



The EU Framework Programme  
for Research and Innovation

# HORIZON 2020



## Ethics Issues Table template

Version 1.1  
11 July 2014

### Disclaimer

This document is aimed at informing potential applicants for Horizon 2020 funding. It serves only as an example. The actual Web forms and templates, provided in the online proposal submission system under the Participant Portal, might differ from this example. Proposals must be prepared and submitted via the online proposal submission system under the Participant Portal.

*Research and  
Innovation*

## History of changes

<b>Version</b>	<b>Date</b>	<b>Change</b>
1.1	11.07.2014	▪ Updates on the ethics issue table and guidance section

Proposal ID	Acronym	Go to
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## 4 - Ethics issues table

The applicable legislation is the Horizon2020 legislative acts (i) (see legal references at the end of the section).

This Table should be completed as an essential part of your proposal. Answer "Yes" or "No" to all of the questions below. If an answer is "Yes", then indicate in the adjacent box at which page in your full proposal further information relating to that issue can be found.

For further explanation on the questions see "[How to Complete your Ethics Self-Assessment](#)" or, for ERC calls, the "Information for applicants" ([Annex 3 - Specific Guidance Related to Ethics](#)).

As explained in these documents, please note that if you answer YES to any of the questions below, you are requested to provide additional information and documentation.

1. HUMAN EMBRYOS/FOETUSES		Page
Does your research involve <a href="#">Human Embryonic Stem Cells (hESCs)</a> ?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Will they be directly derived from embryos within this project?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they previously established cells lines?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does your research involve the use of human embryos?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does your research involve the use of human foetal tissues / cells?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
2. HUMANS		Page
Does your research involve human participants?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they volunteers for social or human sciences research?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they persons unable to give informed consent?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they vulnerable individuals or groups?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they children/minors?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they patients?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they healthy volunteers for medical studies?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does your research involve physical interventions on the study participants?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does it involve invasive techniques?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does it involve collection of biological samples?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
If your research involves processing of genetic information, see also section 4.		

Proposal ID	Acronym	Go to
<b>3. HUMAN CELLS / TISSUES</b>		Page
Does your research involve human cells or tissues (other than from Human Embryos/ Foetuses, i.e. section 1)?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they available commercially?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they obtained within this project?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they obtained within another project?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they deposited in a biobank?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
<b>4. PERSONAL DATA (ii)</b>		Page
Does your research involve personal data collection and/or processing?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does it involve the collection and/or processing of sensitive personal data (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does it involve processing of genetic information?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does it involve tracking or observation of participants?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Does your research involve further processing of previously collected personal data (secondary use)?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
<b>5. ANIMALS (iii)</b>		Page
Does your research involve animals?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they vertebrates?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they non-human primates?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they genetically modified? (iv) ( <a href="#">regulation</a> )	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they cloned farm animals?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Are they endangered species?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Please indicate the species involved(Maximum number of characters allowed: 1000)		

Proposal ID	Acronym	Go to
<b>6. THIRD COUNTRIES</b>		<b>Page</b>
Does your research involve non-EU countries?		<input checked="" type="radio"/> Yes <input type="radio"/> No
<i>Specify the countries involved:(Maximum number of characters allowed: 1000)</i>		
Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)? (v)		<input checked="" type="radio"/> Yes <input type="radio"/> No
Do you plan to import any material from non-EU countries into the EU? <i>For data imports, please fill in also section 4.            For imports concerning human cells or tissues, fill in also section 3.</i>		<input checked="" type="radio"/> Yes <input type="radio"/> No
<i>Specify material and countries involved: (Maximum number of characters allowed: 1000)</i>		
Do you plan to export any material from the EU to non-EU countries? <i>For data exports, please fill in also section 4.            For exports concerning human cells or tissues, fill in also section 3.</i>		<input checked="" type="radio"/> Yes <input type="radio"/> No
<i>Specify material and countries involved: (Maximum number of characters allowed: 1000)</i>		
If your research involves <a href="#">low and/or lower middle income countries</a> , are benefits-sharing measures foreseen? (vii)		<input checked="" type="radio"/> Yes <input type="radio"/> No
Could the situation in the country put the individuals taking part in the research at risk?		<input checked="" type="radio"/> Yes <input type="radio"/> No
<b>7. ENVIRONMENT &amp; HEALTH and SAFETY</b> See legal references at the end of the section. (vi)		<b>Page</b>
Does your research involve the use of elements that may cause harm to the environment, to animals or plants? <i>For research involving animal experiments, please fill in also section 5.</i>		<input checked="" type="radio"/> Yes <input type="radio"/> No
Does your research deal with endangered fauna and/or flora and/or protected areas?		<input checked="" type="radio"/> Yes <input type="radio"/> No
Does your research involve the use of elements that may cause harm to humans, including research staff? <i>For research involving human participants, please fill in also section 2.</i>		<input checked="" type="radio"/> Yes <input type="radio"/> No



Proposal ID	Acronym	Go to
8. <a href="#">DUAL USE</a> (vii)		Page
Does your research have the potential for military applications?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
9. MISUSE		Page
Does your research have the potential for malevolent/criminal/terrorist abuse?	<input checked="" type="radio"/> Yes <input type="radio"/> No	
10. OTHER ETHICS ISSUES		Page
Are there any other ethics issues that should be taken into consideration? Please specify	<input checked="" type="radio"/> Yes <input type="radio"/> No	
<i>Please specify: (Maximum number of characters allowed: 1000)</i>		

I confirm that I have taken into account all ethics issues described above and that, if any ethics issues apply, I will complete the ethics self-assessment and attach the required documents.



Proposal ID	Acronym	Go to
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The list of references is non-exhaustive. More general information and an e-Library containing the most important pieces of legislation relevant to research activities can be found on the [Europa website](#).

(i) [REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) laying down the rules for the participation and dissemination in Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)

[REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)

(ii) [Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data](#)

(iii) [DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2010 on the protection of animals used for scientific purposes](#)

(iv) [Regulation \(EC\) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms](#)

(v) [Nagoya protocol](#)

(vi) Environmental protection

[Directive 2001/18/EC of the European Parliament and of the Council](#) of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration

[Directive 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) of 6 May 2009 on the contained use of genetically modified micro-organisms

[Regulation EC No 1946/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) of 15 July 2003 on transboundary movements of genetically modified organisms

[Directive 2008/56/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL](#) of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive)

[Council Directive 92/43/EEC](#) of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora

[Council Directive 79/409/EEC](#) of 2 April 1979 on the conservation of wild birds

[Council Regulation EC No 338/97](#) of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein

(vii) [COUNCIL REGULATION \(EC\) No 428/2009](#) of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items