



1. Human embryonic stem cells (hESCs) and human embryos (hEs)

This section covers projects with research activities involving human embryonic stem cells (hESCs) and human embryos (hEs).

For research activities involving human embryonic or foetal tissues or cells other than hESCs, see Section 3.

 The following fields of research **are not eligible for funding** under Horizon Europe and cannot therefore be included in proposals:

- research activities directed at human cloning for reproductive purposes
- research activity intended to modify the genetic make-up of human beings that could make such changes heritable (apart from research relating to cancer treatment of the gonads, which may be financed)
- research activities intended to create human embryos solely for the purposes of research or stem cell procurement, including the technique of somatic cell nuclear transfer¹
- research that leads to the destruction of human embryos.²

 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, neither within nor outside the EU, 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.³

Please note that **all proposals involving the use of hESCs or hEs will undergo an ethics assessment**, and the funding of hESC or hE proposals requires and must be approved by the Horizon Europe Programme Committee⁴.

1.1 Ethics issues checklist

Section 1: HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS		YES/NO		Information to be provided in the proposal	Documents be provided/kept on file
Does your activity involve Human Embryonic Stem Cells (hESCs)?		<input type="checkbox"/>	<input type="checkbox"/>		
If YES:	Will they be directly derived from embryos within this project?	<input type="checkbox"/>	<input type="checkbox"/>	<i>Research not eligible for funding</i>	<i>Research not eligible for funding</i>
	Are they previously established	<input type="checkbox"/>	<input type="checkbox"/>	1) Origin and line	1) Copies of ethics

¹ See Article 18(1) of the Horizon Europe Framework Programme and Rules for Participation Regulation YYYY/NN (OJ L XXXX).

² See [Declarations of the Commission \(Framework Programme\) \(2013/C 373/02\)](#). To be soon replaced by a Statement for Horizon Europe with the same rules.

³ See also Article 18(2) of the Horizon Europe Framework Programme and Rules for Participation Regulation YYYY/NN (OJ L XXXX).

⁴ See Article 11(4) of the Horizon Europe Specific Programme Decision NN/YYYY (OJ L XXXX).

	cells lines? Are the cell lines registered in the European registry for human embryonic stem cell lines?			of cells. 2) Details on licensing and control measures by the competent authorities of the Member States involved 3) Declaration confirming that the 6 specific conditions (<i>see below</i>) for research activities involving human embryonic stem cells are met..	approval. 2) Declaration that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hpscreg.eu).
Does your activity involve the use of human embryos?		<input type="checkbox"/>	<input type="checkbox"/>	1) Origin of embryos. 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) Confirmation that informed consent has been obtained.	1) Copies of ethics approval. 2) Informed consent forms and information sheets.
If YES:	Will the research lead to their destruction?	<input type="checkbox"/>	<input type="checkbox"/>	<i>Research not eligible for funding</i>	<i>Research not eligible for funding</i>
Does your research involve the use of other human embryonic or foetal tissues / cells?		<input type="checkbox"/>	<input type="checkbox"/>	<i>See section 3 below</i>	

1.2 How do I deal with the issues?

Your research activities must comply with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards
- applicable international, EU and national law (in particular, the [Statement of the Commission related to research activities involving human embryos or human embryonic stem cells](#) – to be soon replaced by a Statement for Horizon Europe with the same rules).

For research activities involving **human embryonic stem cells (hESCs)**, this means you must make sure that:

- cells were NOT derived from embryos specially created for research or by somatic cell nuclear transfer
- the project uses existing cultured cell lines only

- cell lines were derived from supernumerary non-implanted embryos resulting from in vitro fertilisation
- informed consent has been obtained for using donated embryos for the derivation of the cell lines
- personal data and privacy of donors of embryos for the derivation of the cells are protected according to the data protection rules applicable for the donors and in the EU
- NO financial inducements were provided for the donation of embryos used for derivation of the cell lines.

You must provide the granting authority with a declaration confirming compliance with these conditions (as part of your proposal).

Furthermore:

- each project proposing to use hESC must successfully pass a scientific evaluation during which the necessity of using hESC to achieve the scientific objectives are assessed by independent scientific experts
- each project proposing to use hESC must obtain the approval of the relevant national or local ethics committee prior to the start of the relevant activities within the project
- full compliance with the licensing and control measures for research on hESC as laid down in the relevant applicable national laws and regulations must be confirmed in the application.⁵

For research on **human embryos (hE)**, you must obtain the donors' free and fully informed consent.

In addition, **in your application you must confirm** that your research will NOT:

- 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*)
- result in the destruction of human embryos

1.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part A** of your proposal.

Your proposal must include the **information** referred to in the ethics issues checklist and any **documents** that are already available (*national/local ethics approvals, information sheets and informed consent forms, etc.*). Documents that are not submitted together with the proposal must be kept on file and may have to be provided later on, if requested by the granting authority.

Background documents & further reading

⁵ See also Article 19(2)(d) of the Horizon Europe Framework Programme and Rules for Participation Regulation YYYY/NN (OJ L XXXX).

[Statement of the Commission related to research activities involving human embryonic stem cells](#) — *to be soon replaced by a Statement for Horizon Europe with the same rules.*

FP7: [Recommendations on the ethical review of hESC FP7 research projects \(Opinion 22\)](#), European Group on Ethics in Science and New Technologies.

FP7: [Research on Human embryos/foetus.](#)