D1.1: The consortium's methodological handbook

[WP1 – Theoretical and methodological fundamentals]

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Abstract

This Handbook brings together and describes the SIENNA project's theoretical and methodological approaches for ethical, legal and human rights analyses, societal acceptance and awareness studies, development of research ethics protocols and professional ethical codes. This Handbook is a reference source for work packages 2 (genomics), 3 (human enhancement) 4 (AI and robotics), and 5 (the consortium's proposals), and it will help to ensure theoretical coherence and methodological consistency. The Handbook also offers references to guidance (where to go) about other project matters, such as research ethics and data management, internal communication tools and protocols, event organisation, quality assurance, citations and formatting, dissemination and communications approach, exploitation, and project sustainability.

Document history

Version	Date	Description	Reason for change	Distribution
V0.1	24 Oct 2017	First draft		Authors
V0.2	28 March 2018	Second integrated draft	Integration of approaches	Authors, consortium, stakeholder advisory Board
V0.3	10 April 2018	Third draft	Revisions to approaches based on feedback from April 2018 Uppsala workshop	Consortium and reviewers
V0.4	30 April 2018	Fourth draft (EC submission)	Finalisation post-review	Consortium and European Commission
V0.5	October 2019	Fifth draft	Minor revisions and updates, specifically to s.5.	Consortium
V0.6	November 2020	Sixth draft	Minor revisions and updates, specially Section 7 and conclusion	Consortium

Information in this report that may influence other SIENNA tasks

Linked tasks/WPs	Points of relevance
Task 1.1	This document presents the approach developed in T1.1
Task 1.2	This document presents the approach developed in T1.2
Task 1.3	This document presents the approach developed in T1.3
Task 1.4	This document presents the approach developed for T1.4
Task 1.5	This document presents the approach developed in T1.5
Task 1.6	This document presents the result of T1.6
WPs 2, 3 and 4	This document outlines the theoretical and methodological fundamentals for the tasks in WPs 2, 3 and 4 (Tasks .2-.6)
WP5	The approach outlined here will feed into WP5.

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Executive summary

This Handbook has two parts.

Part I of the Handbook covers sections 1-7.

Section 1 and 2 introduce the Handbook and project, respectively.

Section 3 outlines the **approach for ethical analysis**. This section outlines the SIENNA approach to ethical analysis of human enhancement, human genomics and AI and robotics. SIENNA advocates a single shared approach to the ethical analysis of the three technological areas or fields (i.e., genomics, human enhancement and AI and robotics). The section reviews and assesses current approaches for the ethical analysis of emerging fields and technologies, then presents the SIENNA approach (i.e., a detailed and reasoned six-step approach for ethical analysis). This approach rests to a significant extent on the ability to do foresight analysis. Therefore, the approach includes a detailed statement on our approach to foresight. Finally, the section presents information on the role of stakeholder and public engagement in the project's ethical analysis. This approach will be further applied and tested in subsequent work packages in the SIENNA project, particularly WPs 2, 3 and 4 (tasks 2.4., 2.7, 3.4, 3.7, 4.4 and 4.7) and WP5. In WP6, we hope to further refine and generalise the approach so as to be useful for future ethical analysis of any newly emerging fields and technologies.

Section 4 outlines the **approach for the legal including human rights study (Task 1.2)**, which will aid in carrying out coherent legal research on the three technological fields in Work Packages (WPs) 2, 3 and 4. The results of the legal research will help develop ethical frameworks that take into account existing legal frameworks (SIENNA's objective 1). Together with the outcomes of the ethical and socio-economic analysis, the results of the legal research will inform proposals for revisions of existing legal frameworks (task 5.6). After conducting legal research in WPs 2, 3 and 4, the approach will be evaluated to refine it and arrive at more general methods for legal analysis of emerging technologies (task 6.2), with an overarching goal of developing ethical codes and operational guidelines anchored in human rights standards.

Section 5 outlines the **approach for the study of societal acceptance and awareness (Task 1.3)**. A key feature of SIENNA is that stakeholders, including the general public, will be engaged throughout the process. The involvement of the general public is particularly important; research and innovation into new and emerging technologies carries an ongoing risk of being in tension with public concerns. It is therefore crucial to understand and consider such concerns. One method of exploring the general publics' views of the SIENNA project is through empirical research. The approach described in this section covers an international public opinion survey[1] and five one-day citizen panels[2], with both elements providing data to better understand citizens' awareness, views, ethical concerns and expectations in relation to three technologies under study. The proposed approach comprises:

- Public opinion surveys conducted by telephone in 11 countries, including seven in the EU (France, Germany, Greece, Netherlands, Poland, Spain and Sweden) and four outside of Europe (Brazil, China, South Africa and the United States).
- Citizen panels conducted over one day in five EU countries (France, Germany, Greece, Poland and Spain).

[1] This also relates to Task numbers 2.5, 3.5 and 4.5.
[2] This also relates to Task numbers 2.6, 3.6 and 4.6.

Section 6 briefly presents the **approach to stakeholder analysis and contact list (Task 1.4)**. The section summarises the approach to SIENNA's stakeholder analysis and contact list as specified in Task 1.4 of the SIENNA Description of Action (DoA). According to the task specification, the partners will review and refine the approach proposed for the project's stakeholders and public engagement activities, as well as identify stakeholders in genomics, human enhancement and artificial intelligence (AI) and robotics in EU and non-EU countries. *Deliverable 1.2, Stakeholder analysis and contact list*, reports on and documents this task and its findings in greater detail.

Section 7 sets out the **approach for analysis and development of research ethics protocols and professional ethical codes (Task 1.5).** It describes SIENNA's approach for analysis and development of research ethics protocols and professional ethical codes. To this end, the section first defines 'research ethics protocols' and 'professional codes' (Definition and Terminology). Next, it outlines challenges that may arise during the analysis of ethics protocols and codes, especially during the development of guidelines and codes (Challenges). This is followed by a narrative literature review of existing manuals, screening and scoping on how to write good research ethics protocols and professional ethical codes (General overview of guidance documents on how to write ethics protocols and codes). This section also formulates research questions, which were earlier shared with SIENNA stakeholder board members with the intent of taking their views into account in SIENNA's approach (Research questions). Finally, this section outlines the next steps that will be followed from month 6 to 41 to develop operational guidelines, ethics codes and proposals for improved ethical and legal frameworks (Next steps).

Part II of the Handbook covers some general aspects related to the project. It provides guidance for project partners on where to go for information relating to research ethics, data management, internal communications tools and protocols, guidelines for event organisation, quality assurance, referencing, dissemination and communication, and exploitation and sustainability.

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List of acronyms/abbreviations

Abbreviation	Explanation
ATE	Anticipatory Technology Ethics
CATI	Computer Assisted Telephone Interviewing
D	Deliverable
DoA	Description of Action
DMP	Data management plan
EIA	Ethical impact assessment
ELSI	Ethical, Legal and Social Implications
EMP	Ethical monitoring protocol
EU	European Union
FGD	Focus group discussions
HTA	Health-technology assessment
PI	Principal investigator
R&I	Research and innovation
REC	Research ethics committee
RRI	Responsible research and innovation
T	Task
WP	Work package
VSD	Value-sensitive design

Glossary of terms

Term	Explanation
CATI surveys	Surveys conducted using a Computer Assisted Telephone Interviewing (CATI) method. CATI surveys are administered by interviewers using a quantitative questionnaire.
Citizen panels	A forum for discussion and deliberation of complex, sensitive and/or contentious topics on which it is important to gain a public view. Citizen panels are typically held face-to-face with members of the public and take place over a full day.
Code of conduct	Guidelines to help members, workers, management or researchers conduct themselves in accordance with common values and/or ethical standards.
Cognitive interviews	A versatile technique that allows the critical evaluation of the transfer of information when testing survey questionnaires. It is commonly used in survey research to explore how participants understand, mentally process and respond to the presented material and aims to identify where problems are experienced.
Foresight analysis	A foresight analysis involves approaches to help "look forward" into the (near, medium or longer-term) future of science, technology, the economy and society. The ultimate objective is to identify areas of strategic research and the emerging technologies likely to be particularly salient (and/or beneficial and/or harmful; depending on the reason for the analysis) in any one aspect of society (social, health, economic areas etc…).
Hard law	Authoritative rules backed by coercive force exercised at the national level by a legitimately constituted (democratic) nation-state and constituted in the supranational context by binding commitments voluntarily entered into between sovereign states (typified by public international law).[3]
Human rights matrix	A table structured around established human rights and selected technologies or technological areas that can be used to map human rights impacts of those technologies.
Law	Encompasses both hard 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[4] or, in some instances, a legal act adopted at the national level.

[3] 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.

[4] 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

Term	Explanation
Research ethics committee	Committees that review research applications and give opinions about whether research is ethical.
Research ethics protocol	Sets out how a study or project will deal with issues that are challenging from an ethical perspective.
Self-regulation	Normative instruments, i.e., codes of conduct, ethical codes, adopted by private non-governmental entities.[5]
Stakeholder	A relevant actor (person, group or organisation) who: (1) might be affected by the project; (2) have the potential to implement the project's results and findings; (3) have a stated interest in the project fields; and/or, (4) have the knowledge and expertise to propose strategies and solutions in the fields of genomics, human enhancement and artificial intelligence[6].
Stakeholder analysis	SIENNA defines stakeholder analysis as a process of gathering and analysing qualitative information to determine whose interests should be taken into account in our research and engagement activities. (Definition adapted from the WHO Stakeholder Analysis Guidelines[7]).
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.[8]
Technological artefacts	Physical technological products that are used for practical purposes.
Vulnerable groups	For the purpose of the SIENNA project, vulnerable groups include, among others, people with mental or physical disabilities, residents of retirement and assisted living facilities, patients with incurable diseases, people with addictions and problematic substance use, homeless people, and people that face persecution and exclusion.

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."

[5] Goncales, Maria Eduarda, 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

[6] European Commission, *Stakeholder consultation guidelines 2014,* Public consultation document, 2014, p. 10. http://ec.europa.eu/smart-regulation/impact/docs/scgl_pc_questionnaire_en.pdf

[7] Schmeer, Kammi, "Stakeholder Analysis Guidelines" in *Policy Toolkit for Strengthening Health Sector Reform*, Abt Associates, Inc., Bethesda, MD, 1999, p. 1. http://www.who.int/workforcealliance/knowledge/toolkit/33.pdf

[8] Goncales, Maria Eduarda, 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

Part I SIENNA and its approaches

1. Introduction

1.1 Objectives

The objective of the SIENNA Handbook is to bring together the outputs of Tasks 1.1, 1.2, 1.3, 1.4 and 1.5 (methodological approaches)[9] in a single place and act as a reference source for all consortium partners and as a basis for the work in work packages 2, 3, 4 and 5. The Handbook is managed and updated by Trilateral Research Ltd.

1.2 Structure of the report

This Handbook has two parts. Part I of the Handbook covers sections 1-7. Section 1 and 2 introduce the Handbook and project, respectively. Section 3 outlines the approach for ethical analysis. Section 4 outlines the approach for the legal including human rights study. Section 5 outlines the approach for the study of societal acceptance and awareness. Section 6 briefly presents the approach to stakeholder analysis and contact list. Section 7 sets out the approach for analysis and development of research ethics protocols and professional ethical codes.

Part II of the Handbook covers some general aspects related to the project. It provides guidance for project partners on where to go for information relating to research ethics and data management (section 8), internal communications tools and protocols (section 9), guidelines for event organisation (section 10), quality assurance (section 11), referencing (section 12), dissemination and communication (section 13), and exploitation and sustainability (section 14).

1.3 Scope and limitations

The scope of this Handbook is limited to that outlined in the SIENNA Description of Action (DoA), i.e., it will document the SIENNA approaches for ethical analysis, legal and human rights analysis, the study of societal acceptance and awareness, stakeholder analysis and public engagement approach, and the analysis and development of research ethics protocols and professional ethical codes (tasks 1.1 through 1.5), as well as their benefits, limitations and challenges, (and how these will be addressed) and plans for their implementation.

2. Overview of the SIENNA project

SIENNA is a three-and-a-half-year project (1 October 2017 to 31 March 2021) with 11 core partners and 2 associate partners, focussing on ethical and human rights challenges posed by human genomics, human enhancement and human machine interactions (i.e., AI and robotics).

[9] The approaches in this Handbook benefitted from and take into account feedback received from participants at the SIENNA Fundamentals workshop, held at the SciLifeLab, Uppsala University, 4-5 April 2018.

While human genomics, human enhancement and AI and robotics offer significant benefits to individuals and society, they also present significant ethical challenges, e.g., in relation to human autonomy, equality, personal liberty, privacy, and accountability. In collaboration with a variety of stakeholders, SIENNA will identify and assess the ethical and socio-economic issues, public opinions, legal regulation and human rights implications of each of these areas.

SIENNA will produce a framework for each of the three technologies that will form the basis for the development of research ethics protocols, professional ethical codes, and better ethical and legal frameworks. Before developing their recommendations, the partners will gather ethical views of experts and citizens towards the three technologies in four ways: (1) a major survey of citizens in 11 countries within and outside the EU; (2) panels of citizens in five countries; (3) interviews with experts and stakeholders; (4) workshops with stakeholders including scientists, ethicists, research ethics committees, professional organisations, civil society organisations, industry and policy makers.

SIENNA expects to boost the EU's leadership in developing ethical standards and support its vision of Responsible Research and Innovation (RRI) as a means to foster the design of inclusive research and innovation. The project will improve knowledge of the ethical, human rights and socio-economic impacts of the three technologies, while supporting ethical and responsible decision making by research ethics committees, scientific researchers and policy makers in the three areas. SIENNA will also create added value by generalising its methods for use in other emerging technological domains.

2.1. SIENNA project's objectives

The SIENNA project has three main objectives:

Objective 1: To develop ethical frameworks based on social, ethical and legal analysis and scientific and technological knowledge that address major present and future ethical issues in (a) genomics, (b) human enhancement and (c) human-machine interaction. These frameworks will take into account existing legal and ethical frameworks as well as stakeholder and public opinion, including the public's acceptance and awareness of these technologies.
Objective 2: To translate and adapt these ethical frameworks, in collaboration with relevant stakeholders, so as to produce four practical tools and resources for each technology: (a) operational guidelines for research ethics committees for these technologies, (b) codes of responsible conduct for researchers who develop these technologies, (c) proposals for revisions of existing ethical frameworks, and (d) proposals for revisions of existing legal frameworks, all of which should have acceptance and approval of relevant stakeholders.
Objective 3: To generalise the approaches for developing, translating and adapting ethical frameworks that were established in (1) and (2) so that they can be applied to other new and emerging technologies, and to obtain acceptance from relevant stakeholders for these generalised approaches.

Table 1: SIENNA project objectives

2.2. The SIENNA consortium

The SIENNA consortium comprises of the following partners:

Partner	Short name	Country
Universiteit Twente (project co-ordinator)	UT	Netherlands
Trilateral Research Ltd (deputy co-ordinator)	TRI	UK
Uppsala Universitet	UU	Sweden

Partner	Short name	Country
Helsinkska Fundacja Praw Czlowieka (Helsinki Foundation for Human Rights)	HFHR	Poland
European Network of Research Ethics Committees	EUREC	Germany
Universidad de Granada	UGR	Spain
Ionian University	IONIO	Greece
Universidade Federal do Rio de Janeiro	UFRJ	Brazil
Dalian University of Technology	DUT	China
Fondation Nationale des Sciences Politiques	Sciences Po	France
University of Cape Town	UCT	South Africa
CHUO University (associate partner)	CHUO	Japan
Berkman Klein Center for Internet & Society (associate partner)	BKC	USA

Table 2: The SIENNA consortium

Kantar Public is subcontracted to SIENNA to carry out the societal acceptance and awareness surveys and panels.

2.3. Project management

The University of Twente (led by Prof Dr Philip Brey) co-ordinates the project, supported by Trilateral Research. The partners are agreed that we should work on a consensus, collaborative basis. However, we are also agreed that we will adhere to a formal decision-making structure, which will be in place from kick-off until completion of the project. The project management organisational structure is as follows:

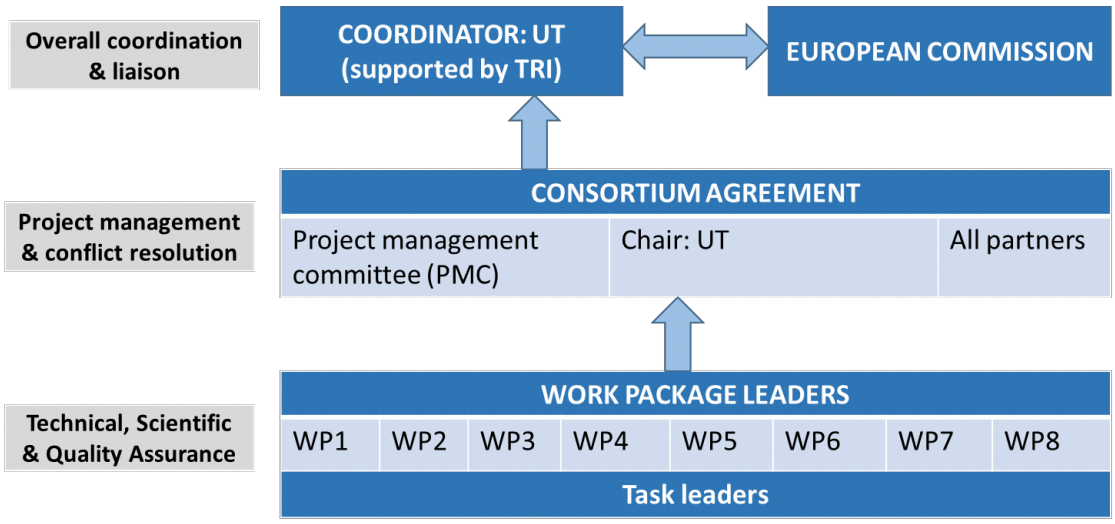

Fig 1: SIENNA organisational structure

The SIENNA Consortium Agreement formalises the organisation of the work between project partners, the management of the project, the rights and obligations of the partners, including, but not limited to, their liability and indemnification and to supplement but not conflict with the provisions of the contract with the EC.

2.4. SIENNA work package leaders

The table below maps the work packages, leaders and person months allocated per work package.

Work package number and description	Work Package leader	Person-months
WP1 Theoretical and methodological fundamentals	Trilateral Research (TRI)	20.00
WP2 Genomics: ethical, legal and social analysis	Uppsala Universitet (UU)	43.00
WP3 Human enhancement: ethical, legal and social analysis	Universiteit Twente (UT)	43.00
WP4 Human-machine interaction (AI and robotics): ethical, legal and social analysis	Universiteit Twente (UT) and Trilateral Research (TRI)	43.00
WP5 The consortium's proposals	European Network of Research Ethics Committees (EUREC)	36.50
WP6 Generalizing project methods, and exploitation measures	Helsinkska Fundacja Praw Czlowieka (HFHR)	41.50
WP7 Communication and dissemination	Uppsala Universitet (UU)	47.00
WP8 Project management	Universiteit Twente (UT)	28.50
WP9 Ethics requirements	Universiteit Twente (UT)	Not prescribed

Table 3: SIENNA work package leaders

Sections 3-7 of this report provide greater detail on the specifics of the final discussed and agreed approaches. Each section covers overview of the approach, terminology, methods to be used, benefits of the approach, scope limitations and challenges (and how these will be addressed), plans for their implementation, and guidelines and recommendations.

3. Approach for the ethical analysis (Task 1.1)

3.1. Introduction and overview

This section of the Handbook outlines the SIENNA approach to ethical analysis of human enhancement, human genomics and AI and robotics. We advocate a single shared approach to the ethical analysis of the three fields. However, the details of our approach will be worked out differently for these fields to accommodate for the unique challenges that each pose. Our approach intends to allow for broad ethical analyses of the technological fields that we study, including ethical analysis of general features of the technology, of specific developed products, and of particular uses of the technology. It moreover allows for the ethical analysis of current and anticipated future technological developments, uses and impacts. Our approach is based on empirical studies of the technology and its uses and impacts, including methods of impact assessment and foresight analysis.

In the next section, we first review and assess current approaches for the ethical analysis of emerging fields and technologies. Having assessed the strong and weak points of current approaches, we present the SIENNA approach in section 3.3. There, we present a detailed and reasoned six-step approach for ethical analysis. This approach rests to a significant extent on the ability to do foresight analysis.

Therefore, we have a detailed statement on our approach to foresight analysis in section 3.4. Finally, our approach also addresses stakeholder and public engagement, and we provide information of the role of stakeholder and public engagement in our ethical analysis.

This approach will be further applied and tested in subsequent work packages in the SIENNA project, particularly WPs 2, 3 and 4 (tasks 2.4, 2.7, 3.4, 3.7, 4.4 and 4.7) and WP5. In WP6, we hope to further refine and generalize the approach so as to be useful for future ethical analysis of any newly emerging fields and technologies.

3.2. Methods for ethical analysis of emerging fields & technologies

In this section, we review strengths and weaknesses of several methods for ethical analyses of emerging technologies to suggest the best approach for SIENNA's ethical analysis of emerging technologies in the areas of genomics, human enhancement and AI & robotics (table 1). Seven methods (or approaches) for ethical analysis were selected for review based on their potential for achieving the specific goals of the SIENNA project, such as methods that include well-developed foresight methods and/or incorporating stakeholder input on emerging technologies. For each of the approaches selected, we provide: i) a short description of the most salient aspects and ii) a brief overview of the most relevant strengths and weaknesses. Our criteria for selecting the methods are outlined below.

There exist a large number of methods for performing ethical analyses of emerging technologies. Many of these can be found in ELSI literature, applied philosophy and other domains. For our work, we have chosen to focus primarily on methods focused on emerging technologies. Literature overviews of these methods and useful ways of categorising them have been presented by Reijers et al.[10] and Brey[11]. In our selection process, we sought methods that primarily deal with the ethical analysis of *impacts* of emerging technologies because we expected such methods would best incorporate consideration of the level of analysis[12] we are aiming for, even though we will focus on additional ethical issues besides impacts. Since we envision foresight analysis and stakeholder and public involvement as integral components for SIENNA, we are most interested in ethical analysis strategies involving these approaches. This means that we have not only considered the relatively small set of methods that are designed specifically to deal with emerging technologies, but also those that are designed to deal with established technologies[13]. Finally, in some instances, we have grouped approaches when they are very similar to one another.

Our method consisted of a limited literature review conducted by the University of Twente, with findings discussed with other partners who helped draft this handbook. We limited our literature review to ethical approaches that explicitly utilise foresight analysis and/or stakeholder engagement for the ethical analysis of entrenched and/or emerging technologies. Some widely-discussed methods of ethical analysis of emerging technologies were excluded due to our inclusion criterion. For example,

[10] Reijers, W., D. Wright, P. Brey, K. Weber, R. Rodrigues, D. O'Sullivan, B. Gordijn, "Methods for Practising Ethics in Research and Innovation: A literature Review, Critical Analysis and Recommendations", *Science and Engineering Ethics*, 2017. https://doi.org/10.1007/s11948-017-9961-8

[11] Brey, P.A.E., "Ethics of Emerging Technologies", in S. O. Hansson (ed.), *Methods for the Ethics of Technology*, Rowman and Littlefield International, 2017.

[12] By "consideration of the level of analysis," we follow Brey's (2012) method of classifying ethical issues at the technology, artefact or application level, with the technology level being the broadest level of analysis and the application level being the most focused level of analysis.

[13] Differentiating emerging and established technologies primarily requires the level of acceptance a technology currently holds, whether in terms of adoption in society, discussion in literature, the existence of coherent and agreed-upon policies, etc.

although Value-Sensitive Design (VSD) is a popular method in R&I literature, that method is more about the practice of embedding ethically-desirable values in design rather than on developing anticipatory insights regarding ethical impacts. Since SIENNA is about building ethical frameworks, VSD lacks the focus on anticipatory ethics that the SIENNA framework requires. Another approach is Van de Poel's Experimental Approach[14], which arises from the view that the development of emerging technologies is often unpredictable, therefore anticipatory approaches are too speculative. Because we cannot predict, we must rely on experimentation, for which Van de Poel offers thirteen conditions based on three widely accepted ethical principles. We agree that the experimental approach could be promising for projects where speculation can be avoided. However, we believe foresight-based approaches are appropriate for SIENNA due to the emerging nature of the fields we will investigate, requiring at least some level of speculation, and we will discuss specific foresight approaches in section 3.4.

Name of method	Description of method	Main strength & weakness
SATORI Ethical Impact Assessment Framework[15]	Built from a comprehensive analysis of existing ethical impact assessment (EIA) approaches. Comprises of six main stages. EIA methods suggested are divided between conceptual versus empirical analysis on either intuitive or explicit ethical issues.	+ Flexible & adaptable: combines many of the strongest elements of existing EIA approaches; allows for use of consultation in ethical analysis - Does not provide detailed instructions how to use different ethical analysis methods
Ethical Impact Assessment (EIA)[16]	Developed from the earlier Principlism approach[17], adding the principles of privacy and data protection to the original list of autonomy, non-maleficence, beneficence and justice. Full method consists of a 14-step process beginning with determining the needs of an EIA assessment.	+ Principles are well-discussed, providing a wide basis to build a principled ethical framework; 14-step process gives clear instruction for EIA to achieve its goals - Not every tool will work for every project, difficult to know what is right in specific cases
Anticipatory Technology Ethics (ATE)[18]	Specifically geared toward emerging technologies by utilising forecasting and futures studies methods to anticipate impacts. Employs three levels of ethical analysis: technology, artefact, and application level.	+ Three levels of ethical analysis allow for a structured & comprehensive analysis of individual technologies - Unclear how ethical evaluations should be

[14] Van de Poel, I., "An Ethical Framework for Evaluating Experimental Technology. Science and Engineering Ethics", (online article), 2015, pp. 1–20. http://link.springer.com/article/10.1007%2Fs11948-0159724-3#/page-1

[15] SATORI, "CEN Workshop Agreement: Ethics assessment for research and innovation - Part 2: Ethical impact assessment framework, CWA 17145-2, June 2017. http://satoriproject.eu/media/CWA17145-23d2017.pdf ; Reijers, W., P. Brey, P. Jansen, R. Rodrigues, R. Koivisto, & A. Tuominen, "A Common Framework for Ethical Impact Assessment.", SATORI Deliverable D4.1, 2016. http://satoriproject.eu/media/D4.1_Annex_1_EIA_Proposal.pdf

[16] Wright, D., "A framework for the ethical impact assessment of information technology", *Ethics and Information Technology,* Vol. 13, 2011, pp. 199–226. http://doi.org/10.1007/s10676-010-9242-6

[17] Beauchamp, Tom L., and James F. Childress, *Principles of biomedical ethics*, Oxford University Press, 2001.

[18] Brey, P.A.E., "Anticipatory Ethics for Emerging Technologies", *Nanoethics*, Vol. 6, 2012, pp. 1–13. https://link.springer.com/article/10.1007%2Fs11569-012-0141-7

Name of method	Description of method	Main strength & weakness
		conducted; does not incorporate consultation
ETICA Approach[19]/ Discourse ethics[20]	Uses discourse analysis in political and research communities to identify emerging technologies followed by identifying applications of the technology in different fields. Bibliometric analysis is used to confirm the most important ethical issues are discussed to lead to policy recommendations.	+ Reviews literature outside of the research/science/academic community to identify ethical issues - Lack of foresight methods may lead to missing expected developments
Techno-ethical Scenarios Approach[21]	Focuses on qualitative impacts, such as on human values, rather than quantitative impacts, such as health risks. Utilises scenario building in a three-step methodology.	+ Scenarios can provide a comprehensive strategy for how to achieve ethically-desirable future outcomes - Scenarios require perhaps the most speculation of the discussed methods
Moral plausibility approach[22]	Presents strategies to evaluate ethical impacts of new and emerging technologies based on critiquing the expectations presented by the developers of the technologies. By investigating the laboratory process, engaging stakeholders, and challenging presumed morality, ethicists can arrive at a more robust assessment of an emerging technology.	+ Dedicated to critiquing speculations; can improve RRI process by exposing unexpected consequences or possible developments - Works best with concrete research projects, may not work well with broader technology categories
Ethical Risk Analysis[23]	Adds ethical considerations to well-developed non-ethical approaches of risk analysis, assessment, management, &	+ Provides quantitative assessments

[19] Stahl, B. C., R. Heersmink, P. Goujon, C. Flick, J. van den Hoven, K. Wakunuma, M. Rader, "Identifying the Ethics of Emerging Information and Communication Technologies", *International Journal of Technoethics*, 1 (4), 2010, p. 27. http://doi.org/10.4018/jte.2010100102 42; Stahl, B. C., "IT for a better future: How to integrate ethics, politics and innovation", *Journal of Information, Communication and Ethics in Society*, 9(3), 2011, pp. 140–156. doi:10.1108/ 14779961111167630

[20] Mingers, J., & G. Walsham, "Toward ethical information systems: The contribution of discourse ethics", *MIS Quarterly*, 34(4), 2010, pp. 833–854.

[21] Boenink, M., T. Swierstra, and D. Stemerding, "Anticipating the Interaction between Technology and Morality: A scenario Study of Experimenting with Humans in Bionanotechnology", *Studies in Ethics, Law and Technology*, 4(2), 2010, p.2.

[22] Lucivero, F., *Ethical Assessments of Emerging Technologies. Appraising the moral plausibility of technological visions*, International Library of Ethics, Law and Technology, Springer, 2016; Lucivero, F., T. Swierstra, M. Boenink, "Assessing Expectations: Towards a Toolbox for an Ethics of Emerging Technologies", *NanoEthics,* 5(2), 2011, pp. 129–141.

[23] Asveld, L., & S. Roeser (eds.), *The Ethics of Technological Risk*, Earthscan Publishers, London, 2009.

Name of method	Description of method	Main strength & weakness
	risk-benefit analysis. Highly focused on quantitative methods.	- Focus on risk may be too limited to capture some potential ethical impacts

Table 4: Overview of existing approaches for ethical impact assessment

Preliminary assessment

Based on our review, we found that some of the most promising approaches that align with the SIENNA project's requirements for ethical analysis, such as Anticipatory Technology Ethics (ATE) and Ethical Impact Assessment (EIA), are subsumed by the SATORI approach. In addition, SATORI's design leaves choices open for a specific project regarding the approach toward ethical analysis, with regards to these tools. In addition, we expect the ATE approaches' use of distinct levels of analysis may prove to be a good fit for SIENNA, as we begin with broad fields of technology that we will need to discuss in terms of specific applications. However, there may be aspects of ethical impact assessment and analysis required in SIENNA that are covered by different approaches, such as how the Moral Plausibility Approach can demonstrate detailed anticipatory ethical conclusions about discrete technologies. We recommend considering aspects of the SATORI and ATE approaches to help develop the ethical analysis for SIENNA, noting the consortium may select a more specific methodology, or develop SATORI by incorporating elements from the other methods in Table 1, as the project moves forward.

3.3. The SIENNA approach to ethical analysis

The SIENNA project addresses the ethical, legal, and social issues of emerging technologies in genomics, human enhancement, and AI and robotics technologies. Specifically, the aim of the ethical study is to identify, analyse and evaluate the ethical issues pertaining to these technologies, and where appropriate, to also provide suggestions for possible solutions for these issues. The subjects of ethical analysis consist both of *current* technology and use, and *potential future* technology and use.

The proposed SIENNA approach consists of six steps, which are intended to be sequential, although in practice some may be performed in parallel and/or iteratively. In the following subsections, we describe each of these six steps (Figure 2). The first three steps are mostly preparation for the actual ethical analysis and are concerned with issues of scope, the aim of the study and description of the technologies, uses and impacts. Steps 4-5 specifically address ethical issues i.e., their identification and analysis, respectively. Step 6, involves making recommendations and/or finding solutions to the ethical challenges. Note that these steps are carried out specifically in SIENNA tasks 2.4, 3.4, 4.4 (step 1-4 and first half of step 5), 2.7, 3.7, 4.7 (second half of step 5) and WP5 (step 6). Moreover, tasks 2.1, 3.1 and 4.1 have resulted in initial descriptions of the technologies and their impacts (steps 2 and 3) that can be built on in these later tasks.

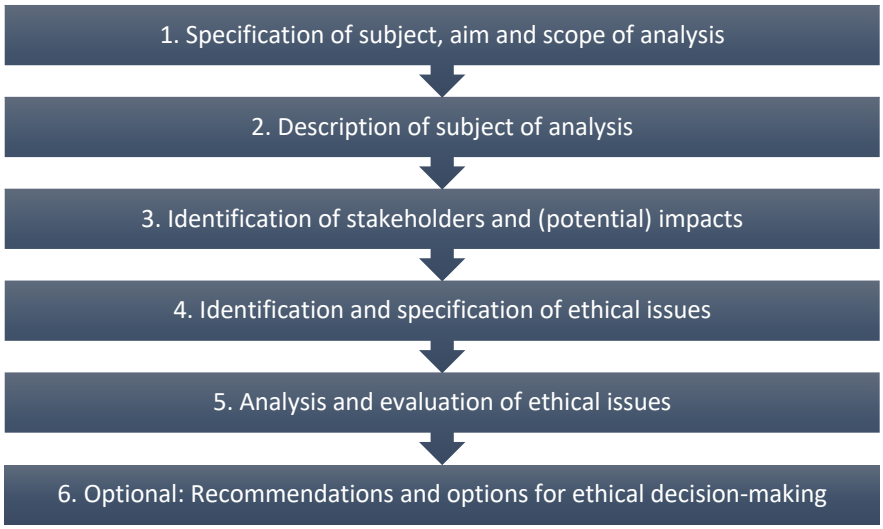

Fig 2: Overview of the SIENNA approach to ethical analysis

Step 1: Specification of subject, aim and scope of ethical analysis

In this step, we identify the subject of the analysis and we specify the kind of ethical analysis to be performed. In SIENNA, the subjects of analysis will be the three technologies that we study, including present and potential future technology subfields, techniques, approaches and methods; technological artefacts (i.e., physical technological products that are used for practical purposes) and procedures designed for practical application outside the field; and the particular uses and applications of these artefacts and procedures by particular users, in particular contexts, and for particular purposes. The subject of analysis may be decided based on many different aspects and/or stakeholder perspectives. For example, in human genomics, we could ask clinicians what ethical, legal or social challenges they face with the advent of high throughput sequencing. Alternatively, we could ask patients what they face/experience when they are trying to decide whether or not to take part in a study.

Once the initial subject identification has been made, the aim(s) of the ethical analysis to be performed will be determined. For example, one aim could be to ensure that the results of the analysis will lead to a mapping of ethical issues, a solution to a problem, and/or recommendations. In SIENNA tasks 2.4, 3.4 and 4.4, we intend to arrive at broad ethical analyses of the three technologies but with limited ethical evaluation (i.e., moral judgement). In tasks 2.7, 3.7 and 4.7, we aim to arrive at ethical evaluations as well, to be followed by recommendations in WP5. (See steps 5 and 6 for further discussion.)

Thirdly, the *scope* of the analysis is determined. Ethical analysis with a broad scope attempts to survey and analyse all or many of the significant ethical issues associated with the subject of analysis. Ethical analysis with a narrow scope may focus more deeply on just one particular ethical issue or ethical principle. In SIENNA, we aim to do broad ethical analysis, covering all the main ethical issues relating to the three technologies we study.

Finally, additional requirements and constraints regarding the analysis may be introduced. We may determine, for example, that ethical analysis will proceed according to particular ethical guidelines or principles, or according to a particular theory, framework or method. In SIENNA, we proceed along the general approach outlined in this document. We impose no additional constraints, except that our ethical evaluations should respect the moral values found in the European Union and the rest of the world (insofar as these values do not conflict with basic universal human rights): we are aiming to develop moral frameworks that can be used in the European Union, first and foremost, but that are also useful to the rest of the world.

Step 2: Description of the subject of ethical analysis

In this step, we describe the subject of the ethical analysis. The description should contain sufficient detail for the intended ethical analysis. For example, if the subject of ethical analysis is the application of CRISPR-cas9 for genetic therapy, we should describe and explain the details of the procedure, including the purpose of the procedure, the goals of genetic therapy and the contexts in which the procedure is likely to be used. Since it may not be entirely clear from the beginning which aspects are most relevant for ethical analysis, subject description and specification may be an iterative process, in which considerations that arise later on in the analysis may prompt further specification of details about the subject. In SIENNA, the methods for this step will include conducting a review of the scientific literature in the technological field (in particular studies that survey the state of the art in a field), reviews of studies of the application and use of a technology, and optional interviews with experts.

Since in SIENNA we want to perform broad ethical analyses, a broad description of the technology is required that includes different subfields, techniques, produced artefacts and uses, both present ones and ones that may take place in the future. Foresight analysis (described in section 1.4) will be used during this step to obtain descriptions of possible, plausible or probable future technologies, applications and uses. Following the proposal in the Anticipatory Technology Ethics approach developed by Brey[24], the technology and its uses will be described at three levels: (1) the *technology level*, the most general level of description, specifies the technology in general, its subfields, and basic techniques and approaches; (2) the *artefact level* gives a systematic description of products that are being developed for practical application outside the field. This includes both technological artefacts (physical entities) and procedures (for achieving practical aims); (3) the *application level* defines particular uses of these artefacts and procedures in particular contexts by particular users. For example, in human enhancement, one can distinguish basic fields and techniques such as prosthetics and nanofiber self-assembly (technology level), resulting in artefacts and processes like nootropic drugs and life-extension gene therapy (artefact level), and particular uses of such artefacts, for instance the use of different types of nootropic drugs by children for educational purposes (application level). Table 5 offers an overview of the three levels of ethical analysis.

For a broad ethical analysis at the application level, we consider different uses of particular technological artefacts and applications (i.e., uses according to proper function, alternative uses, and dual use and malicious use), different user groups (e.g., regular adults, youth, elderly, members of disadvantaged groups), and different application domains (e.g., military, healthcare, industry, education). For applications of medical research, we consider both the use of artefacts in clinical trials and their use after approval, both in medical and possible nonmedical context.

While a good description of a technology and its uses requires a description of the main subfields, techniques, artefacts and uses, a complete description of both present and potential future techniques, artefacts and uses could be very lengthy and complex. The challenge is to identify, above and beyond the most obvious items, those items that appear to be potentially relevant for further ethical analysis. This is why step 2 cannot fully be executed without prior consideration of later steps, in particular step 3, in which stakeholders and potential impacts are identified, and step 4, in which ethical issues are identified. For this reason, steps 2 to 4 should be performed repeatedly until one is confident that those aspects of the technology and its use that are most relevant from an ethical point of view have been identified.

[24] Brey, P.A.E., "Anticipatory Ethics for Emerging Technologies", *Nanoethics*, Vol. 6, 2012, pp. 1–13.

Level of analysis	Object of analysis	Questions for analysis
Technology level	- Aims of the technological field - Broad features of the technological field (central concepts, methods, approaches) - General features and impacts that apply to artefacts and applications emerging from the field	- What are ethical issues, if any, regarding the aims of the field, or of particular subfields, methods and approaches? - What are ethical issues, if any, regarding central concepts, methods, subfields, and approaches in the field? - What are general ethical issues that apply to most or all artefacts and applications coming out of the field and their impacts on society?
Artefact level	- Technological artefacts (products) - Technological procedures (functional procedures developed within the field) (Both developed for use outside the field)	- What ethical issues (typically) occur for certain types of products or procedures (across a wide range of applications of them)?
Application level	- Uses of technological artefacts/procedures in particular domains or contexts, for particular purposes or by particular user groups	- What ethical issues occur with respect to the technology and its specific products in healthcare, defense, domestic use, etc., in non-western countries, in use by children, the elderly, men, people with disabilities, etc.?

Table 5. Overview of the levels of ethical analysis

Step 3: Identification of stakeholders and relevant (potential) impacts

In this step, we specify actual and potential current and future issues and impacts associated with the subject of ethical analysis (to the extent that they are relevant to the stated aims of the ethical analysis). These can be social, economic, environmental, or other kinds of impacts, and may occur at micro-, meso- or macrolevels. Methods to identify current impacts may include doing reviews of the literature (e.g., socio-economic impact assessment literature); brainstorming; interviews with experts, users and stakeholders; and participant observation. Foresight analysis will be used to identify potential future impacts that are associated with projected future developments and uses of the technology. Impacts will be identified in relation to the three levels of description outlined in step 2: broad impacts correlated with the technology in general and its core fields and techniques; impacts correlated with specific artefacts; and impacts correlated with specific uses.

In this step, we also specify all relevant *stakeholders* (e.g., decision makers, those involved in benefitting or being harmed by the subject or its impacts, funders, etc.) and we will plan further at this stage how stakeholders will be engaged (e.g., interviews, panels, or workshops). In step 1, some of the stakeholders that are potentially affected by the subject may have already been identified. However, these may only be those stakeholders that are necessary to understand the technology. In relation to specific ethical issues, there may be other relevant stakeholders that need to be defined and engaged, importantly including those who generally do not have a strong voice in society.

Step 4: Identification and specification of potential ethical issues

In this step, we identify and describe all the ethical issues relevant to the subject including those that pertain to the (potential) impacts uncovered in step 3. Specifically, we identify issues, principles and

values that may be affected or challenged by a given technology, partly based on its applications and impacts that were described in the earlier steps. Some identification and specification of ethical issues may already have been performed in the forgoing steps.[25] As in steps 2 and 3, analysis will take place at the technology, artefact and application levels. Possible outcomes are, for example, the observation that there is the potential for bias in machine learning or a risk that increased knowledge of the human genome invites discrimination (technology level), the identification of risks to privacy from the use of social robots or of dual use of neurostimulators (artefact level), and issues of autonomy and informed consent in the genetic enhancement of children and moral responsibility in the use of killer robots on the battlefield (application level).

Methods for identification and specification of ethical issues at these three levels include literature review that focuses on prior ethics studies of the technology in question, stakeholder and expert consultation, as well as considering a list of questions about the technologies that could help identify ELSI (sometimes presented as "checklists"[26]).

Step 5: Analysis and evaluation of ethical issues

In step 5, we further analyse and evaluate the ethical issues that were identified in step 4 including those raised by stakeholders. This involves, first of all, steps to further clarify, provide details about nuances, and contextualise the ethical issues that were identified, without necessarily arriving at strong moral judgments or solutions. This will involve some or all of the following: identifying different moral values that apply to the issue and potential conflicts between these values, identifying roles, rights and interests of stakeholders, identifying reasons or arguments for and against certain moral judgments, and the pros and cons of particular ways of addressing value conflicts. To perform such analysis, we use instruments for ethical analysis from the field of ethics (i.e., ethical concepts, theories, frameworks and/or arguments).

Ethical analysis may aim at a better understanding of ethical issues and the possible ways of resolving them, but it may also include *ethical evaluation*, by which we mean making and defending moral judgments regarding the goodness or rightness of particular actions, persons, things and events, and the "rightness" or "wrongness" of possible courses of action in relation to the ethical issue. For example, regarding procedures of moral enhancement, a considered moral judgment may be arrived

[25] To the extent the ethical issues have not all been comprehensively identified and specified in steps 1, 2 and 3, they will be identified and specified in step 4. For example, if it was said at step 1 that the aim of ethical analysis is to investigate privacy issues in facial recognition in robot vision, then based on the descriptions of step 2 and 3, it is further explained here why and how this ethical issue seems to occur. If no ethical issues were identified during step 1, then such issues are to be identified during this step. For ethical analysis building on foresight analysis, the identification of ethical issues may already have taken place during the foresight analysis stage, and in fact it would be more ideal if this had already happened at this stage, for two reasons. The first reason is that foresight analysis can cover a large, potentially infinite, number of possible future developments, many of which will not raise major ethical issues. It is therefore better to constrain the search space in foresight analysis to be guided by an interest in those future developments that raise ethical issues. The second reason is that a specification of relevant (potential) impacts (step 3) in relation to particular ethical issues is perhaps better undertaken at the foresight stage, since at this stage the expertise of social scientists and other experts may be present to help assess these impacts.

[26] Several ethical checklists are available. Brey, op.cit, 2012 contains a comprehensive checklist for ethical issues in technology, and the SATORI CEN "pre-standard" for ethics assessment also specifies a large number of ethical issues in relation to the medicine, information technology and engineering fields. See: SATORI, "CEN Workshop Agreement: Ethics assessment for research and innovation - Part 2: Ethical impact assessment framework, CWA 17145-2, June 2017. http://satoriproject.eu/media/CWA17145-23d2017.pdf

at that it would be unethical to perform these procedures for persons incapable of informed consent.[27] These moral judgments may be based on previous analysis, previously accepted ethical theories, principles and guidelines, and input from stakeholders. Note that SIENNA Tasks 2.4, 3.4 and 4.4 ("Analysis of current and future ethical issues") will focus on "neutral" ethical analysis and will avoid moral judgments on key ethical issues. In Tasks 2.7, 3.7 and 4.7 ("Proposal for an ethical framework"), to some extent, considered moral judgments will be made for the three technology fields in order to arrive at ethical frameworks.

In this step, we explore various existing and novel approaches for including stakeholder input (views, experiences, et cetera) in the analysis. Our challenge is to avoid that stakeholder input be ignored in the final evaluation yet also to not allow that stakeholder preferences directly dictate normative conclusions.[28] It can perhaps already be said at this point that stakeholders could make contributions by: (1) identifying and articulating ethical issues that may have been overlooked by ethicists, and commenting on such articulations by ethicists; (2) arriving at moral judgments, jointly or collectively, and commenting on such judgments by ethicists; (3) proposing decisions and solutions in response to ethical issues, and responding to such proposals made by ethicists; and (4) proposing ethical decision-making guidelines, and commenting on such proposals by ethicists.

Step 6: Recommendations and options for ethical decision-making (optional step)

In this step, we execute an optional step after ethical analysis and evaluation which we refer to as *ethical decision-making and guidance*. This step is optional in that mere ethical analysis and ethical evaluation can be aims in themselves. Ethical decision-making and guidance go beyond the moral judgements of the ethical evaluation stage by proposing comprehensive courses of action for one or more actors or proposing specific practices that are intended to provide guidance in ethically contentious cases. For this sixth step, we analyse how moral judgments can be transformed into recommendations for specific actions. Possible ways in which this can be achieved include using models for ethical decision-making, asking stakeholders for recommendations, confronting ethical analyses with policy objectives, and utilising approaches from task 1.5 (ethical codes and procedures) for developing ethical guidelines and research ethics protocols. The precise approaches that we will use for this in SIENNA are still to be determined.

A typical next step towards decision-making and guidance would be to develop a *framework of responsibilities* for different actors with respect to the ethical issue(s). This framework would define actor's individual responsibilities, define tools and mechanisms for supporting these responsibilities, and define specific actions that actors can or should take to satisfy their responsibilities. This framework could amount to specific *(professional) ethical guidelines* for particular types of actors, some of which we will be developing in the SIENNA project (SIENNA WP5). In the context of such a framework of responsibilities for various actors, one could also look specifically at the role of governments in stimulating or enforcing certain responsibilities through *policy-making*. That is, one can ask what policies governments should institute and what actions they should take to stimulate or require other actors to take up certain responsibilities that contribute towards ethical outcomes with respect to new technologies and their application in society.

[27] Note that it is difficult to avoid making some (implicit) moral judgments in ethical analysis, but even so, ethical analysis can then still be neutral on key ethical issues, being those that concern key value conflicts.
[28] Stakeholders may have good moral intuitions and strong values, but they often lack the specific expertise needed to identify and articulate a broad range of ethical issues and arrive at considered moral judgments and comprehensive courses of actions regarding them. An interplay is needed between the expertise of ethicists and the competencies of stakeholders in order to arrive at defensible joint results.

In SIENNA, step 6 will be taken in work package 5, in which we will develop ethical guidelines and other instruments for responsible behaviour for relevant actor-stakeholders in relation to the three technologies. These guidelines and protocols and frameworks will be directed at scientists and innovators, research ethics committees, policy makers, and possibly also individual and organisational users of the technologies. The guidelines will be derived to a significant extent from the ethical frameworks developed in Tasks 2.7, 3.7 and 4.7.

Example: Autonomous cars

Let us consider an example to illustrate the overall approach to ethical analysis. Suppose that in step 1, we determine that we want to assess the operating software of autonomous cars (subject) with the aim of determining ethical issues in the operating decisions that this software makes (aim) and we are specifically interested in ethical issues relating to road safety (scope). In step 2, we then provide a fuller description of this operating system and what it is meant to do and how it operates, and we provide relevant background information about autonomous cars and their uses. In step 3, we identify relevant stakeholders (drivers, other road users, designers, sellers, etc.) and we specify potential impacts of the operating software when using autonomous cars, particularly the consequences of its decisions regarding what could be considered "safety" activities, like braking, or steering when there is risk of a collision. In step 4, we identify particular ethical issues in relation to safety. In this instance, we identify the issue that the software necessarily engages in morally controversial choices on how to prioritise the safety of users in relation to other road users.[29]

In step 5, we analyse and evaluate the moral issues from step 4. We identify and analyse relevant values, such as safety, well-being, responsibility, bias, and rights to life and health, and the way in which they play out and potentially conflict with each other in the operation of the software. We may observe that there is a conflict between different approaches to the system: utilitarian ones and ones that prioritise other rights and interests such as the safety of the user. We may attribute rights, duties and responsibilities to different stakeholders, and may come to particular moral judgments, such as that a utilitarian decision-making mechanism is preferable to non-utilitarian ones or that the moral responsibility of decisions taken by the system ultimately rest with the owner. In step 6, recommendations are made regarding the way in which the operating system ought to operate with respect to safety. This entails recommendations regarding its design, particularly in relation to road safety. For example, recommendations may be to have the system operate according to utilitarian considerations, with equal weight given to different persons or that the benefit of using self-driving cars is not worth the potential harm. More elaborate recommendations may include detailed guidelines for design, and optional attributions of responsibility and liability to users, manufacturers and others.

3.4. The approach to foresight analysis

Introduction to foresight analysis

Foresight analyses and forecasting may differ slightly in meaning (albeit they are sometimes used interchangeably), and each word is given various definitions; however, they both aim to look for information about the future. Historically, foresight analyses have been used primarily for political and/or commercial uses and have changed in nature, approach and meaning over time.

[29] Note, that if futuristic operating systems are to be considered, steps 1, 2, 3 and 4 would also involve, or build on, foresight analysis that includes descriptions of possible future operating systems, relevant stakeholders and impacts, and resulting ethical issues.

> The 'classical' definition is made by Ben Martin (1995a[30],b[31], 1996[32]): '(technology) foresight is the process involved in systematically attempting to look into the longer-term future of science, technology, the economy and society with the aim of identifying the areas of strategic research and the emerging of generic technologies likely to yield the greatest economic and social benefits' . . . Foresight includes qualitative and quantitative means for monitoring clues and indicators of evolving trends and developments and is best and most useful when directly linked to the analysis of policy implications.[33]

Foresight analyses have been used heavily in policy-making, and it is noteworthy that they have come in and out of favour in this domain. Indeed, at certain points in time, such as post-World War II to the 1980's, the foresight approach was perhaps too heavily dependent on having "THE" correct answers, and after some notable failures, the approach went out of favour until it came back in the 1990's using the term 'foresight' instead of 'forecast' (for the purpose of this section, we consider these two terms synonymously). As a methodology in academic fields and/or as a subject or study in academia, foresight analysis is much less common as the methodologies used, do not lend themselves easily to rigorous systematic analyses, nor are there current ways to validate these.

Aims of foresight analysis

Within policy analysis arena, the most important targets, as described by Cuhl (2003)[34] include:

i) to increase the choices
ii) to set priorities and assess impacts and risks
iii) to reveal novel needs, demands, possibilities, ideas
iv) to address specific areas such as economic, technological, social and ecological areas and to also monitor research in these areas
v) to describe the wanted and unwanted future scenarios
vi) to initiate and stimulate ongoing communication

Different approaches in foresight analysis

As described by different individual (academic) authors[35] as well as (industrial or professional) organisations[36], foresight analysis can include the following methodologies:

a) Different types of trend analyses, including modelling
b) Brainstorming
c) Expert and stakeholder panels
d) Scenario planning
e) The Delphi method
f) Critical technologies
g) Technology roadmapping
h) Scoping foresight

[30] Martin, B. R., "Foresight in science and technology", *Technology Analysis & Strategic Management*, 1995, 7, No. 2, pp. 139–168.
[31] Martin, B. R., *Technology Foresight 6: A Review of Recent Overseas Programmes*, HMSO, London, 1995.
[32] Martin, B. R., *Foresight. In STI Review No. 17*, Organisation for Economic Co-Operation, 1996.
[33] Cuhl, K., "From Forecasting to Foresight Processes — New Participative Foresight Activities in Germany", *Journal of Forecasting*, 22, 2003, pp. 93-111 [p. 96]. https://onlinelibrary.wiley.com/doi/full/10.1002/for.848
[34] Ibid.
[35] Doos, L., C. Packe, D. Ward, S. Simpson, A. Stevens, "Past speculations of future health technologies: a description of technologies predicted in 15 forecasting studies published between 1986 and 2010", *BMJ Open*, 7(7), 2017, e016206. http://bmjopen.bmj.com/content/7/7/e016206.long
[36] United Nations Industrial Development Organisation, *Foresight Methodologies, Training Module 2,* 2004. https://www.tc.cz/files/istec_publications/textbook2revisedcf_1171283006.pdf

Strengths and weaknesses of foresight analysis

The pros and cons of this approach will depend greatly on how well the specific methodologies (e.g., see below) are fit for purpose with respect to the goals of the foresight analysis. This will include contextual factors such as the specific aims, the domains/fields of applications, the resources available and what will be done with the results.

As found through a review of the literature by Iden et al (2017)[37], an important weakness of foresight (especially in academic use) is that, it would appear that no one method of foresight analysis is built on a robust and coherent foundation. From this list of approaches, we describe herein a subset based on preliminary proposals made for each of the three areas of technology and discussed internally in the SIENNA project in December 2017. Indeed, each different area of technology may have a set of foresight tools that are best adapted to that context ,as well as to the teams working in these areas in the SIENNA project. The particular approach to foresight analysis for use in the SIENNA project could include the following:

1- Horizon scanning

There is no universally accepted definition of horizon scanning[38] and, indeed, many ambiguities exist, including the fact that the terms foresight and horizon scanning are sometimes used interchangeably. Nonetheless, many of the definitions relate back to the description of the approach as "a systematic technique to identify future threats or opportunities, is an important policy tool used in government and business to manage and proactively respond to upcoming threats and opportunities."[39] Hence, as mentioned above for foresight analysis in general, horizon scanning does not appear to be commonly used in academic research.

a. Literature review (LR)

There are many different approaches to conducting a literature review. The very understanding of a LR and its goals may differ between disciplines (e.g., empirical sciences versus law versus bioethics). Also, important to note is that different domains may use the same label for a different meaning. Differences in approaches rest mostly in the degree to which the search is structured. At one extreme of this spectrum is the systematic literature review where theoretically all literature is carefully searched in a formal and "systemic" way (in biomedicine, the PRISMA group, PRISMA Statement[40]) has identified specific steps to follow); of interest is that there are current efforts to develop systematic review criteria specifically for humanities research (personal communication). The traditional systematic approach is thorough, yet very time consuming, as it necessitates that searches be performed two times and results verified between authors. Furthermore, there may be a formal qualitative analysis done (to evaluate quality of articles) on the articles retrieved which also necessitates multiple authors to contribute to the analysis. At the other end of the spectrum, less stringent and thorough approaches could be the rapid review or the scoping review (depending on the approaches chosen). For a summary of review types, see

[37] Iden, J., L.B. Methlie, G.E. Christensen, "The nature of strategic foresight research: A systematic literature review", *Technological Forecasting & Social Change*, 116, 2017, pp. 87-97. https://www.sciencedirect.com/science/article/pii/S0040162516306035

[38] Carney, J., "The Ten Commandments of Horizon ScanningForesight Projects", UK Government Offic for Science, Foresight blog, 8 March 2018. https://foresightprojects.blog.gov.uk/2018/03/08/the-ten-commandments-of-horizon-scanning/.

[39] Brown M.J., L.V. Dicks, R.J. Paxton, K.C. Baldock, A.B. Barron, M.P. Chauzat, et al., "A horizon scan of future threats and opportunities for pollinators and pollination", *PeerJ*, 4, 2016, e2249. https://peerj.com/articles/2249/

[40] Prisma Group, PRISMA Statement, Accessed 29 April 2018. http://prisma-statement.org/PRISMAStatement/PRISMAStatement.

Grant et al. (2009).[41] Please note that other authors may not necessarily agree with the details of the typology provided by Grant et al. (2009),[42] however the latter provides a good overview. What is common between all approaches is that literature is consulted to come to a type of summary of that literature and, importantly, the methods used to reach this point are described.

Additional examples of reviews include umbrella reviews, which is a review of reviews; scoping reviews, which are meant to give a preliminary assessment of the literature without going in-depth; and overviews, which give a summary of literature, again without going into much depth (but may offer an extensive bibliography, nonetheless).

The types of decisions to make include the type of literature to consult, including academic or grey (including popular media, movies, etc.); keywords to search; inclusion and exclusion criteria; and approach to evaluation/analysis (of quality and/or content).

b. Bibliometric methods: "The term bibliometrics comprises a set of methods used to study or measure texts and information. Whilst bibliometric methods are most often used in the field of library and information science, they have wide applications in other areas. In fact, they are used to explore the impact of their field, the impact of a set of researchers, or the impact of a particular paper."[43] Bibliometric approaches include looking at publication counts, citation counts, impact factor analysis, co-citation and co-word analysis.

2- Consultation with experts/empirical data from experts

Obtaining the input from different stakeholder groups can be done in various ways. Once again, there is no agreement on the definitions of terms used, hence it is important that when labelling an approach, one is transparent about the method used and offers appropriate references.

a. Individual Interview studies (can also be paired interviews)

Interview studies may be conducted in different ways with different goals in mind: e.g., formal, for academic publication; informal, for academic publication; informal interviews for input, but not publication. Since the formal interview study is the most thorough and the other two types follow the same approach except with less rigour, we will only describe the former herein. Interview studies may have different forms including for instance in-depth, structured and semi-structured. In the social sciences and in bioethics, they are frequently used as an exploration tool in order to obtain qualitative information on a topic where little information exists in the literature. For the results of such studies to be eligible for publication in good journals, the process of selecting and recruiting the interviewees, of developing the interview guide, conducting the interviews, recording and transcribing the interviews, and importantly, analysing and reporting the qualitative data must be conducted based on clearly described, valid or known approaches. Each step must be documented. The results of such studies can be used in a variety of ways, for instance, to inform for a secondary research study on the same phenomenon (quantitative study, survey, discrete choice experiments etc.), to help explain a phenomenon with or without theory development, and (esp. in bioethics) to help explain how ethical challenges play out in practice.

b. Focus group discussions

[41] Grant M.J., A. Booth, "A typology of reviews: an analysis of 14 review types and associated methodologies", *Health Information and Libraries Journal*, 26, 2009, pp. 91-108. https://www.ncbi.nlm.nih.gov/pubmed/19490148

[42] Ibid.

[43] European Foresight Platform, "Bibliometrics". Accessed 29 April 2018. http://www.foresight-platform.eu/community/forlearn/how-to-do-foresight/methods/analysis/bibliometrics/.

i. Focus group discussions (FGDs) are similar to interview studies in that there are many different detailed types, and they involve interviewing or obtaining input from stakeholders; however, in focus groups many persons are present during the session (whereas interviews are usually one-on-one or paired).

c. Questionnaires

Questionnaires can be administered via different delivery methods, on their own (as a survey) or as part of a larger approach; herein, we address the Delphi approach which is an example of the latter.

Delphi method

Originally devised to obtain views of experts on the impact of massive atomic bombing[44], the main features of a Delphi study are: "the use of a number of questionnaire rounds, feedback of responses, the opportunity for participants to modify their responses and anonymity of responses."[45] While the Delphi approach may be useful in some cases, it also has some weaknesses. For example, it may be misleading in terms of its robustness; its formalised step-wise approach may over-shadow the highly subjective and value-laden-judgements that need to be made in many of the steps. This could lead readers to consider it a type of quantitative approach with generalizable findings when this is not the case. Importantly, this approach may "overlook reliability measurements and scientific validation of findings"[46]. To be fair, other consultation approaches may have this problem as well; the issue here is that the Delphi approach with all its steps "looks" like a "scientific" method whereby a "good" or "right" answer will be achieved. This is less the case with other more open-ended qualitative approaches. Furthermore, it can be very time-consuming to perform, and there is a need for expert moderators (unless conducted via the internet, which may have the plus of protecting anonymity). Another downside is the need for sub-analysis within analysis. Also, if you are looking for all impacts, this funnelling down to a few impacts may not be so useful.

3- Conceptual scenarios

Scenario approach

Another approach to foresight analysis involves the use and development of scenarios to facilitate conceptual analysis. The term "scenario" is used in many different ways in different disciplines, even within the field of foresight analyses[47] (see special issue in *Technological Forecasting and Social Change* 2013). Hence, it is important to be as specific as possible when using the term as an approach in foresight analysis. Scenarios can be used, for example

i. to allow for thought experiments,
ii. to help brainstorm and conceptualise future contexts and the related impacts of future technologies or services.
iii. to achieve "i" above, as well as be used with expert stakeholders (during interviews or panels) in order to get feedback from stakeholders regarding specific questions about the future scenarios.

[44] Thangaratinam, S., C.W. Redman, "The Delphi technique", *The Obstetrician & Gynaecologist,* 7, 2005, pp. 120-5. https://obgyn.onlinelibrary.wiley.com/doi/abs/10.1576/toag.7.2.120.27071
[45] Ibid.
[46] Thangaratinam and Redman, op.cit., 2005.
[47] United Nations Industrial Development Organisation, *Foresight Methodologies, Training Module 2,* 2004. https://www.tc.cz/files/istec_publications/textbook2revisedcf_1171283006.pdf

The downside of using scenarios is that if you want to be very specific about the details of the scenario, you need to have a team that has a lot of expertise in the technology that you are addressing. Also, the amount of detail if too much can be distracting for stakeholders. The plus side of using scenarios is that you can decide to focus on a relatively 'simple" future occurrence and have stakeholders ponder that specifically (e.g., what do you think would be the biggest impacts from a society where everyone had a chip inside them connected to a geo-location device?).

3.5. Role of stakeholders and the public

Stakeholder engagement and consultation play a crucial role in ethical analysis envisaged in SIENNA. According to the SATORI CEN Workshop Agreement on ethical impact assessment[48], stakeholder engagement can help identify stakeholder ideas and concerns about the future and establish the legitimacy of the ethical impact assessment process. The process benefits from "bringing together different experts and non-experts and enabling them to exchange views, form consensus opinions, and improve one another's understanding of future events".[49]

In SIENNA tasks 2.4 (Analysis of current and future ethical issues: genomics), 3.4 (analysis of current and future ethical issues; human enhancement) and 4.4 (analysis of current and future ethical issues; AI and robotics) we will engage stakeholders to identify and assess current and future ethical issues, perspectives and approaches to them regarding the technology in general, and in relation to specific technologies, domains and applications, including potential mitigation measures. These tasks will be conducted in connection with the subsequent tasks 2.5, 2.6, 3.5, 3.6, 4.5, 4.6, which specifically focus on gathering public opinion through surveys and panels. Furthermore, additional activities will be carried out to engage stakeholders throughout the project, such as requests for information, workshops, interviews and consultation on drafts documents.

Engaging with stakeholders will help identify relevant stakeholder interests[50] regarding impacts of the three technological fields and help contextualise and potentially balance conflicting values[51]. Getting stakeholder input early in the ethical impact assessment process[52] will help make the recommendations, frameworks and codes developed in SIENNA useful and actionable. Stakeholder input will be one of the primary sources of information that enhances the SIENNA ethical impact assessment.

As recommended by established impact assessment guidance, "Engagement should occur throughout the impact assessment process and for the life of the business project or activities. It should be done early and in a proactive and ongoing manner."[53] While SIENNA has already identified key stakeholders with whom to engage during the ethical impact assessment process, the project partners remain

[48] SATORI CEN Workshop Agreement, "Ethics assessment for research and innovation - Part 2: Ethical impact assessment framework", CWA 17145-2, 2017. http://satoriproject.eu/publication_type/standards/
[49] SATORI CEN Workshop Agreement, "Ethics assessment for research and innovation - Part 2: Ethical impact assessment framework", CWA 17145-2, June 2017. http://satoriproject.eu/publication_type/standards/
[50] For discussions around this see Bryson, John M., "What To Do When Stakeholders Matter: Stakeholder identification and analysis techniques", *Public Management Review*, Vol. 6, 2004, pp. 21-53. Meltsner, A., "Political feasibility and policy analysis", *Public Administration Review*, 32, November/December 1972, pp. 859-867; Eden, C. & F. Ackermann, *Making Strategy: The Journey of Strategic Management,* Sage Publications, London, 1998.
[51] Callies, Ingrid et al, "Outline of an ethics assessment framework," SATORI Deliverable 4.2, V.3.0, Sept 2017. http://satoriproject.eu/framework/section-1/
[52] Wright, David, "A framework for the ethical impact assessment of information technology", *Ethics and information technology*, Vol. 13, No. 3, 2011, pp. 199-226 [p. 204]
[53] https://www.humanrights.dk/business/tools/human-rights-impact-assessment-guidance-and-toolbox

flexible and open to including other stakeholders identified during the impact assessment process. Based on work carried out at the proposal-writing stage and Task 1.4 of SIENNA, i.e., identification and analysis of stakeholders, we have identified the following stakeholders with whom to engage[54]:

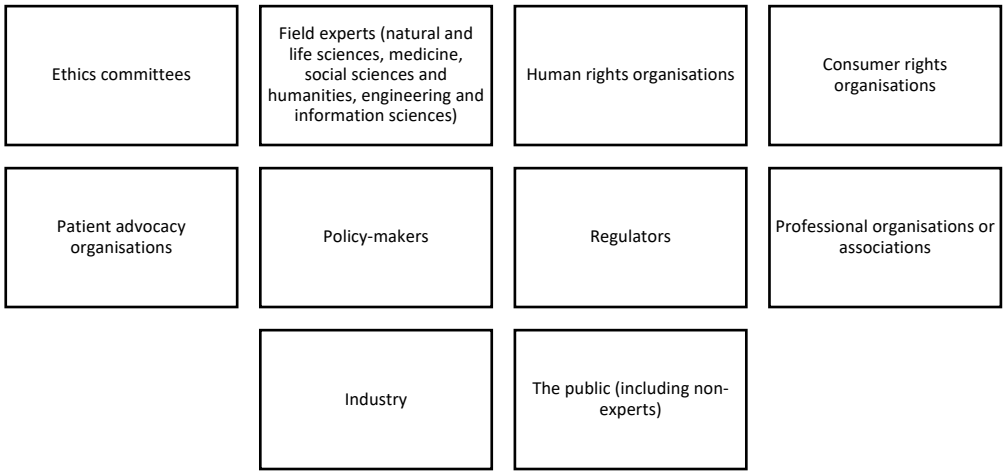

Fig 3: Stakeholders with whom SIENNA will engage

Modes of engagement with stakeholders will vary depending on the need and tools that are best suited for the purpose.

Lay publics will be engaged in the SIENNA project primarily through citizen panels (tasks 2.4, 3.4 and 4.4) and public opinion surveys (tasks: 2.5, 3.5 and 4.5). designed to gain the public's views on genomics, human enhancement and human-machine interaction (AI and robotics). The panels will function as guided fora for discussion and deliberation of complex, sensitive and/or contentious topics. They will help the consortium better understand and explore the awareness and concerns about the applications of technologies in these three fields and related ethical issues, including from the perspective of vulnerable populations. Crucially, the results produced will inform the development of ethical guidelines and recommendations.

In addition to the citizen panels and public opinion surveys, SIENNA engagement activities include stakeholder consultations and stakeholder events (e.g., legal analysis workshop, foresight workshops, workshops on operational codes and guidelines). The stakeholder consultations will take the form of semi-structured interviews via Skype, telephone or face-to-face. Interviews will be carried out with other stakeholders (e.g., policy-makers, representatives from civil society organisations, as well as industry and professional organisations in research and innovation) to find out their opinions about the technologies and their socio-economic, ethical and human rights aspects. Consortium partners will also hold webinars (Tasks 6.5 and 7.5) with stakeholders. Stakeholder workshops and conferences will provide the consortium partners with opportunities to obtain feedback from stakeholders and buy-in for our proposals. The engagement activities aim to reconcile the needs of research teams with the legitimate concerns of citizens about the relevant technologies.

Challenges in involving stakeholders in the ethical analysis/impact assessment activities and how SIENNA will address these

The *SATORI Handbook on Participatory Processes*[55] identifies various challenges in participatory

[54] Refer to SIENNA *Deliverable 1.2 Stakeholder analysis* and contact list for a more detailed analysis.
[55] Shelley-Egan, Clare, David Wright, Rok Benčin, Jelica Šumič Riha, Gregor Strle, Daniela Ovadia, Adelina Pastor Cañedo, Christine Angeli, Menelaos Sotiriou, *SATORI Deliverable D2.1 Report (handbook) of participatory*

processes; our work so far in SIENNA has also highlighted some of these. The table below identifies challenges in engaging stakeholders in the ethical analysis, how and when SIENNA will work to address these challenges.

Challenge	How SIENNA will address this
Preparation stage	
Selection of the right approaches	The consortium/SIENNA partners involved in the research or engagement activity planned, discussed and collaboratively developed (Task 1.1) the best approaches to involve various types of stakeholders in Tasks 2.4, 3.4 and 4.4. This process will be informed by the stakeholder analysis in SIENNA D1.2. and adjusted to the goals set in the tasks 2.4, 3.4, 4.4. Clarity on goals and objectives will also help address this challenge.
Complexity of topic (lack of awareness and knowledge)	SIENNA will foster stakeholder awareness of and accessibility to activities via general channels (e.g., project website, social media). Each stakeholder engagement activity will also involve pre-briefing stakeholders, pointing them to useful and appropriate resources, and answering their queries.
Divergent conditions and perspectives in different countries (e.g., various cultural contexts)	SIENNA partners are aware of and accustomed to working at the EU and national and/or local levels. Having institutional partners in countries where the SIENNA activities are being carried out will help address this challenge (and account for it) during the ethical analysis activities.
Defining stakeholders and target groups beyond the "usual suspects" in ethical analysis activities	SIENNA is carrying out a stakeholder identification and analysis exercise (Task 1.4, results will be presented in D1.2) for each of the three topics. This will help ensure that SIENNA has a diverse and inclusive group of stakeholders. In the ethical analysis activities, SIENNA teams will be mindful of the need to go beyond the usual or loudest voices and interests that get heard in the topic areas. We will also involve and reach out to people in countries where SIENNA does not have partners and will not carry out surveys and panels.
Locating and involving lay publics (i.e., non-experts) to participate in the ethical analysis activities	SIENNA will try and recruit non-experts via its communication activities in WP7. Regarding participation, we will ensure the outcomes of the ethical analysis and the Codes are informed adequately by the views of lay persons/publics – they will be given adequate opportunities to participate via open invitations on the project website to project events and other research activities. The SIENNA tasks focussed on surveys and panels will include lay publics views.
Design of the ethical analysis activity	
Rigidity/inflexibility in approach	The ethical analysis approach that will be applied in SIENNA is designed to be flexible enough to be adapted in the three technological areas and to use various stakeholder engagement approaches and tools (outlined above in this section). The approach is designed to be open to stakeholders' input and sensitive to situation-specific dynamics as they develop, as

processes, July 2014. http://satoriproject.eu/media/Executive-summary_SATORI-D2.1.docx.pdf

Challenge	How SIENNA will address this
	recommended by the SATORI Handbook[56].
Lack of clarity about expectations	Stakeholders will be informed from the outset as to expectations and the kind of impact they can expect through their participation (e.g., via participant information sheets). Stakeholders will be motivated to provide input and actively participate.
Lack of transparency	Participants will be advised on how their contributions to the ethical analysis activities will be taken up and/or acknowledged in other work and our deliverables. SIENNA will work to maximise transparent processes by explaining its methods in publicly-available deliverables that present the results of the ethical analysis (i.e., D2.4 Ethical assessment of genomics, D3.4 Ethical assessment of human enhancement and D4.4 Ethical assessment of HMI).
Implementation of the ethical analysis activity	
Lack of incentive for people to participate	Stakeholders may have various incentives to participate in foresight activities (e.g., learning, networking, lobbying, developing individual or collective strategies).[57] In organising events, we will provide clear information about the agenda, goals, and expected input from the stakeholders during the meetings. We will also try to ensure that the event location and food provided are pleasant and good and that stakeholder travel expenses are paid for as budgeted.
Assuring quality of the activity	This will be addressed using various measures: having a clear approach and methodology and policy for recruitment of stakeholders (addressed in event, task or work plans), good facilitation of activities, fostering an inclusive and participatory approach, managing expectations well, involving people and countries that normally do not participate on an equal footing in such activities.
Feedback and follow-up	
Lack of follow-up	When possible in stakeholder involvement activities we will ensure there is room for feedback from stakeholders and possibilities for follow-up (e.g., via feedback forms, asking stakeholders follow-up questions, directing them to the final published reports). The SIENNA teams carrying out the activity will carefully reflect on the outcomes of the activities and their implications for the future directions of the project.

Table 6: Stakeholder challenges

3.6. Implementation and timelines

Ethical analysis takes place in the following SIENNA tasks:

[56] Shelley-Egan, Clare, David Wright, Rok Benčin, Jelica Šumič Riha, Gregor Strle, Daniela Ovadia, Adelina Pastor Cañedo, Christine Angeli, Menelaos Sotiriou, *SATORI Deliverable D2.1 Report (handbook) of participatory processes,* July 2014. http://satoriproject.eu/media/Executive-summary_SATORI-D2.1.docx.pdf

[57] Saritas, Ozcan, Lisa A Pace and S.I.P. Stalpers, "Stakeholder participation and dialogue in foresight", in Kristian Borch, Sandra M. Dingli, Michael Søgaard Jørgensen (eds.), *Participation and Interaction in Foresight: Dialogue, Dissemination and Visions,* Edward Elgar, Publishing Cheltenham, 2013, pp. 35-69 [p. 49]

- Tasks 2.4, 3.4 and 4.4, all titled "Analysis of current and future ethical issues", and focusing on human genomics, human enhancement, and AI & Robotics, respectively. All three run from month 6 to 23 (March 2018 to August 2019).
- Tasks 2.7, 3.7 and 4.7, all titled "Proposal for an ethical framework", and focusing on the three respective technologies. These tasks run from month 23 to 30 (August 2019 to March 2020).
- Task 5.5, Enhancement of the existing ethical framework (for all three technologies) – months 31-38 (April 2020 to November 2020).
- Task 6.1, Adapt and exploit methods developed in this project for ethical analysis of emerging technologies in other domains – months 30-41 (March 2020 to February 2021).
- Task 6.5, Reconcile needs of researchers and the legitimate concerns of citizens – months 30-41 (March 2020 to February 2021).

The overall timeline is that we first do an ethical analysis of the three technologies aimed at identifying and analysing current and potential future ethical issues (months 6-23). We then use these analyses and the results from our panels of citizens and surveys to arrive at ethical frameworks for the three technologies (months 23-30). Subsequently, we will use our findings to enhance existing ethical frameworks (months 31-38). We will also broaden our approach to ethical analysis to be applicable to any emerging technology (months 30-41) and we will apply our approach to the problem of adequate communication between scientists and citizens regarding ethical concerns (months 30-41).

The table below (table 7) offers a detailed timeline for the first series of these tasks, 2.4, 3.4 and 4.4 (ethical analysis).

Month	Ethical analysis sub-task	Other
6 (March 2018)		Finalise workplan
7 (April 2018)	Start preparations of ethical analysis (3, 5-7) Start work on section 3 (approach) Prepare for local foresight workshop	Start work on section 2 (review) Start work country reports (section 4)
8 (May 2018)	Complete section 3 (approach)	
	Work on stage 1, 2, 3 of ethical analysis	
	Start interview process for foresight analysis	
	Continue preparations for local foresight workshop	
9 (June 2018)	Continue work on stage 1, 2, 3 of ethical analysis	First draft of section 2 (review)
	Local foresight workshops	
	Selection of case studies (artefacts, domains)	
10 (July 2018)	Start with identification of ethical issues/impacts (technology and artefact levels)	First draft country reports (section 4)
	Start with case studies	
11 (August 2018)	Continue with case studies	Write section 4
12 (Sept 2018)	Continue with case studies	Final draft country reports (section 4)

Month	Ethical analysis sub-task	Other
13 (Oct 2018)	Foresight workshops (UT) (or later)	Write section 4
	Continue with case studies	
14 (Nov 2018)	Continue with case studies	
	Legal analysis workshop; discuss interim results	
15 (Dec 2018)	Continue with case studies	
16 (Jan 2019)	Continue with case studies	
17 (Feb 2019)	Continue with case studies	
18 (March 2019)	Early draft ethical analysis	
19 (April 2019)	Continue with case studies	
	Ethical analysis workshop; discuss interim results	
	Panels of citizens (uses interim results)	
20 (May 2019)	Continue with case studies	
21 (June 2019)	Edit and improve draft deliverable	
	Submit for quality assurance by June 15th	
22 (July 2019)	Ethical challenges workshops, early July	
	Process QA + workshop feedback	
23 (Aug 2019)	Submit deliverable early August (EC submission deadline 30 August 2019)	

Table 7: Proposed detailed timeline for SIENNA tasks 2.4, 3.4 and 4.4

In this section of the Handbook, we outlined the SIENNA approach to ethical analysis of emerging technologies, particularly human enhancement, human genomics and AI and robotics. Our detailed six-step approach is intended to allow for broad ethical analysis of the technological fields that we study, including ethical analysis of general features of the technology, of specific developed products, and of particular uses of the technology. It moreover allows for the ethical analysis of current as well as anticipated future technological developments, uses and impacts, and engages stakeholders and the public, who are given a role in shaping the results of the ethical analysis and subsequent recommendations. Our approach is also informed by empirical studies of the technology and its uses and impacts, including methods of impact assessment and foresight analysis.

In our subsequent ethical studies of the three fields that are under consideration in SIENNA, we will further apply and refine our approach. It will be interesting to learn the extent to which the approach fits all three technologies, or to which extent differentiation in approaches will turn out to be necessary for them. We will learn from these findings and they fill provide useful input for the generalized approach for the ethical assessment of emerging fields and technologies that we will develop later on in the project.

4. Approach for the legal including human rights study (Task 1.2)

4.1. Introduction and overview

This section outlines the approach[58] for legal research carried out in the SIENNA project (hereinafter, in this section, the Approach). The basics of the Approach have been set in the SIENNA Description of Actions (DoA) document. The section builds on that work. It provides reasons for the choice of the Approach, as well as outlines its limitations and challenges.

The Approach will be used to carry out legal research in work packages (WPs) 2, 3 and 4. These WPs are devoted to genomics (WP 2) human enhancement (WP 3), and Artificial Intelligence (AI) and robotics (WP 4), further referred to as *the three technological areas* or *fields*. The results of the legal research will help develop ethical frameworks that shall take into account existing legal frameworks (SIENNA's objective 1). In addition, together with the outcomes of the SIENNA ethical and socio-economic analysis, they will inform proposals for revisions of existing legal frameworks (task 5.6).

After carrying out the legal research in WPs 2, 3 and 4, the Approach will be evaluated to refine it and arrive at more general methods for legal analysis of emerging technologies (task 6.2), with an overarching goal of developing ethical codes and operational guidelines that are anchored in human rights standards.

4.2. Terminology

Hard law - authoritative rules backed by coercive force exercised at the national level by a legitimately constituted (democratic) nation-state and constituted in the supranational context by binding commitments voluntarily entered into between sovereign states (typified by public international law).[59]
Human rights matrix - a table structured around established human rights and selected technologies or technological areas that can be used to map human rights impacts of those technologies.
Law - encompasses both hard 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.[60] Regulation can also mean a species of hard law, e.g., a type of EU legal act with

[58] This section also benefited from suggestions, feedback and comments from Marcelo Araujo, Federal University of Rio de Janeiro and Joshua Davis, University of Cape Town and the participants of the SIENNA Fundamentals workshop held on 4-5 April 2018 in Uppsala.

[59] 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.

[60] Lessig, Lawrence, Code and Other Laws of Cyberspace, New York, 1999. See also: 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.

a direct effect defined by Article 288 of the Treaty on the Functioning of the European Union[61] or, in some instances, a legal act adopted at the national level.

Self-regulation - normative instruments, i.e., codes of conduct, ethical codes, adopted by private non-governmental entities.[62]

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.[63]

4.3. Objectives

The objectives of the SIENNA legal research have been pre-defined in the DoA. According to that document, project researchers shall meet the following objectives in relation to the three technological areas:

1. Map and study relevant norms from international and regional legal orders;
2. Explore how the three technological areas might affect the rights of individuals and groups;
3. Explore which human rights standards may be relevant to consider in establishing methods to avoid or alleviate negative impacts and encourage positive impacts;
4. Analyse selected EU and non-EU countries' legislations pertinent to the three technological areas;
5. Compare national laws against the international and regional norms and human rights standards;
6. Analyse the findings in terms of their regulatory-design characteristics[64].

4.4. Benefits of the approach

New technologies raise numerous regulatory questions. Regulatory dilemmas can only be resolved if there is some normative anchor point. The basic normative presupposition[65] of the Approach is that the development and use of new technologies ought to remain consistent with fundamental rights and respect human dignity. Consequently, the mentioned "anchor point" can be found in the common heritage of human rights standards. Human rights have been referred to as the "most general legal and ethical environment to deploy in order to promote and guarantee responsible advances in science

[61] 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."

[62] Goncales, Maria Eduarda, 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

[63] Goncales, Maria Eduarda, 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

[64] See section 4.6.2. for further explanation on "regulatory-design".

[65] On "normative clarity" as a criterion to evaluate legal scholarship see: Rubin, Edward L., On beyond Truth: A Theory for Evaluating Legal Scholarship, *California Law Review*, Vol. 80, Issue 4, July 1992, pp. 889-963 [pp. 915-917].

in technology" and a "touchstone for regulation".[66] All regulatory challenges can be situated in a framework of common overarching principles that constitute the sphere of rights and freedoms.[67] As "invariants in the normative discourse around technological development", and a "common thread defined by concerns about the protection of important values"[68] human rights encompass a wide variety of issues and different legal sub-fields. Due to their normative structure, human rights can help foster the regulatory coherence.[69]

Developments in genomics, human enhancement, AI and robotics have considerable human rights implications[70]. Human rights frameworks have proven to be able to accommodate new social and technological developments. D. Ruggiu rightly points out:

> With regard to the future perspective opened up by scientific research, the flexible nature of human rights principles enables them to adapt to new developments, and to the future impacts of current research. (…) [P]rinciples can serve as a hinge between the present and the future by solving co-ordination issues among instruments of different nature but pursuing the same goals as a whole.[71]

The human rights relevance of the three technological areas, as well as the fact that Europe, both through the EU and the Council of Europe, is politically and legally committed to respect human rights are the two main reasons for choosing the human rights perspective to legal analysis. The ability to adapt general human rights principles to regulatory challenges posed by new technologies is among its main benefits. It may prove particularly helpful in cases where there is no technology-specific legislation and legal questions need to be resolved by using general principles.

In addition, by considering the impacts of the development in the three technological areas on the rights to equality and non-discrimination, a human rights approach to legal analysis can foster a proper consideration of sex, gender and equality issues, which should be "mainstreamed" throughout all stages of the project.[72] Moreover, the exploration of the mandates and competences of different international legal orders and actors therein (such as the UN and its agencies, as well the Council of Europe, the Organization of American States and African Union) will enable us to establish which of them could, potentially in the future, become the driving force behind new legal provisions governing the three technological fields. Furthermore, the approach to analysing EU law will allow us to assess the extent, to which addressing the identified legal issues including human rights challenges, lies within

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[66] Palmerini, Erica, Regulating Emerging Robotic Technologies in Europe: Robotics facing Law and Ethics (RoboLaw), D6.2 Guidelines on Regulating Robotics, RoboLaw project, 2014, p.20

[67] Leenes, Ronald, Erica Palmerini, Bert-Jaap Koops, Andrea Bertolini, Pericle Salvini, Federico Lucivero, "Regulatory challenges of robotics: some guidelines for addressing legal and ethical issues", *Law, Innovation and Technology*, Vol. 9, Issue 1, 2017, pp. 1-44.

[68] Palmerini, Erica, "The interplay between law and technology, or the RoboLaw project in context", in Erica Palmerini and Elettra Stradella (eds.), *Law and Technology. The Challenge of Regulating Technological Development*, Pisa University Press, Pisa, 2013, p. 7-24 [p. 23].

[69] Ruggiu, Daniele, "Temporal Perspectives of the Nanotechnological Challenge to Regulation: How Human Rights Can Contribute to the Present and Future of Nanotechnologies", *Nanotechnologies*, Vol. 7, Issue 3, December 2013, pp. 201-215 [p. 207].

[70] See for example: 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*, published online 27 March 2018. https://www.tandfonline.com/doi/abs/10.1080/17579961.2018.1452177, Rathenau Institute, Human Rights in the Robot Age, 2017. https://www.rathenau.nl/sites/default/files/2018-02/Human%20Rights%20in%20the%20Robot%20Age-Rathenau%20Instituut-2017.pdf.

[71] Ruggiu, Daniele, "Temporal Perspectives of the Nanotechnological Challenge to Regulation: How Human Rights Can Contribute to the Present and Future of Nanotechnologies", *Nanotechnologies*, Vol. 7, Issue 3, December 2013, pp. 201-215 [p. 211].

[72] See SIENNA, Description of Actions, Part B, p. 18.

the competences of the EU. This will be of crucial importance in formulating recommendations on possible changes to existing EU legal frameworks.

Due to resource limitations, it will not be possible to carry out a comparison, between different jurisdictions, that covers all legal issues and all areas of law. Nevertheless, the wide range of countries covered in the project, the combination of general and specific questions for the study of national laws, and the thematic coordination of national research with the analysis of international and regional laws will provide a useful overview of current state of the domestic law and legal responses to some of the key developments in the three technological areas.

4.5. Scope, limitations, challenges and strategies to tackle them

Aside from the need to adjust the scope of the research to available resources, we identified three further challenges. The first one is linked to significant differences between the three technological fields that will be the focus of the research, i.e., different stages of advancement, the degree of controversy, or their acceptance, the risks that they pose, as well as the intrinsic characteristics of a specific technology that make it unique for regulation.[73] In addition, while genomics and AI/robotics are technology specific, human enhancement is less about the use of a *particular* technology and more about the use of *any* technology for a particular purpose.

The divergences between the three areas inevitably results in the need to adapt and elaborate the shared, general approach to fit each technological field. Owing to the broad and distinct nature of each of them, the studies may have to be limited to:

- specific products within the three technological fields;
- fields of applications (e.g., use of robots in workplace or use of algorithms and AI by law enforcement);
- stages of technology (i.e., research, prototyping, testing, marketing, use by early adapters, well-established use);
- specific legal issues (e.g., ones that have not been adequately covered or are seen as critical in terms of their impact).

A combination of different limitations is possible. The scope will have a bearing on the area of law (sub-field) that will be studied e.g., if we choose to study the use of algorithms by law enforcement, the relevant legal area will include criminal law, while if we choose to focus on the use of care robots, the relevant area will include health law. The factors to be taken into consideration when deciding on the scope of legal analysis may include:

- coverage in existing literature (based on the findings and results of Tasks 2.1, 3.1, 4.1, review of legal literature) and, potentially, appearance in the case-law,
- regional and global political priorities,
- impact on society and its values,
- “newness” or novelty of the application,
- controversy.

The second challenge is linked to the differences between regional legal cultures. For SIENNA, the relevant differences are related, for example, to divergent conceptualisations of some rights (for instance “the right to life” in the Council of Europe and the Organization of American States, other examples include such basic concepts as “human dignity” or “privacy”). Moreover, in different legal cultures distinct solutions may be given to conflicts of rights. We will address this challenge by

[73] Palmerini, Erica, “The interplay between law and technology, or the RoboLaw project in context” in Erica Palmerini and Elettra Stradella (eds.), *Law and Technology. The Challenge of Regulating Technological Development*, Pisa: Pisa University Press, 2013, pp. 7-24 [p. 22].

accounting for the differences, the possible conflicts of rights and available solutions. Undoubtedly, the existing differences will require, from the researchers, a deeper level of understanding of rules and concepts to arrive at correct conclusions.[74] Therefore, it will help that legal research in SIENNA shall be accompanied by ethical analysis and studies of the societal acceptance and awareness.

The third potential challenge may be the lack of technology-specific laws. In such cases, we may have to build on more general principles, rules and concepts, and assess whether and how they could apply to the new technologies or applications. In some cases, we may use analogy and locate similar situations to argue whether the same laws could apply in the novel contexts[75] (e.g., whether laws governing cosmetic surgery could provide a reference point or even a model for other cases of human enhancement).

4.6. Research questions, methods and approach

4.6.1. Research questions

Based on the objectives outlined above (section 3), the research will be **guided** by the following questions:

- What are the international and regional laws relevant to the areas of genomics, human enhancement and AI and robotics?
- Which rights of individuals (or groups) may potentially be affected by developments in the three technological areas? Which human rights standards may be relevant to consider in establishing methods to avoid or alleviate negative impacts and encourage positive impacts of those developments?
- To what extent are the existing legal frameworks adequate to deal with challenges posed by developments in the three technological areas?
- How might specific novel legal questions be solved in different jurisdictions according to different legal systems? What are the commonalities and differences between national legal systems with respect to those questions?
- What are the convergences, divergences and gaps between national and international legal orders for the three technologies? What are the possible ways to overcome the gaps?

4.6.2. Methods and approaches to analysing international, regional and national laws

Methods

A combination of doctrinal, functional, and law-in-context methods will be used to address the research questions. We will use the doctrinal method to study relevant laws. Doctrinal method is understood as research that gives "a systematic exposition of the principles, rules and concepts governing a particular legal field or institution and analyses the relationship between these principles,

[74] "Deeper level of the underlying cultural differences is of utmost importance for correctly judging similarities and differences at the surface level, most notably, but not exclusively, when legal systems from states belonging to rather different cultural traditions are compared." Van Hoecke, Mark, "Methodology of Comparative Legal Research", *Law and Method*, December 2015, pp. 1-35 [p. 27]. https://www.bjutijdschriften.nl/tijdschrift/lawandmethod/2015/12/RENM-D-14-00001

[75] Hutchinson, Terry, op. cit., p. 111.

rules and concepts with a view to solving unclarities and gaps in the existing law".[76] The basic aim of the doctrinal method is to describe the existing law in a way that is as neutral and consistent as possible to inform the audience how the law actually reads.[77] Description will be complemented by prescriptive elements to be further elaborated in task 5.6 ("Enhancement of the existing legal frameworks").[78] Typically, the doctrinal method is a two-part process which first involves locating the sources of the law, and then interpreting and analysing the text.[79] In the case of the SIENNA project, we will look at legal issues relevant to the three technological areas. Consequently, the initial steps of our research will consist of mapping the subject of our research in each technological area by identifying main legal issues including human rights implications. The mapping part of the legal research will begin with a literature review and will include the analysis of findings and results of tasks 2.1, 3.1, 4.1 (state of the art reviews). The selection of the sources of the law to be interpreted and analysed will therefore be influenced by those identified legal issues. Following the doctrinal study of norms, we will consider undertaking an analysis of their regulatory design-characteristics. This type of analysis would build on Roger Brownsword's three ethical stances to new technologies (i.e., utilitarian, dignitary, rights-based).[80] These stances offer prescriptive regulatory points of departure, either commanding to foster technology development and use (utilitarian), prohibitive to protect interests of those at risk (dignitary) or permissive to allow private choice (rights-based). Mapping and analysing findings along these characteristics could contribute to evaluation of existing regulation and to an improved design of future frameworks for each of the three technological fields.

For the national studies, particularly, in cases where there is little (if any) technology-specific legislation, for the purpose of comparative research, we may use the functional method. The idea behind it is to "look at the way practical problems of solving conflicts of interest are dealt with in different societies according to different legal systems".[81] The functional method instead of comparing rules, looks at solutions to practical problems with conflicting interests. In other words, in comparative research that uses functional method, the law that is compared is determined by reference to a social problem that is presumed to be similar across different jurisdictions.[82] If this is the case, we may address the question of how existing laws could apply to novel technologies or applications (e.g., are parents legally permitted to give their healthy children cognitive enhancers?).

In addition, to better integrate the legal research with other work in SIENNA, it may be complemented by the use of the law-in-context method,[83] the context being in this case primarily information and knowledge from other tasks (e.g., tasks 2.3, 3.3, 4.3 – "Current coverage by research ethics committees

[76] Smits, Jan M., "What is Legal Doctrine? On the Aims and Methods of legal-dogmatic research", in. Rob van Gestel, Hans-W. Micklitz and Edward L. Rubin (eds.), *Rethinking Legal Scholarship: A Transatlantic Dialogue, Cambridge University Press, New York,* 2017, pp. 207-228 [p. 210]
[77] Smits, Jan M., op. cit., 2017, pp. 213-214.
[78] Smits, Jan M., op. cit.,2017, pp. 216-217.
[79] Hutchinson, Terry, Nigel Duncan, "Defining and Describing What We Do: Doctrinal Legal Research", *Deakin Law Review,* Vo. 17, No. 1, 2012, pp. 83-119 [p. 110]
[80] Brownsword, Roger, *Rights, Regulation, and the Technological Revolution,* Oxford University Press, Oxford, 2008.
[81] Van Hoecke, Mark, "Methodology of Comparative Legal Research", *Law and Method*, December 2015, pp. 1-35 [p. 9].
[82] "A social problem can be defined at a very low level of abstraction—for instance, when the police may stop and search an individual on the street—or a much higher level of abstraction—for instance, how to guarantee fair and effective policing." Bignami, Francesca, "Formal versus Functional Method in Comparative Constitutional Law", *Osgoode Hall Law Journal,* 2016, pp. 442-471 [p. 445]. http://digitalcommons.osgoode.yorku.ca/ohlj/vol53/iss2/3
[83] See Van Hoecke, Mark, "Methodology of Comparative Legal Research", *Law and Method*, December 2015, pp. 1-35.

and in ethical codes", tasks 2.4, 3.4, 4.4 - "Analysis of current and future ethical issues", and tasks 2.5, 3.5, 4.5 - "Societal acceptance and awareness").

Approach to analysing international (including regional) law and to human rights analysis

In this phase of the analysis, we will study relevant international norms and regional legal orders. At the regional level, we will look at Council of Europe, the Organization of American States and African Union. The analysis will consist of:

- identifying relevant organisations (i.e., bodies competent to enact hard and soft law), exploring the scope of their mandate and competences that may provide ground for legal interventions affecting each of the studied technological areas,
- mapping relevant international sources of hard and soft law (i.e., legal documents, case law) and identifying their nature (binding, non-binding), assessing their validity, and relevance to genomics, human enhancement and AI and robotics,
- exploring the background and rationale for adopting the laws and its relationship to genomics, human enhancement and AI and robotics,
- systematising the norms and, when methodologically justified, checking if there are any inconsistencies between them,
- identifying gaps.

First, based on the literature review and the analysis of findings and results of tasks 2.1, 3.1, 4.1 (state of the art reviews) we will identify key legal issues related to each technological area.

Example: *Based on a preliminary literature review, in the case of human enhancement technologies, the following legal issues can be identified:* ○ *the problem of drawing the line between treatment and enhancement, and consequently separating a medical application of a given technology from a non-therapeutic enhancement application and developing a clean distinction between legally allowed (or even obligatory) use and ethically doubtful practice that consequently would be liable to legal regulation or prosecution,*[84] ○ *whether the right to self-determination or the right to identity in relation to the body includes in its scope and justifies human enhancement, and what are the limits, if any, to the possibility of enhancing ourselves,* ○ *once augmentation has been achieved, the question whether the post-human body should afford the guarantees of an organic body and what is the status of non-therapeutic (non-medical) body implants?*[85]

Table 8: Example – legal issues

As a tool to help us, we may use a human rights matrix to help further explore how human rights of individuals and groups may be affected by developments in each technological area. Within the human rights matrix, we will focus on different "generations" of rights.[86] Our point of departure will be the

[84] European Parliament, Science and Technology Options Assessment, Human Enhancement – Study, Brussels, 2009, p. 134. https://www.itas.kit.edu/downloads/etag_coua09a.pdf

[85] Palmerini, Erica, "A legal perspective on body implants for therapy and enhancement", *International Review of Law, Computers & Technology,* Vol. 29, Issues 2-3, 2015, pp. 226-244 [p. 239].

[86] On the concept of "generations" of human rights, and criticism thereof, see for example: Zieck, Marjoleine Y. A., "The Concept of "Generations" of Human Rights and the Right to Benefit from the Common Heritage of Mankind with Reference to Extraterrestrial Realms", *Verfassung und Recht in Übersee / Law and Politics in*

Universal Declaration of Human Rights[87], the International Covenant on Civil and Political Rights[88] and the International Covenant on Economic, Social and Cultural Rights[89], but we will also consider different regional human rights documents (e.g., the European Convention on Human Rights[90], the African Charter on Humans and Peoples' Rights[91]). Filling out the matrix will allow us to map the human rights at stake, identify areas of heightened concern and explore the potential positive impacts of the technologies on human rights. The result of this part of the analysis will be a list of potential human rights implications for each technological area.

After listing the legal issues including human rights challenges, we will identify the organisations who have the competence and authority to address these issues and identify the hard and soft law tools at their disposal. We will look at standards of human rights protection established and elaborated by the treaty monitoring bodies and enforcement bodies that may be relevant to consider in establishing ways to avoid or alleviate negative impacts and promote the positive impacts of the three technologies. Legal instruments, relevant guidance and case law will be studied with the aim of exploring the extent to which the existing body of international and regional law provides appropriate protection to human rights in light of new challenges.[92] This should allow us to identify the gaps and tackle the question of the extent to which existing legal frameworks are adequate to deal with challenges posed by developments in the three areas. Based on the results we will consider how existing human rights standards should shape the future legislation and whether the new challenges should lead to the strengthening or, possibly, to establishment of new human rights,[93] which will feed into recommendations in WP 5 (the Consortium's proposals).

4.6.3. Approach to analysing EU law

The legal system of the European Union has several distinct features that need to be taken into consideration in the analysis. These, among others, include the following characteristics:[94]

- the EU acts only within the limits of the competences that member countries have conferred upon it in the Treaties (principle of conferral laid down in Article 5 of the Treaty on European Union);

Africa, Asia and Latin America, Vol. 25, No. 2, 1992, pp. 161-198 or Macklem, Patrick, "Human rights in international law: three generations or one?", *London Review of International Law*, Volume 3, Issue 1, 2015, pp. 61–92.

[87] UN General Assembly, "Universal Declaration of Human Rights." United Nations, 217 (III) A, 1948, Paris. http://www.un.org/en/universal-declaration-human-rights/

[88] UN General Assembly, International Covenant on Civil and Political Rights, 16 December 1966, United Nations, Treaty Series, vol. 999, p. 171.

[89] UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3.

[90] Council of Europe, European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14, 4 November 1950, ETS 5.

[91] Organization of African Unity (OAU), African Charter on Human and Peoples' Rights ("Banjul Charter"), 27 June 1981, CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982).

[92] Liefaard, Tom, Aart Hendriks and Daniella Zlotnik, From Law to Practice: Towards a Roadmap to Strengthen Children's Rights in the Era of Biomedicine, Leiden, 2017. https://rm.coe.int/leiden-university-report-biomedicine-final/168072fb46

[93] For an example of how this may be done see de Hert, Paul, "A right to identity the internet of things", Strasbourg: UNESCO, 2008. https://pure.uvt.nl/ws/files/1069135/de_Hert-Paul.pdf
The author looks at the case law of the European Court of Human Rights in view of new challenges to identity. He addresses the question whether traditional human rights will adequately protect it or whether there is a need to establish a new human rights – the right to identity.

[94] See Lenaerts, Koen, José A. Gutiérrez-Fons, To Say What the Law of the EU Is: Methods of Interpretation and the European Court of Justice, EUI Working Paper 2013/9, Academy of European Law, p. 5. http://cadmus.eui.eu/handle/1814/28339

- EU legislation is drafted in several languages and the different language versions are all equally authentic; an interpretation of a provision of community law thus involves a comparison of the different language versions;
- EU law uses terminology which is peculiar to it and legal concepts do not necessarily have the same meaning in community law and in the law of various member states
- the role of *travaux preparatoires* for interpreting EU law is still being debated.[95]

Bearing in mind its distinct features, in the case of the EU law, the analysis will focus on exploring the extent to which addressing the identified legal issues including human rights challenges lies within the competences of the EU. This will be achieved by analysing the principle of conferral, as well as the current and possible limits of positive and negative integration in the areas the three technological fields trigger.

4.6.4. Approach to national studies and comparative research

In the next part of the research, we will conduct an analysis of selected EU and non-EU countries' legislations pertinent to the three technological areas, compare the national laws with each other, and with the international and regional norms and human rights standards.

For the analysis of national legislations, we have selected a total of 13 countries, eight EU and five non-EU countries, to provide a wide range of differing norms and underlying values. For the EU comparative analysis, the following countries will be studied to ensure different regional representation: (1) a Nordic state, Sweden; (2) a Benelux state, The Netherlands; (3) a British Isles state, the United Kingdom; (4) a Central European state, Germany; (5, 6 and 7) three Mediterranean (and/or Alpine) countries, France, Greece and Spain; and (8) an Eastern European state, Poland. These countries cover the civil code and common law states, and different constitutional traditions. For a wider comparative perspective beyond the EU, the partners considered coverage in terms of geography, culture, scientific developments and the protection of human rights and shortlisted the following countries for analysis (1) the United States, a North American country; (2) Brazil, a South American country; (3) Japan and (4) China, two Asian countries; and (5) South Africa, an African country.

The leaders of tasks 2.2, 3.2, and 4.2 along with those for task 1.2 will, together, formulate guidelines for national studies in each technological area. The guidelines will combine general and specific questions and consist of an outline for the national reports. As feasible, relevant examples from test studies carried out by 2.2, 3.2, 4.2 task leads will be provided. All partners will be invited to contribute in establishing the list of questions to ensure cultural differences are taken into consideration and there is a common understanding of all terms used.

For the purpose of the comparison between national and international level, the questions to be explored at the national level will be formulated based on the list of issues including human rights implications identified in the previous stages of the legal research. In addition, each national report should include information on the relationship between the international law and national law (whether the approach is monist or dualist). General, exploratory questions may include the following:

[95] According to some scholars the role of travaux preparatoires as a source of law is rather insignificant (see van gestel, Rob, Hans-Wolfgang Micklitz, "Why Methods Matter in European Legal Scholarship", *European Law Journal*, Vol. 20, Issue 3, May 2014, pp. 292–316 [p. 311]), at the same time is has been highlighted that travaux preparatoires have gained increasing importance (see Lenaerts, Koen, José A. Gutiérrez-Fons, To Say What the Law of the EU Is: Methods of Interpretation and the European Court of Justice, EUI Working Paper 2013/9, Academy of European Law, p. 19. http://cadmus.eui.eu/handle/1814/28339

- Are there any specific laws related to the three technologies? Have developments in the technological area led to amendments in constitutional rights and/or legislation bearing on constitutional rights?
- Have there been attempts or plans to adopt new law in response to development in the technological area?

The output of national analysis will be 13 national reports ascertaining the state of law and current legal responses of the three technologies. The results of research at national level will be compared with each other (i.e., horizontal comparison), accounting for differences in each of the legal systems and values that underpin these systems. Afterwards, we will conduct a cross-level comparison between national and international levels to identify convergences, divergences and gaps between them (i.e., vertical comparison). We will take stock of the often divergent, regulatory objectives of the compared legal systems (national, international, regional, EU), as well as potential structural interdependence, which may prevent researchers from treating them as if they were completely separate and independent units.[96] We are interested in the interaction between the different levels (if there is any) - e.g., to what extent the legal solutions to the questions posed are influenced by international norms.

4.7. Plans for implementation

Tasks 2.2, 3.2 and 4.2 start in month 6 of the project (March 2018) and finish in month 18 (March 2019). The specific scope for exploration in these tasks will be established by 2.2, 3.2, 4.2 task leaders based on the state of the art and literature reviews, and in consultation with partners and experts whose advice on the choice of issues to be further explored should be instrumental. The scope of the legal research needs to be aligned with other work (ethical analysis, socio-economic impact assessment, review of ethical codes, citizen panels and surveys) carried out in SIENNA. With regard to limiting the scope of technological areas the decisions will be made after the completion of the state of the art review (end of month 6, i.e., March 2018). Task 2.2, 3.2, 4.2 leaders will formulate questions for national studies after the identification of the main issues and human rights at stake for each technological area.

Proposed timeline for tasks 2.2, 3.2, 4.2 (The exact timelines should be established by 2.2, 3.2, 4.2 task leaders and included in the work plans for each task.)

Months	Stage	Lead responsibility	Others to involve
February 2018	Share the Approach with national partners, collect and incorporate their feedback.	1.2 task lead	
April 2018	Establish work plans for tasks 2.2, 3.2, 4.2.	2.2, 3.2, 4.2 task leads	
March 2018 – April 2018	Map legal issues and human rights challenges in the three areas (based on 2.1, 3.1, 4.1 and literature review).	2.2, 3.2, 4.2 task leads	For each task, partners with more time allocated for that task

[96] Van Hoecke, Mark, op.cit., p. 21.

Months	Stage	Lead responsibility	Others to involve
April – May 2018	Formulate guidelines for national reports (questions and outlines of the national reports). Consult with national partners. Prepare reference reports (examples) - leaders of tasks 2.2, 3.2, 4.2.	2.2, 3.2, 4.2 task leads 1.2 task lead	For each task, partners with more time allocated for that task **National partners**
May 2018 – October 2018	Analyse international, regional, EU laws including human rights standards.	2.2, 3.2, 4.2 task leads	For each task, partners with more time allocated for that task.
June 2018 – October 2018	Work on national reports by national partners. (Task leads are responsible for quality assurance of the national reports)	2.2, 3.2, 4.2 task leads	**National partners**
End of October/ beginning of November 2018 (tbc)	Legal Analysis Workshop (Warsaw)	1.2 task lead	Consortium, EU-lawmakers (2-4), Japanese Associate
November 2018-January 2019	Comparative analysis based on national reports and the results of the research of international, regional and EU laws	2.2, 3.2, 4.2 task leads	For each task, partners with more time allocated for that task.
February 2019-March 2019	Finalise deliverables 2.2, 3.2, 4.2, Quality assurance (deliverables 2.2, 3.2, 4.2)	2.2, 3.2, 4.2 task leads	For each task, partners with more time allocated for that task. Quality assurance reviewers

Table 9: Proposed timeline for tasks 2.2, 3.2, 4.2

4.8. Guidelines and recommendations

The design of the legal research in SIENNA assumes that this Approach will be evaluated at a later stage in the project, to refine it and arrive at more general methods for legal analysis of emerging technologies. Therefore, the Approach should be viewed as a proposal and as a living document. Task leaders should keep track of when they deviate from the proposed approach and what the reasons behind that decision are (ideally, this should be discussed with WP leaders and/or Project Management Committee (PMC) as warranted and documented).

5. Approach for the study of societal acceptance and awareness (Task 1.3)

5.1. Introduction

A key feature of the SIENNA project is that stakeholders, including the general public, will be engaged throughout the process. The involvement of the general public is particularly important; research and innovation into new and emerging technologies carries an ongoing risk of being in tension with public concerns. It is therefore crucial to understand and consider such concerns. One method of exploring the general publics' views of the SIENNA project is through empirical research. This covers an international public opinion survey[97] and five one-day citizen panels[98], with both elements providing data to better understand citizens' awareness, views, ethical concerns and expectations in relation to three technologies under study.

5.2. Overview of approach, terminology and methods to be used

Our proposed approach comprises:

- Public opinion surveys conducted by telephone in 11 countries, including seven in the EU (France, Germany, Greece, Netherlands, Poland, Spain and Sweden) and four outside of Europe (Brazil, South Korea, South Africa and the United States).
- Citizen panels conducted over one day in five EU countries (France, Germany, Greece, Poland and Spain).

In the sections below, we outline our approach to undertaking each element of the research, beginning with the public opinion survey.

Part 1: Public Opinion Survey

We will conduct public opinion surveys in 11 countries (France, Germany, Greece, Netherlands, Poland, Spain, Sweden, Brazil, South Korea, South Africa and the United States) to determine the levels of awareness of the three technologies under study. The surveys will also seek to assess the level of public acceptance of the technologies in relation to a range of applications.

Data collection mode

We recommend that surveys are conducted by Computer Assisted Telephone Interviewing (CATI). A CATI approach holds several advantages over other data collection methods:

- It will deliver a more representative sample than would be achieved by an online method. The dual frame design that we propose will cover more than 90% of the population in all 11 countries. We will minimise any bias in the sample by randomly selecting an adult at random to participate in fixed line households and making repeat calls to numbers to maximise the chance of an interview.
- The role of the CATI interviewer will be important in keeping respondents engaged in the survey, given the potential complexity of some of the topics covered.
- It is a more cost-effective approach compared with face-to-face interviewing. If a face-to-face approach were adopted, we would need to reduce the number of countries and/or respondents per country.

[97] This also relates to Task numbers 2.5, 3.5 and 4.5.
[98] This also relates to Task numbers 2.6, 3.6 and 4.6.

Kantar Public is ideally positioned to conduct CATI surveys across the range of countries proposed and will work across its central and local teams to deliver fieldwork to the high global standards it implements.

Sampling approach

We propose to use a dual frame (mixed landline and mobile) Random Digit Dialling (RDD) sample design with a minimum of five call backs to numbers with non-final outcomes. The dual frame will provide almost complete coverage of the 18+ population whilst the random approach ensures all adults have a non-zero probability of selection. A minimum of five calls to the same number will reduce the level of non-contact and maximise response rates, thus improving the representativeness of the achieved sample and minimising the potential bias from non-responders.

To keep fieldwork costs down yet still maintain high coverage of the population, we will make use of telephone directories augmented by other commercially available sources (especially those harvested from public social media) to build a list assisted sampling frame for the fixed line sample. For the mobile sample there are no publicly available directories; therefore, we will use a traditional RDD approach and draw a sample of random numbers from each country's mobile numbering plan. The person answering the phone will be asked to participate in the mobile sample, whilst in fixed line households one adult aged 18+ will be randomly selected from all adults in the household. Only this person can participate; no replacements will be permitted.

We have costed on the basis of a Fixed/Mobile sample mix in each country that minimises the differences in the population and respondent profiles by age within gender, working status and phone ownership (mobile only, fixed line or both). The mix in each country is included in the table below.

Country	Fixed line %	Mobile %
France	50%	50%
Germany	50%	50%
Greece	50%	50%
Netherlands	40%	60%
Poland	70%	30%
Spain	40%	60%
Sweden	30%	70%
Brazil	20%	80%
South Korea	20%	80%
South Africa	5%	95%
United States	20%	80%

Table 10: Recommended fixed/mobile sample mix per country

The achieved sample in each country will be 1,000 interviews. This size represents a sufficiently large and robust sample in order to support comparison of results across key sub-groups (for example, by age, gender and education level).

Questionnaire development

The questionnaire will need to be carefully designed to reflect the complexity of the topics while also ensuring that information is presented to respondents in language that they understand. Members of our Kantar Public UK team are experts in questionnaire design and have experience of developing questions for a range of challenging topics, including in the fields of science and technology. The content of the survey will be developed by the WP leaders (of each technology domain) in English, and the formulation of the questions will be re-worked iteratively with the Kantar UK team.

As part of the survey development, we will conduct a number of cognitive interviews across three countries (South Africa, Poland and the Netherlands). Cognitive interviewing is a versatile technique that allows the critical evaluation of the transfer of information. It is commonly used in survey research to explore how participants understand, mentally process and respond to the presented material and aims to identify where problems are experienced. This technique will help to capture how respondents may interpret some of the key terms and concepts covered by the research, enabling us to set the parameters of what can be covered by the survey (for example, any concepts that are too challenging to ask about in a quantitative survey), establish appropriate language to use, and assess if any particular terms will need to be adapted for the countries included in the cognitive testing. For the countries not included in the cognitive testing, the appropriateness of language will be assessed as part of the local review and translation stages.

We will conduct 10 cognitive interviews in each of the three countries. Specialist recruitment teams in each country will recruit respondents for these interviews to ensure a broad sample profile (by age, gender and other important demographics). The interviews will be conducted by local researchers, but the full process will be overseen by members of Kantar Public's lead UK-based team. Interviews will be conducted in the local languages in each country. Following completion of the testing, Kantar Public will provide a report that includes recommendations for changes to the questionnaire. In addition to this cognitive testing, local teams in all countries will review draft questionnaires, to ensure appropriateness of language and terminology.

Kantar Public will also conduct a small-scale pilot of 30 interviews across all 11 countries in advance of the start of main stage fieldwork. This will allow us to assess any further issues with the questionnaire and make any necessary revisions.

The average questionnaire length will be 15 minutes. We are confident that this will allow the number of questions required for each technology (around 8 per technology) to be included in the questionnaire, alongside demographic questions[99]. Furthermore, a longer interview length should be avoided to minimise the risk of a loss of engagement among respondents, which can result in higher drop-out rates and poorer data quality.

We set out the key stages and timescales in the questionnaire development process in the 'Plans for implementation' section. We see the key stages in this process as follows:

- Ethics review of the general survey approach (SIENNA lead)[100]
- Review of related surveys to identify existing information and any relevant questions to include in this survey – to involve the PI responsible for each technology domain WP working in partnership with Kantar Public.
- Identification of key objectives for the survey (and panels) in relation to the three technologies – to be led by the PI responsible for each technology domain WP.
- Development of an outline questionnaire based on information needs and existing information – to be led by the PI responsible for each technology domain WP in consultation with Kantar Public
- Refinement and agreement of the questionnaire prior to cognitive testing – led by Kantar Public, including representatives from each survey country, with the technology leads reviewing and approving the questionnaire, and involving members of the wider consortium where required
- Country-specific ethics approvals (as required) or additional ethics approvals from UT ethics committee and addressing ethical issues (Kantar Public and UT)
- Translation of survey into local languages for cognitive interviews

[99] We expect this to include age, gender, education/qualifications, wo0rking status, number of adults in the household, ethnicity and income.

[100] UT's institutional ethics committee will lead the ethics review. This will be supported by an ethics review by partner institutional ethics committees in countries where the activities will occur.

- Back translation
- Cognitive testing – conducted by Kantar Public
- Review of findings from cognitive testing and refinement of the questionnaire – led by Kantar Public, working with the technology leads
- Agreement of the survey questionnaire for the pilot – with technology leads responsible for approval
- Translation of final questionnaire into all survey languages
- Back translation
- Pilot fieldwork (30 interviews per country), to identify any remaining issues with the questionnaire – with fieldwork conducted by each of the survey countries and overseen by Kantar Public UK
- Agreement of the final survey questionnaire following the pilot – with technology leads responsible for final sign-off.

Translation and scripting

Kantar Public Brussels will be responsible for translation of questionnaires and other survey (and panel) related content. The steps for translation are as follows:

- Following agreement of the English questionnaire, a team of independent translators (T1) will translate the questionnaire into each of the required languages.
- This translation is proofread by a different translator (T2), who records any comments they have.
- A project manager then reviews these comments and agrees any revisions with the translators.
- The questionnaires for each language are then back-translated into English by a different translator (T3).
- The back-translated questions are then checked against the original English version by a final translator (T4). Any differences are reviewed closely, and changes agreed as appropriate.

Four different translators will work on each language, with separate responsibility for initial translation, proofreading, back-translation, and final review.

Each stage of the above process is managed and stored in an online platform developed by Kantar Public (NeferTT). This tool offers several benefits, including central monitoring and validation of the translation process, and enables clear version control.

Kantar Public will produce a CATI script for each language using its Nipo scripting platform. The questionnaire will first be scripted in English and, following completion of the translation process, a translated questionnaire for each language will be imported into the Nipo script. The scripting process will be overseen by members of the Kantar Brussels team, who will work closely in specifying scripting requirements and in extensively checking the scripts prior to the start of fieldwork.

The table below, shows the languages the script will be translated into for each survey country.

Country	**Survey languages**
France	French
Germany	German
Greece	Greek
Netherlands	Dutch
Poland	Polish
Spain	Spanish (Castillian)
Sweden	Swedish
Brazil	Portuguese
China	Mandarin

South Africa	Afrikaans, English, Sesotho, Zulu, Xhosa
United States	English (US)

Table 11: Survey languages for each country

Survey briefing

Prior to the start of fieldwork, the Kantar Public research team will brief colleagues in the country call centres about the survey. These briefings will include: background to the research; its importance; an overview of the survey content; briefing on the sampling approach and fieldwork requirements; and a question and answer session. Following this, field managers and supervisors in each country will brief their interviewers, drawing on material from the initial briefing.

Fieldwork preparation and management

Fieldwork will be overseen by the Kantar Public team. Fieldwork across 8 of the 11 countries (all in Europe and South Africa) will be managed through the Triple C coordination centre. This centre was first established for Eurobarometer and combines the efficiency of centralised project management with the skills of the local CATI centres. The Triple C team is responsible for management and release of sample, overseeing and reporting on fieldwork progress, and quality control of fieldwork. The local country call centres are responsible for interviewing and supervision of fieldwork. This approach ensures high standards and consistency in delivery across countries, which are crucial components for projects like this one, where robust international comparisons are required.

Strict quality control will be employed throughout fieldwork. This includes the following:

- All interviewers working on the project will be monitored by a supervisor or call centre manager to ensure compliance with person selection rules and that questions are read as scripted. Across the project, 10% of interviews conducted in each country will be monitored, either live or based on recordings.
- The Triple C team will conduct live monitoring of fieldwork, allowing them to review progress at a country and interviewer level. This will enable them to flag any concerns to countries, for example, non-compliance with contact requirements, high refusal rates or high levels of variation between interviewers in interview length.

Three of the survey countries are not covered by the Triple C infrastructure: Brazil, South Korea, and the United States. Fieldwork will be managed locally in each country based on a clear briefing from the Kantar team. Each country will work to the same requirements as the centralised countries in terms of fieldwork and quality control, and they will be required to provide daily updates to the central team during fieldwork.

Data processing and weighting

Following completion of the survey, Kantar Public will supply a raw data file in an agreed format (SPSS or Excel or both). The data file(s) will include all survey questions, along with other sample-based variables, and be clearly labelled and structured to ensure ease of use.

The survey data will be weighted based on a weighting scheme in line with our standard practice for similar projects[101]. The first stage of weighting will correct for different probabilities of selection associated with the number of adults in each household and each respondent's telephone usage patterns. This weighting will also adjust for the overlapping landline and cell sample frames and the

[101] Examples of other surveys where we have taken a similar approach include the 2016 Google Enumeration Survey and the 2016 and 2017 Pew Global Attitudes Surveys.

relative sizes of each frame and each sample. The second stage of weighting will adjust sample demographics to match population parameters to account for differential non-response. These weights will be calculated on the design weighted data using a 'calibration' approach. At a minimum we would propose to weight by gender, age, working status and region in this second stage.

The approach we describe is standard across such surveys: any telephone survey with a probabilistic design should calculate design weights to account for differential inclusion probabilities (e.g. due to the use of dual frames/number of adults in household) before calculating calibration/rim weights to deal with differential non-response by demographics. These demographics are commonly ones we know from experience do correlate with non-response but also tend to have a relationship with survey outcomes[102].

Reporting

Kantar Public will provide survey reports for each of the three technology areas. The survey reports will be quantitative in nature and will present results for each survey question, broken down by country, alongside commentary. We will also conduct bivariate analysis to draw out socio-demographic differences in results, both within and between countries. We will run significance tests on the data and only report difference that are significant at a 95% confidence level. Each of the three reports will be around 25 pages in length.

The SIENNA partners will have access to the survey data and will be able to produce additional publications beyond the short reports supplied by Kantar Public.

Part 2: Panels of citizens

Kantar Public will arrange, facilitate and analyse one-day panels of citizens in five EU countries (France, Germany, Spain, Poland and Greece). Citizen panels provide a forum for discussion of complex, sensitive and/or contentious topics on which it is important to gain a public view. They give members of the public the time, space and information that they need to consider issues and express opinions on topics about which they otherwise would not be sufficiently informed. Kantar Public will draw on experience of designing and running similar panels – including studies exploring science governance[103], shale gas[104], human genetics and genomics[105], synthetic biology[106], nanotechnology and health[107], and stem cells[108] (among others).

The overarching aim of the panels is to engage a range of citizens in consideration of the issues raised by the three technologies. The specific objectives for the research are two-fold:

- To explore and understand citizens' views of ethical issues associated with the technologies
- To begin to identify policies, ethics codes and regulations that citizens might want to see to address their concerns about these technologies.

[102] For further information on weighting please refer to: http://www.aapor.org/Education-Resources/Reports/Cell-Phone-Task-Force-Report/Weighting.aspx and http://surveyinsights.org/wp-content/uploads/2015/02/Weighting-Procedures-for-Dual-Frame-Telephone-Surveys.pdf.

[103] http://www.sciencewise-erc.org.uk/cms/assets/Uploads/Project-files/Science-Governance-and-Public-Engagement-Nov11.pdf

[104] http://webarchive.nationalarchives.gov.uk/20170110140243/http://www.sciencewise-erc.org.uk/cms/assets/Uploads/Publicengagementwithshalegasandoil.pdf

[105] http://webarchive.nationalarchives.gov.uk/20170110143618/http://www.sciencewise-erc.org.uk/cms/assets/Uploads/Project-files/Genomics-and-trust-report.pdf

[106] http://www.bbsrc.ac.uk/documents/1006-synthetic-biology-dialogue-pdf/

[107] https://www.epsrc.ac.uk/newsevents/pubs/nanotechnology-for-healthcare/

[108] https://www.mrc.ac.uk/documents/pdf/stem-cell-dialogue-final-report/

The proposed approach begins by providing only minimal background information on the topics and obtaining participants' initial views . However, over the course of the panel, expert witnesses (drawn from the SIENNA consortium) provide information to the group, informing participants' discussions. Discussions will build incrementally – first introducing participants to basic principles of the technology, then looking at potential applications and issues of ethical and legal regulation.

Discussions will always start from the point of view of participants, allowing them to frame content, raise questions and identify concerns or areas of uncertainty. Stimulus materials will be used to encourage discussion and provoke debate. Over the course of the day this approach will gain understanding of participants' attitudes. We will conduct a short pre- and post- event questionnaire (4 questions) during the panels, to begin to understand how panellists' views about the topics have developed over the course of the day.

Each panel will include 50 members of the public from a cross-section of demographics[109]. The panels will involve plenary sessions for welcoming and informing participants and broad discussion; smaller break-out sessions whereby the 50 are divided into 5 groups of 10 for in-depth, professionally facilitated, discussion,; and mechanisms for recording how individuals' views change (e.g., questionnaires at the start and end)..

The sample of 50 participants would broadly reflect the demographic profile of each country as far as possible – including: age, gender, ethnicity, educational attainment and/or income.

It will be important to include the views of vulnerable people in this research. Specific vulnerable groups have been identified by the consortium[110] for inclusion in the panels. Participants with these vulnerabilities will be integrated into the panels alongside non-vulnerable participants, with reasonable adjustments made to enable their participation (such as, wheelchair access, interpreter, provision for carer etc.).

Discussions will be led by Kantar Public researchers based in each of the five countries. They will be conducted using a discussion guide and stimulus developed by the Kantar Public team in the UK, and in agreement with the wider SIENNA team. We will conduct a researcher briefing (in English) with all local teams ahead of the panels, and the materials will be translated into local languages.

Discussions will be recorded (in the local language) by note-takers in each of the breakout groups,.[111] We will also audio-record discussions, although the quality of the recordings will depend on the acoustics of the individual venues and therefore cannot be guaranteed.

The analytical approach for the panel data will build upwards from the views of participants, whilst also structured using an analytical framework developed by the Kantar Public UK team, in agreement with the wider SIENNA team. This will involve:

- a process-driven element, whereby local teams will systematically review and examine data – from notes, recordings, pre- and post-event questionnaire data, and any outputs from activities and outputs developed during the panels – against an analytical framework which reflects the key questions for the research. This exercise will help to understand how the

[109] We expect to collect the following demographics: age, gender, ethnicity, family status, working status, educational attainment and/or income.
[110] Including, among others, people with mental or physical disabilities, health and genetic conditions, , and people that face exclusion.
[111] Please note, note takers will record data in the local language. These notes are intended to aid the local research teams in their analysis. While we are able to share these notes more widely, our costs do not currently include translation into other languages.

issues break down into themes and sub-themes, and how these apply across different groups of citizens;
- more intuitive elements involving brainstorm sessions, led by the lead researcher in each country, to consider, for example, what influences panellists' views about ethical issues associated with the technologies, and what principles people prioritise to ensure the technologies are beneficial to society, etc.
- a final element which draws the two together and provides a rounded picture of the issues under exploration.

The final output from the citizen panels will be qualitative in nature and draw out the key themes and insights that emerged from the one-day panels regarding the three technologies. These reports will be developed by the Kantar Public UK team, drawing from partial reports on each of the five panels developed by local Kantar Public researchers in each country (10-15 pages per country; in English; using an agreed template); thus, Kantar Public will deliver three reports that fully integrate the findings from across the five panels for each technology. Each of the three reports will be around 60 pages in length.

Below we provide a summary of the key stages for the citizens panels:
- Ethics review of the general panels approach (SIENNA lead[112]) and addressing ethical issues
- Identification of specific objectives for the citizens panels in relation to each of the three technologies – to be led by the PI responsible for each technology domain
- Review of existing knowledge to inform the recruitment and research approach (for example, identifying sampling and topic coverage priorities, relevant experts and information materials) – to involve the technology leads working in partnership with Kantar Public
- Development of an outline event plan (questions; focus; priorities for each technology) – led by Kantar Public, for discussion with technology leads
- Development of outline recruitment approach (suggested recruitment criteria) – led by Kantar Public, for discussion with technology leads
- Development, refinement and agreement of recruitment tools (quotas, screener) and research materials (event plan, discussion guide, stimulus materials, pre- and post-panel questionnaires) – led by Kantar Public, including representatives from each panel country, with the technology leads reviewing and approving the materials/tools, and involving members of the wider consortium where required
- Recruitment of panel participants – led by Kantar Public
- Translation of recruitment tools and research materials into relevant languages – led by Kantar Public (using the approach outlined above for survey translation)
- Researcher briefing with local Kantar Public teams in each of the panel countries – led by Kantar Public
- Citizen panels take place – led by Kantar Public local teams, involving expert witnesses (drawn from the SIENNA consortium)
- Analysis of panel data at local level, and then combined (across all five panels) for each technology – led by Kantar Public
- Drafting of three reports that fully integrate the findings from across the five panels for each technology – led by Kantar Public.

5.3. Benefits of the approach

The public opinion surveys will provide population measurement of awareness and public acceptance of the three technologies under study. As noted above, the telephone approach proposed for the

[112] UT's institutional ethics committee will lead the ethics review. This will be supported by an ethics review by partner institutional ethics committees in countries where the activities will occur.

survey is recommended over alternative approaches due to its ability to deliver a representative sample, to keep respondents engaged in the research, and in offering a more cost-effective option compared with a face-to-face survey.

The panels of citizens will allow for issues to be explored in some more depth, particularly in relation to the ethical issues associated with the technologies, and in identifying concerns and suggestions relevant to future polices, ethical codes and regulations.

The combination of countries included in the research reflects different levels of development in relation to the technologies, and allows for comparison of results between, as well as within, countries.

5.4. Scope, limitations and challenges

We describe some of the key challenges to the research, and how we propose to meet these, below:

- Developing content on complex topics, ensuring that the research objectives are met and that respondents are able to take on board and respond in an informed way. The questionnaire development testing and review phase will be crucial in assessing what questions we can reasonably ask of people and how to best frame these. The experts in the SIENNA consortium will also have considerable input into the content for the survey and panels, to ensure the key information requirements are being met.
- Prioritising questions and topics to cover in the research. It will not be possible to cover all of the areas of interest in relation to the technologies and difficult decisions may be needed in terms of what to prioritise. We recommend starting on identifying content at an early stage of the development process to ensure there is sufficient time for all parties to freely discuss and settle on priorities.
- Developing content that is appropriate and relevant in each survey or panel country, and for the range of respondents to be included in the research. As above, the questionnaire review and testing phase will be crucial in determining appropriate and relevant content. It is also likely that some complex topics will be outside of the scope of what can be covered in general population surveys.
- Effectively developing and delivering the citizen panels to ensure that the right mix of people are recruited and that they are all able to freely participate.
- Effectively managing the project across a large team. Kantar Public has put in place a project management approach that ensures the project gains the greatest benefit from our mix of expertise. The team will work closely both internally and with the consortium throughout the project to ensure smooth delivery.

A potential limitation of our proposed approach is that the surveys and panels of citizens are quite compressed in the overall SIENNA timetable. Both are scheduled to take place in early 2019, with only a small window between the two stages. For projects with a mixed-method approach (i.e. a mixture of quantitative and qualitative methods), we would usually recommend a larger window between the stages to allow the findings from one method to feed-into the design of the other method. This is not possible within the overall SIENNA timetable due to the need for other tasks to feed into the survey design and based on the deadlines for producing reports from the surveys and panels of citizens. While a larger gap between the two stages would have been preferable, we do not see this as a major limitation as the two methods have different objectives and, even in a longer timeframe, the extent to which one method could be informed by the other would be limited.

5.5. Plans for implementation

We present a timetable for Task 1.3 below (Table 12). This sets out the lead party responsible for each stage, alongside others who need to be involve, so all members of the consortium are aware of their expected commitment.

Dates (all week commencing)	Survey or panel task	Stage	Lead responsibility	Others to involve
April 2018	Both	UT ethics approval	UT	Kantar Public; Trilateral
April-May 2018	Both	Review of relevant surveys and literature; sources to be passed to Kantar Public (to feed-into question design)	WP leaders for each technology	Others in consortium; Kantar Public
Early June 2018	Both	List of key objectives for the survey and panel passed to Kantar Public	WP leaders for each technology	Others in consortium; Kantar Public
Late June 2018	Both	Objectives reviewed by Kantar Public and agreed with technology leads	Kantar Public	WP leaders for each technology
Mid-July 2018	Survey	Basic outline questions circulated for survey	WP leaders for each technology	Kantar Public
Mid-August 2018	Survey	Draft questionnaire for cognitive testing produced by Kantar Public and circulated	Kantar Public	WP leaders for each technology to feed into questionnaire development
Late August 2018	Survey	Draft questionnaire reviewed, and comments sent to Kantar Public	WP leaders for each technology	Others in consortium
December 2018	Panel	Discuss and agree broad outline structure for panel events (questions/ focus/ priorities for each technology)	Kantar Public/ WP leaders for each technology	Others in consortium
Mid-Sept 2018	Both	Country-specific ethics approvals (and or additional UT ethics committee approval) and addressing ethical issues	Kantar Public, UT	Trilateral and partners hosting the panels/surveys
September 2018	Survey	Questionnaire finalised and signed off for cognitive testing	Kantar Public	WP leaders for each technology
September 2018	Survey	Preparations for cognitive testing fieldwork (e.g., translations, probe guides)	Kantar Public	Members of consortium in each cognitive testing country to review translated questionnaires

Dates (all week commencing)	Survey or panel task	Stage	Lead responsibility	Others to involve
Early October 2018	Survey	Cognitive testing fieldwork	Kantar Public	Members of consortium welcome to observe interviews
December 2018	Panel	Develop and circulate summary recruitment approach for panel events for discussion (suggested recruitment criteria)	Kantar Public	WP leaders for each technology to be involved in discussions about recruitment criteria
November2018	Survey	Reporting from cognitive testing	Kantar Public	
December 2018	Survey	Questionnaire updated based on findings from cognitive testing	Kantar Public	WP leaders for each technology to be involved in discussions on questionnaire
January 2019	Panel	Develop and circulate outline structure of research materials for panels (topic guide outline; list of stimuli; pre/post questionnaire topics)	Kantar Public	WP leaders for each technology to be involved in review / discussion of outline structure
December 2018 – February 2019	Panel	Draft panel recruitment materials developed and circulated (quotas; screening tools)	Kantar Public	WP leaders for each technology (and others?) to review
December 2018 – January 2019	Survey	Questionnaire reviewed (including translations) and signed-off for pilot	WP leaders for each technology	Others in consortium
Jan – Feb 2019	Panel	Draft panel research materials produced and circulated (topic guide; stimulus)	Kantar Public	WP leaders for each technology (and others?) to review
Feb 2019	Panel	Draft panel recruitment materials reviewed, and comments sent to Kantar Public (quotas; screening tools)	Kantar Public	WP leaders for each technology (and others?) to review
December 2018 to January 2019	Survey	Preparations for pilot – translations and questionnaire programming	Kantar Public	Members of consortium in each cognitive testing country to review translated questionnaires
January 2019	Survey	Pilot fieldwork	Kantar Public	

Dates (all week commencing)	Survey or panel task	Stage	Lead responsibility	Others to involve
February 2019	Panel	Panel recruitment materials revised and signed off	Kantar Public/ WP leaders for each technology	
February 2019	Panel	Draft research materials for panels reviewed and comments sent to Kantar Public (topic guide; stimulus)	Kantar Public	WP leaders for each technology (and others?) to review
February 2019	Survey	Review of pilot feedback; any recommendations to questionnaire shared; questionnaire signed off for main stage	Kantar Public	WP leaders for each technology
February 2019	Survey	Preparations for main stage fieldwork – e.g. updates to translations and script	Kantar Public	
March 2019	Panel	Panel recruitment commences	Kantar Public	
Early March 2019	Survey	Start of main stage survey fieldwork	Kantar Public	
March 2019	Panel	Revised panel research materials (v2) circulated for review	Kantar Public	WP leaders for each technology (and others?) to review
March – April 2019	Panel	Draft (v2) research materials for panels reviewed and comments sent to Kantar Public (topic guide; stimulus)	Kantar Public	WP leaders for each technology (and others?) to review
April 2019	Panel	Panel research materials revised and signed off	Kantar Public / WP leaders for each technology	
Late April 2019	Survey	End of main stage survey fieldwork	Kantar Public	
April 2019	Panel	Panel research materials translated; and researcher briefing with local teams	Kantar Public	Members of consortium in each cognitive testing country to review translated questionnaires
May 2019	Survey	Raw data from survey produced	Kantar Public	Data to be shared with consortium
April – May 2019	Panel	Panels of citizens held	Kantar Public	Experts from consortium
Early-June 2019	Survey	First draft of survey reports provided	Kantar Public	

Dates (all week commencing)	Survey or panel task	Stage	Lead responsibility	Others to involve
Late-June 2019	Survey	Feedback on survey reports	WP leaders for each technology	Other members of consortium
July 2019	Panel	First draft of panel reports provided	Kantar Public	
August 2019	Survey	Revised survey reports provided	Kantar Public	
August 2019	Panel	Feedback on panel reports	WP leaders for each technology	Other members of consortium
August 2019	Panel	Revised panel reports provided	Kantar Public	
August 2019	Both	Final reports signed off by consortium	WP leaders for each technology	

Table 12: Surveys and panels implementation timetable

5.6. Division of responsibilities

Table 13 below outlines the lines of responsibility between Kantar Public and the SIENNA partners across each stage of Task 1.3.

Method	Stage	Kantar Public responsibilities	SIENNA partners' responsibilities
Survey	Questionnaire development	Lead responsibility for developing the survey questionnaire	Provision of key information requirements, outline questions and review of other surveys / literature Review of draft questionnaires provided by Kantar Public
	Translations	Translating the survey questionnaires into each language, including full verification process	Review of translated questionnaires
	Cognitive testing	Recruiting samples for cognitive testing Conducting cognitive interviews Reporting on cognitive interviews	Option to observe cognitive interviews Review and feedback on cognitive testing reports
	Pilot	Delivery of pilot fieldwork	Option to listen to recordings from pilot interviews

Method	Stage	Kantar Public responsibilities	SIENNA partners' responsibilities
	Sampling	Provision of a sample specification Drawing samples of phone number for CATI surveys	Review and sign-off on sample specification
	Fieldwork	Briefing interviewers Conducting CATI interviews Monitoring fieldwork progress Supervision and validation of interviews	n/a
	Data processing	Delivery of data files to agreed specifications Data checking	Input into data specifications Review of data files
	Weighting	Provision of a weighting specification Weighting the survey data	Review and sign-off on weighting specification
	Reporting	Provision of a survey report for each technology area	Review of survey reports Additional reporting and preparing publications
Panels of citizens	Research materials development	Lead responsibility for developing research materials for the citizen panels (incl. event plan, stimulus)	Identify specific panel objectives for each of the three technologies (PI responsible for each technology domain) Review existing knowledge to inform research approach (topic coverage priorities, relevant experts, information for stimulus materials) Review of draft research materials provided by Kantar Public
	Sampling and recruitment	Lead responsibility for developing recruitment materials for the citizen panels (incl. sample frame, recruitment screeners) Identify and recruit all panel participants	Review existing knowledge to inform recruitment approach (priority sampling criteria) Identify and recruit expert witnesses to attend panels
	Translation	Translating the recruitment and research materials into each language	Review of translated recruitment and research materials

Method	Stage	Kantar Public responsibilities	SIENNA partners' responsibilities
	Fieldwork	Briefing moderators / experts Moderating panel events	N/a (except for expert attendance)
	Analysis	Live note-taking (and audio recording) during panel events Analysis of panel data at local country level Analysis of combined panel data	N/a
	Reporting	Provision of a panel report for each technology area	Review of panel reports Additional reporting and preparing publications

Table 13: Surveys and panels – division of responsibility

6. Approach to stakeholder analysis and contact list (Task 1.4)

6.1. Introduction

This section summarises the approach to SIENNA's stakeholder analysis and contact list as specified in Task 1.4 of the SIENNA Description of Action (DoA). According to the task specification, the partners will review and refine the approach proposed for the project's stakeholders and public engagement activities, as well as identify stakeholders in genomics, human enhancement and artificial intelligence (AI) and robotics in EU and non-EU countries. SIENNA *Deliverable 1.2, Stakeholder analysis and contact list*, reports on and documents this task and its findings in greater detail.

6.2. Overview of the approach – terminology and approach to be used

Before setting out SIENNA's definition and approach to stakeholders and stakeholder analysis, we take a very short look at some definitions of 'stakeholder'. In addition to situating SIENNA's approach within the relevant literatures, briefly considering these definitions (and stakeholder analysis generally) helps to highlight how different accounts identify who or what counts as a stakeholder to a company or project.[113]

R.E. Freeman's 1984 book *Strategic Management: A Stakeholder Approach*[114] stands as a landmark and originator of debates in the field of management studies regarding the meaning, identification, role and value of stakeholders (and stakeholder theory generally).[115] Freeman defined stakeholder as "an individual or group of individuals which can affect or be affected by the achievement of organizational objectives".[116] Mitchell et al. describe this definition as broad because it is "based on the empirical reality that companies can indeed be vitally affected by, or they can vitally affect, almost anyone".[117] It contrasts with other definitions representing narrow views of who or what counts as a stakeholder from Freeman and Reed[118], Clarkson[119], Hill and Jones[120], as well as Donaldson and Preston[121]. Unlike

[113] Mitchell, Ronald K., Bradley R. Agle, and Donna J. Wood, "Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What Really Counts", *Academy of Management Review*, Vol. 22, No. 4, 1997, p. 853.
[114] Freeman, R. Edward, *Strategic Management: A Stakeholder Approach*, Pitman, Boston, 1984.
[115] Mitchell, et al., op cit., p. 853.
[116] Freeman, op cit., p. 46.
[117] Mitchell, et al., op cit., p. 857.
[118] Freeman, R. Edward, and David L. Reed, "Stockholders and Stakeholders: A New Perspective on Corporate Governance", *California Management Review*, Vol. 25, No. 3, 1983, p. 91: A stakeholder is that "on which the organization is dependent for its continued survival".
[119] Clarkson, Max B.E., "A stakeholder framework for analyzing and evaluating corporate social performance", *Academy of Management Review*, Vol. 20, No. 1, 1995: 97: Stakeholders "are placed at risk as a result of a firm's activities".
[120] Hill, Charles W. L., and Thomas M. Jones, "Stakeholder-agency theory", *Journal of Management Studies*, Vol. 29, No. 2, 1992, p. 133: Stakeholders are "constituents who have a legitimate claim on the firm … established through the existence of an exchange relationship" who supply "the firm with critical resources (contributions) and in exchange each expects its interests to be satisfied (by inducements)".
[121] Donaldson, Thomas and Lee E. Preston, "The stakeholder theory of the corporation: Concepts, evidence, and implications", *Academy of Management Review*, Vol. 20, No. 1, 1995, p. 85: Stakeholders are "persons or groups with legitimate interests in procedural and/or substantive aspects of corporate activity".

broad views, narrow ones are "based on the practical reality of limited resources, limited time and attention, and limited patience of managers for dealing with external constraints".[122]

The above represent a small selection of notable scholarly definitions of the term 'stakeholder'; however, the definitions (along with the broad to narrow scale on which they sit) help to illustrate a central point: who and what gets classified as a stakeholder can affect and be affected by the resources, interests and activities that a project, company etc. have, control or pursue.[123] Since the appearance of Freeman's book, other fields and disciplines, such as environmental studies[124] and political science[125], have (to varying degrees and in various ways) integrated the concept, identification and analysis of stakeholders.[126] This is to say, that while the origins of the stakeholder definition and different stakeholder approaches are associated with management and corporate governance, the value, integration and use of stakeholder approaches stretches beyond its academic roots.

For SIENNA, we adapted a definition of stakeholder from European Commission guidelines[127] that takes into account the project's three technological fields and activities, as well as the interests and expertise of stakeholders. Consequently, SIENNA defines 'stakeholder' as a relevant actor (person, group or organisation) who: (1) might be affected by the project; (2) have the potential to implement the project's results and findings; (3) have a stated interest in the project fields; and/or, (4) have the knowledge and expertise to propose strategies and solutions in the fields of genomics, human enhancement and artificial intelligence[128]. This multi-part definition, then, aims to account for all the relevant actors – stakeholders – who can affect or be affected by SIENNA. Its scope also emphasises inclusion, diversity and (ideally) a large number of stakeholders.

The above definition serves as a basis for our approach to stakeholder analysis. As with the topic of stakeholder itself, stakeholder analysis and the various approaches to it remain topics of ongoing discussion within management studies, among others.[129] For now, a review of such topics will be set aside in favour of sketching the outline of SIENNA's approach to stakeholder analysis. As adapted from Schmeer, stakeholder analysis means "gathering and analyzing qualitative information to determine whose interests should be taken into account when developing and/or implementing a policy or program"[130] or, in SIENNA's case, an H2020 project.

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[122] Mitchell, et al., op cit., p. 857.
[123] Bonnafous-Boucher, Maria, and Jacob Dahl Rendtorff, *Stakeholder Theory: A Model for Strategic Management*, Chaim, Springer, 2016, p. 2.
[124] Cf. Reed, Mike S., "Stakeholder participation for environmental management: A literature review", *Biological Conservation*, Vol. 141, No. 10, October 2008, pp. 2417-2431.
[125] Cf. De Bussy, Nigel M., and Lorissa Kelly, "Stakeholders, politics and power: Towards an understanding of stakeholder identification and salience in government", *Journal of Communication Management*, Vol. 14 no. 4, pp. 289-305.
[126] Ibid.
[127] European Commission, *Stakeholder consultation guidelines 2014, Public consultation document*, 2014, p. 10. http://ec.europa.eu/smart-regulation/impact/docs/scgl_pc_questionnaire_en.pdf
[128] European Commission, *Stakeholder consultation guidelines 2014,* Public consultation document, 2014, p. 10. http://ec.europa.eu/smart-regulation/impact/docs/scgl_pc_questionnaire_en.pdf
[129] Missonier, Stephanie, and Sabrina Loufrani-Fedida, "Stakeholder analysis and engagement in projects: From stakeholder relational perspective to stakeholder relational ontology", *International Journal of Project Management*, Vol. 32, 2014, p. 1108. For differing views and definitions of stakeholder analysis, see: Aaltonen, Kirsi, "Project stakeholder analysis as an environmental interpretation process", *International Journal of Project Management*, Vol. 29, 2011, pp. 165–183; and Achterkamp, Marjolein C., and Janita F.J. Vos, "Investigating the use of the stakeholder notion in project management literature, a meta-analysis", *International Journal of Project Management*, Vol. 26, 2008, pp. 749–757.
[130] Schmeer, Kammi, "Stakeholder Analysis Guide lines" in *Policy Toolkit for Strengthening Health Sector Reform*, Abt Associates, Inc., Bethesda, MD, 1999, p. 1.

In line with Schmeer's definition, but expanding on certain project-specific aspects, the purpose of SIENNA's stakeholder analysis is: to inform and guide the SIENNA consortium by ensuring that it takes into account and engages with the relevant stakeholders and works collaboratively with them in producing a fit for purpose framework for each of the three technological fields, which will form the basis for the development of research ethics protocols, professional ethical codes, and better ethical and legal frameworks. The stakeholder analysis, then, will help SIENNA adopt an inclusive approach to stakeholder identification and determinations of stakeholder salience, indicating those stakeholders that may have an impact on the project and its outcomes. In particular, it will help SIENNA improve its understanding of who are the 'leaders' and 'influencers' in the fields under investigation and which stakeholders should additionally be included.

To accomplish its purpose, the stakeholder analysis employs key steps derived from the SIENNA DoA[131] and academic accounts[132]: (1) identification of stakeholders in genomics, human enhancement and AI and robotics in EU countries and internationally in collaboration with SIENNA partners through literature reviews, expert networks, and relevant FP7 and H2020 projects; (2) classification of stakeholders according to, among others, stakeholder types within the three technological fields (while ensuring a well-rounded sex/gender split); (3) review of, and supplementing the compiled lists for completeness and gaps in stakeholders identified. This multi-step process is not a one-off set of activities; it will continue throughout the project's lifespan.

As the remainder of this approach indicates, the stakeholder analysis endeavours to ensure that SIENNA comprehensively identifies stakeholders, defines their respective relationships with the project, establishes their relative importance in delivering the project's objectives and the role they will play, as well as gives insight into individual tactics and messages for engagement with different types of stakeholders.

6.3. Steps involved in the task

The SIENNA stakeholder identification and analysis task involved/will involve the following steps:

- Planning and preparing documents (October 2017)
- Identifying stakeholders (guided by the above-stated definition) by collecting information from various sources and populating the contact lists (23 October 2017 – 16 February 2018). The approach used to identify stakeholders includes the following steps:
    - **Identification of stakeholders** in genomics, human enhancement and AI and robotics in EU countries and internationally in collaboration with SIENNA partners through literature reviews, expert networks, and relevant FP7 and H2020 projects.
    - **Classification** of stakeholders according to, among others, stakeholder types within the three technological fields (while ensuring a well-rounded sex/gender split).
    - **Review** of the compiled lists using the following questions:
        - Have all important stakeholders been listed?
        - Are all categories adequately represented?
        - Has a broad cross-section of stakeholders been included and represented, not just the most vocal, prominent, renowned or expert?
        - Have gender aspects been factored in to identify different types of female stakeholders?
        - Does it include representatives of vulnerable groups/populations?

[131] SIENNA, Description of Action, Grant Agreement No. 741716, Part A, p. 11
[132] Roeder, Tres, *Managing Project Stakeholders: Building a Foundation to Achieve Project Goals*, Wiley, Hoboken, NJ, 2013, ch. 3.

- Are there any new stakeholders that are likely to emerge as a result of the project?

- **Analysis of information** (February - March 2018)
- **Writing of the deliverable** (January - March 2018)
- **Review of the deliverable** (April 2018)
- **Finalisation and report submission to EC** (30 April 2018).

6.4. Benefits of the approach

The SIENNA approach emphasises inclusion, diversity and gathering a large number of stakeholders. By attracting a diverse and numerically large group of stakeholders, SIENNA hopes to communicate with individuals from a wide range of backgrounds, disciplines and interests. Such diversity will expand the impact of the project, benefit stakeholders and (ideally) continually increase the diversity and number of stakeholders through word of mouth. While the approach encourages field experts and other individuals with specialised knowledge of the three technological fields, it also aims to attract interested lay persons and others who may lack technology-specific knowledge or expertise. In this regard, the approach affirms the benefits of inclusiveness and the opportunity for SIENNA to gain from expert and non-expert opinions and views.

6.5. Stakeholders and types, challenges, how SIENNA will address them

Target number of stakeholders

The plan was to identify a large number of stakeholders to enable SIENNA to achieve its objectives. Ambitiously, SIENNA set a target of 300 stakeholder contacts for each of the three technological fields (genomics, human enhancement, and AI and robotics) to provide a large pool of people to consult and engage with during the project's research and engagement activities. The table below details the types of stakeholders SIENNA will identify and engage throughout the project's lifespan.

Types of stakeholders (categories)
Civil society
Clinician
Consultancy
Ethics committee
Field expert
Funding organisation
Genetic counsellor
Impact assessment expert
Individual/lay person
Industry including standards organisations
Media
Medical doctor
Patient
Patient advocacy
Policy-maker
Professional organisation/society/association

Types of stakeholders (categories)
Regulatory/advisory body
Related projects and networks
Science academy
Worker association

Table 14: Types of stakeholders

Stakeholders will be identified from scientific domains/fields such as medicine, life sciences, natural sciences, social sciences and humanities, physical sciences and the engineering and information sciences. We will target non-EU and EU countries with particular attention paid to those under-represented in the SIENNA coverage areas and countries such as Bulgaria, Croatia, Czechia, Lithuania, Romania, Serbia, Slovenia etc.

As described in greater detail in *D1.2, Stakeholder analysis and contact list*, the use of the SIENNA contacts list (prepared in this task) is restricted to the following purposes:

- To engage with stakeholders and experts in SIENNA research and engagement activities (WPs 2-6)
- To disseminate results, and communicate news about the project, e.g., newsletters (WP7)
- To issue invitations to SIENNA events, e.g., workshops (WPs 2-6)

In line with the preceding, SIENNA's public opinion surveys and citizen panels will not use the contact list prepared in Task 1.4 and presented in *D1.2*. As detailed in Section 5 of this Handbook (Task 1.3), Kantar will reach over 1,000 individuals for the public opinion surveys by using a "dual frame (mixed landline and mobile) Random Digit Dialling (RDD) sample design". For the citizen panels, Kantar will invite "40 members of the public from a cross-section of demographics" and ten vulnerable participants in each of the five countries in which panels will take place.

6.6. Challenges

The following list details some of the challenges in compiling a contact list and analysing the identified stakeholders.

- **Lack of identifiable experts on the topic**

If this challenge arises, which may be the case for human enhancement technology, for example, we will scan a wider variety of sources using different keywords to mitigate this risk. SIENNA partners who are topical experts will support the identification of relevant contacts. Furthermore, we will continue to cultivate contacts as the project progresses.

- **Privacy and data protection concerns**

The task leader will ensure suitable privacy and data protection measures are in place while compiling the lists. The lists will be compiled using publicly available information, will not collect any sensitive information, will be password-protected and restricted to authorised users within the consortium. The lists will not be shared via email. They will be shared and stored securely on the project's SharePoint repository. SIENNA will only collect essential information needed to fulfil project objectives. Privacy notices will be provided. Contacts listed will be asked explicitly to opt-in. If not, they will be removed from the list.

- **Limited availability of information on certain types of stakeholders**

Industry contacts, lay publics and other types of stakeholders on the topics can be difficult to find. SIENNA will mitigate this by using partner networks and building its profile through its communication and dissemination activities to attract participation from difficult-to-find individuals and groups.

- **Subjectivity in identification**

If identifying stakeholders comes to rely too heavily on the same sources or views about 'perfect' SIENNA stakeholders, SIENNA partners will re-evaluate the identification process. The analysis will aid in highlighting imbalances in representation of stakeholder types. Mitigation measures include expanding and altering the channels through which SIENNA connects with individuals and organisations, including dissemination and institutional networks. In addition, requesting input about appropriate stakeholders from SIENNA partners who have different expertise from different academic disciplines and geographic locations can help to ameliorate the over- or under-representation of stakeholders caused by subjectivity in identification.

- **Consider and balance diverse and potentially conflicting stakeholders' interests**

Considering and balancing stakeholder interests can increase support and legitimacy of SIENNA activities and outputs, a point made within stakeholder theory generally[133]; furthermore, balancing stakeholder needs is a prerequisite described in the DoA. If conflicts between stakeholders' interests arise, the relative importance of the stakeholder(s) to a particular activity or fulfilment of a project objective will aid in balancing interests. In this regard, the relative importance of stakeholders will assist in case-by-case assessment and resolution of conflicts of interest.

6.7. Plans for implementation (responsibilities and timelines)

Task 1.4 runs from October 2017 to April 2018. Updates are planned for 2019 and September 2020 (month 36). The total person months (PM) allocated to this task are: 4.5. Trilateral Research leads this task with 1.8 PMs, University of Twente has 1 PM, Uppsala University has 0.7, Helsinki Foundation for Human Rights has 0.5, EUREC has 0.2, UGR 0.1, IONIO 0.1, and CNRS 0.1.

Sub-tasks	Responsibility	Deadline	Status
Develop task plan and deliverable outline	TRI	11 October 2017	Completed
Create template for contact list compilation [core partners to review]	TRI (UU).	11 October 2017	Completed
Present plan, template to all SIENNA partners and discuss at Kick-off meeting.	TRI	12 October 2017 (pre-circulation of plan) KOM: 19-20 October 2017	Completed
Research, populate the password protected contact list [Ask all EU partner organisations to fill in template (identify stakeholders from	TRI (lead), UT, UU, EUREC, IONIO, UFRJ, UGR, HFHR	23 October 2017-21 December 2017 (regular reminders in between)	Completed

[133] Reynolds, Scott J., Frank C. Schultz, David R. Hekman, "Stakeholder Theory and Managerial Decision-Making: Constraints and Implications of Balancing Stakeholder Interests, *Journal of Business Ethics*, Vol. 64, No. 3, 2006, p. 293.

Sub-tasks	Responsibility	Deadline	Status
their networks and publicly available information, etc. in G, HE and HMI]; compile the list.[134]			
Set up subscription form on SIENNA website	UU	October-November 2017	Completed
Draft T1.4 approach document for Handbook	TRI	January 2018	Completed
Conduct stakeholder analysis, write deliverable 1.2	TRI, UT	3 January 2018 – 28 March 2018	Completed
Review deliverable 1.2	Selected peer reviewers/consortium partners	April 2018	Completed
Revise and submit deliverable submission	TRI – UT to upload.	30 April 2018	Completed
First mailshot with privacy notice to all persons listed to gain their consent for participation in SIENNA mailings if not subscribed.	UU	Early 2018 (precise timing to be confirmed)	Completed
Use and maintenance of the list and using it for impact (Task 7.5) (update list in 2019, M18 and September 2020, M36)	UU	Project duration	Ongoing

Table 15: T1.4 plans for implementation

6.8. Guidelines and recommendations (for the task)

There are some key elements of an effective stakeholder analysis which we recommend considering in SIENNA. These are:[135]

- Identify stakeholders
- Define their relationship with the project
- Establish their relative importance in delivering our objectives
- Establish the role they will play
- Give insight into personalised tactics and messages for different stakeholders.

First, SIENNA must identify stakeholders in a comprehensive manner, taking into account the technological fields. This begins with the terms set out in the DoA[136] and the definition of stakeholder. The contact list and its various categories developed in *D1.2* help to guide the ongoing collection of contacts. Furthermore, the contact list helps to guide re-evaluation of stakeholders (e.g., whether SIENNA involves a diverse range of stakeholders).

[134] This will be a database for stakeholder contacts (divided per technology) available in the SIENNA Sharepoint repository, but also used for SIENNA, as a whole.
[135] UK government web archive, "Stakeholder engagement and analysis", 7 December 2010. http://webarchive.nationalarchives.gov.uk/20120118171914/http://hcai.dh.gov.uk/files/2011/03/Presentation_Stakeholder_engagement_FINAL_071210.pdf
[136] SIENNA, Description of Action, Grant Agreement No. 741716, Part A, p. 11: "SIENNA's stakeholder and public engagement analysis and contact lists for genomics, human enhancement and human-machine interactions in EU countries and internationally".

Second, the relationship of stakeholders to SIENNA is neither static nor (necessarily) limited to a single form of consultation, engagement or research activity: stakeholders will have different relationships depending on their expertise, role and form of engagement. Certain stakeholders will inform the project through participating in citizen panels or public opinion surveys. Other stakeholders, ethicists for example, will offer expert opinion about the project's outputs. SIENNA must categorise its contact list (and continually update it) on the basis of and with respect to the relationships different shareholders have to the project and its activities. The contact list prepared for *D1.*2 lays the groundwork for such categorisation; furthermore, the DoA indicates the engagement and research activities that will involve stakeholders (and, by extension, the relationship(s) stakeholders have to the project).

Third, SIENNA must establish the relative importance of stakeholders to the project in delivering its objectives. Determining the relative importance of stakeholders depends on the relationship(s) they have with the project – guideline/recommendation 2 – and the project's three main objectives.[137] For example, the relative the public's relative importance is tantamount during the public opinion surveys and citizen panels. Individuals will offer SIENNA input about their awareness and acceptance of genomics, human enhancement and AI and robotics. By contrast, stakeholders such as professional organisations and research ethics committees (RECs) will have a much greater relative importance (compared to lay persons in this example) in enabling SIENNA to achieve its second objective.

Fourth, SIENNA must establish the role stakeholders will play in the project. First, as noted in preceding guidelines/recommendations above, the role of stakeholders in the project depends on SIENNA actively and continually engaging stakeholders throughout the project's duration and, potentially, after the project ends. Still, the project envisages defined roles for different types of stakeholders. For example, one role of RECs is to adopt SIENNA's proposed operational guidelines described in Objective 2(a); however, RECs are not merely instruments of the project. Adoption of operational guides (speculatively) depends on RECs' support of and engagement with the project and its outputs. The role of stakeholders in this respect depends on SIENNA establishing reciprocal relationships that benefit the project and stakeholders. That is, SIENNA gains insights from stakeholder input through engagement, and the stakeholders gain knowledge, among other things, from participation in engagement activities.

Fifth, SIENNA must develop personalised tactics and messages for different stakeholders. This recommendation closely tracks the work done in *D7.3, Dissemination and communication plan*, where more details are available. Even so, the preceding points regarding SIENNA's active, ongoing engagement and involvement of stakeholders in fulfilling its objectives, as well as establishing and maintaining relationships with stakeholders forms a crucial part of personalisation of tactics and messages for different stakeholders.

[137] SIENNA, Description of Action, Grant Agreement No. 741716, Part B, p. 4. (1) To develop ethical frameworks based on social, ethical and legal analysis and scientific and technological knowledge that address major present and future ethical issues in (a) genomics, (b) human enhancement and (c) human-machine interaction. These frameworks will take into account existing legal and ethical frameworks as well as stakeholder and public opinion, including the public's acceptance and awareness of these technologies. (2) To translate and adapt these ethical frameworks, in collaboration with relevant stakeholders, so as to produce four practical tools and resources for each technology: (a) operational guidelines for research ethics committees for these technologies, (b) codes of responsible conduct for researchers who develop these technologies, (c) proposals for revisions of existing ethical frameworks, and (d) proposals for revisions of existing legal frameworks, all of which should have acceptance and approval of relevant stakeholders. (3) To generalise the approaches for developing, translating and adapting ethical frameworks that were established in (1) and (2) so that they can be applied to other new and emerging technologies, and to obtain acceptance from relevant stakeholders for these generalised approaches

7. Approach for analysis and development of guidance documents and tools for researchers, ethics committee members and other stakeholders (Task 1.5)

7.1. Introduction and overview

The development of ethical frameworks that address major current and future ethical issues in the three areas – human genomics, human enhancement and AI and robotics – is one of SIENNA's central objectives (Objective 1 in the DoA). Beside this overall purpose, SIENNA follows certain objectives for the analysis and development of ethical proposals. These objectives are outlined in the description of each WP in the DoA. First of all, the SIENNA partners aim to understand how ethical challenges in genomics, human enhancement, and AI and Robotics are addressed (i) in documents that are developed to give guidance on how to write the ethical part of research protocols, and (ii) professional ethics codes, both in different EU countries and internationally. This objective will be addressed in WPs2-4, in tasks 2.3, 3.3, 4.3. The deliverables for these tasks will be surveys of REC approaches and ethical proposals for the three fields. By month 11 of the project (August 2018), the SIENNA partners will have an overall view about the quality of the existing protocols and codes in the three fields. Based on this, the objectives described in WP5 ("Develop elements that complement operational guidelines for research ethics committees, including ethical assessments of non-medical research" and "synthesise the findings of the previous WPs and produce the finalised codes for the three technology areas") will be followed. One of SIENNA's objectives is also to adapt and exploit the methods developed in this project for legal analysis of emerging technologies in other domains (task 6.2) and to adapt methods for translating ethical analysis into instruments for the ethical development and deployment of emerging technologies (task 6.3).

The following sections describe SIENNA's approach for analysis and development of guidance documents and tools for researchers, research ethics committee members and other stakeholders. To this end, we first define 'research ethics protocols' and 'professional codes' (Definition and terminology and scope of contribution of SIENNA). This is followed by a narrative literature review of existing manuals, by screening and scoping on how to write good research ethics protocols and professional ethical codes (General overview of guidance documents on how to write ethics protocols and codes). Next, we outline challenges that may arise during the development of codes and other ethical frameworks (Challenges and how to address them). We also formulate research questions, which were earlier shared with SIENNA stakeholder board members with the intent of taking their views into account in SIENNA's approach (Research questions). Finally, we outline the next steps that will be followed from months 6 to 41 (March 2018 to February 2021) to develop operational guidelines, ethics codes and proposals for improved ethical and legal frameworks (Procedure and steps).

7.2. Definition and terminology and scope of contribution of SIENNA

The objective of task 1.5 is to define the approach for the analysis and development of two different kinds of documents: guidance documents on how to write research ethics protocols and professional ethical codes. Both types of documents have, fundamentally, the same *long-term objective*: their aim is to enable ethically reliable research and sound methodologies. With respect to processes and methods in research, ethics protocols and codes aim to ensure that actors such as researchers or

sponsors treat human beings with respect (related to persons, human biological materials or personal data) and take care of living beings and the natural and social environment. Ethics protocols and codes should be grounded on ethical principles (e.g., beneficence, solidarity, justice). However, research ethics protocols and professional ethical codes differ greatly in their *short-term objectives* and their particular fields of application. Therefore, they must be treated as two separate kinds of documents with their own specifications.

Guidance for writing research ethics protocols and templates for RECs

The objective of having researchers write and submit for evaluation, research ethics protocols, is to ensure that research practices match ethical (and in some cases, legal) requirements concerning means, goals and consequences of research. These requirements are sometimes defined in national law and may differ from country to country and from discipline to discipline regarding their specification. However, there are usually widely accepted cross-cultural key principles (e.g., some form of consent, openness and honesty, right to withdraw, protection from harm, and confidentiality). Research ethics protocols help explained how researchers and other people involved in a project intend to ensure compliance with key ethical principles. The protocol must set out how the researcher/study/project will deal with issues that are challenging from an ethical perspective.

In a research ethics protocol, direct and indirect ethical aspects of a field of research have to be addressed, that means, e.g., not only the direct impact of a study for involved subjects, but also the indirect impact for other people, other living beings, the society and the nature as a whole have to be taken into account. Moreover, all foreseeable short and long-term consequences have to be considered. The identification of critical ethical aspects is challenging – benefits, risks and burdens have to be taken into account. It is very important to differentiate between ethical issues related to goals and means, respectively. There are cases in which a goal is ethically justifiable but the means to reach this goal are not, and vice versa. By carrying out research, different ethically relevant entities can be harmed (e.g., human beings – including embryos, minors, vulnerable persons, healthy individuals), animals, the society, the environment and endangered species (flora and fauna).

Considering the three SIENNA areas of technologies from an ethical perspective, researchers must identify which common ethical principles (e.g., justice, beneficence), issues, tensions etc. apply, but also which are specific to the particular SIENNA areas. Therefore, the SIENNA partners will review existing ethical theories and approaches regarding genomics technologies (in WP2, task 2.4), human enhancement (in WP3, task 3.4) and AI and Robotics (in WP4, task 4.4). An ethical impact assessment of current and future ethical issues will also be conducted. Moreover, the SIENNA project will look at the requirements for ethical reviews of research (as presented via the need to write ethical protocols reviewed by ethics committees) and the way research ethics committees (RECs) proceed in the reviewing process. The reviewing procedures in the non-medical research field are not extensively regulated and differ in EU Member States. SIENNA will refer to the findings of the SATORI[138] and the ENERI[139] projects. The results of the analysis of research ethics protocols could be used to develop templates for RECs to harmonize the process of ethical assessments concerning the technologies considered by SIENNA.

Professional ethical codes

Professional ethical codes are mostly used by groups and in organisations as guidelines to help members, workers and management conduct themselves in accordance with common values and ethical standards. Ethical codes can be more specific to the research context and can strengthen habits and attitudes of individuals in institutions and may outline the ethical standards of a profession, institution or organisation.

[138] http://satoriproject.eu
[139] http://eneri.eu

Many institutions and professional organisations have a code of conduct. One professional code developed for researchers in general is "The European Code of Conduct for Research Integrity" developed by *All European Academies* (ALLEA). The Code states:

> Good research practices are based on fundamental principles of research integrity. They guide researchers in their work as well as in their engagement with the practical, ethical and intellectual challenges inherent in research. These principles are: Reliability in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources. Honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way. Respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment. Accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.[140]

These principles are mandatory for all HORIZON 2020-funded research projects. Therefore, they must also be considered for the SIENNA codes developed for each of the three technological areas – human genomics, human enhancement and AI and robotics. SIENNA will specify the research ethics options in those fields and will translate them into specified codes of conduct. After an analysis of the existing professional codes of conduct of the involved disciplines and professions and how they can be applied on the three research areas, SIENNA aims to supplement these ethics codes for professionals with specific guidelines for the technologies in questions. SIENNA will also evaluate whether applicable existing guidelines could be improved. Before the development of codes and other ethical frameworks can start, the SIENNA partners will have to deal with the following questions: Which method for reviewing existing codes is productive? Over what geographical range and in which time period should the surveys be conducted? How will the existing codes be analysed? How will gaps be identified?

7.3. General overview of guidance documents on how to write ethics protocols and codes

The European Commission has issued guidelines on "How to complete your ethics self-assessment."[141] These guidelines are designed to help applicants in getting a proposal 'ethics-ready' for Horizon 2020 funding. They provide help both with the ethics issues table and the ethics self-assessment. This document has important checks, such as: "Your research must comply with:

- ethical principles
- applicable international, EU and national law."

Moreover, the guidance provides detailed information about informed consent and information about specific cases, e.g., research involving children. All in all, the guidelines give a very good overview about ethical challenges and how to meet them. As the European Commission described it: "This document is however no more than a 'how to' guide. It covers most of the ethics issues arising in research projects and gives advice on dealing with classic cases. Cases that are not covered must therefore be dealt with outside this guide." For the three areas, SIENNA has to identify those cases.

A preliminary narrative scoping review of literature was conducted to identify documents: i) to help researchers write their research protocols, and ii) to guide in the development of codes. This preparatory work revealed that there is a huge variety of manuals addressing the subject of how to

[140] ALLEA. The European Code of Conduct for research Integrity, Revised Edition, Berlin, 2017, p. 4. https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf
[141] European Commission. How to complete your ethics self-assessment. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

write research ethics protocols and professional ethical codes. For both, the most relevant examples are highlighted next to an overview of the discussed theme.

There are lots of different checklists available online that enable researchers to identify sensitive ethical issues in their research projects. The checklists are often presented in the form of decision-making trees and can be helpful to identify relevant ethical challenges. However, sometimes they fail to provide the specific guidance. E.g., the advice is sometimes to seek scrutiny by internal university research ethics committee. But there are also ethics checklists which contain very detailed information about how to handle each case. E.g., the *Ethics Checklist* developed by the *Manchester Metropolitan University*[142]. This checklist contains detailed information regarding informed consent, data protection, information about dealing with stress and anxiety caused by research procedures, about how to inform participants about potential risks and many other topics. Here are two examples of ethics checklists, which can be used to write research ethics protocols:

- Plymouth Marjon University. Guidance: Initial Research Ethics Checklist & Ethics Review Protocol.[143]
- The University of Western Australia. How to write a good ethics application for human subject research.[144]

Manuals offering guidance on how to write professional ethical codes are also available in different formats and with different content. Manuals, which exist mostly in the business context, contain information about how to write a good ethics code. The main idea is to write a simple and easily understandable code which informs about the main principles and key values of the firm/institute. Therefore, first of all the key values have to be identified. Almost all examples also include information about the implementation and effectiveness of the ethical code. Here are examples of some manuals:

- B Resource Guide: Creating a Code of Ethics.[145]
- Business Queensland. Writing a code of conduct.[146]
- Lighthouse: Developing a code of conduct. A Step-by-step guide.[147]

On the whole, the narrative literature review of manuals/guides how to write research ethics protocols and professional ethical codes shows that there are good checklists and manuals available. However, the extent to which they actually offer guidance, are used, and/or are effective in reaching their aims is an open question. In view of the three areas of technologies in SIENNA – human genomics, human enhancement and AI and robotics – the partners will identify and analyse the relevant ethical, legal and social issues per area. Against this analytical background, good ethics codes for these areas and plans for implementation and effectiveness can be developed.

7.4. Challenges (and how to address them)

The analysis and development of guidance documents for RECs, researchers, users and other stakeholders may face different challenges.

[142] Manchester Metropolitan University, Ethics checklist. http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/MMU-Ethics-Check-List-v9-10-Jan-2017.pdf
[143] https://www.marjon.ac.uk/media/2015-website-images/research/B.-Guidance-for-Initial-Research-Ethics-Checklist-&-Ethics-Review-Protocol_October2017.pdf
[144] http://www.research.uwa.edu.au/staff/human-research/good-application/good-application
[145] http://nbis.org/nbisresources/human_resources/howto_create_employee_code_ethics_corp.pdf
[146] https://www.business.qld.gov.au/running-business/employing/taking-on-staff/staff-code-conduct/writing
[147] https://www.lighthouse-services.com/documents/Developing%20a%20Code%20of%20Conduct%20[A%20Step-by-Step%20Guide].pdf

Three different fields
First of all, codes for the three fields with common, but also different, ethical challenges have to be developed. Therefore, the right structure has to be chosen. The challenge will be to identify the special ethical issues in each of the three fields. SIENNA will meet this challenge in the following way: It will carry out a survey of guides on how to write research ethics protocols and professional ethics codes in different EU and selected non-EU countries that will show which ethical issues in the three areas have already been covered. Furthermore, interviews with representatives of research ethics committees and/or research integrity offices and/or leading members of professional organisations will help to inform to what extent they are aware of ethical issues in these three fields, and what their expectations look like. Both the surveys and the interviews will be conducted from month 6-11 (March 2018-August 2018) in task 2.3 (WP2), task 3.3 (WP3) and task 4.3 (WP4).

Cultural and national differences
Another challenge relates to cultural and national differences. SIENNA will have to find a way to respect these in the codes. The differences can be found in legal frameworks, historical experience, or variations in practical implementation.

Stakeholder informed approach
SIENNA's stakeholder approach includes not only external inputs of relevant stakeholders. The SIENNA project has as an important focus on the inclusion of stakeholders throughout the different tasks in its work flow. Specifically, for tasks 5.2, 5.3, 5.4, we will integrate views from those stakeholders who are essentially involved in the review and evaluation mechanisms in research such as the network of RECs and various professional organizations identified as important (policy) actors. These groups will work closely with the partners in adopting or revising protocols and guidelines for their own organisations. This is an important step for the implementation of codes and guidelines.

Implementation of the protocols, codes and ethical frameworks through professional organisations
Professional organisations will play a crucial role in the development and acceptance of ethical considerations for the implementation of professional ethical codes. SIENNA can learn from the long history of the medical profession, which shows that codes may start with a simple utterance, such as the Hippocratic Oath, and gradually evolve into internationally binding rules, such as the Declaration of Geneva[148] or the Declaration of Helsinki. WMA even claims in the "Declaration of Helsinki"[149] and the "Declaration of Taipei on ethical considerations regarding health databases and biobanks"[150] that other professions should adopt the ethical principles laid down in these codes. SIENNA will have to determine whether this is a realistic option or whether other professional organisations need to improve their own activities that might also lead to some elements of *voluntary harmonisation procedures* or *standard operation procedures* concerning ethical reflections with regard to the research field in question. The implementation procedures reflect the way certain professions are willing to regulate themselves according to the principle of subsidiarity rather than waiting for external regulations by law or soft law. These considerations need also to be reflected against the background of the relation between science and its organisations on the one hand and civil society and its stakeholders on the other hand.

[148] World Medical Association, 2017. https://www.wma.net/policies-post/wma-declaration-of-geneva/
[149] World Medical Association, Declaration of Helsinki, Ethical Principles For Medical Research Involving Human Subjects, 2013. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
[150] World Medical Association, Declaration of Taipei on ethical considerations regarding health databases and biobanks, 2016. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

Implementation of the codes, practical tools and ethical frameworks through regulatory and advisory bodies

For the implementation of codes, practical tools and other ethical guidance documents, it is not only the integration of professional organisations that is important, but also of regulatory and advisory bodies. Therefore, the SIENNA stakeholder board contains not only members from professional organisations in science, engineering and medicine, but also from regulatory and advisory bodies such as the Council of Europe, UNESCO, and the World Health Organization (WHO) that also take part in creating research ethics protocols, professional ethical codes, and ethical and legal frameworks. For these organisations, the SIENNA plan is to help them develop policy-oriented guidelines rather than professional guidelines (task 5.6, 6.4). SIENNA will organise workshops with these stakeholders to discuss existing protocols and codes and to develop new protocols and codes based on wider stakeholder input. The SIENNA project strives to develop processes for self-regulation in research.

7.5. Research questions

The analysis and development of guidance documents on how to write research ethics protocols, professional ethical codes and other practical tools will be guided by the following research questions:

- *State of the art:* To what extent are the existing guidance documents and codes adequate to deal with challenges posed by developments in the three areas (human genomics, human enhancement, and AI and Robotics)?
  The main objectives of WPs2-4 is to answer this question, i.e., to understand how the three fields are addressed by guidance documents on how to write research ethics protocols and professional ethics codes in different EU countries and internationally. The ethical challenges in the three fields will be examined in tasks 2.4, 3.4 and 4.4. A survey of research ethics protocols and professional ethics codes will be conducted in tasks 2.3, 3.3 and 4.3.
- *Format*: What format should the SIENNA documents have? Does it make sense to develop a *core module* that deals with general ethical issues and *three specific advanced modules* for each field, or does every technology requires a code formulated from scratch? Is a code the right format for all three SIENNA fields or do we need other kind of guidance documents or other practical tools?
- *Content:* What are the ethical challenges in the three areas and how can SIENNA meet them?
- *Implementation*: How can the implementation of SIENNA codes or other guidance documents for the three technology fields be facilitated and ensured?
  These questions (and more) will be addressed in WP6, to generalise and adapt the methods developed in the project to other areas, and thus effectively exploit the results of the project and to contribute to the development of new approaches in addressing ethical and legal issues related to emerging technologies.
- *Effectiveness:* How could the effectiveness of the SIENNA products be assessed?
- *Stakeholder informed approach*: How could stakeholder views be integrated from the start and during the development of the SIENNA products?

7.6. Procedure and steps

Step 1: Survey of research ethics protocols and professional ethical codes
(months 6-11; tasks 2.3, 3.3, 4.3)

The SIENNA project will **survey guides for research ethics protocols and professional ethical codes** in different EU countries and internationally and determine to what extent and how they refer explicitly or implicitly to human genomics, human enhancement and AI and Robotics. This will happen from months 6-11 in WP 2 (task 2.3; lead: UU, EUREC), WP 3 (task 3.3; lead: EUREC) and WP 4 (task 4.3; lead: EUREC).

Identification of the most relevant documents

UU together with EUREC will lead the survey for task 2.3, EUREC will lead tasks 3.3 and 4.3. UU and EUREC will have a Skype meeting in April 2018 to discuss the most relevant way to conduct the surveys (document review, stakeholder input) and how best to analyse the documents. For example, the following questions may be considered:

- Which ethical challenges are addressed in the document?
- How are these ethical challenges addressed?
- How is the document structured?
- Which format (checklist, continuous text) is used in the document?
- Is the document clearly understandable?

Based on the criteria for analysis, summaries of each document will be made and these summaries, in turn, will be analysed for similarities and differences. Based on this analysis, as well as consultation with expert stakeholders, we will consider how to improve existing ethical codes.

The outcomes of this approach will be outlined in reports, which will be delivered in month 11 i.e., August 2018 (D2.3 Survey of REC approaches and codes for genomics, D3.3 Survey of REC approaches and codes for human enhancement, D4.3 Survey of REC approaches and codes for HMI).

In order to find out how ethical challenges in the three fields can be addressed in research ethics protocols and professional ethics codes, it is important to know more about these ethical challenges. Therefore, the tasks 2.3, 3.3 and 4.3 are strongly connected to the tasks 2.4, 3.4 and 4.4. (months 6-23). In these tasks, the SIENNA partners will review existing ethical theories and approaches regarding the three fields. The partners will perform an ethical impact assessment of current and future ethical issues. EUREC (task leader 2.3, 3.3 and 4.3) and UU (task leader 2.3 and 2.4) will therefore exchange with UT (task leader of 3.4 and 4.4) in different Skype meetings and via email.

Step 2: Development of operational guidelines, ethics codes and proposals for improved ethical and legal frameworks

(months 12-41; task 5.1-5.6)

At this point, SIENNA will have a good insight into the ethical challenges in the three fields, and how these are currently addressed in protocols and codes. The next step is the development of operational guidelines, ethics codes and proposals for improved ethical frameworks. This will happen in WP 5 from months 12 to 41. EUREC as WP leader will organise regular video meetings with all task leaders to discuss procedural steps.

Develop elements to complement operational guidelines for research ethics committees beyond biomedical research

(months 12-41; task 5.1; task lead: EUREC)

Documents such as the Declaration of Helsinki, the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects[151], and the WHO and ICH Guidelines for Good Clinical Practice[152] demonstrate the development and application of ethical and scientific standards for carrying out biomedical research on human subjects. Compliance with these guidelines helps to ensure that the dignity, rights, safety and well-being of research participants are promoted and that the investigations lead to reliable results. Even when the concept of "biomedical research" used in the guidelines may be used in a broad sense. While ethical reviews outside of the field of biomedical science are increasing, they are still few, and mostly focus on research that directly involves human

[151] https://cioms.ch/shop/product/international-ethical-guidelines-for-biomedical-research-involving-human-subjects-2/

[152] https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

participants (e.g., interviews with patients, etc…). SIENNA will examine the scope of existing operational guidelines for research ethics committees in the biomedical field and will investigate if and how these operational guidelines could be extended to other research areas.

The work on this task will start in month 12 (September 2018). EUREC as task leader will develop a work plan. The following steps will be involved in the process: First, a search of operational guidelines for RECs will be performed. From this list, the guidelines will be divided into categories of good and bad examples for operational guidelines for research ethics committees (beyond biomedical research). This will include the identification of criteria that allow for the discernment of good and bad protocols. (months 12-24) Afterwards, elements to complement those guidelines will be developed (months 25-31). In October 2020 an online workshop will be organised by EUREC. At this two-day workshop, representatives from RECs (mainly EUREC members) and the SIENNA consortium will come together to discuss the question if and how guidance documents from the biomedical field could be helpful to review research projects in other research areas. End of January 2021, a draft version of D5.1 Report documenting elements to open and complement operational guidelines for research ethics committees will be written and circulated for review. In month 41, D5.1 will be submitted to the European Commission.

<u>Development of strategies, codes and other practical tools for researchers and stakeholders in the three SIENNA fields</u>
(month 12-41; task 5.2, 5.3, 5.4)
The SIENNA partners will develop strategies, codes and other tools for the three fields together with and for stakeholders. This work will start in month 12 (September 2018). UU will lead the development of a code of responsible conduct for researchers in genomics, UT will develop ethical frameworks for human enhancement and TRI for AI and Robotics. EUREC as WP leader will organise the collaborative work. The steps in this process will be (as outlined already in the DoA and described in more detail here):

(a) *developing a common vision for the ethical proposals:* The outcomes of tasks 2.3, 3.3 and 4.3 should be used for this task. The reports on surveys of REC approaches and codes for the three fields (Deliverables D2.3, D3.3 and D4.3) will show which ethical challenges are addressed in protocols and codes and which gaps must be closed. Based on this knowledge, concrete ideas on how to work on ethical proposals should be prepared in month 15 for each of the three fields. The different task leaders should work together and exchange ideas and drafts.
(b) *consulting the ethical frameworks, academic organisations and stakeholders and preparing draft version of ethical proposals:* The work on the ethical proposals starts in month 15. In September/October 2020 online workshops will be held for each SIENNA technology with stakeholders. At these workshops, besides the consortium, professional and regulatory organisations, civil society organisations, experts and policy makers will come together to discuss the development of ethical tools for the three SIENNA areas.
(c) *publishing drafts of the developed tools and guidelines on the SIENNA website for stakeholder and public commentary:* The discussions with stakeholders will influence the further work on the codes. The partners will revise the documents and prepare a new version for publication on the SIENNA website. Together with WP7, a strategy will be outlined on how to make these drafts visible and how to get as much feedback as possible.
(d) *revision and preparation of the final versions of the ethical proposals:* In the last project phase public feedback will be integrated in the ethical proposals. Finally, draft versions of D5.2 Central elements of a code of responsible conduct for researchers in genomics (UU), D5.3 Methods for promoting ethics in human enhancement (UT) and D5.4 Multi-stakeholder strategy and practical tools for ethical AI and robotics (TRI) will be circulated for review and finally delivered to the European Commission in month 41.

Enhancement of the existing legal framework by networking with legislators and relevant committees about the three topics
(months 27-34; task 5.6; task lead: HFHR)
Based on the results of Tasks 2.2, 3.2 and 4.2, this task will identify potential changes needed in the existing legal and human rights frameworks (i.e., international, EU and/or national) that might be necessary or desirable to create an environment in which the proposed ethical tools could be implemented most effectively. To achieve this task, SIENNA will consult with regulators, policy-makers at the EU and national-level, as well as the legal experts in the project's Advisory Board. While recognising that changes in legal frameworks are not instantaneous and often fraught with difficulty, this task will offer recommendations to policy-makers on how our codes of conduct might fit into, be supported and reinforced by existing legislation. The recommendations will be further exploited in Task 6.4.

Adapt methods for translating ethical analysis into instruments for the ethical development and deployment of emerging technologies
(months 23-42; task 6.3; task lead: EUREC)
In this task, the partners will arrive at general methods for translating ethical analysis into frameworks and methods for the ethical guidance of emerging technologies. The generalized methods will be based on the methods that were used for specific technologies in tasks 2.7, 3.7, 4.7 and 5.1 – 5.4. This will include generalized methods for developing codes, operational guidelines, Ethics by Design approaches, policy guidance, guidance documents for research ethics committees, and other methods in support of the ethical development and deployment of emerging technologies.

7.7. Overview of the steps outlined in task 1.5

The figure below presents an overview of the steps outlined in the approach:

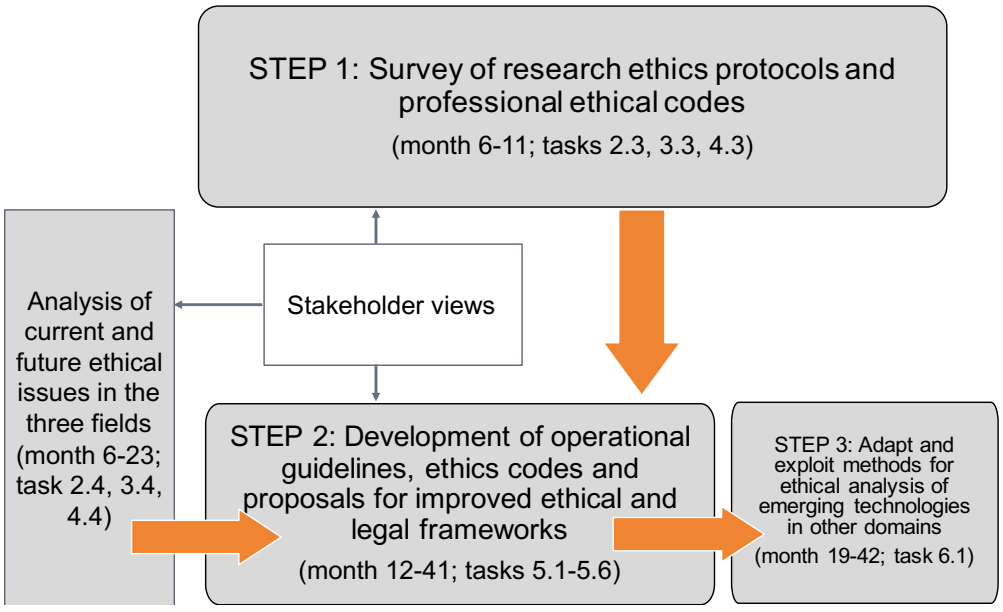

Fig 4: Overview of Task 1.5 approach

Part II General aspects

8. Research ethics and data management

The SIENNA ethical monitoring protocol or EMP (Deliverable 8.2) outlines the SIENNA research ethics commitments and policies. All SIENNA partners will abide by and signify their adherence to the protocol.

The SIENNA data management plan or DMP (Deliverable 8.1) details how the SIENNA consortium will manage, collect and process the project's data. The DMP provides detailed information on the project data lifecycle, privacy, and the project's policies for data collection, storage, access, sharing, protection, retention, and destruction. All consortium members shall refer to the DMP if questions about SIENNA's data policies and practices arise. Trilateral Research maintains and updates the DMP during SIENNA's three-and-a-half-year lifespan and monitors and reports on its implementation in the project's interim and final reviews.

9. Internal communication tools and protocols

Communication is the responsibility of all consortium members. The partners have agreed that communication between consortium members will be inclusive and that all partners should receive copies of correspondence relevant to the project. Such an approach will aid awareness about the progress of the project and decision-making. For communication with third parties, the consortium has agreed that copies may be limited to the project coordinator and the relevant work package leader. Where appropriate, partners will use monthly e-meetings (via GoToMeeting, Skype or other conference calling methods), including webinars and online workshops, to communicate regarding the project, work packages and tasks. The consortium will supplement these e-meetings with face-to-face meetings, video conference calls, e-mail correspondence and formal written correspondence. Rules for the formal communication within the consortium (e.g., time frames for announcement of meetings, sending out minutes and means of communication) have been defined and agreed upon in the consortium agreement. Internal communication tools and protocols will be reviewed and discussed with the project management committee and actions will be taken soon as any problems are identified to ensure that internal communication flows smoothly during the project.

10. Guidelines for organising events

Section four of the SIENNA Consortium Agreement of 10 August 2017 identifies the requirement for all consortium partners to abide by standard guidelines when organising SIENNA workshops and conferences. SIENNA has developed guidelines for organising events which provide specific, supplementary instructions and guidelines for organising, managing and following up on SIENNA events. These are available on the project repository, SharePoint, for consultation by all partners. These will be updated/revised based on feedback received from SIENNA event participants and consortium partners.

11. Quality assurance

SIENNA has a specific task i.e., task 8.5 aimed at assuring the high quality of project outputs. All partners are responsible for delivering high quality outputs and for peer-review of deliverables. Trilateral leads this task and will facilitate and manage the peer-review process of deliverables in discussion with WP leaders, lead authors and design templates for project deliverables, citation guidelines, and follow up on any corrective actions with WP leaders. All consortium partners are expected to familiarise themselves with the quality assurance process and guidelines issued (and saved on SharePoint). There is a deliverables review tracking sheet on SharePoint that can be accessed by all partners to check the status of deliverables in the review process.

12. Referencing (citations) and formatting guidelines

The SIENNA consortium will follow the EU format for citations and references (issued at the start of the project to all partners). Guidelines can be found in the WP8, T8.5 folder on SharePoint.

13. Dissemination, communication approach

The SIENNA communication and dissemination plan (Deliverable 7.3) includes strategies, tools, tactics and action plans for scientific dissemination, internal and external communications for the SIENNA project. It outlines a tentative list of audiences, objectives and includes key messages for internal and external communications and an initial action plan for 2017-2018. It outlines a three-step approach to external communications, where tactics in the initial phase (month 1-12) focus on raising awareness of the existence of the project, identifying and connecting with stakeholders. In the second phase (month 12-30), tactics will move from raising awareness to active collaboration with key stakeholders to develop strategy for impact collaboration, involving stakeholders in shaping key messages. Networks, projects and initiatives identified in the first year will be assessed for potential collaborations that could support the dissemination of outputs from, and impact of, the SIENNA project. The third phase of SIENNA communications (months 31-42) will build on the knowledge produced in the first and second phases.

14. Exploitation and sustainability

SIENNA *WP6 Generalizing project methods and exploitation measures* is dedicated to generalising and adapting the methods developed in the project to other areas and exploiting the results of the project. This work package is led by the Helsinki Foundation for Human Rights (HFHR) and all partners will contribute. It runs from months 19-42 (April 2019 to March 2021). The key outputs of this task will include:

- Adapting methods for ethical analysis of emerging technologies
- Adapting methods for legal analysis of emerging technologies
- Step-by-step-guidance from ethical analysis to ethical codes and operational guidelines
- Methodology to help public research funding organisations reconcile the views and interests of scientists and citizens
- A sustainability plan that will present options and strategies for promoting the project's legacy – the plan will focus on follow-up activities for (a) the codes of conduct, (b) other research outputs and (c) networks developed during the project's stakeholder engagement activities. The sustainability team will collaboratively explore options and devise suitable strategies in consultation with the project's Scientific Advisory Board, and the Board of Professional

Organisations. It will also explore the potential of fostering further partnerships both within H2020 and amongst the international research community.

15. Conclusion

This Handbook documents the SIENNA approaches for ethical analysis, legal and human rights analysis, the study of societal acceptance and awareness, stakeholder analysis, and the analysis and development of research ethics protocols and professional ethical codes (tasks 1.1 through 1.5), benefits, limitations and challenges (how to address these) and plans for implementation.

The Handbook was reviewed and updated to take into account any significant developments in the project or recommendations from the project stakeholders or the Commission. Discussion of updates to and revision of the Handbook are included as a standing item on the SIENNA project management committee meeting agendas. Partners leading the approaches advise Trilateral of any updates and revisions that need to be made. Trilateral updates and issues or shares revised versions.

References

Approach to ethical analysis – references

- Asveld, L., & S. Roeser (eds.), *The Ethics of Technological Risk*, Earthscan Publishers, London, 2009.
- Beauchamp, Tom L., and James F. Childress, *Principles of biomedical ethics*, Oxford University Press, 2001.
- Boenink, M., T. Swierstra, and D. Stemerding, "Anticipating the Interaction between Technology and Morality: A scenario Study of Experimenting with Humans in Bionanotechnology", *Studies in Ethics, Law and Technology*, 4(2), 2010.
- Brey, P.A.E., "Anticipatory Ethics for Emerging Technologies", *Nanoethics*, Vol. 6, 2012, pp. 1–13. https://link.springer.com/article/10.1007%2Fs11569-012-0141-7 .
- Brey, P.A.E., "Ethics of Emerging Technologies", in S. O. Hansson (ed.), *Methods for the Ethics of Technology*, Rowman and Littlefield International, 2017, pp. 175-192.
- Brown M.J., L.V. Dicks, R.J. Paxton, K.C. Baldock, A.B. Barron, M.P. Chauzat, et al., "A horizon scan of future threats and opportunities for pollinators and pollination", *PeerJ*, 4, 2016, e2249. https://peerj.com/articles/2249/
- Bryson, John M., "What To Do When Stakeholders Matter: Stakeholder identification and analysis techniques", *Public Management Review*, Vol. 6, 2004, pp. 21-53.
- Callies, Ingrid et al, "Outline of an ethics assessment framework," SATORI Deliverable 4.2, V.3.0, Sept 2017. http://satoriproject.eu/framework/section-1/
- Carney, J., "The Ten Commandments of Horizon ScanningForesight Projects", UK Government Offic for Science, Foresight blog, 8 March 2018. https://foresightprojects.blog.gov.uk/2018/03/08/the-ten-commandments-of-horizon-scanning/.
- Cuhl, K., "From Forecasting to Foresight Processes — New Participative Foresight Activities in Germany", *Journal of Forecasting*, 22, 2003, pp. 93-111. https://onlinelibrary.wiley.com/doi/full/10.1002/for.848
- Doos, L., C. Packe, D. Ward, S. Simpson, A. Stevens, "Past speculations of future health technologies: a description of technologies predicted in 15 forecasting studies published between 1986 and 2010", *BMJ Open*, 7(7), 2017, e016206. http://bmjopen.bmj.com/content/7/7/e016206.long
- European Foresight Platform, "Bibliometrics". Accessed 29 April 2018. http://www.foresight-platform.eu/community/forlearn/how-to-do-foresight/methods/analysis/bibliometrics/.
- Grant M.J., A. Booth, "A typology of reviews: an analysis of 14 review types and associated methodologies", *Health Information and Libraries Journal*, 26, 2009, pp. 91-108.
- https://www.ncbi.nlm.nih.gov/pubmed/19490148
- Iden, J., L.B. Methlie, G.E. Christensen, "The nature of strategic foresight research: A systematic literature review", *Technological Forecasting & Social Change*, 116, 2017, pp. 87-97. https://www.sciencedirect.com/science/article/pii/S0040162516306035
- Lucivero, F., *Ethical Assessments of Emerging Technologies. Appraising the moral plausibility of technological visions*, International Library of Ethics, Law and Technology, Springer, 2016.
- Lucivero, F., T. Swierstra, M. Boenink, "Assessing Expectations: Towards a Toolbox for an Ethics of Emerging Technologies", *NanoEthics,* 5(2), 2011, pp. 129–141.
- Martin, B. R., "Foresight in science and technology", *Technology Analysis & Strategic Management*, 1995, 7, No. 2, pp. 139–168.
- Martin, B. R., *Foresight. In STI Review No. 17*, Organisation for Economic Co-Operation, 1996.

- Martin, B. R., *Technology Foresight 6: A Review of Recent Overseas Programmes*, HMSO, London, 1995.
- Meltsner, A., "Political feasibility and policy analysis", *Public Administration Review*, 32, November/December 1972, pp. 859-867; Eden, C. & F. Ackermann, *Making Strategy: The Journey of Strategic Management,* Sage Publications, London, 1998.
- Mingers, J., & G. Walsham, "Toward ethical information systems: The contribution of discourse ethics", *MIS Quarterly*, 34(4), 2010, pp. 833–854.
- Prisma Group, PRISMA Statement, Accessed 29 April 2018. http://prisma-statement.org/PRISMAStatement/PRISMAStatement.
- Reijers, W., D. Wright, P. Brey, K. Weber, R. Rodrigues, D. O'Sullivan, B. Gordijn, "Methods for Practising Ethics in Research and Innovation: A literature Review, Critical Analysis and Recommendations", *Science and Engineering Ethics*, 2017. https://doi.org/10.1007/s11948-017-9961-8
- Reijers, W., P. Brey, P. Jansen, R. Rodrigues, R. Koivisto, & A. Tuominen, "A Common Framework for Ethical Impact Assessment.", SATORI Deliverable D4.1, 2016. http://satoriproject.eu/media/D4.1_Annex_1_EIA_Proposal.pdf
- Saritas, Ozcan, Lisa A Pace and S.I.P. Stalpers, "Stakeholder participation and dialogue in foresight", in Kristian Borch, Sandra M. Dingli, Michael Søgaard Jørgensen (eds.), *Participation and Interaction in Foresight: Dialogue, Dissemination and Visions,* Edward Elgar, Publishing Cheltenham, 2013, pp. 35-69
- SATORI, "CEN Workshop Agreement: Ethics assessment for research and innovation - Part 2: Ethical impact assessment framework, CWA 17145-2, June 2017. http://satoriproject.eu/media/CWA17145-23d2017.pdf
- Shelley-Egan, Clare, David Wright, Rok Benčin, Jelica Šumič Riha, Gregor Strle, Daniela Ovadia, Adelina Pastor Cañedo, Christine Angeli, Menelaos Sotiriou, *SATORI Deliverable D2.1 Report (handbook) of participatory processes,* July 2014. http://satoriproject.eu/media/Executive-summary_SATORI-D2.1.docx.pdf
- SIENNA *Deliverable 1.2 Stakeholder analysis, 2018.*
- Stahl, B. C., "IT for a better future: How to integrate ethics, politics and innovation", *Journal of Information, Communication and Ethics in Society*, 9(3), 2011, pp. 140–156.
- Stahl, B. C., R. Heersmink, P. Goujon, C. Flick, J. van den Hoven, K. Wakunuma, M. Rader, "Identifying the Ethics of Emerging Information and Communication Technologies", *International Journal of Technoethics*, 1 (4), 2010. http://doi.org/10.4018/jte.2010100102 42
- Thangaratinam, S., C.W. Redman, "The Delphi technique", *The Obstetrician & Gynaecologist,* 7, 2005, pp. 120-5. https://obgyn.onlinelibrary.wiley.com/doi/abs/10.1576/toag.7.2.120.27071
- United Nations Industrial Development Organisation, *Foresight Methodologies, Training Module 2,* 2004. https://www.tc.cz/files/istec_publications/textbook2revisedcf_1171283006.pdf
- Van de Poel, I., "An Ethical Framework for Evaluating Experimental Technology. Science and Engineering Ethics", (online article), 2015, pp. 1–20. http://link.springer.com/article/10.1007%2Fs11948-0159724-3#/page-1
- Wright, D., "A framework for the ethical impact assessment of information technology", *Ethics and Information Technology,* Vol. 13, 2011, pp. 199–226. http://doi.org/10.1007/s10676-010-9242-6

Approach to legal analysis – references

- Bignami, Francesca, "Formal versus Functional Method in Comparative Constitutional Law", *Osgoode Hall Law Journal,* 2016, pp. 442-471. http://digitalcommons.osgoode.yorku.ca/ohlj/vol53/iss2/3

- 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.
- Brownsword, Roger, *Rights, Regulation, and the Technological Revolution,* Oxford University Press, Oxford, 2008.
- Council of Europe, European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14, 4 November 1950, ETS 5.
- de Hert, Paul, "A right to identity the internet of things", Strasbourg: UNESCO, 2008. https://pure.uvt.nl/ws/files/1069135/de_Hert-Paul.pdf
- European Parliament, Science and Technology Options Assessment, Human Enhancement – Study, Brussels, 2009, p. 134. https://www.itas.kit.edu/downloads/etag_coua09a.pdf
- Goncales, Maria Eduarda, 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
- Goncales, Maria Eduarda, 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
- Hutchinson, Terry, Nigel Duncan, "Defining and Describing What We Do: Doctrinal Legal Research", *Deakin Law Review,* Vo. 17, No. 1, 2012, pp. 83-119.
- Leenes, Ronald, Erica Palmerini, Bert-Jaap Koops, Andrea Bertolini, Pericle Salvini, Federico Lucivero, "Regulatory challenges of robotics: some guidelines for addressing legal and ethical issues", *Law, Innovation and Technology*, Vol. 9, Issue 1, 2017, pp. 1-44.
- Lenaerts, Koen, José A. Gutiérrez-Fons, To Say What the Law of the EU Is: Methods of Interpretation and the European Court of Justice, EUI Working Paper 2013/9, Academy of European Law, p. 19. http://cadmus.eui.eu/handle/1814/28339
- Liefaard, Tom, Aart Hendriks and Daniella Zlotnik, From Law to Practice: Towards a Roadmap to Strengthen Children's Rights in the Era of Biomedicine, Leiden, 2017. https://rm.coe.int/leiden-university-report-biomedicine-final/168072fb46
- Organization of African Unity (OAU), African Charter on Human and Peoples' Rights ("Banjul Charter"), 27 June 1981, CAB/LEG/67/3 rev. 5, 21 *I.L.M.* 58 (1982).
- Palmerini, Erica, "A legal perspective on body implants for therapy and enhancement", *International Review of Law, Computers & Technology,* Vol. 29, Issues 2-3, 2015, pp. 226-244.
- Palmerini, Erica, "The interplay between law and technology, or the RoboLaw project in context", in Erica Palmerini and Elettra Stradella (eds.), *Law and Technology. The Challenge of Regulating Technological Development*, Pisa University Press, Pisa, 2013, p. 7-24.
- Pamerini, Erica, *Regulating Emerging Robotic Technologies in Europe: Robotics facing Law and Ethics (RoboLaw), D6.2 Guidelines on Regulating Robotics*, RoboLaw project, 2014, p. 20.
- Patrick, Macklem, "Human rights in international law: three generations or one?", *London Review of International Law*, Volume 3, Issue 1, 2015, pp. 61–92.
- Rubin, Edward L., On beyond Truth: A Theory for Evaluating Legal Scholarship, *California Law Review*, Vol. 80, Issue 4, July 1992, pp. 889-963.
- Ruggiu, Daniele, "Temporal Perspectives of the Nanotechnological Challenge to Regulation: How Human Rights Can Contribute to the Present and Future of Nanotechnologies", *Nanotechnologies*, Vol. 7, Issue 3, December 2013, pp. 201-215.
- Smits, Jan M., "What is Legal Doctrine? On the Aims and Methods of legal-dogmatic research", in. Rob van Gestel, Hans-W. Micklitz and Edward L. Rubin (eds.), *Rethinking Legal Scholarship: A Transatlantic Dialogue,* Cambridge University Press, New York, 2017, pp. 207-228.

- UN General Assembly, "Universal Declaration of Human Rights." United Nations, 217 (III) A, 1948, Paris. http://www.un.org/en/universal-declaration-human-rights/
- UN General Assembly, International Covenant on Civil and Political Rights, 16 December 1966, United Nations, Treaty Series, vol. 999, p. 171.
- UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3.
- van gestel, Rob, Hans-Wolfgang Micklitz, "Why Methods Matter in European Legal Scholarship", *European Law Journal*, Vol. 20, Issue 3, May 2014, pp. 292–316.
- Van Hoecke, Mark, "Methodology of Comparative Legal Research", *Law and Method*, December 2015, pp. 1-35. https://www.bjutijdschriften.nl/tijdschrift/lawandmethod/2015/12/RENM-D-14-00001
- Zieck, Marjoleine Y. A., "The Concept of "Generations" of Human Rights and the Right to Benefit from the Common Heritage of Mankind with Reference to Extraterrestrial Realms", *Verfassung und Recht in Übersee/Law and Politics in Africa, Asia and Latin America,* Vol. 25, No. 2, 1992, pp. 161-198.

Approach for the study of societal acceptance and awareness – references

- American Association for Public Opinion Research, Weighting in RDD Cell Phone Surveys, Undated. http://www.aapor.org/Education-Resources/Reports/Cell-Phone-Task-Force-Report/Weighting.aspx
- British Market Research Bureau (BMRB) (Kantar Public's former name), "Stem cell dialogue", initiated by the Biotechnology and Biological Sciences Research Council (BBSRC) and the medical Research Council (MRC), and funded by the Department of innovation, university and Skills' Sciencewise programme**,** 2008. https://www.mrc.ac.uk/documents/pdf/stem-cell-dialogue-final-report/
- British Market Research Bureau (BMRB) (Kantar Public's former name), "Nanotechnology for healthcare", Prepared for: Engineering and Physical Sciences Research Council, July 2008. https://www.epsrc.ac.uk/newsevents/pubs/nanotechnology-for-healthcare/
- British Market Research Bureau (BMRB) (Kantar Public's former name), "Synthetic Biology Dialogue", 2009-2010. https://bbsrc.ukri.org/documents/1006-synthetic-biology-dialogue-pdf/
- Department for Business Innovation and Skills, The Government's Approach to Public Dialogue on Science and Technology, September 2013. http://webarchive.nationalarchives.gov.uk/20170110130238/http://www.sciencewise-erc.org.uk/cms/assets/Publications/Sciencewise-Guiding-PrinciplesEF12-Nov-13.pdf
- Elkasabi, M. A., "Weighting Procedures for Dual Frame Telephone Surveys: A Case Study in Egypt. Survey Insights: Methods from the Field. Weighting: Practical Issues and 'How to' Approach", 2015. http://surveyinsights.org/wp-content/uploads/2015/02/Weighting-Procedures-for-Dual-Frame-Telephone-Surveys.pdf
- Google Enumeration Survey, 2016.
- Pew Global Attitudes Surveys, 2016. http://www.pewglobal.org/category/publications/2016/
- Pew Global Attitudes Surveys, 2017. http://www.pewglobal.org/category/publications/2017/
- TNS BMRB (Kantar Public's former name), and Involve, "Genomics and trust: designing a new framework for Government advice on genetics and society", final report, Department of Health, May 2011. http://webarchive.nationalarchives.gov.uk/20170110143618/http:/www.sciencewise-erc.org.uk/cms/assets/Uploads/Project-files/Genomics-and-trust-report.pdf
- TNS BMRB, (Kantar Public's former name), "Public engagement with shale gas and oil", December 2014.

http://webarchive.nationalarchives.gov.uk/20170110140243/http://www.sciencewise-erc.org.uk/cms/assets/Uploads/Publicengagementwithshalegasandoil.pdf

Approach for stakeholder analysis and contact list – references

- Aaltonen, Kirsi, "Project stakeholder analysis as an environmental interpretation process", International Journal of Project Management, Vol. 29, 2011, pp. 165–183.
- Achterkamp, Marjolein C., and Janita F.J. Vos, "Investigating the use of the stakeholder notion in project management literature, a meta-analysis", *International Journal of Project Management*, Vol. 26, 2008, pp. 749–757.
- Bonnafous-Boucher, Maria, and Jacob Dahl Rendtorff, Stakeholder Theory: A Model for Strategic Management, Chaim, Springer, 2016.
- Clarkson, Max B.E., "A stakeholder framework for analyzing and evaluating corporate social performance", *Academy of Management Review*, Vol. 20, No. 1, 1995, pp. 92–117.
- De Bussy, Nigel M., and Lorissa Kelly, "Stakeholders, politics and power: Towards an understanding of stakeholder identification and salience in government", *Journal of Communication Management,* Vol. 14 no. 4, pp. 289-305.
- Donaldson, Thomas and Lee E. Preston, "The stakeholder theory of the corporation: Concepts, evidence, and implications", *Academy of Management Review*, Vol. 20, No. 1, 1995, pp. 65-91.
- European Commission, *Stakeholder consultation guidelines 2014, Public consultation document*, 2014. http://ec.europa.eu/smart-regulation/impact/docs/scgl_pc_questionnaire_en.pdf
- Freeman, R. Edward, *Strategic Management: A Stakeholder Approach*, Pitman, Boston, 1984.
- Freeman, R. Edward, and David L. Reed, "Stockholders and Stakeholders: A New Perspective on Corporate Governance", *California Management Review*, Vol. 25, No. 3, 1983, pp. 88-106.
- Hill, Charles W. L., and Thomas M. Jones, "Stakeholder-agency theory", *Journal of Management Studies*, Vol. 29, No. 2, 1992, pp. 131-154.
- Missonier, Stephanie, and Sabrina Loufrani-Fedida, "Stakeholder analysis and engagement in projects: From stakeholder relational perspective to stakeholder relational ontology", *International Journal of Project Management*, Vol. 32, 2014, pp. 1108–1122.
- Mitchell, Ronald K., Bradley R. Agle, and Donna J. Wood, "Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What Really Counts", *Academy of Management Review*, Vol. 22, No. 4, 1997, pp. 853-886.
- Reed, Mike S., "Stakeholder participation for environmental management: A literature review", *Biological Conservation*, Vol. 141, No. 10, October 2008, pp. 2417-2431.
- Reynolds, Scott J., Frank C. Schultz, David R. Hekman, "Stakeholder Theory and Managerial Decision-Making: Constraints and Implications of Balancing Stakeholder Interests, *Journal of Business Ethics*, Vol. 64, No. 3, 2006, pp. 285-301.
- Roeder, Tres, *Managing Project Stakeholders: Building a Foundation to Achieve Project Goals*, Wiley, Hoboken, NJ, 2013.
- Schmeer, Kammi, "Stakeholder Analysis Guide lines", Policy Toolkit for Strengthening Health Sector Reform, Abt Associates, Inc., Bethesda, MD, 1999.

Approach for analysis and development of research ethics protocols and professional ethical codes – references

- ALLEA, The European Code of Conduct for research Integrity, Revised Edition, Berlin, 2017. https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

- B Corporation, “B Resource Guide: Creating a Code of Ethics”, 2007. http://nbis.org/nbisresources/human_resources/howto_create_employee_code_ethics_corp.pdf
- ENERI project. http://eneri.eu
- European Commission, “How to complete your ethics self-assessment”, 2018. http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf
- Lighthouse, “Developing a Code of Conduct: A Step-By-Step Guide”, White paper, Nov. 2013. https://www.lighthouse-services.com/documents/Developing%20a%20Code%20of%20Conduct%20%5bA%20Step-by-Step%20Guide%5d.pdf
- Manchester Metropolitan University, Ethics checklist, 2017. http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/MMU-Ethics-Check-List-v9-10-Jan-2017.pdf
- Plymouth Marjon University, *Guidance: Initial Research Ethics Checklist & Ethics Review Protocol,* 2017. https://www.marjon.ac.uk/media/2015-website-images/research/B.-Guidance-for-Initial-Research-Ethics-Checklist-&-Ethics-Review-Protocol_October2017.pdf
- Queensland Government, Business Queensland, “Writing a code of conduct”, 2017. https://www.business.qld.gov.au/running-business/employing/taking-on-staff/staff-code-conduct/writing
- SATORI project. http://satoriproject.eu
- The Council for International Organizations of Medical Sciences (CIOMS), “International Ethical Guidelines for Biomedical Research Involving Human Subjects”, 2002. https://cioms.ch/shop/product/international-ethical-guidelines-for-biomedical-research-involving-human-subjects-2/
- The University of Western Australia, “How to write a good ethics application”, Undated. http://www.research.uwa.edu.au/staff/human-research/good-application/good-application
- World Medical Association, Declaration of Geneva, 2017. https://www.wma.net/policies-post/wma-declaration-of-geneva/
- World Medical Association, Declaration of Helsinki, Ethical Principles For Medical Research Involving Human Subjects, 2013. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- World Medical Association, Declaration of Taipei on ethical considerations regarding health databases and biobanks, 2016. https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/