

**YUFE4Postdocs Ethics Self-assessment form**

This checklist is largely based on the Horizon Europe Ethics Self-Assessment Checklist but has been adapted for the specific purposes of the YUFE4Postdocs call.

For more detailed information on how to complete the ethics self-assessment please consult the Ethics & Diversity chapter in the guideline for applicants and the Horizon Europe guideline on [*How to complete your ethics self-assessment*.](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf)

The YUFE4Postdocs Ethics self-assessment form should be saved in this format: ‘Full name of applicant\_Ethics’.

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| **Section** |  |  | **Guidance notes** | |
| 1.Human Embryonic Stem Cells and Human Embryos |  |  |  | |
| 1.1 Does this activity involve Human Embryonic Stem Cells (hESCs)? | Yes | No | Activities that involve hESCs directly derived from embryos are ineligible for funding.  If the hESCs you will use are previously established cells lines and/or registered in the European registry for human embryonic cells lines, you must provide information about the origin and line of cells, the licensing and control measures of the countries involved and declare that you have met the specific conditions for involving human embryonic stem cells | |
| 1.2 Does this activity involve the use of human embryos? | Yes | No | Your application should include details about the origin of the embryos, the recruitment, inclusion and exclusion criteria and informed consent procedures and confirmation that informed consent has been obtained | |
| 2. Human Cells/Tissues (not covered by section 1) |  |  |  | |
| 2.1 Does this activity involve the use of human cells or tissues? | Yes | No | Your application should include details of how you will keep track of the origin of the cells and tissues you use, produce and collect and confirmation that you will obtain the necessary accreditation/designation/authorisation/licensing for using, producing or collecting the cells or tissues and free and fully-informed consent of the donors | |
| 1. Humans |  |  |  | |
| 3.1 Does this activity involve human participants? **If yes**, answer questions 3.2 to 3.8 below. **If no**, move on to question 3.9 | Yes | No | Concerning all research or study participants, persons concerned by the project activities, etc., regardless of its nature or topic. | |
| 3.2 Is their participation voluntary? | Yes | No | Your application should include details on the recruitment, inclusion and exclusion criteria and informed consent procedures and details on unexpected findings policy |  |
| 3.3 Are they healthy volunteers for medical studies? | Yes | No | Your application should include details on the recruitment, inclusion and exclusion criteria and informed consent procedures and details on unexpected findings policy | |
| 3.4 Are they patients for medical studies? | Yes | No | Provide details on the impairment/disease/condition/disability of the patients. | |
| 3.5 Are they potentially vulnerable individuals or groups? | Yes | No | Your application should include details on the type of vulnerability, which can be highly contextual. Also describe the procedures in place to ensure participants are not to be subjected to any form of coercion and undue inducement. | |
| 3.6 Are they children/minors? | Yes | No | Your application should include thorough reasoning on why the involvement of children is necessary, on the age range of the minors and on how consent from parents/legal guardians will be obtained. | |
| 3.7 Are there other persons unable to give informed consent? | Yes | No | Other persons unable to give consent include certain elderly populations, persons judged as lacking mental capacity | |
| 3.8 Does this activity involve interventions (physical also including imaging technology, behavioural treatments etc.) on the study participants? | Yes | No | Your application should provide information on the ethical implications of the chosen methodology, a risk assessment, and a detailed explanation on how you will minimise harm. | |
| 3.9 Does it involve invasive techniques e.g., collection of human cells or tissue, surgical or medical interventions, invasive studies on the brain etc? | Yes | No | Include a risk assessment for each technique and for the overall project or procedures. | |
| 3.10 Does it involve collection of biological samples? | Yes | No | Provide details on the samples and the collection procedure. | |
| 3.11 Does it involve conducting a clinical study as defined by the [Clinical Trial Regulation (EU 536/2014)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products). If yes, answer questions 3.12 and 3.13 | Yes | No | ’Clinical study’ means any investigation in relation to humans intended:   1. to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; 2. to identify any adverse reactions to one or more medicinal products; or 3. to study the absorption, distribution, metabolism and excretion of one or more medicinal products;   With the objective of ascertaining the safety and/or efficacy of those medicinal products. | |
| 3.12 Is it a [clinical trial](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536#d1e736-1-1)? | Yes | No | Your application should contain a risk assessment and details on the medical products that are being used, details on the impairment/disease/condition/disability of participants. Details of the recruitment, inclusion and exclusion criteria and informed consent procedures and details on the incidental findings policy. | |
| 3.1 Is it a [low intervention clinical trial](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0536#d1e736-1-1)? | Yes | No | Your application should contain a risk assessment and details on the medical products that are being used, details on the impairment/disease/condition/disability of participants. Details of the recruitment, inclusion and exclusion criteria and informed consent procedures and details on the incidental findings policy. | |
| 1. Personal Data |  |  |  | |
| Does this activity involve processing or personal data?  **If yes,** does it involve the processing of special categories of personal data e.g., 1) sexual orientation, disability status, ethnicity, gender identity, political opinion, religious or philosophical beliefs  2) genetic, biometric, health    **If yes**, does it involve profiling, systematic monitoring of individuals or processing of large scale of special categories of data or intrusive methods of data processing such as surveillance, geo-location, tracking etc | Yes | No | Your application should provide details on how and why these personal data are collected, include a project specific data protection policy, a potential data transfer plan and information on whether or not these personal data will be anonymised/pseudonymised. | |
| Yes | No | Your application should provide information on why the gathering of these special categories of personal data is justified and how these data will be processed. | |
| Yes | No | Your application should provide information on why the gathering of these special categories of personal data is justified and how these data will be processed. | |
| Yes | No | Your application should provide details of the methods used and a risk assessment of the ethics risks related to the processing of these data. Explain how the rights and freedoms of participants/data subjects will be safeguarded and how harm will be prevented. Elaborate on how data subjects will be informed about the possibility of profiling, its possible consequences, and how their fundamental rights will be safeguarded. | |
| Does this activity involve further processing or previously collected personal data (including the use of pre-existing data sets or sources, merging existing data sets?) | Yes | No | Provide details on the source and processing of the data and how the rights of data subjects will be safeguarded. | |
| Is it planned to export personal data from the EU to non-EU countries? | Yes | No | Your application should specify the type of personal data and countries involved | |
| Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country? | Yes | No | Your application should specify the type of personal data and countries involved | |
| Does this activity involve the processing of personal data relating to criminal convictions or offences? | Yes | No | Your application should provide details on the personal data that are being processed and the legal basis for this processing. Furthermore, provide a risk assessment for the processing and explain how harm will be prevented and the rights of subjects will be safeguarded. | |
| 5. Animals | | | | |
| 5.1 Does this activity involve animals? **If yes**, answer questions 5.2 to 5.6 below. **If no**, go to question 6 | Yes | No | Provide details on the numbers of animals to be used, the nature of the experiments, procedures, and techniques to be used. Provide details on the species and a thorough justification for their use. Provide details on how animal welfare will be ensured and on how the 3Rs Principle will be implemented; Replace, Reduce, Refine. | |
| 5.2 Are they vertebrates? | Yes | No |  | |
| 5.3 Are they non-human primates (NHP) e.g., monkeys, chimpanzees, gorillas etc | Yes | No | Do any YUFE institutions cover this type of research? | |
| 5.4 Are they genetically modified? | Yes | No | Provide specific information on how the anticipated impact will be minimised | |
| 5.5 Are they cloned farm animals? | Yes | No |  | |
| 5.6 Are they an endangered species? | Yes | No | Give thorough justification on why there is no alternative to using this species. | |
| 6. Countries | | | | |
| 6.1 Will some of the activities be carried out in non-EU (this includes the UK) countries? | Yes | No | Your application should provide information on the countries involved and details on the activities to be carried out. Also include a risk-benefit analysis. All activities must be legal in both EU Member States and non-EU countries | |
| 6.2 Where non-EU countries are involved, do the activities undertaken in these countries raise potential ethical issues? | Yes | No | Provide details on the materials and the countries involved. | |
| 6.3 Is it planned to use local resources? | Yes | No | For example, animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna, or flora samples, etc. | |
| 6.4 Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? | Yes | No | Specify the material and the countries involved | |
| 6.5 Is it planned to export any material (other than data) from the EU to non-EU countries? | Yes | No | Specify the material and the countries involved | |
| 6.6 Does this activity involve [low and/or middle-income countries](https://datahelpdesk.worldbank.org/knowledgebase/articles/906519) | Yes | No | Your application should include details of the benefit-sharing actions planned | |
| 6.7 Could the situation in the country put the individuals taking part in the activity at risk? | Yes | No | Your application should provide details on the safety measures to be taken, including training for staff and insurance cover. | |
| 7. Environment, Health, and Safety | | | | |
| 7.1 Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)? | Yes | No | Your application should provide details on safety measures to be implemented and on (if applicable) you will apply the precautionary principle. | |
| 7.2 Does this activity deal with endangered fauna and/or flora/protected areas? | Yes | No | More information can be found in [The Habitats Directive](https://ec.europa.eu/environment/nature/legislation/habitatsdirective/index_en.htm). | |
| 7.3 Does this activity involve the use of substances or processes that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, as a possible impact)? | Yes | No | Your application should provide details of the health and safety procedures. | |
| 8. Artificial Intelligence (AI) | | | | |
| 8.1 Does this activity involve the development, deployment and/or use of AI? **If yes**, answer questions 8.2 to 8.8. **If no**, go to question 9. | Yes | No | There are [six general ethical principles that any AI system must preserve and protect](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf):   * respect for human agency, autonomy, dignity and freedom; * privacy and data governance; * fairness; * individual, social and environmental well-being; * transparency; * accountability and oversight | |
| 8.2 Could the AI system/technique potentially stigmatise or discriminate against people? | Yes | No | Based on for example, sex, race, ethnic or social origin, age, genetic features, disability, sexual orientation, language, religion or belief, membership of a political group. Provide information on how you will avoid potential bias, discrimination, or stigmatisation. | |
| 8.3 Does the AI system/technique interact, replace, or influence human decision-making processes? | Yes | No | For example, issues affecting human life, health, wellbeing, or human rights or economic, social, or political decisions. Provide a detailed explanation on how humans will maintain meaningful control over the most important aspects of the decision-making process. | |
| 8.4 Does the AI system/technique have the potential to lead to negative social and/or environmental impacts either through intended applications or through plausible alternative uses | Yes | No | Negative social impacts include for example, on democracy, media, labour markets, freedoms, educational choices, and mass surveillance. | |
| 8.5 Does this activity involve the use of AI in a weapons system? **If yes,** answer questions 8.6 to 8.9 | Yes | No | Your application should provide justification for the need and a detailed explanation on how humans will maintain meaningful control. Also address how you will minimise potential misuse (see questions 10.1 – 10.3). | |
| 8.6 Is it possible to establish which specific function(s) are automated/autonomous in the weapons system | Yes | No | Your application should provide justification for the need and a detailed explanation on how humans will maintain meaningful control. Also address how you will minimise potential misuse (see questions 10.1 – 10.3). | |
| 8.7 If the weapons system has AI-enabled functions could these functions render the weapons system indiscriminate? | Yes | No | Your application should provide justification for the need and a detailed explanation on how humans will maintain meaningful control. Also address how you will minimise potential misuse (see questions 10.1 – 10.3). | |
| 8.8 Does the design include the possibility of an autonomous mode for self-protection? **If yes**, answer question 8.9. **If no,** go to question 9 | Yes | No | Your application should provide justification for the need and a detailed explanation on how humans will maintain meaningful control. Also address how you will minimise potential misuse (see questions 10.1 – 10.3). | |
| 8.9 Can the system reliably distinguish between targets (threats) and non-targets? | Yes | No | Your application should provide justification for the need and a detailed explanation on how humans will maintain meaningful control. Also address how you will minimise potential misuse (see questions 10.1 – 10.3). | |
| 8.10 Does the AI to be developed/used in the project raise any other ethical issues not covered by the questions above? | Yes | No | Other ethical issues could include subliminal, covert, or deceptive AI, AI that is used to stimulate addictive behaviours, life-like humanoids/robots etc. | |
| 9. Dual-use and military applications | | | | |
| 9.1 Does your research have the potential for military applications? | Yes | No | Research intended to be used for a military application or with the aim to serve military purposes, cannot be funded. Projects involving the defence industry or military organisations are not automatically excluded from funding, however, their participation can be justified only if they are involved in research activities exclusively focused on civil applications | |
| 9.2 Does your research involve dual-use items or other items for which an authorisation is required? | Yes | No | Dual-use items have both a civic and military application. All dual use items can be found in Annex I of the [European Regulation on export-control of dual use items](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ%3AL%3A2021%3A206%3AFULL&from=EN). For the UK consult the following list: [UK Strategic Expert Control Lists](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1052560/uk-strategic-export-control-lists.pdf). | |
| 10. Misuse, security, and human rights | | | | |
| 10.1 Does your research have the potential for misuse of research results? | Yes | No | Can your research/research results be misused for unethical purposes? The main focus is on misuse for terrorist or criminal activities, or on applications that can be used to violate human rights or compromise the safety of people, animals or the environment. Reflect not only on your own intentions but on the possibility of the research results falling into ‘the wrong hands’. | |
| 10.2 Might the activities lead to, or might the chosen partners be involved in, human rights violations? | Yes | No | Certain types of partners, activities and contexts may call for heightened vigilance. For example:   * non-academic partners like the police, the army or other (public or private) security services; * companies in sectors with large-scale violations of workers’/residents’ rights; * a governmental partner in a country with a poor reputation for human rights violations; * an academic institution closely associated with one of the above; * the use of dual-use/misuse sensitive materials, e.g. surveillance technologies. | |
| 10.3 Do you take security measures to prevent misuse? | Yes | No | Your application should provide information on how you will maximize damage control, safeguard fundamental rights, and implement the principle of due diligence on the careful handling of the research data. | |
| 11. Other Ethics Issues | | | | |
| 11.1 Are there any other ethics issues that should be taken into consideration? | Yes | No | New ethical issues might arise when working on highly innovative activities and new-emerging technologies, e.g. new developments in the fields of neurobiology, human-machine interaction, developments in nanotechnology, genetic enhancement, the creation of androids and cyborgs, etc. | |
| Ethical dimension of the objectives, methodology and likely impact | | | | |
| Explain in detail the identified ethical considerations in relation to:   * Objectives of the activities (e.g., study of vulnerable populations etc.) * Methodology (e.g., clinical trials, involvement of children, protection of personal data, etc.) * The potential impact of the activities (e.g., environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.) | | | | |
| Compliance with ethical principles and relevant legislations | | | | |
| Describe how the identified ethical considerations will be addressed to adhere to the ethical principles and what will be done to ensure that the activities are complaint with the EU/national legal and ethical requirements of the country or countries where the tasks are to be carried out. | | | | |
| Alignment with YUFE values of equity, diversity, and inclusivity | | | | |
| In relation to the identified ethical considerations, describe how you will promote equality of opportunity, be sensitive to the needs of different groups of people, respectful of cultural differences and ensure that the research environment is inclusive for all e.g., by being mindful of the colonial history of places, by adopting a proactive approach to including and supporting participants with disabilities, health conditions or impairments both physical and mental. | | | | |