Human Enhancement: Ethics Guidelines

This document offers ethics guidelines for research in and development and application of human enhancement technologies and procedures. This is the first time that extensive guidelines for human enhancement have been proposed. The guidelines aim to be international in scope. The guideline document consists of seven sections in which guidelines are presented (sections 1 – 7). These are preceded by a preamble that defines scope and key terms, describes the status of human enhancement as a new type of practice, and provides moral and legal foundations for the guidelines. The guidelines are followed by a section which discusses the use and implementation of the guidelines (section 8). A glossary follows at the end.

These guidelines are intended for researchers, developers, and (para)medical practitioners that work in areas in which human enhancement could be an objective or unintended consequence. These include fields in biomedicine, biomedical engineering and human-machine interaction. The guidelines could also have utility for other stakeholders, for instance for policy makers and research funders. It is recommended that these guidelines are incorporated in ethics guidelines and research ethics protocols for relevant fields.

These guidelines have been developed as part of the European Union-funded SIENNA project, which aims at ethical and human rights assessment and guidance of emerging technologies.[1] They are the result of extensive analysis, and extensive consultation with stakeholders, including academic experts in the fields of ethics, biomedicine, biomedical engineering, computer science, and social science, and stakeholders from industry, government, and civil society. The guidelines build on extensive prior studies of human enhancement in the SIENNA project. See especially SIENNA D3.1 'State-of-the-art Review',[2] D3.4 'Ethical Analysis of Human Enhancement Technologies',[3] and D3.7 'Proposal for an ethical framework for human enhancement'.[4] A description of the process by which these guidelines have been developed can be found in deliverable D5.3 'Methods for promoting ethics for human enhancement'.[5]

[1] The SIENNA project, 'Stakeholder-Informed Ethics for New technologies with high socio-ecoNomic and human rights impAct', aims at ethical and human rights assessment and guidance for human genomics, human enhancement, and artificial intelligence & robotics. SIENNA is funded under the European Union's H2020 research and innovation programme (grant agreement No 741716). This document and its contents reflect only the work of SIENNA and does not intend to reflect views of the European Commission. The European Commission is not responsible for any use that may be made of the information it contains.

[2] Jensen, S. R., Nagel, S., Brey, P. A. E., Ditzel, T., Rodrigues, R., Broadhead, S., & Wright, D. (2018). SIENNA D3.1: State-of-the-art Review: Human Enhancement (Version V1.1). Zenodo: https://zenodo.org/record/4066557#.X9yEOi2l1pQ

[3] Jensen, S. R. 2020. SIENNA D3.4: Ethical Analysis of Human Enhancement Technologies (Version V1.1). Zenodo: https://zenodo.org/record/4068071#.X9yDpi2l1pQ

[4] Kühler, M., Wagner, N.-F., & Brey, P. A. E. (2020). SIENNA D3.7: Proposal for an ethical framework for human enhancement (Version V10). Zenodo: https://zenodo.org/record/4275579#.X9yLoy2l1pQ

[5] Brey, P. A. E., & Erden, Y. J. D5.3: Methods for promoting ethics for human enhancement, forthcoming.

Preamble

Definitions and scope

- *Scope:* These guidelines apply to the following practices:
  - Clinical, pre-clinical and non-medical applied research and development for which human enhancement is its central aim or one of its aims;
  - Applied research and development that is directed at or results in medical or non-medical devices, drugs or medical treatment regimens that can be used for human enhancement with few or no modifications. For this type of research and development, the guidelines prescribe that if such products and processes are likely to violate these guidelines, mitigating actions should be taken either to develop them in a different way, to help prevent them from being used in unethical ways, or to consider not developing them at all if these other remedies are not likely to work;
  - The deployment of products and processes in or on the human body with human enhancement as the central aim or one of the aims.

- *Human enhancement:* Human enhancement does not refer to a specific technology or application, but a wide field of interventions and technologies that aim at improving human beings beyond what is considered typical, or as sometimes problematically referred to as 'normal.' Human enhancement is defined in SIENNA as 'a modification aimed at improving human performance and brought about by science-based and/or technology-based interventions in or on the human body' (D3.1). Examples of possible (future) human enhancements are prosthetic limbs that outperform natural limbs, drugs that boost cognitive capacities beyond usual range, and genetic modification of age-related genes that allow people to become 150 years old.

- *Enhancement versus therapy:* Human enhancement is often contrasted with therapeutic interventions (see also p. 2 below). In SIENNA therapeutic enhancement indicates those interventions 'that are often performed to return an individual's health/performance to their baseline but may also increase health/performance beyond the baseline' (D3.4). It needs to be taken into account that the distinction between enhancement and therapy remains problematic. How should the line be drawn between a treatment that makes someone *well* by removing a disease, injury or other health problem (therapeutic), and enhancement, which involves adding to or improving the abilities of a healthy person? This depends on how terms like 'healthy', 'normal' or 'average' are defined and applied, which can be done in different ways. It is important to note that systemic power disparities also influence the definition and application of these terms.

- *Types of human enhancements:* Human enhancements can be classified and defined in a number of ways.[6] The following are distinctions that stand on their own, but which have particular ethical significance, and so are important to highlight here:

  1. *By area, application or function.* The following types of enhancement can be distinguished in this way: **cognitive** (interventions that enhance cognitive function, such as intelligence or

[6] Cf. Categories and definitions in Jensen, S. R. 2020. SIENNA D3.4: Ethical Analysis of Human Enhancement Technologies (Version V1.1). Zenodo: https://zenodo.org/record/4068071#.X9yDpi2l1pQ

memory); **affective and emotion** (interventions that improve and/or provide greater control over a human's affective states, such as one's mood or disposition); **physical** (interventions that improve physical abilities or introduce new ones, including for performance or endurance), **moral** (interventions that modulate or foster attitudes and behaviours that are considered morally or socially acceptable), **cosmetic** (interventions that improve the cosmetic appearance or traits of a human being) and **longevity** enhancements (interventions that improve durability and that extend the lifespan). Not that these categories may not be mutually exclusive. For instance, a medication could result in both affective *and* moral enhancement.

2. *By reversibility.* A distinction can be made between those enhancements that are reversible and those that are irreversible and cannot realistically be removed or undone.

3. *By relation to the body.* A distinction can be made between enhancements internal to the body (e.g. neural implants) and those external to it (e.g. wearables that enhance ability), although this distinction is not always clear in some technologies or techniques.

4. *By relation to therapy.* A distinction can be made between therapeutic and nontherapeutic enhancements. Therapeutic enhancement covers cases in which treatment of unhealthy persons is performed to a degree beyond what might be considered average or 'normal', i.e. statistically usual or typical health; whereas non-therapeutic enhancement covers cases in which people considered and designated 'healthy' undergo modifications with the explicit aim to improve certain of their characteristics or capabilities.

5. *By field or technique.* Enhancements can also be categorised by the scientific field that they stem from or the technique that is used. For example, one can distinguish genetic enhancement, neural enhancement and prosthetic enhancement.

Status of Human Enhancement

- *Relation of human enhancement to medicine:* In this document we define medicine as the science and practice of diagnosis, prognosis, treatment, and prevention of disease, which encompasses the promotion of health. Human enhancement is not necessarily concerned with any of these goals and would therefore seem to fall outside the scope of medicine. That is, unless the definition of medicine is changed. In practice, some human enhancement technologies are developed as a by-product of therapeutic innovation (as a kind of 'dual use'), whereas others are developed in nonmedical settings. Where its relation to medicine is unclear, it will also be unclear whether the laws, institutional requirements, conventions and ethics guidelines that apply to medicine would also apply to human enhancement.

- *Human enhancement as a morally controversial practice:* Human enhancement is a polarising topic, with strong advocates for and against. Among the advocates that take a strongly pro-enhancement position are those who are sometimes called transhumanists. Meanwhile, those who advocate against it are 'enhancement critics', sometimes also called bioconservatives. Some transhumanists argue that human enhancement should be an individual choice and emphasise the

potential benefits to the individual and society. Bioconservatives tend to emphasise health risks, risks to equality and risks to well-being, and often take a principled stand, with some arguing that human enhancement amounts to 'playing God' or subverting human nature. Some of the risks and ethical concerns that are raised may be associated particularly with enhancements that are irreversible and internal to the body – for example, a permanent neural implant that permanently alters the workings of the brain evokes more questions than a prosthesis that can be externally connected and removed.

It is important to recognise that the above labels may not capture a single group of people with singular perspectives. A binary presentation of these positions can obscure the fact that there are many stakeholders in this conversation, and not all will hold singular views on the topic of human enhancement. For instance, a person may be very willing to consider the positives that come from cosmetic surgery but be uncomfortable with drugs that change brain states or behaviours. Someone else may not have strong opinions about types of human enhancement but may be particularly concerned about the longevity or reversibility of an enhancement. Taking this complexity of positions and perspectives into account needs to be at the heart of any discussion about guidelines for human enhancement. In any event, given that human enhancement is morally controversial, and could lead to applications that cause harm to humans, its potential benefits should be well-established before research and development is to proceed (e.g. societal value, beneficence, and/or nonmaleficence).

- *Human enhancement as a new practice*: Ambitions to improve human abilities are not new. Potential enhancement through prostheses, cosmetics and performance enhancing drugs have been around for a long time. However, contemporary tools and techniques have now led to new types of enhancement and have vastly extended the scope and success of enhancement technologies. Because of its novelty, these new practices and applications may end up in grey zones – professionally, institutionally, legally, and morally. Human enhancement research that does not also have medical purpose (therapeutic or preventive) will usually not be covered by existing medical regulations and protocols, will not usually qualify for clinical trials, and most medical research ethics committees will not assess it.[7]

Moral foundations for ethics guidelines

The ethics guidelines that follow are based on five key values with universal appeal: well-being, autonomy, informed consent, equality, justice, and (moral and social) responsibility. These values have been put forward based on a combination of considerations: their recognition in philosophical ethics and in international declarations and treaties such as the *Universal Declaration of Human Rights*[8] and the *Charter of Fundamental Rights of the European Union*[9], their relevance to ethical assessments of

[7] Note that legal issues, including human rights challenges related to human enhancement, can be found in SIENNA D3.2 'Analysis of the legal and human rights requirements for Human Enhancement Technologies in and outside the EU'. This document explores international, EU and regional laws and human rights standards on these topics.

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

[9] 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.refworld.org/docid/3ae6b3b70.html [accessed 12 October 2020]

human enhancement, and their support for inclusion in these guidelines by stakeholders, as provided in the various consultation rounds for this document.

Other moral values that are sometimes proposed in relation to human enhancement, such as liberty, bodily integrity, human dignity, and privacy, are not explicitly referenced in these guidelines, because stakeholders held that the key ethical issues in human enhancement did not revolve around these values. To some of these values, there is indirect reference; e.g., liberty is indirectly referenced in autonomy and informed consent. Note, finally, that most of these values have a strong basis in human rights law in many countries, including informed consent, equality, justice, and, to a lesser extent, autonomy. Well-being, or welfare, is not explicitly referenced in human rights law, but its promotion is a central policy objective in many countries.

Ethics Guidelines

The ethics guidelines are structured in eight sections. Four of these, Sections 1 to 4, are structured around ethical principles and moral values (well-being, informed consent, autonomy, justice and equality). Section 5 covers research plus safety and efficacy studies for human enhancement. Section 6 focuses on the application of human enhancement in society, while Section 7 covers ethical issues specific to genetic enhancement. Finally, Section 8 briefly discusses the use and implementation of these guidelines. The principles are not listed in order of priority. Instead they should be read and understood collectively, and as holding equal priority.

1. Human Enhancement and Individual Well-Being

- The well-being of the recipient of an enhancement should be paramount. 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 being clear about if a treatment is irreversible and why, and what potential there is for an alternative, reversible enhancement 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.

- Assessments of the risks and benefits of human enhancement for the recipient, especially those that are irreversible, should be extensive and based on empirical studies. They should 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 of an enhancement.

- 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.

- A high ethical benchmark needs to be applied to cases in which an enhancement causes, or risks 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.

- A high ethical benchmark needs to be applied to cases in which an enhancement affects emotions and affect, cognition and other mental capacities. It needs to be taken into account that these capacities are interrelated, and that they are related to a person's values, beliefs, judgements, and personality, so that changing one element will also affect some or all of the others.

2. Human Enhancement and Informed Consent

- Human enhancement requires informed consent. Recipients should be informed about the nature, significance, implications, benefits and risks of the enhancement, and then 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.

- In order to guarantee proper conditions for informed consent, human enhancements should only be administered by organisations and individuals with the professional background and required knowledge and training that enables them to properly assess and communicate risks and benefits and to verify that decisions by recipients are taken freely.

- A very high threshold must be applied to the enhancement of children (paediatric enhancement) and of individuals unable to give informed consent, all of which 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.

3. Human Enhancement and Autonomy

A technology or treatment aiming at human enhancement is only permissible if it does 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. This includes taking into account contemporary or future legal implications regarding the ownership of human enhancement technologies, e.g. licencing of software, or hardware that could become indivisible from the user, and how these matters impact on autonomy. Excluded are interventions that:

- 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;

- 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;

- Changes 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 changes to personality and identity, 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. Human Enhancement, Justice and Equality

It needs to be recognised that human enhancement could diminish existing inequalities but can also 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 therefore should:

- 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;[10]

- Avoid promoting or perpetuating discrimination of either enhanced or non-enhanced persons by anticipating and mitigating where possible these kinds of outcomes;

- Not propagate 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;

- Be accessible to all if 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.

[10] For social impact assessment, see European Commission, EUR 21702 – *Assessing the Social and Environmental Impacts of European Research*, Report to the European Commission, Directorate-General for Research, 2005, at https://op.europa.eu/en/publication-detail/-/publication/f5bed899-225c-44c9-8864-39a59cc94a9b. For ethical impact assessment, see the standard developed in CEN working document CWA 17145:2017-2, 2017, retrievable at https://satoriproject.eu/media/CWA17145-23d2017.pdf.

5. Human Enhancement Research and Safety and Efficacy Studies

Preclinical research will usually not be aimed at human enhancement but may involve enhancement, for instance, of human cells and tissue. Our ethics guidelines are aimed at clinical research. For pre-clinical research, ethical requirements will be more liberal, since that research is not typically applied to humans. New biomedical or behavioural interventions are tested out in clinical trials, in which their efficacy and safety are studied by trying them out on human participants. Clinical trials are highly regulated in most countries.[11] In most countries, it will be difficult to attain permission for clinical trials for enhancement interventions that do not also have a medical (therapeutic or preventative) purpose. 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 require safety and efficacy studies to take place before the new intervention can be applied in society.

- Clinical trials for human enhancement are morally and legally required if the intervention that is studied is primarily therapeutic, and in addition has a possible application towards enhancement.

6. Human Enhancement and Society

Human enhancement could have serious implications not just for recipients, but also to the institution of medicine and other social institutions, to families, communities, and other social groups, and to society as a whole. Therefore, social responsibility should be paramount in research, development and deployment of human enhancement.

- Human enhancement research and development should be preceded and accompanied by social and ethical impact assessments that do 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 dual use. 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.

- Public funding bodies should decide after consultation with stakeholders whether enhancement research should be publicly funded. If so, then such public funding, specifically research aimed at interventions in the body, should only be provided if it can be shown in advance that the research is likely to be able to adhere to these ethics guidelines, and that a risk/benefit assessment for recipients, and a social/ethical impact assessment for society, have a positive outcome.

[11] In the European Union, they are regulated by Directive 2001/20/EC and new Regulation 536/2014.

- The commercial market for human enhancement should be regulated so as to ensure that the interests of recipients, as well as those of society are paramount. Products should meet the requirements set out in these guidelines, and it should be assessed per product category whether commercial advertising should be allowed, and if so, what restrictions it is subjected to. Advertising should not lead consumers to believe that certain enhancements are necessary for their well-being and success or for them to fit into society, or that not acquiring the enhancement causes them to be deficient.

- Human enhancements that are internal to the body or are irreversible should not be specifically developed to be applied in the workplace or in education. This includes by normalising human enhancement for employment prospects, career progression and development, or education, and thus creating undesirable social pressure for it to be used. There should not be work requirements or educational requirements that directly refer to, or indirectly rely on, the presence of human enhancement.

7. Genetic Enhancement

Genetic enhancement is the introduction of changes into a genome or epigenome in order to modify and improve nonpathological human traits. Whilst genetic changes occur naturally all the time, genetic enhancement involves the introduction of genetic changes through an artificial process. Genetic enhancement can take place in three ways: through germline modification (germline genetic enhancement), embryo selection and somatic genetic modification.

Germline genetic enhancement is the genetic engineering or modification of sperm or egg cells or very early embryos in order to produce enhanced human traits. Genetic enhancement through embryo selection is a second way in which offspring can be generated with enhanced features. Embryo selection is a process in which embryos are genetically profiled prior to implantation through pre-implantation genetic diagnosis. In embryo selection for human enhancement, embryos are selected that have genomes that are expected to result in superior traits. Both germline genetic enhancement and embryo selection for enhancement are controversial procedures that are outlawed in many countries. Germline genetic enhancement is often prohibited as part of a more general prohibition of germline genetic modification. Embryo selection is allowed in most countries, but only to avoid implantation of embryos with serious defects that could result in serious disease or mortality. It is rarer that selection on the basis of other characteristics is allowed. [12]

Both germline genetic enhancement and embryo selection are controversial because they could be done for eugenic purposes, i.e., for apparently improving the genetic quality of a human population by excluding people and groups judged to be inferior and promoting those judged to be superior. There are therefore important moral reasons to be cautious, so that the equal dignity of all humans is respected. Further issues include the risk of creating a lack of diversity among humans, and the risk of creating designer babies that are shaped to accommodate the desires and preferences of parents and

[12] See Bayefsky, M. J. (2016). Comparative preimplantation genetic diagnosis policy in Europe and the USA and its implications for reproductive tourism. *Reproductive biomedicine & society online*, *3*, 41-47. https://doi.org/10.1016/j.rbms.2017.01.001.

of society. Germline genetic enhancement is also controversial because it does not allow for informed consent by descendants, and because there may be unforeseen risks to modification of the germline.

Somatic genetic enhancement involves the genetic modification of bodily cells other than sperm or egg cells in order to enhance the functionality of tissues and organs. It is also morally controversial, although less so than germline enhancement. It is controversial because it involves medically permanent alterations to healthy human tissues and organs that are medically unnecessary, and because it could be used to biologically reengineer human beings to make them have desired traits, which could be understood as a type of eugenics. Somatic genetic engineering for therapeutic and preventative purposes is much more widely accepted, unlike germline genetic engineering for these same purposes. Because of the unclear boundary between enhancement, therapy and prevention, scenarios are therefore likely to ensue in which somatic gene editing undertaken for therapeutic or preventative purposes is seen to amount to human enhancement.

For the time being, the above objections to genetic enhancement justify stringent ethics guidelines. Since both genetic engineering and our moral attitudes concerning it are still evolving, it is however conceivable that a more permissive approach can be taken at some point in the future.

- Germline genetic enhancement should not be undertaken, nor should clinical research be undertaken with the aim of facilitating this kind of procedure.[13]

- Genetic enhancement through embryo selection should not be undertaken, nor should clinical research be undertaken with the aim of facilitating this kind of procedure.

- Somatic genetic enhancement should not be undertaken, nor should clinical research be undertaken with the aim of facilitating this kind of procedure. Precautions should be taken that somatic genomic editing techniques used for therapy and prevention are not used for enhancement.[14]

8. Incorporation of these Ethics Guidelines

Many existing fields can yield innovations for human enhancement. The following are among those most likely to lead to such innovations and applications, but the list is not exhaustive: artificial intelligence; biomaterials; exoskeletons; genomics; human-machine interaction; information and communication technologies; nanomedicine; neural engineering and neurotechnology; pharmaceutics; prosthetics; tissue engineering and bioprinting. Given the likelihood for enhancement

[13] Note that germline genetic engineering, whether therapeutic, preventative or enhancing, is currently prohibited in many countries. The European Oviedo convention, art. 13, 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.' (Council of Europe, *Convention on Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, European Treaty Series - No. 164, 1999 (http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164).). The EU Charter has a clause which specifies 'the prohibition of eugenic practices, in particular those aiming at the selection of persons,' which appears to rule out germline modification (European Union, *Charter of Fundamental Rights of the European Union*, 26 October 2012, 2012/C 326/02, article 3.2.d. available at: http://data.europa.eu/eli/treaty/char_2012/oj

[14] Note that article 13 of the Oviedo convention also prohibits somatic genetic enhancement.

innovations, these guidelines may have particular relevance for people working in the above fields, including where there could be unintended potential for human enhancement applicability.

It is recommended that these guidelines are incorporated in national as well as cross-European ethics guidelines and research ethics protocols for relevant fields, particularly identified in the preamble of this document, as well as in ethics guidelines and research ethics protocols for the field of biomedicine. Since human enhancement is currently not an institutionalised practice, it is moreover recommended that new regulations, policies, protocols and procedures for human enhancement research, development, funding, and application are developed that are consistent with and supportive of these guidelines.

These guidelines will require periodic revision. To that end, it is recommended that an international expert working group is set up to assess when and how the guidelines should be amended, including in editing the guidelines listed above, and by adding new guidelines as appropriate. This group will need to have sufficient breadth of expertise so as to ensure the accuracy and efficacy of the guidelines, and to ensure they are relevant for both contemporary as well as near future issues that can arise as a result of new and emerging developments in human enhancement technologies. The group will also need to consult relevant stakeholders prior to any update to the guidelines.

We propose that this body will oversee and analyse trends in HE; assess moral and social consequences of developments in human enhancement; and provide information and advice for the tasks that are generated by the above guidelines. This expert working group fits with a proposal in the STOA study on human enhancement technologies, which proposed the creation of 'A European Body on Human Enhancement Technologies'. The study describes the aims of the body as being to 'develop a normative framework for human enhancement that can guide the formulation of EU policies in this field,' including for regulation. They recommended representation that ensured 'European cultural diversity', a range of expertise, and scope for public consultation.[15]

Until the establishment of such a working group, the guardian of these guidelines is the University of Twente, in casu prof. dr. Philip A. E. Brey and dr. Yasemin J. Erden. For inquiries about these guidelines, contact dr. Erden at y.j.erden@utwente.nl.

Glossary

Affective and emotional enhancement: interventions that improve and/or provide greater control over affect and/or emotion. This might be related to social norms and values, and/or the pathologising of certain behaviours and tendencies.

Autonomy: self-governance or self-determination. It is the ability to have one's own thoughts and to construct one's own goals and values, and the freedom to make one's own decisions and to perform actions based on them. Connected with this are terms such as 'relational autonomy', which seek to show how interpersonal relationships feed into autonomy, and how disparities, for instance in power, can affect a person's autonomy, sometimes unjustly.

[15] G Coenen, C. *et al* (2009). *Human Enhancement*. Especially pp. 148-150. https://www.europarl.europa.eu/stoa/en/document/IPOL-JOIN_ET(2009)417483 [accessed 10 October 2020].

Clinical Trials: while there is no worldwide accepted definition of 'Clinical Trials', for the purposes of these guidelines these are understood to be trials: on drugs or medical devices; involving human beings outside these fields e.g. surgery, neurology etc.; with identifiable data; or with stored biological material of human origin.

Cognitive enhancement: interventions that improve cognitive abilities, including pharmaceutical cognitive enhancement (PCE), implanted neural interface (INI) & brain-computer interface (BCI), neuro-stimulation & neuromodulatory techniques, virtual & augmented reality (VR/AR) and memory enhancers. These may impact personal identity, for instance by altering someone's moods, cognition, behaviour, and basic personality traits.

Cosmetic enhancement: interventions that seek to alter or 'improve' the cosmetic traits of a human being, including as associated with norms of beauty and of societal expectations.

Genetic enhancement: enhancement achieved through genome editing or embryo selection. It can be practiced on somatic or germline cells. Somatic genetic enhancement involves the genetic modification of bodily cells other than sperm or egg cells in order to enhance the functionality of tissues and organs. Germline genetic enhancement involves the genetic modification of sperm or egg cells or very early embryos in order to produce enhanced human traits.

Informed consent: processes and procedures to ensure that participation in studies and trials is entirely voluntary. Researchers must be proactive in seeking consent, ensure that participants are adequately informed and understand all salient details about the research before consent is given (e.g. aims, methods, implications, benefits, risks, data handling and management, right to refuse or withdraw, procedures for incidental findings etc.). Processes for consent differ for vulnerable people, including children or adults with limited mental capacities. In such cases, informed consent must be obtained from a legally authorised representative, alongside assent from a participant wherever possible, and it is incumbent on the researchers to ensure that they have sufficient information to enable the representative to provide consent on behalf, and in the best interests, of the participants.

Longevity enhancement: interventions that extend a human's expected lifetime, whether as preventative, e.g. vaccines, or to improve one's senescence or durability, e.g. stopping or slowing the aging process or improving one's ability to survive or recover from harm or damage.

Moral enhancement: interventions that modulate or otherwise allow a person to improve their moral bearing. These may offer scope to 'correct' behaviours considered deviant in one's society, or which greatly alter or allow for the modulation of moral deliberation. These can include drugs that prevent problematic sexual behaviour, or drugs that reduce implicit bias.

Physical enhancement: interventions that improve or introduce new physical abilities, such as performance, endurance, or the addition of new abilities (additive).