

ETHICAL GUIDANCE FOR RESEARCH WITH A POTENTIAL FOR HUMAN ENHANCEMENT

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² Especially: Erden, Yasemin J. and Philip Brey, **D5.3: Methods for promoting ethics for human enhancement**, forthcoming. See also:

Jensen, Sean R., Saskia Nagel, Philip Brey, Tanne Ditzel, Rowena Rodrigues, Stearns Broadhead, and David Wright, SIENNA **D3.1: State-of-the-art Review: Human Enhancement** (Version V1.1), 2018. Zenodo: <https://zenodo.org/record/4066557#.X9yEOi2l1pQ>

Jensen, Sean R., SIENNA **D3.4: Ethical Analysis of Human Enhancement Technologies** (Version V1.1), 2020. Zenodo: <https://zenodo.org/record/4068071#.X9yDpi2l1pQ>

Prudhomme, Marie, SIENNA **D3.5: Public views of human enhancement technologies in 11 EU and non-EU countries** (Version V4), 2020. Zenodo: <https://zenodo.org/record/4068194#.YDZiXS2l1pQ>

Kantar (Public Division), SIENNA **D3.6: Qualitative research exploring public attitudes to human enhancement technologies** (Version V3), 2019. Zenodo: <https://zenodo.org/record/4081193#.YDZxTi2l1pQ>

Kühler, Michael, Nils-Frederic Wagner, and Philip Brey, SIENNA **D3.7: Proposal for an Ethical Framework for Human Enhancement** (Version V10), 2020. Zenodo: <https://zenodo.org/record/4275579#.X9yLoy2l1pQ>

1. INTRODUCTION

This document aims to help researchers to consider, examine, and address ethical issues associated with human enhancement. Human enhancement refers to a wide field of interventions and technologies that aim at improving human beings beyond what might otherwise be considered typical or average. Enhancements can include prosthetics that outperform average human limbs; drugs that boost human cognitive capacities; or genetic modification to immunise against disease. Human enhancement can, thus, be defined as a modification aimed at improving human performance beyond what might be described as ‘normal’ functioning and brought about by science-based and/or technology-based interventions in or on the human body. Human enhancement is often contrasted with therapy; whereas therapy is intended to restore human health or functioning to typical levels, enhancement intends to augment human functioning beyond what is considered typical or usual. A further distinction can be made between *therapeutic enhancement*, in which treatment of unhealthy persons enables them to perform to a degree beyond typical health, and *non-therapeutic enhancement*, in which healthy persons undergo modifications with the explicit aim to augment certain of their characteristics or capabilities.

This document is intended for the following types of projects:

- Projects in which human enhancement is an explicit aim, either through research intended to facilitate human enhancement applications, or through the development of products or techniques intended for human enhancement.
- Projects that have unforeseen, unpredicted or unintended potential enhancement applications, by which is meant that research and/or development is undertaken for therapeutic or other non-enhancement purposes, but the results of the project also have a clear potential for human enhancement.

Human enhancement tends to raise significant ethical issues and is often controversial, both from the point of view of medicine, medical ethics, and from a wider societal point of view. This is because it involves the modification, often permanently, of key aspects of a person’s identity, including the human body, cognition, affect, and morality, and because it results in human beings that are beyond typical, average or ‘normal’, or even with ‘superhuman’ capabilities. It is for this reason more controversial than many forms of medical therapy. Human Enhancement is therefore also polarising. Pro-enhancement advocates, sometimes called transhumanists, tend to emphasise the potential benefits to individuals and society, and to promote individual choice. Meanwhile ‘enhancement critics’, sometimes described as bioconservatives, tend to emphasise health risks, risks to equality and to well-being, with some arguing that enhancement subverts ‘human nature’.

Controversial enhancements differ from familiar methods for the augmentation of human abilities, especially those that do not involve the modification of the human body and mind beyond typical levels. This latter category would include night goggles that allow a person to see in the dark, or stimulants like coffee that helps a person to maintain focus and stay awake. Accordingly, the guidance in this document is particularly centred on human enhancement in the form of implants, drugs, genetic enhancement or machines, and especially interventions that are irreversible, internal to the body, have long term impacts (physical, psychological, social), have a limited timespan or require updates, or have implications for the privacy of groups and individuals.

The guidance in this document is designed to be cross-disciplinary, and not limited to a particular field of science, engineering or medicine. It aims to cover all fields in research and development (R&D) where human enhancement potential may occur. Although it has wider application, this document has been composed for Horizon Europe ethics review and it thereby also complements other documentation for the ethics review procedure in Horizon Europe.

2. KEY INFORMATION ON HUMAN ENHANCEMENT

Human enhancement has been around for a long time. We have cosmetic surgery, performance-enhancing drugs, and powered exoskeletons. Developments in a number of fields point to the potential for many new enhancement technologies in the coming decades that can augment human physical and mental abilities. They include genetics and genomics, tissue engineering and bioprinting, biomaterials, neural engineering and neurotechnology, pharmaceuticals, prosthetics, nanomedicine, information and communication technologies, in particular artificial intelligence and augmented reality, and the field of human-machine interaction.

Applications of human enhancement can be envisioned in any **social domain**, including, but not limited to:

1. **Healthcare:** This domain comprises mainly institutional healthcare, including the relation between and amongst medical personnel and patients, and is mostly concerned with therapeutic enhancement.
2. **Education:** This domain comprises all stages of mainly institutional education, ranging from preschool to university, as well as wide effects on society resulting from the introduction of human enhancement technologies in education.
3. **Workplace:** This domain covers situations at work, including the relation between employers and employees, and the wider societal impacts of changes in the workplace.
4. **Military/defence:** This domain comprises military/defence institutions and their personnel as well as the likely impact of human enhancement technologies on the understanding and practice of future armed conflicts.
5. **Home and recreation:** This domain covers the use of human enhancement technologies purely for private or recreational purposes, including possible off-label use, and its related impact on society in general.

Human enhancements can be divided into six broad **functional categories**:

1. **Physical** enhancements are interventions that improve or introduce new physical abilities. Potential targets for physical enhancement are performance, endurance, or the addition of new abilities (additive). Performance enhancements increase the capacity to effectively complete physically demanding tasks, like running quickly or lifting heavy objects. Endurance enhancements increase the capacity to engage in physically demanding tasks for extended periods of time. In some cases, performance and endurance enhancements will overlap, i.e., a single intervention may increase performance in such a way that it also improves endurance, or vice-versa. Additive enhancements add new physical abilities that an individual could not have without the enhancement, i.e. adding novel abilities, like seeing clearly in the dark.
2. **Cognitive** enhancements are interventions that improve cognitive abilities. Potential targets for cognitive enhancement are intelligence, clarity and creativity. Intelligence enhancements improve capabilities associated with intellectual abilities, such as critical thinking, reasoning, memory or comprehension of ideas. Clarity enhancements are primarily related to focus but can also apply to enhancements that increase abilities associated with maintaining rigor during cognitive tasks. Creativity enhancements may improve inventiveness, artistic ability, design-related tasks, or, more broadly, the ability to think of new ideas or concepts. Finally, the distinction between cognitive and physical enhancements may not always be clear, for instance in the case of sensory enhancement, which includes a physical and cognitive dimension.
3. **Affective & emotion** enhancements are interventions that improve and/or provide greater control over a human's affective states. Potential targets for affective and emotion enhancement are mood and emotional dispositions. Mood enhancements give a user control over their mood, such as by allowing a

user to quickly, perhaps (in the future) even instantaneously, transition from feeling anxious about work, e.g. while at home, to feeling more comfortable or relaxed. Emotional enhancements alter the user's emotional state, for example by making a user feel happy quickly after taking a pill.

4. **Cosmetic** enhancements are interventions that improve the cosmetic appearance or traits of a human being. There are two subcategories of cosmetic enhancement: aesthetic and body modification. Aesthetic enhancements improve one's physical features to better accord with social ideals, such as cosmetic plastic surgery. Body modification entails augmenting a person by introducing new (primarily) cosmetic features, such as 'installing' magnetic fingertips. Cosmetic enhancements share a grey area with physical enhancements.
5. **Moral** enhancements are interventions that modulate or foster attitudes and behaviours that are considered morally or socially acceptable. Potential targets for moral enhancement range from limited enhancements, for example interventions designed to 'correct' behaviours considered deviant in one's society, to more robust interventions that greatly alter or allow for the modulation of moral deliberation, for instance by reducing implicit bias.
6. **Longevity** enhancements are interventions that extend a human's expected lifetime or make someone less frail and more able than usual for their age. Longevity enhancements may be preventative or may reverse, limit or mitigate against senescence and enhance durability. Preventative enhancements stop or reduce negative effects of disease or disability, such as via a vaccine. Senescent enhancements stop or slow down the aging process of the body. Durability enhancements improve one's ability to survive or recover from harm or damage.

At this point in time, cosmetic enhancements already constitute a big market, physical and cognitive enhancements exist in limited form, and affective & emotion enhancement, moral enhancement and longevity enhancement are still largely science fiction, although basic techniques are being developed that could make such enhancements feasible in the future.

It should be taken into account that human enhancement has a complex relation to the field of medicine. Medicine encompasses the promotion of health, as well as the science and practice of diagnosis, prognosis, treatment, and prevention of disease, and excludes currently available cosmetics and cosmetic surgeries unless they are corrective. Human enhancement is not typically concerned with either of these goals, and therefore seems to fall outside the scope of medicine as well as medical ethics. In practice, some human enhancement technologies are developed as a by-product of therapeutic innovation, including where enhancement is not foreseen, predicted or intended, whereas others are developed in nonmedical settings. Given its unclear relation to medicine, it will often be unclear whether the laws, institutional requirements, conventions and ethics guidelines that apply to medicine also apply to human enhancement.

3. GENERAL STEPS FOR THE ETHICAL ASSESSMENT OF HUMAN ENHANCEMENT

It is assumed in this document that your research project meets the criteria mentioned in the introduction, in that investigating or facilitating human enhancement is an explicit aim of the project or that there is a clear potential for the project results to be used for human enhancement. To test for this more thoroughly, we suggest that you answer the following questions:

1. **Is the research partially or wholly directed at developing, testing or doing enabling research for techniques, processes, products, materials or methods aimed at supporting interventions in or on the body that result in the augmentation of human physical or mental capabilities or qualities beyond typical, average, or ‘normal’ levels?**

Example: The project is directed at developing at new pharmaceuticals for healthy individuals to increase their ability to concentrate and perform cognitive tasks.

Example: The project is directed at developing (techniques for) exoskeletons for the augmentation of human strength, with their use by healthy individuals in the workplace as one of the intended applications.

2. **Is the research partially or wholly directed at developing techniques, processes, products, materials or methods that could be used, without significant additional R&D, for the augmentation of human physical or mental capabilities or qualities beyond typical, average, or ‘normal’ levels?**

Example: The project is aimed at developing a new type of cochlear implant that will, if appropriate settings are applied, allow users to also hear sounds beyond the typical human range.

Example: The project is directed at developing a new type of exoskeleton for use by people with physical impairments, which can however also be used, with minimal adaptations, by healthy individuals to increase their physical abilities.

If you answer at least one of these questions affirmatively, we recommend that you implement in your project the following procedure and general steps:

- (1) In your **project proposal**, identify human enhancement as an ethical issue that will be analysed and addressed in your project. Indicate in which project task(s) ethical assessment and mitigation will be carried out, and do a preliminary assessment of potential ethical issues, and how they can be mitigated. At this point, it should also be determined if the project potentially raises ethical issues with human enhancement that would be prohibitive for the project (see for instance Section 4.1 below) to proceed in its envisioned form. If so, modify the project design until the objection has been resolved. Consider the involvement of an ethics expert/adviser with suitable expertise, for instance in the research team and/or consortium.
- (2) Upon **inception of the project**, carry out an extended assessment of the ethical issues with human enhancement in the project, and develop a mitigation strategy. This will build on but also extend the

work undertaken in step one, i.e. the planning stage, but will include additional details and methods for mitigation. Carrying out the mitigation strategy is the responsibility of the consortium as a whole, and researchers that contribute to research on human enhancement, or with human enhancement as a likely application, should be actively involved in the assessment and mitigation process.

Section 4 of this document offers guidance for performing an extended ethical assessment. It contains ethics guidelines for human enhancement research that should be considered and applied in the assessment of your planned research. A trained ethicist with experience in ethical assessment of STEM research should be able to carry out such an assessment, in collaboration with the researchers who need to interact with the ethicist and inform them of the nature of the planned research. Note, however, that the guidelines only cover ethical issues relating to human enhancement, not other ethical issues that may occur in research. A complete ethical assessment of the planned research will also consider other ethical issues, such as, for example, ethical issues in research with human subjects, the use of personal data, the use of human cells and tissues, and dual use. An ethics assessment may also uncover special ethical issues relating to human enhancement that are not immediately covered by the ethics guidelines provided in section 4.³

The initial ethical assessment is carried out at the beginning of the project. It should identify ethical issues that should be mitigated in the project. Subsequently, a mitigation strategy should be developed. It is recommended that the mitigation strategy is developed in collaboration between involved ethicists and researchers. It should address how ethical issues are avoided, eliminated or lessened through changes in the research design, or through research policies, or other mitigation actions.

- (3) **Over the course of the project**, update the ethical assessment and mitigation strategy, and monitor compliance with the mitigation strategy, and whether such actions successfully mitigate the ethical issues. As research proceeds, new ethical issues may emerge, or existing ethical issues may need to be reassessed, so it is recommended that the ethical assessment is updated throughout the project. It is also recommended that the mitigation strategy is updated throughout the project, and that progress in attaining mitigation goals is documented. Periodic monitoring is needed to ensure that the mitigation strategy is followed and to verify if mitigation actions are successful. If this is not the case, interventions are needed.
- (4) **Document** both the assessment, the mitigation strategy, and the processes by which both are carried out, for later reference.

In what follows, we will provide more information on ethical issues arising from human enhancement, guidance for the ethical assessment of research with human enhancement implications, as well as recommendations for mitigating steps to address ethical issues.

³ For a step-by-step methodology for ethical assessment of new technology, see P. Brey et al., D6.1: Generalised methodology for ethical assessment of emerging technologies, forthcoming at <https://www.sienna-project.eu/publications/deliverable-reports/> and on Zenodo.

4. IDENTIFYING AND MITIGATING ETHICAL ISSUES IN HUMAN ENHANCEMENT

The ethics guidance that we offer in this document is based on key values with wide applicability: well-being, autonomy, privacy, consent, equality, justice, and (moral and social) responsibility. These values take into account a combination of considerations: their recognition in philosophical ethics and in international declarations and treaties such as the *Universal Declaration of Human Rights*⁴ and the *Charter of Fundamental Rights of the European Union* (cited in Section 5 below) and their relevance to ethical assessments of human enhancement. By consulting this document in conjunction with other ethics guidance such as those listed in Section 5, the researcher can take into account broader moral values in relation to human enhancement, such as liberty, bodily integrity, and human dignity. Many of the values we describe here have a strong basis in human rights law in many countries, including informed consent, equality, justice, and, to a lesser extent, autonomy. Others, like well-being or welfare, may not be explicitly referenced in human rights law, but may instead be promoted as policy objectives at the national level. It is important to note that ethical evaluation of a technology is affected by the type and quality of risk that it engenders. For instance, a permanent neural implant that alters the workings of the brain may evoke more questions and concerns than a prosthesis that is externally connected and easy to detach. Higher risk categories include interventions that are irreversible, internal to the body, have long term impacts (physical, psychological, social), have a limited timespan or require updates, or have implications for the privacy of groups and individuals.

In this section we identify the most important ethical issues that are most relevant to research, development and application of technologies with human enhancement potential, and we offer mitigation practices to avoid harm and promote ethical practice. These mitigation practices can be applied according to Figure 1: Flowchart of Actions below. The guidance is not meant to be exhaustive or exclude other approaches. Instead, it is intended to complement existing ethical processes and procedures, as well as typical health, safety and risk assessments.

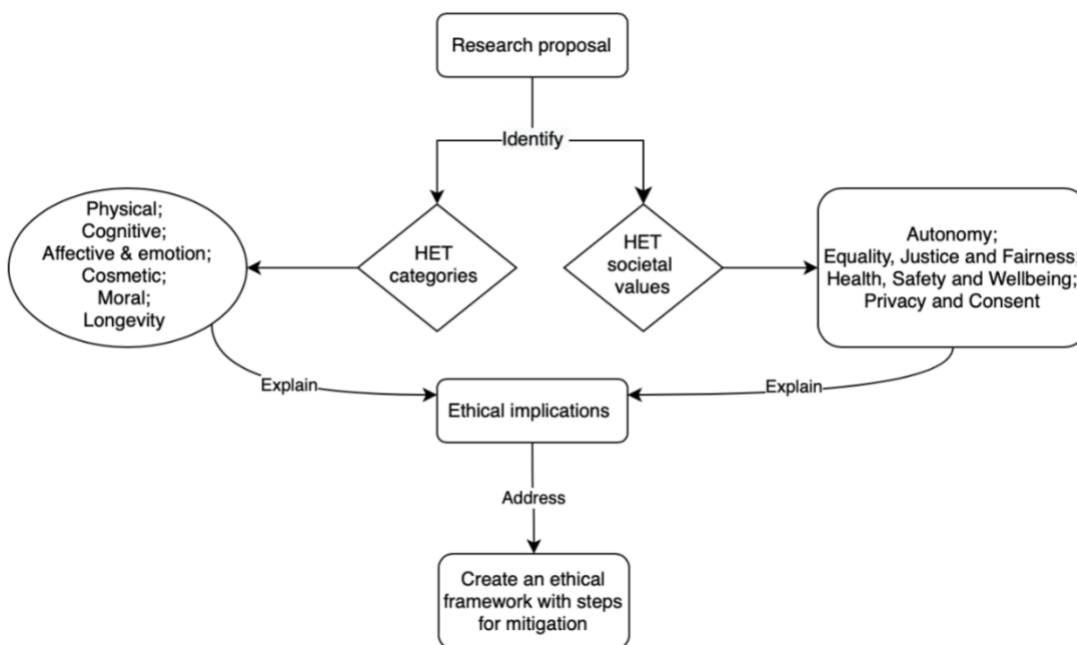


Figure 1 Flowchart of Actions

⁴ United Nations, *Universal Declaration of Human Rights*, 1948: https://www.ohchr.org/EN/UDHR/Documents/UDHR_Translations/eng.pdf [accessed 15 November 2020]

The flowchart should be used alongside the mitigations suggested in the sections below. These are grouped in the following categories: (4.1) Basic moral and legal permissibility; (4.2) Autonomy; (4.3) Health, safety and wellbeing; (4.4) Fairness and equality; (4.5) Informed consent and privacy.

4.1. BASIC MORAL AND LEGAL PERMISSIBILITY

A first question to ask is whether the research objectives, as well as the principal means and methods by which these objectives are achieved, meet standards of basic moral and legal permissibility. It should be recognised that research explicitly aimed at human enhancement is often unethical or even illegal, and therefore it should be evaluated carefully whether or how a proposed project can proceed. Genetic enhancement (whether somatic or germline) is illegal under the legally-binding Oviedo Convention, which states: “An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.” (Chapter IV, art. 13).¹ Human enhancement research that aims at interventions in which healthy tissue or organs are damaged or destroyed without medical necessity is considered unethical. Clinical trials or experiments which expose human subjects to significant health or safety risks without there being a clear medical benefit are also likely to be unethical.

Mitigation measures: If your project includes any of these practices, then it should be modified so as to avoid them. If this turns out not to be possible, then the project unfortunately cannot proceed and will not be eligible for funding.

4.2. AUTONOMY

Autonomy concerns a person’s ability to decide and act on their own authentic desires and preferences, without being unduly influenced, coerced or manipulated by others. Human enhancement can undermine or promote autonomy, whether by affecting a person’s disposition, desires and interests, altering their mood, or changing their personality. There could also be social pressure, including in educational or work contexts.

Mitigation measures: Human enhancement should not limit a person’s ability and freedom to make their own choices, and to have the full range of cognitive, affective and conative states that underly human autonomy. Accordingly, your research design should be such that any envisioned or potential human enhancement applications:

- do not impair the potential and capacity for human rationality and independent thought, for instance by limiting a person’s ability to imaginatively, critically, and autonomously engage with arguments and ideas, and to reflect on and amend their own position;
- do not deprive a person of their scope for broad and complex human desires and emotions, for instance, by inhibiting all but singular desires that fit the needs of governments or market forces, or by restricting empathy and conscience for the purposes of dispassionate law enforcement or for military applications;
- do not change the personality of an individual in a way that either distorts or limits their potential to maintain existing control over their identity. This includes, for instance, where an enhancement impacts on an integrated conception of self, i.e. as a self that persists in time (past and present), and as located in one person, or to a person’s potential to live authentically, so that their actions are congruent with their beliefs, desires, and memories. Ordinary personality changes, as occur through a person’s life, happen within a framework of decisions and actions, interpersonally and via introspection, and human enhancement should not disrupt this.

4.3. HEALTH, SAFETY AND WELLBEING

The value of being in good health and in a safe environment, as well as one's individual feeling or perception of being healthy and safe. As science-based and/or technology-based interventions in or on the human body, enhancement unavoidably includes risks for both health and safety. Such risks need to be carefully weighed against the expected benefits. Hence, a good case has to be made for why human enhancement interventions warrant taking the risks involved.

Mitigation measures: Human enhancement technologies should prioritise the health, safety and well-being of the recipient of an enhancement. As such, enhancements, especially those that are irreversible, should provide a clear benefit to the individual's life, with a likelihood that their overall well-being is increased not just in the short term, but over their lifespan. This includes:

- assessments of the risks and benefits of human enhancement for the recipient, especially those that are internal to the body and irreversible. These should be extensive and based on empirical studies. They must also include consideration of side effects beyond the medical domain, including psychological and social consequences, such as potential loss of identity and of self-esteem, addiction, and social stigmatisation. Where the enhancement is directly or indirectly related to, or impacts on children, future risks must be considered. This includes, for instance, any loss of future privacy due to the need for long-term monitoring;
- assessments of the risks and benefits of human enhancement for the recipient should take into account any unique characteristics and circumstances of the recipient that pertain to membership of a vulnerable group. This includes the recipient's physical and psychological features, cultural background, health, social network, and occupation;
- providing sufficient information and being clear if a treatment is irreversible, and if so why, and what potential there is for alternative, reversible enhancement(s) that would serve the same or similar purpose. It also requires a careful weighing of potential benefits and harms to the recipient over an extended period of time, taking into account the unique characteristics and circumstances of the recipient, their own perspectives and wishes, as well as any potential changes in their circumstances and life choices over time;
- only in exceptional cases permitting enhancements that cause, or risk causing, the loss of necessary biological human function, or has a risk of causing substantial or serious side effects, such as harm to health, chronic pain or other harms, especially if the enhancement is irreversible;
- the application of caution to cases in which an enhancement affects emotions and affect, cognition and other mental capacities. In such cases it needs to be taken into account that these capacities are interrelated, and that they are tied up with a person's values, beliefs, judgements, and personality, so that changing one element will also affect some or all of the others;
- taking into account that, as currently defined, clinical trials could only be performed for therapeutic enhancement research and not for non-therapeutic enhancement research. For therapeutic enhancement, clinical trials will be a moral and legal necessity. For non-therapeutic enhancement, equivalent safety and efficacy studies will be necessary. Human enhancement research aimed at new interventions internal to the body will require safety and efficacy studies to take place before the new intervention can be applied in society, but the health and safety risks of such studies without a proven medical benefit might make it difficult to get ethics approval for such studies;
- not neglecting to address contemporary or future legal implications regarding the ownership of human enhancement technologies, including the licencing of software and hardware that could become indivisible from the user. Researchers and developers should also consider in advance any implications

arising from such and ensure that these can be fully understood by recipients in advance of any human enhancement process or procedure.

4.4. FAIRNESS AND EQUALITY

The value of treating everyone equally, justly and fairly, can be affected by human enhancement in many ways. On the one hand, enhancement could diminish existing inequalities, while on the other it could cause new inequalities by providing individuals and groups with superior abilities not possessed by others. It may also exacerbate existing social inequalities as well as engender new ones by creating new social identities and challenging or reifying existing conceptions of identity, including what is considered ‘normal’ or typical, unusual or deviant. Human enhancement could also unjustly and unfairly improve a person’s chances in competitive situations, as seen for instance with doping in sport.

Mitigation measures: in the development and deployment of technologies intended for or with a potential application to human enhancement, take mitigation actions, to the extent possible, with the objective:

- of research and development being preceded and accompanied by a social and ethical impact assessment that does not just consider benefits and risks to individuals, but also implications for other stakeholders and for society as a whole. These assessments should include the possibilities of misuse and for unforeseen, unpredicted or unintended potential enhancement applications. They should, in addition, involve relevant stakeholders (both those that are directly and indirectly affected) and it should be ensured that there is enough support from stakeholders for research and development to proceed;
- to avoid the perpetuation or exacerbation of existing inequities or inequalities between groups and communities. Whether enhancements are likely to do so can be established via social or ethical impact assessments;
- to avoid the promotion or perpetuation of discrimination of either enhanced or non-enhanced persons by anticipating and mitigating where possible these kinds of outcomes;
- of not propagating harmful stereotypes pertaining to average versus disabled bodies, or standards of beauty or presentability that rest on prejudicial stereotypes, for instance about gendered, racialised or ethnic identities or other protected characteristics;
- of taking into account where the abilities bestowed by the enhancement are amongst those abilities considered most important for having success in life, such as intelligence, memory, self-confidence, strength, dexterity, and endurance, among other qualities. In the case where such enhancements are made available, then consider how such enhancements could be made accessible to people equally.

4.5. INFORMED CONSENT AND PRIVACY

The related values of being in sufficient control over decisions in one’s personal life, and over one’s personal data. Human enhancement may affect the values of privacy and consent whether in the generation or capture of personal data, like location or usage data, or in the access or use of such data. While issues about data, privacy, and informed consent are already well managed in ethics self-assessment, human enhancement technologies bring a number of more specific issues to the fore.

Mitigation measures: For technologies with human enhancement capacity, it should be ensured that:

- recipients are fully informed about the nature, significance, implications, benefits and risks of enhancement, especially if it is irreversible, in order to make a free and unconstrained choice. Ideally,

intended recipients of an enhancement should be involved early in the decision and planning processes for the design and development of technologies and procedures that have higher risks or are irreversible;

- recipients are fully informed about any data and privacy implications of an enhancement, and consent to them. Personal data are kept and processed according to the requirements of the EU General Data Protection Regulation (GDPR);
- consideration is given to who can provide informed consent. Since children are unable to provide informed consent, paediatric enhancement is problematic and may be illegal. The same applies to other individuals unable to give informed consent, and again this must be in conformity with national law. Enhancements for these groups should only be considered if the enhancements have already proven to have clear benefits and minimal risks for adults capable of informed consent and have become widely accepted for them, and if empirical studies confirm that a similar benefit-risk ratio would apply to recipients unable to give informed consent. Paediatric enhancement must take into account the UN Convention on the Rights of the Child, in particular it must observe the principle of a child's best interests, as well as a child's needs and rights more generally.
- extreme caution is taken for enhancements with intended applications in the workplace, in education, for military purposes, and in other contexts in which individuals may not have a free choice on whether to be enhanced but may be pressured or required to do so by others. Such pressure will inevitably exist if enhancements become normalised in these contexts. It is not advised that any enhancements are developed for these contexts that are internal to the body and/or irreversible. For other types of enhancement, the risks to coercive enhancement need to be assessed and mitigated.

5. ADDITIONAL FRAMEWORKS FOR ADDRESSING ETHICAL ISSUES IN HUMAN ENHANCEMENT

There are various international guidance documents and frameworks that either address human enhancement explicitly (though often briefly), or that contain ethics guidelines that could be applied to human enhancement. Most of these are ethics guidance documents for biomedicine. We here present them briefly.

- **The SIENNA ethics guidelines for human enhancement:**⁵ ethics guidelines, on which this current guidance document is based. The only known guidelines to focus on human enhancement specifically.
- **The World Medical Association (WMA) Declaration of Helsinki:**⁶ a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.
- **World Health Organisation (WHO) Standards & Operational Guidance for Ethics Review of Health-Related Research with Human Participants:**⁷ provides guidance to research ethics committees and to the researchers who design and carry out health research studies.
- **Oviedo Convention**⁸ - protection of human rights & dignity of the human being with regard to the application of biology & medicine.
- **International Ethical Guidelines for Health-related Research Involving Humans:**⁹ prepared by the Council for International Organisations of Medical Sciences (CIOMS). These guidelines seek to show how the ethical principles of the Declaration of Helsinki can be effectively applied. Emphasis is on research having scientific and social value, with provisions for involving vulnerable groups in research and for describing under what conditions biological samples and health-related data can be used for research.
- **The Charter of Fundamental Rights of the European Union:**¹⁰ seeks to strengthen and protect fundamental, universal values of human dignity, freedom, equality and solidarity, and reaffirms rights as they result from, e.g. the European Convention for the Protection of Human Rights and Fundamental Freedoms. It also includes key prohibitions about the human body (Article 3), including treating it as a source of financial gain (3.1c) and the prohibition of the reproductive cloning of human beings (3.1d).
- **Universal Declaration on Bioethics and Human Rights:**¹¹ prepared by UNESCO, seeks to address ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions. This universal framework of principles and procedures guides actions (individuals, institutions, corporations etc.), promotes respect for human dignity, protects human rights, and encourages equitable access to medical, scientific and technological developments. It also seeks to safeguard and promote the interests of present and future generations.
- **Report of the IBC on updating its reflection on the Human Genome and Human Rights:**¹² by the International Bioethics Committee, which centres on five ethical principles and societal challenges: respect for autonomy and privacy, justice and solidarity, understanding of illness and health as a complex and including multiple factors (inc. behavioural, social, and environmental determinants of health), cultural, social and economic context of science, and responsibility towards future generations.

⁵ The SIENNA ethics guidelines for human enhancement, forthcoming: <https://www.sienna-project.eu/enhancement/codes-and-guidelines/>

⁶ WMA Declaration of Helsinki, seventh revision 2013: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> [accessed 12/10/20]

⁷ WHO Guidance document, 2011: <https://www.who.int/ethics/publications/9789241502948/en/> [accessed 12/10/20]

⁸ Oviedo Convention and its Protocols, 1999: <https://www.coe.int/en/web/bioethics/oviedo-convention> [accessed 12/10/20]

⁹ CIOMS guidelines, 2016: <https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf> [accessed 12/10/20]

¹⁰ European Union, *Charter of Fundamental Rights of the European Union*, 26 October 2012, 2012/C 326/02, article 3.2.d. available at: https://www.europarl.europa.eu/charter/pdf/text_en.pdf [accessed 12/10/20]

¹¹ UNESCO declaration, 2005: <https://en.unesco.org/themes/ethics-science-and-technology/bioethics-and-human-rights> [accessed 12/10/20]

¹² International Bioethics Committee report, 2015: <https://unesdoc.unesco.org/ark:/48223/pf0000233258> [accessed 12/10/20]