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# Global Response Against Child Exploitation



**Instrument:** Research and Innovation Action Proposal

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## D1.4 SELP Guidelines for GRACE

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1. SELP Responsibility and Process

# 1. Introduction

## 1.1. Overview

The DoA describes the related task T1.3 as:

*“Operating in line with ethical, legal and data protection standards is a top priority. Having identified that the research/development process on the one side and the tool/operation on the other side have unique needs with regard to legal, ethical and data protection aspects the project will address them separately. T1.3 will deal with a focus on the research/innovation work of the consortium while T9.1-T9.4 will address legal, ethical and data protection concerns related to the tool and its operation. T1.3 will be responsible for delivering the Ethical, Legal and Data Protection Guidelines for Innovation that will provide consortium members with all appropriate ethical and safety approvals related to the progression of the project and conduct of research within the GRACE. The guidelines will include relevant guidance, consent forms and information sheets to be used throughout the projects innovation activities; considering the unique nature of the project and subsequent issues related to data protection, law and ethics that may occur as a result of working in this field. The guidelines and supporting documentation will be based on the existing competent authority. This task will include the development of a strategy and action plan to govern the management and protection of all data accessed or created within the project. The consortium will deal with all data sources (in terms of storage, protection, retention and destruction) by fully complying with the above-mentioned data protection legislation. An initial version will be delivered in M6 and then updated throughout the life of the project. The work in this task will be reported in D1.3.”*

In the initial phase of the GRACE project, the decision was taken to separate the development of the Data Management Plan from the Societal, Ethical, Legal and Privacy (SELP) guidelines. The Data Management Plan is established in Deliverable D1.3. This Deliverable D1.4 focuses on the SELP guidelines for the project. The main objective of this Deliverable is to remind and enhance Consortium Member’s awareness of their research’s SELP context by providing an overview of the full particulars regarding the SELP compliance required for carrying out research in the course of the GRACE project. As underlined in the description above, Task T1.3 focuses on SELP issues with regard to the research, while the separate Tasks T9.1-T9.4 also explore the use of the GRACE solution.

In an effort to ensure that any research and work for the GRACE project is compliant with international, EU and individual Member State ethics frameworks and regulations, the SELP guidelines provided in this Deliverable D1.4 aim to raise awareness of and to direct necessary precautions regarding societal, ethical and legal issues emerging from the kind of research carried out by any Consortium Member. Maintaining highest SELP standards is of utmost relevance for the Consortium.

Based upon the structure as Consortium for the purposes of the GRACE project, the SELP guidelines provided in this Deliverable D1.4 complete the bottom-up approach required for SELP compliance in research projects with multiple organizations involved. Rather than unilaterally replacing any individual processes for legal and ethical compliance within the organization of each Consortium Member, the SELP guidelines provided here are intended to supplement and build on the SELP approach of each Consortium Member. Therefore, the

SELP guidelines are based on the premise that each Consortium Member not only has already established and maintains individual policies for ethical and legal compliance, but also already has reliable processes in place for taking measures ensuring SELP compliance on which their research and activities for and during the GRACE project can draw.

## 1.2. Relation to Other Deliverables

This Deliverable D1.4 is related to the following other GRACE deliverables:

### Receives inputs from:

Deliv. #	Deliverable title	How the two deliverables are related
D9.1	Ethical Report	The Ethical Report focuses on ethical issues in the context of the proposed GRACE solution, while D1.4 focuses on SELP compliance in relation to the research leading to the solution.

Table 1 – Relation to other deliverables – receives inputs from

### Provides outputs to:

Deliv. #	Deliverable title	How the two deliverables are related
D2.4	User requirements	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D2.7	Standardised Taxonomy and Information Exchange Formats	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D2.10	Technical Specifications and Architecture	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D2.14	Security and auditing mechanisms report	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines

		most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D3.4	Data acquisition module	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D3.7	Data pre-processing module	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D3.10	Data loading and mapping module	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D3.4	Content management and integrity module	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D4.1	Modules for Visual Information Processing	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D4.2	Modules for Audio Information Processing	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D4.3	Modules for Unstructured Text Processing	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D4.4	Digital evidence tamper detection	Following a bottom-up approach, D.1.4 builds

	module	on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D5.1	Report on Federated Learning infrastructure and processes	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D5.2	Federated data annotation tools	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.3.
D5.3	Report on Federated Learning strategies	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D5.4	Secure data exchange mechanism	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D5.5	Federated Learning system analysis	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D6.2	Module(s) to perform content analysis and classification	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D6.3	Module(s) to perform content-based geo-location	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in

		D9.5.
D6.4	Module(s) to perform analysis of knowledge graphs for evidence data fusion	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D6.5	Module(s) to perform prioritisation on OSP referral data	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D6.6	Module(s) for predictive analysis of short and long-term trends in CSEM	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D7.1	Orchestration Framework	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D7.3	GRACE system	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D7.6	GRACE Collaborative applications	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D7.9	Technical validation report	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D8.1	Pilots scenario definition	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines

		most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D8.4	Pilots preparation plan	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D8.7	Report on pilots' execution	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D8.10	Report on pilots' evaluation & assessment	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D9.1	Ethical Report	While Deliverable D9.1 expounds the ethical foundation and all concerns regarding law enforcement's use of Big Data, Machine Learning and AI in investigations concerning CSEM, Deliverable D1.4 derives from these foundations and concerns guidelines for SELP compliance based on a bottom-up approach necessary in research projects.
D9.3	Legal Report	While D1.4 establishes guidelines for all research activities of the GRACE project, D9.3 analyses all legal aspects concerning CSEM.
D9.5	Overall legal and ethical framework	While D1.4 establishes guidelines for all research activities of the GRACE project, D9.5 will focus on the gradually evolving GRACE solution and further elaborates the guidelines of D1.4 as well as develops guidelines for the GRACE solution.
D9.7	Architecture for technical safeguards – "security and privacy by design"	While D1.4 establishes guidelines for all research activities of the GRACE project, D9.7 will focus on protecting the GRACE solution "by design" in terms of security and privacy compliance.
D9.9	Review Mechanism and Procedure	While D1.4 establishes guidelines for all research activities of the GRACE project, D9.9 will ensure that the operation of the GRACE

		solution will be in accord with all rules, regulations and ethical principles by providing not only a specifically-designed check list for before as well as a set of guidelines and instructions for while operating the GRACE solution.
D10.1	GRACE communication, visibility and dissemination plan	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D10.2	GRACE website, social media presence and dissemination materials	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D10.3	GRACE exploitation plan and business models	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D10.4	Development of GRACE training packages for EUROPOL and MS LEAs	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D10.6	Stakeholder and policy recommendations for addressing online CSEM	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.
D10.86	Best Practices on Victim support for LEA first responders	Following a bottom-up approach, D.1.4 builds on the SELP compliance mechanisms of each Consortium Member establishing guidelines most relevant for all activities of the GRACE project which will be further elaborated in D9.5.

Table 2 – Relation to other deliverables – provides outputs to

### 1.3. Structure of the Deliverable

The SELP guidelines provided in this Deliverable D1.4 present an overview of all ethical and legal issues relevant in the course of developing of the GRACE solution.

- Section 2 is dedicated to ethics. It provides insights into the historical origins of ethics in research as well as the emergence of authoritative standards and the pivotal role of ethical compliance in EU funded research in general and the GRACE project in particular.
- Section 3 provides an overview of the relevance of legal standards relevant with regard to guiding scientific research.
- Section 4 provides an overview of societal aspects – namely the public engagement.
- Section 5 describes the SELP monitoring process.
- Section 6 highlights several concrete legal and ethical issues that need to be taken into consideration during the development of GRACE.
- Section 7 provides a summary of the results elaborated in the analyses in the previous sections 2. – 6. (7.1.) and points out next steps in light of the legislative Proposal for an Ethical Framework which is already scheduled for the first half of 2021 (7.2.).

## 2. Ethics in Research

The terms “ethics”<sup>1</sup> and “morality”<sup>2</sup> refer to the study of normative behaviour.<sup>3</sup> Ethics in Research is a specialized discipline within the more general field of ethics that focuses on issues arising out of conducting research with a focus on determining the moral acceptability of research, its borders and principles<sup>4</sup> While science and scientific research has a long history, the reflection and discourse about its ethics and especially about its potentially limiting factors appears a rather new phenomenon. The necessity to debate and strive for universal ethical standards for research is a direct consequence of the realization that without such guiding and occasionally limiting factors, the positive effect of scientific research can be significantly reduced or even eliminated by the side effects or consequences of its unethical undercurrent(s). The grave violations of ethical standards in research briefly highlighted in section 2.1. below as well as the ethical research standards developed in their response emerged in the field of medical research. Because medical science and research benefit from a long history and shared professional culture, accounts of the moral obligations and virtues of medical professions have developed over centuries.<sup>5</sup> The universal four classic principles of medical ethics provide a common ground onto which ethical guidelines for information technology seem to have converged<sup>6</sup>: (1) respect for human autonomy, (2) non-maleficence, (3) beneficence and (4) justice (see

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<sup>1</sup> Derived from the Greek “ethos” – character/custom.

<sup>2</sup> Derived from the Latin synonym referring to manner/custom.

<sup>3</sup> *Peach*, An Introduction to Ethical Theory in Penslar, Research Ethics: Cases and Materials, 1995, page 13.

<sup>4</sup> *Peach*, An Introduction to Ethical Theory in Penslar, Research Ethics: Cases and Materials, 1995, page 13.

<sup>5</sup> Mittelstadt, “Principles Alone Cannot Guarantee Ethical AI”, Nature Machine Intelligence, November 2019, p. 5 <https://ssrn.com/abstract=3391293>.

<sup>6</sup> Cows/Floridi, Prologemina to a White Paper on an Ethical Framework for a Good AI Society, SSRN of 19 June 2018, <https://dx.doi.org/10.2139/ssrn.3198732>, pp. 1-14; Floridi et al., “AI4People – An Ethical Framework for a Good AI Society: Opportunities, Risks, Principles, and Recommendations, Minds and Machines” (2018), Vol. 26, p. 689 (p. 696).

section 2.5 in Deliverable D9.1).<sup>7</sup> The standards and accounts of being a ‘good’ medical professional, however, have not entirely prevented ethical negligence in clinical practice and medical research. Although such failures as well as new technologies, treatments, and changing social values have caused ethical standards to be revised, throughout the long history of medical practice and research, it was not until recently that the need for research ethics has emerged.<sup>8</sup>

## 2.1. The “Dark” History of Ethics Violations in the Context of Research

Unfortunately, the history of science is beset with examples of what today are considered grave violations of ethical foundations. This has been revealed particularly in the course of medical research. While there had been various forms of torture as part of medical research in medieval times, violations of ethical science and research are particularly well documented in the 20<sup>th</sup> century. During the Third Reich medical researchers in Germany carried out some of the most atrocious and horrifying experiments in the name of science.<sup>9</sup> In this regard, German medical research did not only legitimize the eugenic and racial programs – medical science and research also played a major role in the development of the euthanasia program.<sup>10</sup> Similar violations, though not comparable in scale were also documented in Japan during the Second World War. Especially the infamous medical Unit 731<sup>11</sup> is held responsible for thousands of deaths during medical experiments carried out as part of operations in China.<sup>12</sup>

The dark history of gravely unethical practices in scientific research did not end with World War II. Investigations revealed grave violations of ethical standards in research carried out by authorities in the former German Democratic Republic<sup>13</sup> as well as in the United States of America, where after 1945 thousands

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<sup>7</sup> The groundbreaking work for the medical field by Beauchamps/Childress, “Principles of Biomedical Ethics” is e.g. referred to by Schöne-Seifert, “Prinzipien und Theorien in der Medizinethik”, in Ach/Bayertz/Siep, Grundkurs Ethik, Vol. II, p. 9 (p. 16).

<sup>8</sup> Mittelstadt, “Principles Alone Cannot Guarantee Ethical AI”, Nature Machine Intelligence, November 2019, p. 5 <https://ssrn.com/abstract=3391293>.

<sup>9</sup> See for more detail: *Nicosia/Huener*, Medicine and Medical Ethics in Nazi Germany – Origins, Practices, Legacies, 2002.

<sup>10</sup> *Charny*, Encyclopedia of Genocide, Vol. 1, 1999, page 413.

<sup>11</sup> Unit 731 is described as medial unit operating in Chinese territory and carrying out excruciatingly cruel experiment - mainly on Chinese prisoners. For more details see: *Charny*, Encyclopedia of Genocide, Vol. 1, 1999, page 413.

<sup>12</sup> *Pua/Rogers*, Unit 731 – The Forgotten Asian Holocaust, 2019;

<sup>13</sup> See *Erices/Grunz/Frewer*, Secret Trials behind Walls: The Role of the State Security Services in East German Human Experiments, 1961-1989, in *Schmidt/Frewer/Sprumont*, Ethical Research, The Declaration of Helsinki, and the Past, Present and Future of Human Experimentation, 2020, page 190 et seq.

of human radiation experiments were conducted without therapeutical benefit and in blatant violation of ethical norms.<sup>14</sup>

## 2.2. Early Developments of Ethics Standards for Research

As a response to the discovery of widespread fundamental human rights' violations and decency, various approaches were undertaken to develop ethical standards that serve as limitation and guidance for scientific research. Two of the most renowned formalisations of ethical research principles ones are the Nuremberg Code and the Declaration of Helsinki.

### Nuremberg Code

After the Second World War, leaders in government, military and economy were held responsible in a series of military tribunals that took place in Nuremberg Germany. Those trials can be characterized as one of the first trials based on international law. The first trial after the War Crime Trial of various infamous war criminals focused on 23 German physicians responsible for conducting unethical medical procedures.<sup>15</sup> A key focus of the trial were the horrific medical experiments conducted on inmates of concentration camps.<sup>16</sup> As part of this trial and prior to the court's verdict, a memorandum was presented that contained six principles of legitimate medical research based upon natural law and the Hippocratic Oath. These six principles were later revised to ten by the court. They cover the most basic ethics of (medical) research including *voluntary consent*<sup>17</sup> and *proportionality* of risk and benefit.<sup>18</sup> The Nuremberg Code was never officially adopted outside the verdict but nevertheless became one of the most important sources of ethics in research.

### Declaration of Helsinki

The atrocities in the context of research carried out during the Second World War did not only lead to the Nuremberg Code, but also laid the foundation for the Declaration of Helsinki. The Declaration of Helsinki establishes a set of basic recommendations that serve as guidance for medical doctors

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<sup>14</sup> See *Welsome*, *The Plutonium Files: America's Secret Medical Experiments in the Cold*, 2000.

<sup>15</sup> See in this regard: *Harmon*, *The Doctor's Trial at Nuremberg* in *Reginbogin/Safferling*, *Die Nuernberger Prozesse, Voelkerstrafrecht seit 1945, Internationale Konferenz zum 60 Jahrestag*, 2006, page 164 et seq.

<sup>16</sup> *Caplan*, *The Doctors Trial and Analogies to the Holocaust in Contemporary Bioethical Debates* in *Annas/Grodin*, *The Nazi Doctors and the Nuremberg Code*, page 259.

<sup>17</sup> Principle 1: The voluntary consent of the human subject is absolutely essential.

<sup>18</sup> Principle 6: The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

when conducting research involving human subjects.<sup>19</sup> It was adopted by the 18<sup>th</sup> World Medical Assembly in 1964 and revised in 1975. It references the International Code of Medical Ethics<sup>20</sup>, that is an equally important document but not specific to research. The basic principles established by the Helsinki Declaration for example include the requirement for *proportionality* of risk and benefit<sup>21</sup>, safeguarding the *integrity* of the research subject<sup>22</sup> and need for *informed consent*.<sup>23</sup>

### More recent and sector-specific codifications

Since the early developments various sector-specific guidelines and codifications have been developed. Of particular relevance for GRACE are guidelines that specifically focus on research in the field of artificial intelligence. In recent years, various<sup>24</sup> guidelines have been developed (for an overview and discussion see section 2.4. in Deliverable D9.1) that include, but are not limited to those established by the European Commission's High-Level Expert Group on Artificial Intelligence<sup>25</sup>, the OECD Recommendations of the Council on Artificial Intelligence<sup>26</sup> and the Montreal Declaration for Responsible Development of Artificial Intelligence<sup>27</sup>. They especially focus on issues such as privacy protection, non-discrimination, accountability, safety, transparency and human control requirements.

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<sup>19</sup> Baker, The Declaration of Helsinki and the Foundations of Global Bioethics in *Schmidt/Frewer/Sprumont, Ethical Research, The Declaration of Helsinki, and the Past, Present and Future of Human Experimentation, 2020*, page 47 et sec.

<sup>20</sup> The International Code of Medical Ethics was adopted by the World Medical Association in 1949 and amended in 1968 and 1983.

<sup>21</sup> Basic Principle 4: Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

<sup>22</sup> Basic Principle 6: The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.

<sup>23</sup> Basic Principle 9: In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely-given informed consent, preferably in writing.

<sup>24</sup> For an overview see: *Hagendorff, The Ethics of AI Ethics: An Evaluation of Guidelines, Minds and Machines, 2020*, page 99 et seq.

<sup>25</sup> Independent High-Level Expert Group of Artificial Intelligence, *Ethics Guidelines for Trustworthy AI, 2019*.

<sup>26</sup> Recommendation of the Council on Artificial Intelligence, OECD/Legal/0449.

<sup>27</sup> The Montreal Declaration for a Responsible Development of Artificial Intelligence was first announced in November 2017 at the Forum on the Socially Responsible Development of AI, held in Montréal.

## 2.3. Ethics in the Context of EU-Funded Research

The European Commission clearly emphasized the importance of ethics in EU funded research:<sup>28</sup>

*“For research funded by the European Union, ethics is an integral part of research from beginning to end and ethical compliance is pivotal to achieve real research excellence.”*

In addition, the relevance of ethics in the context of H2020 funded projects is also specifically addressed by the secondary legislation governing H2020.<sup>29</sup> Regulation (EU) 1291/2013 states that research and innovation activities supported by Horizon 2020 should respect fundamental ethical principles. The specific issue of ethics is addressed by Art. 19:

### *Article 19 Ethical principles*

*1. All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.*

*Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.*

*2. Research and innovation activities carried out under Horizon 2020 shall have an exclusive focus on civil applications.*

*3. The following fields of research shall not be financed:*

*(a) research activity aiming at human cloning for reproductive purposes;*

*(b) research activity intended to modify the genetic heritage of human beings which could make such changes heritable <sup>[21]</sup>;*

*(c) research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.*

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<sup>28</sup> See in this regard: European Commission, Ethics for Researchers, Facilitating Research Excellence in FP7, 2013.

<sup>29</sup> Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC.

4. *Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden.*

5. *The fields of research set out in paragraph 3 of this Article may be reviewed within the context of the interim evaluation set out in Article 32(3) in the light of scientific advances.*

For the submission of the GRACE proposal, various ethics considerations needed to be addressed. After a vigorous screening process, the GRACE project has been selected for funding and a wealth of tasks related to ethics are now woven into all research and other activities throughout the project. This ensures that ethical compliance will gain the key role it deserves for the entire duration of the GRACE project.

### 3. Legislative Framework for Research

Especially with regard to GRACE, there are several legal issues that need to be taken into account. While those will be addressed in detail by two separate Deliverables at a later stage,<sup>30</sup> the following overview focuses on more general aspects of legal compliance in research.

There is no single legal framework that addresses all or even a significant part of the issues relevant with regard to scientific research in general and GRACE in particular. Three of the most relevant legal sources for ethical research are the Council of Europe Convention on Human Rights<sup>31</sup> including its protocols, the European Union Charter of Fundamental Rights<sup>32</sup> and the General Data Protection Regulation<sup>33</sup>.

#### 3.1 Council of Europe Convention on Human Rights

The Council of Europe Convention on Human Rights contains major articles that are of relevance for scientific research – especially when it comes to interactions with humans. Examples are Art. 2 (Right to life), Art. 3 (Prohibition of torture), Art. 8 (right to respect for private and family life) and Art. 14 (Prohibition of discrimination).

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<sup>30</sup> Deliverable 9.2 and Deliverable 9.3.

<sup>31</sup> Council of Europe Convention for the Protection of Human Rights and Fundamental Freedoms, ETS 5.

<sup>32</sup> Charter of Fundamental Rights of the European Union.

<sup>33</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

The Council of Europe has adopted one Convention<sup>34</sup> specifically addressing the protection of human rights and the dignity of human beings with regard to research. However, this Convention and its Additional Protocol<sup>35</sup> specifically focus on applied research in biology and medicine rendering it less relevant for the GRACE project.

### 3.2 European Union Charter of Fundamental Rights

The Charter of Fundamental Rights is de-facto the first Bill of Rights developed specifically for the European Union.<sup>36</sup> It partly overlaps with the Council of Europe Convention on Human Rights that is, however, more focused on civil and political rights. Out of the 54 articles<sup>37</sup> contained in six chapters the first two chapters addressing human dignity and fundamental freedoms are most relevant<sup>38</sup> with regard to research – namely Art. 3 (Right to the integrity of the person), Art. 7 (Respect of private and family life), Art. 8 (Protection of Personal Data) and Art. 13 (Freedom of the Arts and Science).

### 3.3 European Union General Data Protection Regulation

Before the introduction of the General Data Protection Regulation, EU Member States either considered privacy as an important fundamental human right underpinning human dignity and other values such as freedom of association and freedom of speech,<sup>39</sup> or took a less comprehensive approach to the protection. With the General Data Protection Regulation, the European Union has established a harmonized framework.<sup>40</sup> Despite this harmonization, open questions remain and even simple issues such as the

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<sup>34</sup> Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, ETS 164.

<sup>35</sup> Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, ETS 195.

<sup>36</sup> *Zetterquist*, The Charter of Fundamental Rights and the Res Publica in *Di Federico*, The EU Charter of Fundamental Rights, From Declaration to Binding Instrument, 2011, page 3.

<sup>37</sup> Regarding details and interpretations see: *Peers/Hervey/Kenner/Ward*, The EU Charter of Fundamental Rights, A Commentary, 2014.

<sup>38</sup> Regarding the relevance see: European Commission, Ethics for Researchers, Facilitating Research Excellence in FP7, 2013, page 5.

<sup>39</sup> *Friedewald/Wright/Gutwirth/Mordini*: Privacy, data protection and emerging sciences and technologies: towards a common framework - Innovation: The European Journal of Social Science Research, Vol. 23, Iss. 1, March 2010, page 61 et seq.

<sup>40</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation); For a general introduction see: *Voigt/von dem Bussche*, The EU General Data Protection Regulation, 2017.

definition of “privacy” and the threshold for data to be “identifiable” are challenging.<sup>41</sup> While some issues are controversially discussed, there is very little dispute that the introduction of new technologies challenges privacy as they facilitate the collection, storage, processing and combination of personal data at a larger scale and faster pace than ever. The EU GDPR is a key legal framework when it comes to scientific research which involves the use of personal data, Art. 4(1) GDPR. As will be expounded in depth in the specific Deliverable dedicated solely to the legal issues,<sup>42</sup> the protection of human individuals in relation to the processing of their personal data is a fundamental right. Article 8(1) of the Charter of Fundamental Rights of the European Union and Article 16(1) TFEU state that everyone has the right to the protection of personal data concerning themselves. In general, any processing must be in compliance with the principles and rules stipulated in the GDPR as well as in compliance with the relevant supplementing Member States’ national data protection legislation or specific data protection law applicable to involved EU entities such as Regulation 2018/1725 and Regulation 2016/794 (Europol Regulation). This does apply in general as well as to GRACE in particular.

## 4. Societal Issues

Potential societal issues that could arise with regard to research carried out as part of GRACE are mainly focused on equality and public engagement in research. The social issues relevant for GRACE can be linked to European Commission’s guidance for Responsible Research and Innovation<sup>43</sup> that includes helpful indicators for promoting and monitoring Responsible Research and Innovation.<sup>44</sup> The European Commission defines Responsible Research and Innovation as follows:

*“Responsible research and innovation is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation.”<sup>45</sup>*

Responsible Research and Innovation has become an important European Union policy component that is today deeply ingrained into the Horizon 2020 research programme in order to achieve smart, sustainable

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<sup>41</sup> Svantesson, A Legal Method for Solving Issues of Internet Regulation; Applied to the Regulation of Cross-Border Privacy Issues. EUI Working Papers LAW No. 2010/18.

<sup>42</sup> GRACE Deliverable D9.2.

<sup>43</sup> Owen, R., Macnaghten, P. and Stilgoe, J., 2012. Responsible research and innovation: From science in society to science for society, with society. *Science and public policy*, 39(6), pp.751-760; Von Schomberg, R., 2013. A vision of responsible research and innovation. *Responsible innovation: Managing the responsible emergence of science and innovation in society*. pp.51-74.

<sup>44</sup> Schomberg, A vision of responsible research and innovation. Responsible innovation: Managing the responsible emergence of science and innovation in society, 2013; Indicators for promoting and monitoring Responsible Research and Innovation, EU Commission, 2015.

<sup>45</sup> Indicators for promoting and monitoring Responsible Research and Innovation, EU Commission, 2015.

and inclusive growth.<sup>46</sup> The European Commission identifies several areas and associated indicators potentially bear relevant for fulfilling the policy aims. These include Public Engagement, Equality, Science Education, Open Access, Ethical Issues, Governance, Sustainability, Social Justice and Inclusion. Some of these issues will be addressed within D9.1 as they relate to the GRACE solution. However, two aspects are also of relevance for the research itself: Gender Equality and Public Engagement.

Concerning Gender Equality, the GRACE Consortium is already well aware of the dangers emanating from societal stereotypes in the context of CSE depicting the victim as female and the offender as predominately male, despite a recent increase in male victims and female offenders. Ensuring that no CSEM report is prioritised over another by the GRACE solution because of gender influences, all research and every designing process conducted for the GRACE project has to ensure that women and men benefit equally from the GRACE solution. Only when an individual's victim status is not identified by his or her gender, then both genders have a chance to equally benefit the research undertaken for the GRACE project.

Regarding Public Engagement, the Commission's aim is to bridge the gap between the research community and society at large.<sup>47</sup> It encourages researchers to ensure a public engagement.<sup>48</sup> Members of the GRACE Consortium should pay particular attention to engaging with the public at large as much as classification requirements allow for especially because public engagement provides a valuable opportunity to communicate the purpose of the GRACE project to society so that the needs and support of law enforcement are understood in their important fight against CSEM.

## 5. GRACE SELP Responsibility and Compliance Process

Based upon the overall concept of GRACE, the responsibility for SELP compliance lies, first and foremost, with each Consortium Member. Each Consortium Member should ensure that it has appropriate policies, procedures and resources to ensure that especially ethics and legal screening takes place. However, GRACE provides additional resources in case Consortium Members need assistance. The graphic in fig. 1 visualizes the process.

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<sup>46</sup> Horizon 2020 - European Commission. 2020. *Responsible Research & Innovation - Horizon 2020 - European Commission*. Available at: <https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation>.

<sup>47</sup> Responsible Research and Innovation, Europe's ability to respond to societal challenges, European Commission, 2014.

<sup>48</sup> Responsible Research and Innovation, Europe's ability to respond to societal challenges, European Commission, 2014, page 1.

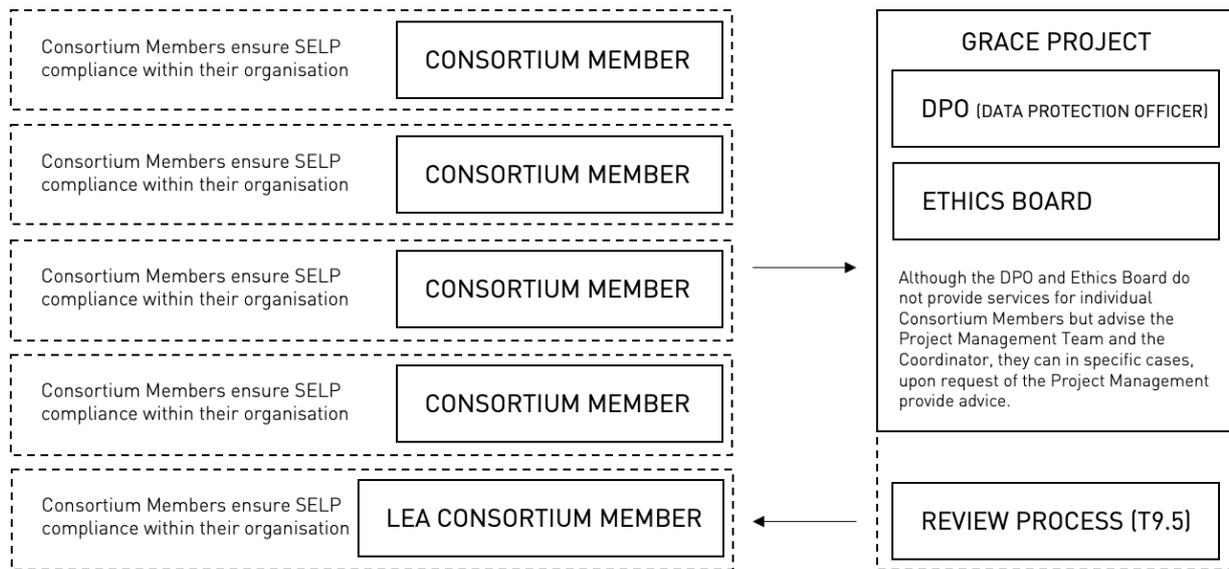


Fig. 1: SELP Responsibility and Compliance Process

### 5.1 Consortium Members as First Line of Defense

Consortium Members are the first line of defense when it comes to SELP compliance. Based upon experiences from various research projects a bottom-up approach is more likely to succeed compared to a top-down approach. The two main reasons are: First of all, each organization usually has its individual policies, structures, processes and resources. It would go along with significant challenges if an organization, that participates in different research projects, would need to adjust to various centralized SELP processes controlled by the respective project management. Apart from this, despite harmonization throughout the EU, the relevant legal frameworks of the EU Member States and EU agencies show certain differences. As a consequence, organizations in different EU Member States or at the EU level might have to adhere to different legal standards.

### 5.2 Ethics Board

The Ethics Board (EB) is a key institution of the GRACE project. It directly reports to the Project Management Team (PMT) and the Project Manager (PM). The EB is not an institution that provides advisory services to individual Consortium Members. It is therefore not a direct line of defense with regard to SELP compliance. However, Consortium Members could approach the PMT or PM with regard to specific issues that could then be forwarded to the EB.

## 6. General SELP Recommendations

As pointed out above, it is most demanding to elaborate a comprehensive and universal equilibrium for all eventualities concerning ethical and legal issues that could be of relevance for the research for and development of the GRACE solution. Especially with regard to the fact that there are various ethics standards and guidelines and differing national laws it is important that each Consortium Member familiarizes itself with all applicable standards and norms. This includes but is not limited to the ethics guidelines, policies and standards of each organization and profession and the national and regional legal standards that apply to the Consortium Member's work carried out as part of GRACE.

**As a general advice: Make sure that – especially when it comes to tasks with potential ethics/legal issues – you go through frequent screenings. If there are issues of special concern, discuss them with your organization's ethics/legal compliance officer/department or reach out to GRACE's PMT. Document your considerations and the processes.**

### 6.1 Adhere to the Following Fundamental Ethics Principles

The following list of ethics principles is neither exclusive nor conclusive. Rather, each ethics-sensitive task emerges in its own context involving unique requirements. However, the following general ethics principles are fundamental and hence form a good starting point:

- **Informed Consent:** If you are interacting with humans or with personal data, make sure that you act on the basis of informed consent. This means in essence that you need to provide the individual participant in your research with appropriate information in a comprehensible format about what you are planning to do and how it will affect the individual as well as the individual's personal data. After this, get the individual's consent and maintain continuous dialogue. Make sure that you document the process including the information provided as well as the actual consent.
- **Relevance:** The overall aim of GRACE is to improve the services provided by law enforcement and to support law and order by creating a positive impact on society. However, do not solely focus on the overall aim of the project but make sure that on a micro level your research and task is actually producing results that benefit society.
- **Prevent harm:** Design the research in a way that – if possible – prevents harm right from the beginning. Be especially careful when there is an a priori research to believe that negative consequences could occur. If it is possible to conduct research without involving research subjects or real personal data, avoid it.
- **Risk Management:** The degree of risk to be taken when conducting research should never exceed the degree of importance enjoyed by the problem to be solved by the research.
- **Exercise control:** If your research involves human participants, the human participant should be at liberty to bring their contribution to an end at any time.
- **Protect privacy:** If your research includes any personal data or information, make sure that you

protect the personal data and information as well as the privacy of all individuals. Wherever possible, use anonymized data. If this is not possible, consider using pseudonymized data or random datasets .

- **Public engagement:** Make sure that you keep engaged with the public and are transparent about your work. In addition, listen to the public and treat societal concerns with the necessary seriousness which may include forwarding them to the PM and/or PMT.
- **Dual use:** Familiarize yourself with the special requirements and limitations that apply if the technology you are developing as part of GRACE could be considered dual-use items (items, including software and technology, which can be used for both civil and military purposes). In the context of research, dual use can be interpreted as potential misuse of research.
- **Artificial intelligence:** When using, designing or implementing artificial intelligence, make sure that you comply with basic ethics principles such as privacy protection, fairness and non-discrimination, accountability, transparency, safety, human oversight, social cohesion and explainability.<sup>49</sup>

## 6.2 Legal Standards

The following list of legal standards principles is not conclusive. Each task might have its own legal implication. The list does not contain general/fundamental sources such as the Council of Europe Convention on Human Rights<sup>50</sup> or the EU Charter of Fundamental Right<sup>51</sup> but focuses on topics specific for GRACE:

**Data Protection:** The interaction with personal data is heavily regulated within the European Union and its Member States. Any interaction with personal data during the research should go through screening and follow the GRACE Data Management Plan (DPM).<sup>52</sup> This is especially relevant for the collection of personal data through the use of crawlers.

**Illegal Content:** GRACE focuses on Child Sexual Exploitation Material (CSEM). It is important to keep in mind that any interactions with CSEM by anybody outside the competent units (especially within the justice and law enforcement ecosystem) might qualify as serious criminal offences that can lead to criminal investigations. The fact that GRACE aims to support law enforcement in their fight against CSEM does not in itself justify the interaction with CSEM by researchers outside the justice and law enforcement ecosystem. It is, therefore, of particular importance that Consortium Members ensure legal compliance in this regard.

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<sup>49</sup> More details are provided in D9.1.

<sup>50</sup> Council of Europe Convention for the Protection of Human Rights and Fundamental Freedoms, ETS 5.

<sup>51</sup> Charter of Fundamental Rights of the European Union.

<sup>52</sup> See Deliverable D1.3.

## 7. Conclusion

### 7.1. Summary

This Deliverable D1.4 has derived concrete and practical SELP guidelines for the development of all tools and functionalities in the course of the GRACE project. Following the bottom-up approach required for SELP compliance in research projects with multiple organizations, the SELP guidelines provided here supplement and build on the SELP approach of every single Consortium Member.

In section 2., some of the gravest violations of ethical standards in the name of scientific research have been briefly highlighted (section 2.1. above) which have led to the emergence of ethical research standards developed in the field of medical research as a response (see 2.2. above). SELP compliance has become an essential pillar of modern research and the European Union is fully committed to ensuring that EU-funded research takes place in compliance with ethical and legal standards (see 2.3. above).

In section 3., focusing on more general aspects of legal compliance in research, insights have been provided on three of the most relevant legal sources for ethical research. The Council of Europe Convention on Human Rights including its protocols (see 3.1. above), the European Union Charter of Fundamental Rights (see 3.2 above) and the General Data Protection Regulation (see 3.3. above).

In section 4., the potential societal issues regarding any research carried out in the course of the GRACE project have been identified as centred around equality (especially gender equality) and public engagement in research for which helpful guidance can be drawn from the European Commission's guidance for Responsible Research and Innovation.

In section 5., the structure of and approach to SELP responsibility and compliance has been laid out for the course of the GRACE project. First, this involves the implementation the bottom-up approach necessary in research projects with multiple organizations (see 5.1. above). Second, the Ethics Board (EB) established for the GRACE project plays a key role in coordinating SELP compliance (see 5.2. above).

In section 6., SELP recommendations are provided taking into account that the ultimate responsibility lies with each Consortium Member to elaborate a comprehensive equilibrium addressing all ethical and legal issues relevant for its research including all its activities during the GRACE project. As a starting point, a list of the most fundamental ethics principles for scientific research has been provided including the need for informed consent, relevance of the research, preventing harm, risk management, the exercise of control, protecting privacy, public engagement and restrictions with regard to dual use (see 6.1. above). Similarly, a list of legal standards principles has been presented focusing on the areas of data protection and dealing with illegal content which are most specific to the GRACE project (see 6.2. above).

### 7.2. Future Work

While Deliverable D9.1 has provided a thorough assessment of all potential ethical concerns related to use of Big Data, Machine Learning and AI in the law enforcement ecosystem with regard to investigations concerning CSEM, Deliverable D9.2 will analyse the legal environment and define the potential legal concerns. Task 9.3 will then develop overall legal and ethical recommendations as guidance for the use of all



functionalities of the GRACE tools and platform and present them in Deliverable D9.3. Operating in line with ethical and legal standards is a top priority of the GRACE project.

## ANNEX I. - Declaration of Helsinki

Recommendations guiding medical doctors in biomedical research involving human subjects Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964 and as revised by the 29th World Medical Assembly, Tokyo, Japan, October 1975.

### INTRODUCTION

It is the mission of the medical doctor to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission. The Declaration of Geneva of the World Medical Association binds the doctor with the words: "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "Any act or advice which could weaken physical or mental resistance of a human being may be used only in his interest." The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease. In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies a fortiori to biomedical research. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects. In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research. Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected. Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, The World Medical Association has prepared the following recommendations as a guide to every doctor in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Doctors are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

### I. BASIC PRINCIPLES

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.
3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.
4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.

5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.
6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
7. Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.
8. In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely-given informed consent, preferably in writing.
10. When obtaining informed consent for the research project the doctor should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship.
11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.
12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

## II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (Clinical Research)

1. In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, reestablishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient – including those of a control group, if any – should be assured of the best proven diagnostic and therapeutic method.
4. The refusal of the patient to participate in a study must never interfere with the doctor-patient relationship.
5. If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I, 2).

6. The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

### III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (Non-Clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers – either healthy persons or patients for whom the experimental design is not related to the patient’s illness.

3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.

4. In research on man, the interest of science and society should never take precedence over considerations related to the wellbeing of the subject.

## ANNEX II. The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

## **ANNEX III. Charter of Fundamental Rights of the European Union (Excerpt)**

### **Article 1 Human dignity**

Human dignity is inviolable. It must be respected and protected.

### **Article 2 Right to life**

1. Everyone has the right to life.
2. No one shall be condemned to the death penalty, or executed.

### **Article 3 Right to the integrity of the person**

1. Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular:
  - (a) the free and informed consent of the person concerned, according to the procedures laid down by law;
  - (b) the prohibition of eugenic practices, in particular those aiming at the selection of persons;
  - (c) the prohibition on making the human body and its parts as such a source of financial gain;
  - (d) the prohibition of the reproductive cloning of human beings.

### **Article 4 Prohibition of torture and inhuman or degrading treatment or punishment**

No one shall be subjected to torture or to inhuman or degrading treatment or punishment.

### **Article 5 Prohibition of slavery and forced labour**

1. No one shall be held in slavery or servitude.
2. No one shall be required to perform forced or compulsory labour.
3. Trafficking in human beings is prohibited.

### **Article 6 Right to liberty and security**

Everyone has the right to liberty and security of person.

**Article 7 Respect for private and family life**

Everyone has the right to respect for his or her private and family life, home and communications.

**Article 8 Protection of personal data**

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority.

**Article 9 Right to marry and right to found a family**

The right to marry and the right to found a family shall be guaranteed in accordance with the national laws governing the exercise of these rights.

**Article 10 Freedom of thought, conscience and religion**

1. Everyone has the right to freedom of thought, conscience and religion. This right includes freedom to change religion or belief and freedom, either alone or in community with others and in public or in private, to manifest religion or belief, in worship, teaching, practice and observance.
2. The right to conscientious objection is recognised, in accordance with the national laws governing the exercise of this right.

**Article 11 Freedom of expression and information**

1. Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers.
2. The freedom and pluralism of the media shall be respected.

**Article 12 Freedom of assembly and of association**

1. Everyone has the right to freedom of peaceful assembly and to freedom of association at all levels, in particular in political, trade union and civic matters, which implies the right of everyone to form and to join trade unions for the protection of his or her interests.
2. Political parties at Union level contribute to expressing the political will of the citizens of the Union.

Article 13

Freedom of the arts and sciences

The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

#### **Article 14 Right to education**

1. Everyone has the right to education and to have access to vocational and continuing training.
2. This right includes the possibility to receive free compulsory education.
3. The freedom to found educational establishments with due respect for democratic principles and the right of parents to ensure the education and teaching of their children in conformity with their religious, philosophical and pedagogical convictions shall be respected, in accordance with the national laws governing the exercise of such freedom and right.

#### **Article 15 Freedom to choose an occupation and right to engage in work**

1. Everyone has the right to engage in work and to pursue a freely chosen or accepted occupation.
2. Every citizen of the Union has the freedom to seek employment, to work, to exercise the right of establishment and to provide services in any Member State.
3. Nationals of third countries who are authorised to work in the territories of the Member States are entitled to working conditions equivalent to those of citizens of the Union.

#### **Article 16 Freedom to conduct a business**

The freedom to conduct a business in accordance with Union law and national laws and practices is recognised.

#### **Article 17 Right to property**

1. Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest.
2. Intellectual property shall be protected.

#### **Article 18 Right to asylum**

The right to asylum shall be guaranteed with due respect for the rules of the Geneva Convention of 28 July 1951 and the Protocol of 31 January 1967 relating to the status of refugees and in accordance with the Treaty on European Union and the Treaty on the Functioning of the European Union (hereinafter referred to as 'the Treaties').

#### **Article 19 Protection in the event of removal, expulsion or extradition**

1. Collective expulsions are prohibited.
2. No one may be removed, expelled or extradited to a State where there is a serious risk that he or she would be subjected to the death penalty, torture or other inhuman or degrading treatment or punishment.

#### **Article 20 Equality before the law**

Everyone is equal before the law.

#### **Article 21 Non-discrimination**

1. Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited.
2. Within the scope of application of the Treaties and without prejudice to any of their specific provisions, any discrimination on grounds of nationality shall be prohibited.

#### **Article 22 Cultural, religious and linguistic diversity**

The Union shall respect cultural, religious and linguistic diversity.

#### **Article 23 Equality between women and men**

Equality between women and men must be ensured in all areas, including employment, work and pay.

The principle of equality shall not prevent the maintenance or adoption of measures providing for specific advantages in favour of the under-represented sex.

#### **Article 24 The rights of the child**

1. Children shall have the right to such protection and care as is necessary for their well-being. They may express their views freely. Such views shall be taken into consideration on matters which concern them in accordance with their age and maturity.
2. In all actions relating to children, whether taken by public authorities or private institutions, the child's best interests must be a primary consideration.
3. Every child shall have the right to maintain on a regular basis a personal relationship and direct contact with both his or her parents, unless that is contrary to his or her interests.

**Article 25 The rights of the elderly**

The Union recognises and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life.

**Article 26 Integration of persons with disabilities**

The Union recognises and respects the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community.

## **ANNEX IV. Council of Europe Convention Human Rights (Excerpt)**

**ARTICLE 2**

Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.

Deprivation of life shall not be regarded as inflicted in contravention of this article when it results from the use of force which is no more than absolutely necessary:

- (a) in defence of any person from unlawful violence;
- (b) in order to effect a lawful arrest or to prevent escape of a person lawfully detained;
- (c) in action lawfully taken for the purpose of quelling a riot or insurrection.

**ARTICLE 3**

No one shall be subjected to torture or to inhuman or degrading treatment or punishment.

**ARTICLE 4**

No one shall be held in slavery or servitude.

No one shall be required to perform forced or compulsory labour.

For the purpose of this article the term forced or compulsory labour' shall not include:

- (a) any work required to be done in the ordinary course of detention imposed according to the provisions of Article 5 of this Convention or during conditional release from such detention;
- (b) any service of a military character or, in case of conscientious objectors in countries where they are recognized, service exacted instead of compulsory military service;
- (c) any service exacted in case of an emergency or calamity threatening the life or well-being of the community;
- (d) any work or service which forms part of normal civic obligations.

## ARTICLE 5

Everyone has the right to liberty and security of person.

No one shall be deprived of his liberty save in the following cases and in accordance with a procedure prescribed by law:

- (a) the lawful detention of a person after conviction by a competent court;
- (b) the lawful arrest or detention of a person for non-compliance with the lawful order of a court or in order to secure the fulfilment of any obligation prescribed by law;
- (c) the lawful arrest or detention of a person effected for the purpose of bringing him before the competent legal authority of reasonable suspicion of having committed an offence or when it is reasonably considered necessary to prevent his committing an offence or fleeing after having done so;
- (d) the detention of a minor by lawful order for the purpose of educational supervision or his lawful detention for the purpose of bringing him before the competent legal authority;
- (e) the lawful detention of persons for the prevention of the spreading of infectious diseases, of persons of unsound mind, alcoholics or drug addicts, or vagrants;
- (f) the lawful arrest or detention of a person to prevent his effecting an unauthorized entry into the country or of a person against whom action is being taken with a view to deportation or extradition.

Everyone who is arrested shall be informed promptly, in a language which he understands, of the reasons for his arrest and the charge against him.

Everyone arrested or detained in accordance with the provisions of paragraph 1(c) of this article shall be brought promptly before a judge or other officer authorized by law to exercise judicial power and shall be entitled to trial within a reasonable time or to release pending trial. Release may be conditioned by guarantees to appear for trial.

Everyone who is deprived of his liberty by arrest or detention shall be entitled to take proceedings by which the lawfulness of his detention shall be decided speedily by a court and his release ordered if the detention is not lawful.

Everyone who has been the victim of arrest or detention in contravention of the provisions of this article shall have an enforceable right to compensation.

**ARTICLE 6**

In the determination of his civil rights and obligations or of any criminal charge against him, everyone is entitled to a fair and public hearing within a reasonable time by an independent and impartial tribunal established by law. Judgement shall be pronounced publicly by the press and public may be excluded from all or part of the trial in the interest of morals, public order or national security in a democratic society, where the interests of juveniles or the protection of the private life of the parties so require, or the extent strictly necessary in the opinion of the court in special circumstances where publicity would prejudice the interests of justice.

Everyone charged with a criminal offence shall be presumed innocent until proved guilty according to law.

Everyone charged with a criminal offence has the following minimum rights:

- (a) to be informed promptly, in a language which he understands and in detail, of the nature and cause of the accusation against him;
- (b) to have adequate time and the facilities for the preparation of his defence;
- (c) to defend himself in person or through legal assistance of his own choosing or, if he has not sufficient means to pay for legal assistance, to be given it free when the interests of justice so require;
- (d) to examine or have examined witnesses against him and to obtain the attendance and examination of witnesses on his behalf under the same conditions as witnesses against him;
- (e) to have the free assistance of an interpreter if he cannot understand or speak the language used in court.

**ARTICLE 7**

No one shall be held guilty of any criminal offence on account of any act or omission which did not constitute a criminal offence under national or international law at the time when it was committed. Nor shall a heavier penalty be imposed than the one that was applicable at the time the criminal offence was committed.

This article shall not prejudice the trial and punishment of any person for any act or omission which, at the time when it was committed, was criminal according the general principles of law recognized by civilized nations.

**ARTICLE 8**

Everyone has the right to respect for his private and family life, his home and his correspondence.

There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

**ARTICLE 9**

Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief, and freedom, either alone or in community with others and in public or private, to manifest his religion or belief, in worship, teaching, practice and observance.

Freedom to manifest one's religion or beliefs shall be subject only to such limitations as are prescribed by law and are necessary in a democratic society in the interests of public safety, for the protection of public order, health or morals, or the protection of the rights and freedoms of others.

#### **ARTICLE 10**

Everyone has the right to freedom of expression. this right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers. This article shall not prevent States from requiring the licensing of broadcasting, television or cinema enterprises.

The exercise of these freedoms, since it carries with it duties and responsibilities, may be subject to such formalities, conditions, restrictions or penalties as are prescribed by law and are necessary in a democratic society, in the interests of national security, territorial integrity or public safety, for the prevention of disorder or crime, for the protection of health or morals, for the protection of the reputation or the rights of others, for preventing the disclosure of information received in confidence, or for maintaining the authority and impartiality of the judiciary.

#### **ARTICLE 11**

Everyone has the right to freedom of peaceful assembly and to freedom of association with others, including the right to form and to join trade unions for the protection of his interests.

No restrictions shall be placed on the exercise of these rights other than such as are prescribed by law and are necessary in a democratic society in the interests of national security or public safety, for the prevention of disorder or crime, for the protection of health or morals or for the protection of the rights and freedoms of others. this article shall not prevent the imposition of lawful restrictions on the exercise of these rights by members of the armed forces, of the police or of the administration of the State.

#### **ARTICLE 12**

Men and women of marriageable age have the right to marry and to found a family, according to the national laws governing the exercise of this right.

#### **ARTICLE 13**

Everyone whose rights and freedoms as set forth in this Convention are violated shall have an effective remedy before a national authority notwithstanding that the violation has been committed by persons acting in an official capacity.

#### **ARTICLE 14**



The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status.