Annex 1 to Order No 33/2023 by of 30 May 2023 by the Director of the National Science Centre laying down the guidelines for applicants to complete the ethics issues form in the funding proposal

GUIDELINES FOR APPLICANTS TO COMPLETE THE ETHICS ISSUES FORM IN THE PROPOSAL

The ETHICS ISSUES form constitutes part of the research funding proposal, and it serves the purpose of improving the quality of research and raising researchers' awareness of the ethical problems they may face in the research endeavours they are planning.

The data provided will be used by expert panels for the evaluation of the project in terms of its conformity with ethical research and its employment of good practices developed for the research disciplines concerned. Failure to fill out or incomplete filling out of the ETHICS ISSUES form may be treated by the Expert Team as a reason for denying funding to the proposal.

The National Science Centre has prepared guidelines to help applicants in filling out the aforementioned form. The questions below are suggestions meant to facilitate the process.

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1. Studies on human embryos or human embryonic and fetal tissue.

The following types of research are not eligible to be funded from the resources of the National Science Centre:

- research aimed at cloning humans for reproductive purposes;
- research aimed at modifying hereditary human genetic material;
- research aimed at creating human embryos solely for the purposes of research or the procurement of stem cells, including therapeutic cloning by somatic cell nuclear transfer (SCNT).

Research involving the use of human stem cells, obtained both from adults and from embryos, is eligible for funding depending on its specific type and objective. It must be approved by a designated research ethics committee and ensure compliance with the domestic provisions in force in the member states of the European Union (the "EU") that cooperate in the project; the documents must be attached to the first annual report accounting for the period in which the research has been commenced. Detailed information on the permissibility of research using human embryonic stem cells (hESC) and induced pluripotent stem cells (hiPSC) can be found on the website of the Human Pluripotent Stem Cell Registry: https://hpscreg.eu/.

The possibility and permissibility of research on human embryos is regulated by detailed provisions in force in the Republic of Poland, such as the Act on Infertility Treatment of 25 June 2015.

1.1 Does the research involve the use of human embryos?

If the answer is "YES," please provide information concerning:

- their place of origin, i.e. institution and country and the donor's informed consent to their use in research (cell line derivation);
- the protection of donor privacy and personal data;
- the approval of a designated bioethics committee (or who the applicant will seek it from; institution and country) for the use of the embryos in the research project.

1.2 Does the research involve the use of human embryonic or fetal tissues/cells?

If the answer is "YES," please:

a) consider the following issues:
   - have the cell lines already been established?
   - will the cells be taken directly from embryos or foetuses during the project?

b) provide information concerning:
   - the source of the cells or tissues with information that informed consent has been granted by the doner to donate the material for research;
   - the approval of a designated bioethics committee (institution and country) for the use of the embryos or foetuses donated for research.

In the case of genetic modifications to the material please fill out Point 7.1.

1.3 Does the research involve Human Embryonic Stem Cells (hESCs)?

If the answer is "YES," please:

a) consider the following issues:
   - have the cell lines already been established?
   - will the cells be taken directly from embryos during the project?

b) provide information concerning:
   - the legal basis for the research project;
   - documents certifying that the cell line has been entered into the European registry https://hpscreg.eu/ ;
   - the approval, obtained or pending, of its use in research, granted by a designated research ethics committee (institution and country), as well as the informed consent of the embryo donor to use the cells in the study.

In the case of genetic modifications to the material please fill out Point 7.1.

2. Research involving human subjects

Research involving human subjects means any research in which people are participants. Such research may include the collecting of biological samples, the use of personal data, medical and psychological intervention, interviews, observations, the use of previously collected information, etc.

Please remember that participation in the study must be completely voluntary; researchers must obtain the informed consent of all study participants or their legal representatives, as well as secure the approval of a designated ethics committee before the project can be launched. In research where methodology advises against obtaining the informed consent of study participants, the researcher must present evidence of a waiver of procedure for obtaining the consent, and describe the actions they have taken to carry out the research in an ethical manner.

The committee's approval form and the receipt of entry into the Central Register of Clinical Trials (if applicable) must be attached to the first annual report covering the period in which the study begins.

Research involving human subjects conducted within the framework of international cooperation should comply with the law and the ethical standards adopted in a given country, as well as with the norms accepted in Poland. Whenever the standards differ, the more rigorous provisions shall take precedence.

Please consider whether any ethical issues may determine how long research results will be stored, accessed or disseminated and whether they can be transferred, e.g. whether the study participant has consented to their transfer outside the country. See Point 4.

2.1 Does the research project involve human subjects?

If the answer is “YES,” please:
a) consider the following issues:
   - will the participants be volunteers?
   - are the studies comparative and will people from other countries be tested in addition to participants from Poland?
   - are there minorities or immigrants in the study group?
   - are there particularly sensitive people in the study group, e.g. people prone to mental trauma or suffering from mental health disorders, the terminally ill, victims of traumatic experiences or members of their families?
   - does the study group include individuals with a limited capacity to perform acts in law?
   - does the study group include individuals deprived of their liberty (detained, in custody)?
   - does the study group include pregnant or breastfeeding women?
   - does the study group include persons who are incapable of giving legal consent?

- does the study group include minors? Will they draw direct advantage from the research project?
- do the participants include individuals who will act as the study or as the control group in the medical experiment? See Point 2.3;
- will the samples and data collected in the study be anonymised or pseudonymised for the purposes of future use? See Point 4;
- does the informed consent form include information on the future use of samples, material and personal data? See Point 4;
- does the informed consent of the study participant include information on the possibility of withdrawing from the trial at any time and without any consequences?
- how will research material and data (including personal data) be stored and secured? See Point 4.

b) provide information concerning:
- the informed consent, obtained or pending, of study participants to participation in the project (including minors older than sixteen) and its form (e.g. written, oral, registered);
- where methodology advises against obtaining the informed consent of study participants: steps and procedures the researcher has taken to carry out the research in an ethical manner;
- the approval, obtained or pending, of a designated bioethics committee or research ethics committee of the country concerned (institution and country);
- the mode and form (e.g. written, oral) of informing study participants of the objective and nature of the experiment as well as possible risks associated with their participation in the study;
- the consent, obtained or pending, of the statutory representative and the minor, in accordance with the principles laid down in Article 25 of the Medical Profession Act of 5 December 1996, concerning the requirement of obtaining consent for the medical experiment from the subject.

2.2 Does the research project involve any active physical or psychological intervention affecting study participants?

If the answer is “YES,” please:

a) consider the following issues:
- does the study involve invasive techniques, e.g. biopsy, contrast agent, transcranial magnetic stimulation?
- will samples of material be taken by non-invasive methods, e.g. urine, or saliva?
- does the study involve a deliberate modification of human behaviour, using, for instance, techniques such as different types of interventions, cognitive training, psychotherapy, etc. (this also applies to situations where the intervention is expected to benefit the patients, e.g. improve their memory)?
- does the study address controversial issues or topics that require particular tact and caution?
- is the study long, tiring and physically or mentally taxing?
- has the researcher planned for the procedure to include methods of debriefing after the events in which the study participants took part?
- has the researcher planned for assistance to study participants in the event of crisis, including the releasing of emotional load?

b) provide information concerning:
- the kind of medical intervention, the kind of sampled biological material or the psychological intervention method;
- the potential procedure for debriefing or waiver of it (if applicable);
- the ways to minimise study risk for the study participants.

2.3 Does the study use human genetic material? Does your research involve processing of genetic information?

Genetic data are treated as special personal data, protected in accordance with Article 4 (13) of the General Data Protection Regulation (hereinafter referred to as "GDPR"), understood as personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question.

If the answer is “YES,” please:

a) consider the following issues:
- does the researcher have the informed consent (obtained in the framework of earlier research) of all study participants to the use of their samples in future genetic research? See Point 4;
- has the researcher obtained the approval of the bioethics committee (institution and country), including for genetic research procedures planned within the framework of the project?
- how will genetic data protection be guaranteed at every stage of the project?

b) provide information concerning:
- the approval, obtained or pending, of a bioethics committee, in accordance with the Medical Profession Act of 5 December 1996;
- the informed consent, obtained or pending, of all study participants.

2.4 Is the study a medical experiment within the meaning of the Medical Profession Act of 5 December 1996 (Journal of Laws of 2018, item 617, as amended)?

It should be kept in mind that a medical experiment with human subjects may only be conducted as long as it is positively reviewed by an independent bioethics committee.
This means that the study must be carried out in the previously approved way; any changes (e.g. in the kind or amount of sampled material or the sampling venue) likewise require prior committee approval.

If the answer is “YES,” please:
a) consider the following issues:
- is the medical experiment designed for the purposes of research or treatment?
- does the medical experiment constitute a clinical trial? See Point 2.5; - is the study a single or a multicentre trial?
- how will the participants be recruited?
- who will be in charge of their recruitment?
- is there a need to recruit healthy subjects for a control group?
- is the study a medical experiment with the use of biological material taken from living persons, within the meaning of the Medical Profession Act of 5 December 1996? See Point 3;
- is the study a medical experiment with the use of biological material taken from deceased persons (sampled when the subjects were still alive)? See Point 3;

b) provide information concerning:
- the study centres (for multicentre trials);

- the informed consent, obtained or pending, of study subjects to participation in the medical experiment or the use of their separated body fragments or biological material in research;
- the approval, obtained or pending, of the bioethics committee, in accordance with the Medical Profession Act of 5 December 1996 (applicable to medical experiments with human subjects or research on human genetic material).

2.5 Does the research project include applicable non-commercial clinical trials that must be registered in the Central Register of Clinical Trials (https://www.clinicaltrialsregister.eu/), in accordance with the Pharmaceutical Law of 6 September 2001 (Journal of Laws of 2017, item 2211, as amended) and the Act on medical devices of 20 May 2010 (Journal of Laws of 2017, item 211, as amended)?

If the answer is "YES," please:
a) consider the following issues:
   - is the study a single or a multicentre trial?
   - how will the participants be recruited?
   - is there a need to recruit healthy subjects for a control group?
b) provide information concerning:
   - the non-commercial nature of the trial (in a separate section of the proposal form describe a detailed justification that the research including clinical trials related to a medicinal product or a medical device is of non-commercial nature);
   - the study centres (for multicentre trials);
   - the informed consent, obtained or pending, of all study participants;
   - the approval, obtained or pending, of a bioethics committee (institution and country), in accordance with the Medical Profession Act of 5 December 1996;
   - registration of the study in the Central Register of Clinical Trials.

3. Human cells/tissues

This section covers information on research involving the procurement, production or use of human cells or tissues (except those of embryonic origin, see Point 1), including genetically modified cells or cell lines taken from commercial sources (biobanks), sampled during the research project, obtained from research conducted at other centres, or from the entity's own repositories. In this section please account also for research carried out on biological material taken from human remains. Research on biological material taken from human remains may be carried out on the condition that the deceased person has expressed their informed consent while alive.

3.1 Does the proposed research use commercially available human cells or tissues, other than those indicated in Point 1 (e.g. cell lines)?

If the answer is "YES," please:
a) consider the following issues:
   - will the project use human stem cells other than embryonic stem cells?
   - will the cells or tissues be sourced from biobanks in Poland, e.g. the Polish Stem Cell Bank?
   - will the cells or tissues be sourced from biobanks outside Poland (countries)?
   - will the project use human cell lines, including genetically modified cell lines, purchased in a cell bank such as ATCC, ECACC?

- are the researchers involved in the research project already in possession of the cells (cell lines) or tissues to be used in the study or will the cells (cell lines) or tissues used in the study be purchased within the framework of the project?
- how long will the material be stored and how will it be discarded once the project has been finished?

b) provide information concerning:
- origin of the material (name of the provider);
- the authenticity certificates (institution and country) or the method for confirming the authenticity of cells, cell lines or tissues.

3.2 Does the research project use human biological samples taken within the framework of the project, or from another project, or received from non-commercial sources (i.e. laboratories, other institutions)?

If the answer is "YES," please:

a) consider the following issues:
- will the cells or tissues be taken directly from study participants during the performance of project tasks? See Point 4;
- will the study be conducted on cells or tissues sourced from another project, lab or entity in Poland or abroad? See Points 4 and 6;
- will stem cells be derived from the project or will new cell lines be created in the project? See Point 4;
- will the study use biological material taken from organs removed from the human body or medical waste tissue (e.g. amputated limbs, placenta, skin)? See Point 4;
- will the study use biological material taken from deceased persons (sampled while they were still alive)?
- will the study use biological material taken from human remains? See Point 4;
- will the biological material be isolated for immediate use in the project or stored for future research purposes? See Point 4;

b) provide information concerning:
- the origin of cells or tissues, e.g. directly from the donor, from the entity's own repositories (institution and country);
- the name of the institution from which the material will be taken (if different from the research entity);
- material sampling procedures, including storage time and conditions;
- the informed consent, obtained or pending, of donors to the procurement, use and storage of their biological material for research purposes, including their secondary use, as well as the handling of medical waste, along with the identification of the tissue owner;
- the approval, obtained or pending, of a designated bioethics committee (institution and country) for the procurement or use of biological material for research purposes (its scope must fall within the scope of the informed consent granted by the donor);
- material anonymisation or pseudonymisation method (if applicable); See Point 4;
- the agreement (institution and country), signed or pending, on the transfer of reagents or biological material and personal data between institutions (e.g. *Material Transfer Agreement* and *Data Transfer Agreement*[1]) or other documents certifying official research cooperation (if applicable).

[1] A Material Transfer Agreement is an agreement between institutions that regulates the scope of research cooperation involving the transfer of reagents or biological material and personal data, on the strength of which the recipients may use them for their own research purposes. The document outlines the rights of the donor and the recipient, especially those relating to property, patents and intellectual copyright. The agreement should be signed by the representatives of both institutions before the reagents and samples are dispatched. If the material to be transferred is of human origin, the document should also contain information on the approval obtained from appropriate ethics committees and the informed consent of donors or study participants, including consent to the transfer of these materials beyond the country's borders.

- data, obtained or pending, on the informed consent expressed by the deceased while alive for the post-mortem use of their biological material for research purposes (if applicable);
- data, obtained or pending, on the decision of the appropriate prosecutor, in accordance with Article 4 of the Regulation of the Minister of Justice of 30 October 2007 (if the material was taken during a forensic post-mortem);
- the decision, obtained or pending, of the starost to hand over unidentified human remains for research purposes, in accordance with Article 10 (2) of the abovementioned Cemeteries and Burial Act of 31 January 1959 (Journal of Laws of 1959, no. 11, item 62, as amended) (if applicable).

Where cells or tissues are to be transferred from a non-EU country, please indicate the legal basis for such transfer. See Point 6.
In the case of genetic modifications to the material please fill out Point 7.1.

4. Personal data

This section covers information on all personal data, regardless of the way in which they are collected, processed, organised, used and stored.

In accordance with Article 4 (1) of the GDPR, personal data means any information relating to an identified or identifiable natural person ("data subject"). Such identifiers may be in particular:

- a name, an identification number, location data, an online identifier;
- one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Information that does not fall within the purview of the General Data Protection Regulation (GDPR) includes anonymous data, or data anonymised in such a way that the data subject cannot be identified anymore (or at all), and the data of deceased persons.

When creating the provisions on the procurement, processing and storage of personal data contained in the informed consent form, please take into account Article 5 (e) of the GDPR, which allows personal data to be kept in a form which permits identification of data subjects for longer than is necessary for the purposes for which the personal data are processed. Importantly, the provisions should include informed consent to the transfer of personal data beyond the research-conducting institution, including to other EU and non-EU countries.

4.1 Does the research involve personal data processing?

If the answer is “YES,” please:
a) consider the following issues:
   - will the collected or processed personal data belong to the special category, i.e.
   - concerning health, genetic information, intimate life, political views, ethnicity or religious beliefs?
   - will the project collect, process, use or store biometric, genetic or health data?
   - will the project involve continuous surveillance or observation of study participants, e.g. audio or video recording, monitoring, geolocation or other data processing methods that may infringe on their personal rights and freedoms?
   - will the personal data be anonymised[2]?

[2] Anonymisation is a process involving the irreversible removal of all information allowing the data subject to be identified by the data controller or a third party. Anonymised data are no longer treated as personal data because they do not allow specific data subjects to be identified.

- will the personal data be pseudonymised[3]?

b) provide information concerning:
   - the kind of collected personal data and method of their protection;
   - the justification for the processing of the special category of personal data;
   - the method used for the anonymisation or pseudonymisation of personal data or the reasons why the data cannot be anonymised or pseudonymised;
   - the personal data risk assessment.

4.2 Does your research involve further processing of personal data (secondary use) from other sources outside the research entity?

If the answer is "YES," please:
a) consider the following issues:
   - does the collection of personal data require the approval of the data administrator?
   - are the data anonymised or pseudonymised?
   - do the personal data come from publicly available sources?
   - will personal data be exported to non-EU countries?
   - will personal data be imported from other EU or non-EU countries?

b) provide information concerning:
   - type and origin of the personal data obtained (country, institution);
   - justification for the processing of personal data obtained from outside the research entity;
   - the compliance of personal data collection with the domestic law in force in the country where the data were acquired;
   - the method used for the anonymisation or pseudonymisation of personal data or the reasons why the data cannot be anonymised or pseudonymised;
   - the consent of the data administrator to their processing by the research entity;
   - a declaration that the personal data are publicly available and may be used in the project;
   - the consent for the transfer of personal data outside of (or to) the research institution, including to or from the EU or non-EU countries.

Personal data processing requires the free and informed consent of study participants (or their legal representatives). In accordance with the principle of minimising the use of personal data, no data should be collected that are not necessary for the proper documentation of the research project. Researchers should cooperate closely with the Data Protection Inspector at the research entity in order to ensure compliance with the personal data protection provisions when handling the data of study participants, as well as project staff.

5. Animals

This section covers experiments on animals or research that involves the production or use of animal cells or tissues (including embryonic and larval material) taken from commercial sources, sampled during the research project, obtained from research conducted at other centres, or from the entity's own repositories (biobanks).

If the study includes genetically modified animals or cell cultures derived from genetically modified animals, also fill out Point 7.1.

[3] Pseudonymisation – refers to the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, provided that such information is kept separately and subject to technical and organisational measures to ensure non-attribution to an identified or identifiable person. Pseudonymised personal data continue to constitute personal data within the meaning of GDPR provisions.

Animal research conducted within the framework of international cooperation should comply with the law and the ethical standards adopted in a given country, as well as with the norms (including those pertaining to animal welfare) accepted in Poland. Whenever the standards differ, the more rigorous provisions shall take precedence. If animal biological material is transferred from another research entity, including a foreign-based institution, the same principles shall apply as in the case of human biological material (see Point 3).

The approval of a local animal research ethics committee and the consent of the Minister of Environment to the contained use of GMOs and other permits by appropriate authorities should be attached to the annual report covering the period during which the animal research project was launched.

5.1 Does the research use vertebrates or cephalopods?

If the answer is "YES,"

a) consider the following issues:
   - will the research use laboratory animals?
   - will the research project use adult specimens, larval or embryonic forms?
   - will the research project use primates? - will the research project use livestock?
   - will the research project use free-living (wild) animals?
   - will the research involve species under strict protection in accordance with the Regulation of the Minister of Environment of 6 October 2014 on animal species protection? See Point 7.2;
   - will the research involve alien species of animals, qualified by the Minister of Environment as animals which upon release may pose a threat to native species or habitats?
   - does the project plan for the use of animals from commercial sources or from the entity's breeding centres?
   - does the project plan for the use of animals from other institutions within the framework of research cooperation (institution and country)?

b) provide information concerning:
   - the origin of animals, e.g. the name of their provider or donor;
   - the approval, obtained or pending, of the local animal research ethics committee (institution and country);
   - the permission, acquired or pending, of the Regional Director for Environmental Protection or the Director-General for the Environmental Protection (if applicable);
   - persons responsible for experiments on animals.

5.2 Does the research involve the use of animal biological specimens (such as blood, urine, etc.)?

In research projects using biological material, special care should be taken to take measures that minimise the pain, suffering, distress or permanent bodily injury inflicted on research animals. If death cannot be avoided, the research procedure should be planned and carried out in such a way as to cause the death of as few animals as possible and reduce the time and severity of their suffering to the minimum.

If the answer is "YES," please provide information concerning:

a) the animal species;
   - the type of sampled biological material, the sampling method;
   - derived cell lines (If applicable);

- the source of biological material, e.g. tasks performed within the framework of the project, the entity's own repositories, name of the donor institution, country of origin;
- the agreement, signed or pending, on the transfer of biological material between institutions (*Material Transfer Agreement*) (if applicable).

5.3 Does the research use commercially available animal tissues or cells, or cell lines?

If the answer is "YES," please provide information concerning:

- the type of cells or tissues; the origin of cell lines or tissues, e.g. the country of origin of the biological material and the name of its provider;
- the authenticity certificates or the method for confirming the authenticity of tissues or cells.

6. Scientific collaboration with non-EU countries

This section concerns research conducted in cooperation with non-EU countries, including studies:

- carried out, in part or in full, in non-EU countries;
- involving participants from outside the EU;
- involving material exported to or imported from non-EU countries.

Research conducted outside the European Union, irrespective of the domestic law of the country in question, must first and foremost comply with the legal and ethical standards accepted in Poland. The project must also ensure compliance with the provisions of international declarations signed by the countries in question, such as, e.g. the Nagoya Protocol, Convention on Biological Diversity and, in the case of low- and medium-income countries, best practices laid down in the Global Code of Conduct for Equitable Research Partnerships" (www.globalcodeofconduct.org), adopted by the National Science Centre.

When using resources imported from non-EU countries, especially human or animal material, protected plant and animal species, human remains or historical artefacts, researchers should take care to respect the cultural traditions of their country of origin and create opportunities for mutual gains from the scientific and technological progress achieved thanks to the research project. This is particularly important when the research is conducted in low- and medium-income countries (as defined by the World Bank), in the case of which special attention should be paid to the involvement of local research groups, study participants and stakeholders in the entire research process (from planning to the publication of research results), obtaining feedback and evaluation of the research that has been completed.

6.1 May activities related to research in countries outside the EU constitute a risk of raising ethical concerns?

If the answer is "YES," please:

a) consider the following issues:
   - are activities acceptable in terms of research ethics applicable in these countries?
   - may activities result in a stigmatisation, incrimination, discrimination or other violation of personal rights of study participants?
   - may activities result in a violation of the local community's interest?
   - have any measures been taken to protect the personal rights of study participants or local communities?
   - do the study participants understand the information disclosed to them?

- have the local research groups, study participants and stakeholders been involved in the development of the project and, if justified, preparation of the report on research results as co-authors?
- is any research-related feedback expected from the study participants and stakeholders?
- are the investigators intending to make any effort to avoid exposing the study participants (including, in particular, communities with limited access to health care and medical services) to the risks of pandemic, epidemic and other threat to public health?

b) provide information concerning:
- the ethical dilemmas involved in the implementation of the research project in non-EU countries;
- the risk and benefit analysis concerning the cooperation;
- a confirmation that the research project can be conducted in non-EU countries in accordance with their domestic laws and ethical standards.

6.2 Will the research use local human, cultural or natural resources, e.g. human beings, animals, plants, human or animal genetic material, human remains, historical artefacts, protected plant or animal species, endangered fauna or flora samples etc.?

If the answer is "YES," please provide information concerning:
- the type of local resources to be used in the research project;
- the approval, acquired or pending, of an appropriate ethics committee (institution and country), especially if the research project involves human genetic material (if applicable);
- compliance with the provisions of the Nagoya Protocol to the Convention on
- Biological Diversity, in the case of research on genetic material (if applicable);
- the agreement confirming the establishment of research cooperation with the foreign research institution/institutions;
- the permission, acquired or pending, of appropriate state authorities for the use of local cultural or natural resources, e.g. archaeological or historical artefacts, protected plant or animal species. See Point 8.

6.3 Will the research require the importing of any material from outside the EU or the export of any material outside the EU?

For information on the transfer of human cells or tissues, see Point 3; for data transfer, go to Point 4.

a) If the answer is "YES," please provide information concerning:
- the kind of imported material;
- the kind of exported material;
- the agreement (institution and country), signed or pending, on the transfer of material, including biological material and personal data, between institutions (e.g. Material Transfer Agreement and Data Transfer Agreement) or other documents that certify the establishment of official research cooperation (if applicable);
- the permission, obtained or pending, for the export of the material to non-EU countries (if applicable);

- the permission, obtained or pending, of appropriate authorities for the importation of the materials in question (e.g. human remains, artefacts) to Poland (if applicable), specifying the materials in question and naming the approving institution;
- the permission for the export of the materials from the Polish institutions (if applicable).

6.4 If the research involves low- and/or medium-income countries, are benefits-sharing measures foreseen?

If the answer is "YES," please:
a) consider the following issues:
   - will the research contribute to the development of local specialist knowledge?
   - will the research contribute to the development of research infrastructure in the country concerned?
   - will the research potentially contribute to the reduction of local highly-qualified staff (e.g. nurses, laboratory staff) to the minimum?
   - will the research contribute to the distribution of results, data access, technology transfer or publication in the country concerned?
   - will the research potentially benefit the local community (property resources, equipment)?
   - have the local research groups been involved in the project development?
   - will the research project be carried out in collaboration with the local research groups?
   - does the research project provide for benefit sharing for the participating groups, transfer of the research results, remuneration, other products for the local community etc.?
   - will the local co-investigators and experts be involved in the analysis and publication (as co-authors) of research results?
b) provide information concerning:
   - the cooperating institution/institutions;
   - an intention to engage co-investigators in the research project and publication of research results;
   - direct benefits for the study participants or the local communities.

6.5 Could the situation in the country put the individuals taking part in the research at risk?

If the answer is "YES," please
a) consider the following issues:
   - will the research project be conducted in important places of religious worship?
   - will the research project be conducted in nature reserves, national parks or other sites of particular cultural importance for the local community?
   - will the research project be conducted in countries that are politically unstable? See Point 7.3;
   - may the research project expose study participants to any health risk, including in the context of a pandemic/ epidemic?
b) provide information concerning:
   - the sources of potential risk;
   - the measures taken to eliminate the risk.

7. Environment, health, safety (including genetically modified material)

This section covers research that may have a potentially negative impact on the natural environment, plants and/or animals, as well as the health and safety of researchers involved in the project.

7.1 Does the research involve the use of genetically modified microorganisms, organisms, tissues or cells (GMO, GMM)?

If the answer is "YES," please:

a) consider the following issues:
- does the research project use genetically modified microorganisms (GMMs) or organisms (GMOs)?
- does the research use any cells, cell lines or tissues that have been genetically modified?
- does the research project include introducing its own genetic modifications in the biological material?
- into which category of the contained use of GMMs and GMOs do the microorganisms and organisms used in the research fall?
- does the research project plan for the intentional release of GMOs into the environment?
- what harmful consequences for humans, animals and plants can the GMOs and GMMs used in the research have?

b) provide information concerning:
- the characteristics of the type of GMMs or GMOs used in the project;
- the assessment of environmental and human health risk in the case of research involving contained use of category III and IV GMMs;
- the methods for preventing hazards and their potential effects;
- the approval, obtained or pending, of the Ministry of Environment for the operation of a genetic engineering lab by the research entity;
- the approval, obtained or pending, of the Minister of Environment for the contained use of GMOs or GMMs, or intentional release of GMOs into the environment under the research project.

7.2 Does your research deal with endangered fauna and/or flora and/or protected areas?

If the answer is "YES," please:

a) consider the following issues:
- what category of protected areas is involved in the research project?
- will the research project require the collection of material such as plants, fungi or animals in protected areas?
- will the research project involve the collection of protected wild plants or fungi?
- will the research project require the collection of fossils?
- will the research project require the destruction of soils?
- will the research project involve capturing or killing wild animals?

b) provide information concerning:
- the exemption, obtained or pending, from the bans referred to in Article 15 (1) of the Act on Environmental Protection of 16 April 2004 (if applicable);
- the consent, obtained or pending, of the director of the national park or protected area to research activity (type of protected area, type of research material);

- any possible risk run by research which affects the natural environment, animals or plants;
- the lack of alternative solutions to the research project.

7.3 Does your research involve the use of elements that may cause harm to humans, including research staff?

If the answer is "YES," please:

a) consider the following issues:
- will the research project use hazardous chemicals?
- will the research project use hazardous physical factors?
- will the research project involve biological material that may be hazardous for the research team, e.g. pathogens?
- do the researchers hold certificates from the providers of animals, biological samples or cell lines to confirm that they are pathogen-free?
- will the biological samples or cell lines be tested for pathogens (if applicable)?
- will the research project involve animals that pose a threat to human life and health?
- will the research project be conducted in countries with a high risk of tropical diseases?
- will the research project be conducted under difficult climatic or geographical conditions?
- will the research project be conducted in countries that are politically unstable?

b) provide information concerning:
- the categories of hazardous factors or conditions to which the research staff or study participants will be exposed;
- the measures or steps taken to minimise the risk to research staff;
- the anticipated risks of participation in the study and course of action in the event that the safety and health of study participants and staff are at threat, including information on the insurance of study participants and compensation to cover any potential damage that may result from the study (if any).

8. Cultural heritage

This section concerns research that uses or affects the resources of cultural heritage, culturally protected areas, people inhabiting them, the natural environment and the animals and plants that are related to them.

When using the resources of cultural heritage, researchers should take care to respect the cultural traditions of their country of origin and create opportunities for mutual gains from the scientific and technological progress achieved thanks to the research project. This is particularly important when the research is conducted in low- and medium-income countries (as defined by World Bank).

8.1 Does the research involve the use of the resources of cultural heritage, including humans, flora and fauna, their material remains, material and immaterial cultural artefacts and areas protected for their cultural value? (YES/NO)

If the answer is "YES," please provide information concerning:
- the type and characteristics of the resources of cultural heritage and culturally protected areas to be used in non-invasive research of cultural heritage;
- the type and characteristics of the resources of cultural heritage and culturally protected areas, and how the research project will affect those resources/areas; also, how it might affect their potential modification in the case of invasive research of cultural heritage;

- the type and characteristics of the samples to be used in specialist research using human and animal remains of historical value;
- the origin and manner of obtaining other research material;
- the consent, acquired or pending, of potential study participants to participation in the project or the reasons why such consent cannot be obtained (if applicable);
- the taking into account of the opinions, attitudes and customs of the current inhabitants of the culturally protected areas or the areas that house elements of the heritage included in the study (e.g. archaeological sites);
- the permission, acquired or pending, of appropriate state authorities (institution and country) for the use of local resources of cultural heritage or areas protected for their cultural value;
- the permission, obtained or pending, of appropriate authorities for the importation of material cultural artefacts to Poland.

9. Abuse and dual use

9.1 Does the research use or produce a dual-use product (e.g. pathogens, software, technologies) with a potential application in civilian or military operations?

Dual-use products are defined as goods, software or technology that can be used both for civilian and military purposes. Out of concern for international peace and security, the European Union has taken measures to control the export, transit and sale of dual-use products, as well as to prevent the dissemination of weapons of mass destruction.

If the answer is “YES,” please:

a) consider the following issues:

- if the goods or information resulting from the project require a licence in order to be exported outside the EU, in accordance with the EU Export Control Regulation No 428/2009?

b) provide the following information:

- the category of goods placed on the checklist that forms annex I to the Council Regulation (EC) No 428/2009;
- the method for securing the licence for export outside the EU;
- the method for securing the permission to publish the results of research on the goods that meet the dual-use criterion.

9.2. Does your research output have the potential for malevolent/criminal/terrorist abuse?

If the answer is “YES,” please:

a) consider the following issues:

- can the materials, methods, technologies or knowledge resulting from the project be modified or enhanced in such a way as to harm people, animals or the environment?
- can the materials, methods, technologies or knowledge resulting from the project be used in criminal or terrorist actions?
- can the results of the research project concern issues that threaten human rights,
- e.g. concern discrimination or stigmatisation?

b) provide the following information:

- abuse risk assessment (crime-related or endangering environment and/or people);
- steps taken to prevent unethical use of the research project’s results.

10. Additional information sections of the proposal form in ZSUN/OSF

If the answer to any question is “YES,” please:

1. *describe the measures taken to ensure the compliance of the research project with the principles of good practice accepted in a given research field/discipline, provide information on the permissions already granted, or explain how the conditions will be met [in English]; use up to 10,000 characters.*

If the answer to the question in Point 2.5 (Does the research project constitute non-commercial clinical trials) is “YES”, please:

2. *provide a detailed justification that the research including clinical trials related to a medicinal product or a medical device is of non-commercial [in English], up to 2,500 characters.*