its critical role.

One common change ambition at all three levels is to **create new and/or promote existing avenues/mechanisms for actionable enforcement of existing laws and effective redress** for human rights impacts. Between the international and EU-levels, common change ambitions include clarifying and/or expanding the scope of key concepts to cover new technological challenges and **addressing discrimination gaps.** Common EU and national level change ambitions include **increasing the reliability and security** of AI and robotics products and services; making them **respectful of EU values** (applicable to Member States), **fundamental rights and freedoms** and **reducing mass and disproportionate surveillance** of individuals designed into or perpetuated by AI and robotics.

The challenges at each level are many; they need to be addressed, but they are not insurmountable with the right efforts. Particularly, we need to carefully consider when to regulate (as regulation not keeping pace with technological development is a well-recognised concern that was echoed in the SIENNA panels), what to regulate (design, development[248], deployment, specific applications and/or uses), and the tussle between the need to ensure good and appropriate regulation while not making hasty[249] and ineffective legislation. There needs to be more focus on the application of the technologies than on the technologies themselves.[250]

Other tensions must also be considered and duly engaged with. Particularly relevant are the tensions between individual rights and collective rights (e.g., collective right to health), which have once again come to the foreground with the technological and policy responses to the COVID-19 pandemic. Power conflicts are another major point of tension – who regulates technology and their motivations for such regulation also come into play (whether regulation is for the benefit of the developers and deployers or for the benefit of the adversely impacted and/or for all society)[251]. There is also the tension caused by the re-purposing of AI and robotics technologies (use for purpose which was not its intended original use[252]) where such actions might fit (albeit uncomfortably within what is technically lawful) but would conflict with EU values and cross ethical boundaries. There is also the complexity associated with regulating and/or overseeing surveillance, as pointed out by one of the webinar participants, "this is on par with the complexity of the technology itself. It's not something that can be solved by a simple formula. It requires layers of work".[253]

[248] In the SIENNA citizen panels, regulation was widely seen as being necessary, not only once the technologies are introduced into society, but in the development stages as well. See SIENNA/Kantar Public, "D4.6: Qualitative research exploring public attitudes to AI and robotics", 31 August 2019.
[249] Also re-iterated by one expert via email.
[250] David W. Wood in SIENNA AI and robotics webinar, 17 June 2020.
[251] This concern came out in the SIENNA citizen panels. See. SIENNA/Kantar Public, "D4.6: Qualitative research exploring public attitudes to AI and robotics", 31 August 2019.
[252] E.g., thermal imaging access control tech used in border security being deployed in office buildings, shops, educational establishments.
[253] SIENNA AI and robotics webinar, 17 June 2020.

We must also consider that legal changes (and the specific recommended actions) by themselves might not be enough and/or sufficient. But at the same time, the significance of the proposed measures and actions seriously comes into its own given the inadequacy and/or failure of other mechanisms, e.g., industry self-regulation[254], ethics-washing[255], deployment of technologies with no or inadequate impact assessments and/or public consultations, failure of public campaigns and protest mechanisms to stop the deployment of problematic and human rights-infringing technologies. As identified in the webinar, a layered approach is important - using existing legislation and diverse regulatory mechanisms, and/or creating new ones where required and where existing ones are determined to fall short while further considering the specific sectors and uses of AI and robotics. Due consideration must be paid to how the law can require and/or incentivise the right technical, standardisation and ethical measures too.

Our range of recommended actions, if taken-up, will help create an environment for ethical and human-rights respectful AI and robotics. SIENNA will share these recommendations with policy-makers and regulators at the international, EU and national levels to promote their awareness and bring change where possible and as needed.

6. Conclusions

Putting together recommendations for all three technological areas studied here allows for the formulation of some more generic observations, along with separate conclusions for each of the fields presented in the chapters 3, 4 and 5.

At the highest level, it cannot be reiterated enough that there is no silver bullet type of a regulatory action to enhance the legal frameworks for the new technologies. Making their governance more compliant with human rights and ethical values is a multi-layered and continuous task that requires simultaneous actions on different levels, with diverse tools and involvement of a wide range of actors. Some of the recommendations presented in this report contained direct references to ethical elements (e.g., emphasising the need to further ethics as an integral part of health technology assessment or encouraging the use of 'ethics by design' for AI and robotics), others took on board ethical issues in possible broader social and economic policies (such as addressing the abuse in dominant market positions in the AI field or ensuring that benefits from advances in human genetics and genomics are

[254] Council of Europe Expert Committee on human rights dimensions of automated data processing and different forms of artificial intelligence (MSI-AUT), *A study of the implications of advanced digital technologies (including AI systems) for the concept of responsibility within a human rights framework*, 2019, p. 76. https://rm.coe.int/responsability-and-ai-en/168097d9c5

[255] Wagner, Ben, "Ethics as an escape from regulation: From ethics-washing to ethics-shopping" in Emre Bayamliogl, Irina Baraliuc, Liisa Albertha, Wilhelmina Janssens, Mireille Hildebrandt (eds.), *Being profiling. Cogitas ergo sum*, 2018, pp. 1-7.

made available to all); most of the recommendations, however, focus on upholding certain ethical principles without explicitly using 'ethics' language.

Many of recommendations marked in this report as having the highest priority for implementation rely on existing frameworks. There are many robust instruments relevant for the studied technological domains already in place at the international, EU and national levels – and it is important not to reinvent the regulatory wheel.[256] It might be useful to look at this set of recommendations using the concept of three types of regulatory dimensions: norms (setting standards), monitoring (gathering information) and mechanisms for responding to deviations from the standards.[257] With regard to norms, a repeated recommendation was to provide interpretive guidance specifically addressing the challenges related to the examined technologies through general comments, recommendations, reports, guidelines etc. (for international human rights treaties, but also for relevant EU secondary law, e.g., GDPR, Medical Devices Regulation, Clinical Trials Regulation or In Vitro Diagnostic Medical Devices Regulation). As for monitoring, some of the most urgent recommendations included paying more attention to the impacts of the technologies in question in the existing general monitoring measures (e.g., through UN Special Procedures, UPR, treaty monitoring measures, NHRIs). High-priority recommendations that rely on existing mechanisms for responding to deviations from the standards referred to improved enforcement of existing laws and guaranteeing effective redress. Beside, urgent recommendations relating to the measures already in place included promoting the uptake of the existing instruments (for example a number of EU member states still have not signed or ratified the Oviedo Convention) and reviewing the sufficiency of frameworks vis-à-vis the new challenges and/or with a goal of reducing fragmentation of legislation.

We have, however, also identified challenges with a high priority in case of which relying primarily on the existing frameworks (even in a creative way) may not be the optimal way forward. This involves cases where the need to have a comprehensive framework requires expanding the scope of application of norms beyond what may be consistently interpreted from the current regulation (for instance a specific regulatory framework for AI and robotics products and services) and/or where particular risks call for more decisive responses, by drawing red lines (e.g., prohibition of AI-based racial profiling or prohibition on the use of automated facial recognition technology in public places) or in a form of stronger protection measures (e.g., for vulnerable groups such as children or minorities).

The above presentation of interpretative measures and selective legislative interventions should not be though understood as turning away from considering new instruments, institutions or procedures – for example setting out procedures to carry out HRIAs for AI and robotics applications or considering the needs for new legal categories (e.g., brain data) or rights (such as mental privacy or right to

[256] On reinventing regulatory wheel, see: Brownsword, Roger, "So What Does the World Need Now? Reflections on Regulating Technologies" in Brownsword Roger and Karen Yeung (eds.), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes,* Bloomsbury Academic, Oxford, 2008, pp.25-27.

[257] These three regulatory dimensions (elements) were presented in Murray, Andrew and Colin Scott, "Controlling the New Media: Hybrid Responses to New Forms of Power", *Modern Law Review,* vol. 65, no. 4, 2002, pp. 491–516 and elaborated in Brownsword, Roger, "Code, Control, and Choice: Why East is East and West is West", *Legal Studies,* vol. 25, no. 1, 2006, pp. 1 - 21.

gen(omic) data) – especially looking beyond the most urgent regulatory actions. Although caution with creating new bodies is advised, such measures do help to institutionalise oversight of regulatory frameworks and to coordinate fragmented efforts between different stakeholders – and hence we recommend among others creating or designating a European Agency for AI and national authorities responsible for human genetics and genomics.

The **key take-always** for each of the field may be summarised as follows.

For **human genetics and genomics,**

- At the **international level**, the key take-away is that a human genetics and genomics treaty is necessary to overcome the existing challenges and fulfil responsibilities towards future generations. Although SIENNA acknowledges the difficulty in agreeing on several important principles relating to the HGGT, the state of the art of the technologies on the one hand and the need for further developments, on the other hand, require it to be addressed as an urgent priority of the UN. Additionally, there is a need to continue clarifying how the existing human rights norms respond to the specific questions in the area of genetics of genomics, including new and emerging technologies in the field and their applications.
- At the **EU level**, key take-away is the need to remove hurdles associated with regulatory fragmentation and approach to the governance of human genetic and genomic technologies. As a longer-term objective, SIENNA has identified and shed light into the avenues to ensure better potential to exploit the area of human genetics and genomics to further the EU objectives, in particular those relating to research and technological development, including if the European Health Union is advanced.
- At the **national level**, key take-away is the urgent need to revisit comprehensiveness, oversight, and enforcement strategies of the national legal frameworks and their capability to adequately respond to the scientific advances in the area of human genetics and genomics.

For **human enhancement technologies,**

- The key take-away at the **international level** is that there is a need for more interpretative guidance on how international law relates to HE challenges. Considering the diversity of HET and the low level of institutionalisation of the field, a regulatory approach that seeks to address all the relevant issues in one legal instrument might not the best way to start. A more incremental building of understanding and consensus with a number of legal instruments may be more helpful at this stage.
- At the **EU level**, the key take-away is that the EU should take up a more leading role in data protection in the HE context, especially with regard to the challenges associated with the brain data. Moreover, product safety legislation in the HE context may require further scrutiny (following some positive steps already taken in this area).
- The key take-away at the **national level** is that national legislator should review and monitor how their respective legislation responds to the HE challenges and ensure that these responses are in line with the general human rights protection commitments.

For **AI and robotics**,

- At the **international-level,** the key take-away is the need to *clarify how the existing human rights framework applies to AI/robotics* (e.g., via creating new specific rules). While adoption of a new human rights treaty for AI and robotics is a low priority fraught with difficulties, changes to existing relevant laws that protect certain values underlying human rights may be desirable and more feasible.
- At the **EU-level,** the key take-away is the *urgency to ensure consistency and a harmonised approach across the European Union* and *establish common governance standards* to address AI and robotics ethical and human rights-related risks while recognising that *flexibility and sector and/or use specificity regulation are critical***.** It is also *not opportune to pursue, at this time, the creation of a specific legal status for autonomous systems*
- At the **national-level,** the key take-away is to ensure that any *changes in legislation are fit for purpose and in accordance with the country's international obligations, especially with regards to human rights and fundamental values*. There is also need for *legal clarity and guidance*.

It is also important to remember that the three technological areas studied within the SIENNA project, despite all their differences, have overlapping issues and concerns. These technological fields are also significantly converging.[258] Therefore certain regulatory actions may be helpful for more than one of the fields. For example, the ongoing review of the EU product safety and liability framework, conducted primarily in the context of AI challenges, may bring results that will be also relevant (directly or indirectly) for some of human enhancement technologies (e.g., ICT implants, wearables, brain-computer interface systems), among others with regard to aspects related to cybersecurity, connectedness or mental safety issues. Similarly, the recommendation to address non-medical applications of HGGT through reshaping existing frameworks in the EU could be also important for the genetic enhancement, while the proposed HRIAs for AI and robotics, when conducted for applications that intersect with the two other discussed fields, should be also aware of human rights impact specific for them.

The results of this report will be shared with relevant policy makers and regulators at the international, EU and national levels within the WP6 activities of the SIENNA project. We hope that our recommendations will help in discussions on enhancing the legal frameworks for human genetic and genomics, human enhancement technologies and AI and robotics.

[258] E.g., Dias, Raquel, Ali Torkamani, "Artificial intelligence in clinical and genomic diagnostics", *Genome Medicine*, vol. 11, no. 70 , 2019.

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