3. Human cells or tissues

This section refers to projects with research activities using, producing or collecting human cells or tissues (including human foetal or embryonic tissues or cells, other than hESC).

You may obtain cells or tissues:

- from commercial sources
- as part of this research project
- from another research project, laboratory or institution
- from a biobank.

3.1 Ethics issues checklist

Section 3: HUMAN CELLS / TISSUES		YES/ NO		Information to be provided in the proposal	Documents to be provided on request
Does your activity involve human cells or tissues (other than those covered by *section 1*)**?**		☐	☐	Please provide information in one of the subcategories below.	
If **YES**:	Are they human embryonic or foetal cells or tissues?	☐	☐	1) Origin of human foetal tissues/cells. 2) Details on informed consent procedures. 3) Confirmation that the informed consent has been obtained. 4) If applicable, details on the induced human pluripotent cell lines.	1) Copies of ethics approvals. 2) Informed consent forms and information Sheets. 3) If applicable, registration certificates of the cell lines and project from the hPSCreg.
	Are they available commercially?	☐	☐	1) Details on cell types and provider (company or other).	1) Copies of import licences (if relevant).
	Are they obtained within this project?	☐	☐	1) Details on cell types including the source of the material, the amount to be collected and the procedure for collection.	1) Copies of ethics approvals (if relevant). 2) Informed consent forms and information sheets.

				2) Details on the duration of storage and what will be done with the material at the end of the research. 3) Confirmation that informed consent has been obtained.	
	Are they obtained from another project, laboratory or institution?	☐	☐	1) Details on cell types. 2) Country where the material is stored. 3) Details of the legislation under which material is stored. 4) Details on the duration of storage and what will you do with it at the end of the research project? 5) Name of the laboratory/institution. 6) Country where the laboratory/institution is located. 7) Confirm that material is fully anonymised or that consent for secondary use has been obtained.	1) Authorisation by primary owner of cells/tissues (including references to ethics approvals) 2) Copies of import licences (if relevant). 3) Statement from the primary laboratory/institution that informed consent has been obtained.
	Are they obtained from a biobank?	☐	☐	1) Details on cell types 2) Details on the biobank (name and country where it is located) 3) Details of the legislation under which material is stored. 4) Confirmation that material is fully anonymised or that consent for secondary use has been obtained.	1) Copies of import licences (if relevant). 2) Statement of biobank that informed consent has been obtained.

3.2 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, EU Directive 2004/23).

  Under this Directive, the handling of cells and tissues is subject to specific rules *(in particular, concerning donor selection/protection; accreditation/designation/authorisation/ licensing of tissue establishments and tissue and cell preparation processes; quality management of cells and tissues; procurement, processing, labelling, packaging, distribution, traceability, and imports and exports of cells and tissues from and to third countries)*.

The main obligations are to:

- keep track of the **origin** of the cells and tissues you use, produce or collect

and to obtain:

- the necessary accreditation/designation/authorisation/licensing for using, producing or collecting the cells or tissues
- free and fully informed consent of the donors.

Specific cases

Cells or tissues from clinical practice (secondary use) — For human cells or tissues which you or others have derived from clinical practice *(e.g. waste material from surgery or other operations*) provide evidence *(e.g. copies of examples of informed consent documentation)* that the donors have given informed consent for the use of their waste cells or tissues (either specifically for the research or generally, for any secondary use).

If, for the purposes of your research, you intend to collect more **additional material** than would normally be collected during the standard clinical procedure *(e.g. a larger than normal tissue sample or a sample that includes some additional adjacent material)*, you must ensure that informed consent has also been given for collecting additional material. You must also explain the need for such material in your grant proposal and show that you have obtained appropriate ethics approvals.

Secondary use for future research — If you intend to store the material for future use in other projects, you must:

- confirm that you have obtained the donor's consent for such secondary use
- state the legislation under which the material will be stored
- state how long it will be stored and what you will do with it at the end of the research.

Biobanking — Biobanks raise significant ethical issues concerning informed consent, privacy and data protection.

'Biobanks' are repositories for the storage of biological samples (usually human) and play a significant role in biomedical research. These 'libraries' provide researchers with access to large numbers of tissue samples, genetic material and associated data.

If your project has the aim or results in the setting up a biobank, you must ensure that there is strict compliance with appropriate European and national ethical standards (in particular, regarding privacy and data protection; *see section 4*).

You must confirm that informed consent has been obtained and show that you have obtained all necessary ethics approvals (or that you are exempted under national law).

⚠ No samples or associated data may be placed in the biobank before all appropriate consents and ethics approvals have been obtained

You will need to make a report on key aspects of the biobank's activities, including in particular:

- information on which donors will be excluded/included *(e.g. competent adults, children and minors, adults unable to provide informed consent, individuals in an emergency setting, etc.)*
- details of the material that will be 'banked', including:
  - personal (coded or fully identifiable) biosamples
  - personal information associated with a sample *(e.g. name/code, gender, age, etc.)*
  - personal data resulting from analysis of a sample *(e.g. analysis of genetic material or a genome)*
  - anonymised biosamples
  - anonymised data resulting from analysis of a sample (from which individuals could be identified) and
  - epidemiological (population level) data
- information on the standard procedures for:
  - accepting material into the biobank
  - processes and standards for sample-quality assurance and ensuring accuracy of data and information
  - handling requests for release of samples/data from the biobank *(including fair and just financial arrangements and benefit-sharing for third countries)*.

Genetic testing — For using or storing human cells or tissues for genetic testing, you must obtain the donor's informed consent for the genetic testing, and show that you have obtained approval from the relevant ethics and data protection bodies; and any licence required under national legislation.

Transfer to/from non-EU countries — If your research project involves the transfer of cells and tissues from/to non-EU countries, you must comply with the specific provisions on import/export under Directive 2004/23/EC *(see also section 6)*.

Moreover, since human cells and tissues constitute personal data, you must also comply with the rules on data transfer to/from non-EU countries *(see section 4)*.

3.3 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 grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** that are already available. Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the granting authority.

Background documents & further reading

EU Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p.48).

EU page on tissues and cells