Explanatory notes

1. This document can be used by UCD researchers who answered YES to any questions in the ***Ethics Issues Checklist*** in the proposal forms.

2. Contents of this template are applicable to Irish jurisdiction only. However, a similar template can be used with regard to other jurisdictions, where specific local requirements will need to be assessed by the researcher(s).

3. Detailed guidance on how to complete your Ethics Self-Assessment Statement with definitions, explanations, and exemplary cases are contained in H2020 Programme Guidance: How to complete your ethics self-assessment

4. Other relevant **H2020 EU legislation & guidelines** are available on H2020 Ethics web portal

5. Please note that he information provided in this document is not exhaustive and its purpose is to steer researchers towards specific requirements only. The resources included in this template were chosen to best exemplify what guidelines may need to be considered by researchers and referenced in their Ethics Self-Assessment Statements.

Instruction 1: Describe how the proposal meets the national legal and ethical requirements of the country

Table 1: This table gives an overview of the legal and ethical requirements applicable to research with humans or animals conducted in Ireland.

Research Subjects	Legislative Requirements (EU & Irish legislation and international conventions that Ireland is signatory of)	Name of the Competent Authority (if applicable) – for licensing & authorizations	National Ethical Best Practice Requirements & Guidelines*	UCD (Institutional) Ethical Best Practice Requirements
All Humans (Clinical Trials of Drugs or Medical Devices)	Data Protection Acts 1988 & 2003 Declaration of Helsinki 1964 (amended 2013) European Convention on Human Rights Act 2003 Control of Clinical Trials Act, 1987 Control of Clinical Trials and Drugs Act, 1990 European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations, 2004 (**S.I. 190 of 2004**) European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations 2004 (**S.I. 878 of**	Health Products Regulatory Authority (HPRA)	Data Protection Guidelines on Research in the Health Sector HSE National Consent Policy ICRIN Info page **Ethical Review** is required by one of '**Recognized' Research Ethics Committees** (with jurisdiction over the entire state)	UCD Code of Good Practice in Research UCD Research Ethics – policies & guidelines concerning human research

Research Subjects	Legislative Requirements (EU & Irish legislation and international conventions that Ireland is signatory of)	Name of the Competent Authority (if applicable) – for licensing & authorizations	National Ethical Best Practice Requirements & Guidelines*	UCD (Institutional) Ethical Best Practice Requirements
All Humans (clinical trials continued)	**2004**) European Communities (Clinical Trials on Medicinal Products for Human Use) (Amendment No.2) Regulations 2006 (**S.I. 374 of 2006**) European Communities (Clinical Trials On Medicinal Products For Human Use) (Amendment) Regulations 2009 (**S.I. 1 of 2009**)			
Adult Humans (non- clinical trials, fields of science and humanities. Incl. personal data and non-embryonic human cells/tissues)	Data Protection Acts 1988 & 2003 Declaration of Helsinki 1964 (amended 2013) European Convention on Human Rights Act 2003 S.I. No. 158/2006 - European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 S.I. No. 598/2007 - European Communities (Human Tissues and Cells Traceability	Health Products Regulatory Authority (HPRA) - donation, procurement, testing, processing, preservation, storage or distribution of tissues or cells for human applications	Data Protection Guidelines on Research in the Health Sector HSE National Consent Policy ICRIN Info page Irish Council for Bioethics Recommendations on the Use of Human Biological Material in Research	UCD Code of Good Practice in Research **Ethical Review** is required either by a local (i.e. hospital, prisons service etc.) and/or UCD Research Ethics Committee (enquire directly in UCD Office of Research Ethics)

Research Subjects	Legislative Requirements (EU & Irish legislation and international conventions that Ireland is signatory of)	Name of the Competent Authority (if applicable) – for licensing & authorizations	National Ethical Best Practice Requirements & Guidelines*	UCD (Institutional) Ethical Best Practice Requirements
Adult Humans (continued)	Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) Regulations 2007			
Minor Humans (under 18 years of age)	Data Protection Acts 1988 & 2003 Declaration of Helsinki 1964 (amended 2013) European Convention on Human Rights Act 2003 United Nations Convention on the Rights of the Child (UNCRC) 1989	Not applicable	Data Protection Guidelines on Research in the Health Sector Department of Health and Children Guidance for Developing Research Projects Involving Children HSE National Consent Policy	UCD Code of Good Practice in Research **Ethical Review** is required either by a local and/or UCD Research Ethics Committee (enquire directly in UCD Office of Research Ethics)
Humans with Disability	Data Protection Acts 1988 & 2003 Declaration of Helsinki 1964 (amended 2013) European Convention on Human Rights Act 2003	Not applicable	Data Protection Guidelines on Research in the Health Sector National Disability Authority Ethical Guidance for Research with People with Disabilities HSE National Consent Policy	UCD Code of Good Practice in Research **Ethical Review** is required by a local and/or UCD Research Ethics Committee (enquire directly in UCD Office of Research Ethics)

Research Subjects	Legislative Requirements (EU & Irish legislation and international conventions that Ireland is signatory of)	Name of the Competent Authority (if applicable) – for licensing & authorizations	National Ethical Best Practice Requirements & Guidelines*	UCD (Institutional) Ethical Best Practice Requirements
Human Embryos, Stem Cells and Cloning	Convention on Human Rights and Biomedicine (Convention of Oviedo) and Additional Protocol on Prohibition of Human Cloning European Commission Statement on Research Activities Involving Human Embryonic Stem Cells	Not applicable	Data Protection Guidelines on Research in the Health Sector Ethical, Scientific and Legal Issues Concerning Stem Cell Research Opinion (Irish Council for Bioethics, 2008)	UCD Code of Good Practice in Research **Ethical Review** is required by a local and/or UCD Research Ethics Committee (enquire directly in UCD Office of Research Ethics)
Animals	Animal Health and Welfare Act, 2013 European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (SI 543 of 2012) European Union (Protection of Animals used for Scientific Purposes) (Amendment) Regulations 2013 (SI 434 of 2013) European Union (Protection of Animals used for Scientific Purposes) (Amendment) Regulations 2014 (SI 174 of 2014)	Health Products Regulatory Authority (HPRA)	HPRA – The 3R's (scroll down to links to guidelines endorsed by HPRA) UK NC3Rs	UCD Code of Good Practice in Research UCD Policy on the Use of Animals for Research & Teaching UCD AREC Guidelines (access by staff only) **Ethical Review** is required by UCD Animal Research Ethics Committee (enquire directly in UCD Office of Research Ethics)

Table 2: This table refers to legal and ethical requirements with regard to areas of special ethical considerations:

- health & safety, and environmental impact of your research
- Ethical best practice requirements if your research is to take place in the so-called "**low and/or lower middle income countries**".
- Dual-use items
- Exclusive focus on civil applications
- Potential misuse of research results

Area for Consideration	Legislative Requirements	Name of the Competent Authority (if applicable)	Best Practice Requirements & Guidelines	UCD (Institutional) Best Practice Requirements
Health & Safety / Environmental Impact	Legislation re: Health & Safety and Use of Chemical/Dangerous Substances Environmental Legislation Legislation re: Genetically Modified Organisms (GMO's)	Health & Safety Authority Environmental Protection Agency	Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Guidelines Health & Safety Authority - Chemical Agents in Healthcare Health & Safety Authority - Safe Supply, Use & Management of Chemicals (incl. carcinogens, nanotechnology etc.)	UCD Home Visits / Face-To-Face Interviews Safety Guidelines UCD Laboratory Biosafety Guide UCD Chemical Safety Guide UCD Fieldwork Safety Guidelines UCD Risk Assessments Guidelines
Third/Non-EU Countries	All research should be carried out within the law of the country where the study will take place. **It is the researcher's responsibility** to comply with all such requirements in that country – such as access to participants, data and/or material transfer and insurance.	It is the researcher's responsibility to comply with regulatory requirements of the country where the study will take place, including **licensing** and **authorization** requirements as per Irish/EU regulatory framework.	The Ethics of Research Related to Healthcare in Developing Countries (Nuffield Council on Bioethics, UK) Ethics in research and international cooperation (European Council)	UCD Code of Good Practice in Research **Double Ethical Review** is required: first by an appropriate local (if available) **and** by UCD Research Ethics Committee (enquire directly in UCD Office of Research Ethics)

Area for Consideration	Legislative Requirements	Name of the Competent Authority (if applicable)	Best Practice Requirements & Guidelines	UCD (Institutional) Best Practice Requirements
Dual-Use Items	EC Regulation No 428/2009 Export Licensing Legislation	Ireland: Department of Jobs, Enterprise & Innovations, Export Licensing Unit	EC Guidance note: Research involving dual-use items	There are no UCD policies or guidelines referring to dual-use items in research. UCD researchers should comply with relevant legislation and EC guidelines.
Exclusive focus on civil applications*	EC Horizon 2020 Regulation No. 1291/2013	Not applicable	EC Guidance note: Research with an exclusive focus on civil applications	There are no UCD policies or guidelines referring to exclusive focus on civil applications in research. UCD researchers should comply with relevant EU regulations and EC guidelines.
Potential misuse of research results**	Relevant international law is listed in H2020 Programme Guidance: How to complete your ethics self-assessment (pp.36-37) Ireland: Department of Foreign Affairs website contains a list of relevant legislation and regulations concerning biological and chemical weapons See also: '**Health & Safety / Environmental Impact'** section at the top of this table	Ireland: Health & Safety Authority (for the use of certain chemical and biological agents only)	EC Guidance note: Potential misuse of research EC Guidance note: Research on refugees, asylum seekers & migrants (p.5) UK Medical Research Council – Managing risks of research misuse	Currently, there are no specific UCD policies and guidelines concerning potential misuse of research results. UCD researchers should comply with relevant legislation and EC guidelines. For guidelines regarding **health and safety** requirements when using chemical or biological agents, please contact UCD SIRC (as per section '**Health & Safety / Environmental Impact'** at the top of this table.

***NOTE 1:** Participation of military partners and development of generic technologies and knowledge is permitted under H2020 programme provided that the research itself has a clear focus on civil applications.

__NOTE 2:__ If applicable, your Ethics Self-Assessment Statement should also include a **Risk Assessment section detailing how this risk will be mitigated. This area does not refer to research misconduct but to the potential risk of potential misuse of materials, technologies and information (data) generated by the project.

Instruction 2: Explain <u>in detail</u> how you intend to address the issues in the ethical issues table, in particular with regard to research objectives, methodology, and the potential impact of the research.

The above instruction is closely linked to the requirements of any ethical review and concerns the following:

- Justification for including human participants (or animals)
- Identification of potential risks to participants and means of mitigating them.
- Detailed description of selection, recruitment, and consent processes
- Description of methods of data collection, analysis, storage, archiving, transfer, and destruction (if applicable)
- Description of how confidentiality of data will be maintained.

Below are some general tips on what to include your statement:

- Address each issue that you identified in the ***Ethics Issues Checklist*** individually
- Describe how legislative/regulatory and ethical requirements will be fulfilled and confirm your compliance with relevant regulations in terms of obtaining applicable authorizations and licensing; provide timeframes for submitting required documents to the funding body.
- Identify research ethics committees which will review and approve all aspects of the proposal. If the proposal is multinational/multisite, identify local ethical review requirements in each participating country, and provide details and timeframes in your statement.
- Describe in detail consenting procedures, provide copies of Information leaflets and consent forms templates (for <u>each</u> category of participants).