Fundação
para a Ciência
e a Tecnologia

ETHICS SELF-ASSESSMENT GUIDE

RESTART PROGRAMME – 3RD EDITION

JUNE 2025

Please use this list as guidance for identifying the main ethical issues concerning your research plan activities.

ETHICS ISSUE 1: HUMAN EMBRYOS/FOETUS

1. Does this research involve Human Embryonic Stem Cells (hESCs)?
    1.1 If yes, will they be directly derived from embryos within this project?
    1.2 If yes, are they previously established cells lines?
2. Does this research involve the use of human embryos?
    2.1 If yes, will the research lead to their destruction?
3. Does this research involve the use of human foetal tissues/cells?

ETHICS ISSUE 2: HUMANS

1. Does this research involve human participants?
    1.1 If yes, are they volunteers for social or human sciences research?
    1.2 If yes, are they persons unable to give informed consent?
    1.3 If yes, are they vulnerable individuals or groups (children, patients, discriminated people, minorities, persons unable to give consent, people of dissenting, immigrant or minority communities, sex workers, etc.)?
    1.4 If yes, are they children/minors?
    1.5 If yes, are they patients?
    1.6 If yes, are they healthy volunteers for medical studies?
2. Does this research involve physical interventions on the study participants?
    2.1 If yes, does it involve invasive techniques?

ETHICS ISSUE 3: HUMANS CELLS/TISSUES

1. Does this research involve human cells or tissues? (other than from Human Embryos/Foetuses, see section 1)
    1.1 If yes, are they available commercially?
    1.2 If yes, are they obtained within this project?
    1.3 If yes, are they obtained from another project, laboratory or institution?

1.4 If yes, are they obtained from biobank?

ETHICS ISSUE 4: PROTECTION OF PERSONAL DATA

1. Does this research involve personal data collection and/or processing?
    1.1 If yes, does it involve the collection and/or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?
    1.2 If yes, does it involve processing of genetic information?
    1.3 If yes, does it involve tracking or observation of participants?
2. Does this research involve further processing of previously collected personal data secondary use)?

ETHICS ISSUE 5: ANIMALS

1. Does this research involve animals?
    1.1 If yes, are they vertebrates?
    1.2 If yes, are they non-human primates (NHPs)?
    1.3 If yes, are they genetically modified?
    1.4 If yes, are they cloned farm animals?
    1.5 If yes, are they endangered species?

ETHICS ISSUE 6: THIRD COUNTRIES

1. In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?
2. Is it planned 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.)?
3. Is it planned to import any material – including personal data – from non-EU countries into the EU?
4. Is it planned to export any material, including personal data –from the EU to non-EU countries?
5. In case the research involves low and/or lower-middle income countries, are any benefit-sharing actions planned?
6. Could the situation in the country put the individuals taking part in the research at risk?

ETHICS ISSUE 7: ENVIRONMENT & HEALTH AND SAFETY

1. Does your research involve the use of elements that may cause harm to the environment, to animals or plants?
2. Does your research deal with endangered fauna and/or flora/protected areas?
3. Does your research involve the use of elements that may cause harm to humans, including research staff?

ETHICS ISSUE 8: DUAL USE

Does this research involve dual-use items (goods, software, technology that can be used for both civilian and military applications and/or can contribute to the proliferation of weapons of mass destruction) in the sense of Council Regulation (EC) No 428/2009, or other items for which an authorisation is required?

ETHICS ISSUE 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS

Could your research raise concerns regarding the exclusive focus on civil applications?

ETHICS ISSUE 10: MISUSE

Does your research have a potential for misuse (potential for malevolent/criminal/terrorist abuse) of research results?