NATIONAL SCIENCE CENTRE
POLAND

Guidelines for applicants to complete the Ethics Issues form in the proposal

In a bid to raise research quality, the National Science Centre has prepared a special form devoted to Ethics Issues in Research, which is now required as part of the application for research funding, and inquiries about the potential ethical challenges associated with the proposed research project.

The following instructions are meant to assist you in filling in the form, with the help of the questions proposed below.

The form is subject to evaluation and it may influence the ultimate review of the proposal. The data provided will be used by expert panels as an indicator of the degree to which the principal investigator is aware of the ethical and legal issues associated with the research project.

Contents:

1. Research on human embryos

This section covers research projects involving the manipulation of human embryos. The following types of research are not eligible to be funded from Polish public resources:

- 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 aimed at destroying human embryos.

Research projects that involve the manipulation of human stem cells taken from adults or embryos may be funded depending on their specific type and objective. They must be approved by a designated research ethics committee and ensure compliance with the domestic provisions in force in the EU member states that cooperate in the project. Detailed information on the permissibility of research on 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 of 25 June 2015 on infertility treatment.

1.1. Will the research project use human embryonic stem cells (hESC)?

If the answer is "YES", please...

a) consider the following issues:
   - will the research be conducted in Poland or abroad within the framework of international cooperation?
   - will the cells be taken directly from embryos during the project?
   - have the cell lines already been established?

b) provide information concerning:
   - the legal basis for the research project;
   - the country of origin of the cell line and the name of its provider;
   - detailed cell line data;
   - documents certifying that the cell line has been entered into the European registry;
   - the approval, obtained or pending, of its use in research, granted by a designated research ethics committee, as well as the informed consent of the embryo donor.

1.2. Will the research project use human embryos?

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

- their source;
- 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 for the use of the embryos in the research project.

1.3. Will the research project use tissues or cells taken from human embryos?

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

- the source of these cells or tissues;
- the donor's informed consent, obtained or pending, to their use in research;
- the approval of a designated ethics committee, obtained or pending, for the use of donated embryos in research.

2. Research with human subjects

By research involving human subjects, it is meant any research in which people participate. Examples may include the collection of biological samples, the use of personal data, medical 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, as well as secure the approval of a designated ethics committee before the project can be launched. 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.

If the research project is conducted within the framework of international cooperation, please describe the process of securing the informed consent of all study participants and the approval of the designated research ethics committee, in accordance with the provisions in force in the country in question.

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

2.1. Will the research project involve human subjects?

If the answer is "YES", please...

a) consider the following issues:
   - will the participants be volonteers?
   - Are there particularly sensitive people in the study group; prone to mental trauma or suffering from mental health disorders, terminally ill, victims of traumatic experiences or members of their families, minorities, immigrants?
   - Are the studies comparative and will people from other countries be tested in addition to participants from Poland?

- are study participants fully capable of expressing informed consent to participation?
- does the study group include individuals with a limited capacity to perform acts in law?
- does the study group include minors? See point 10;
- do the participants include individuals who are ill or patients of medical centres, who serve as the study group in the medical experiment? See point 2.3;
- do the participants include healthy persons, who serve as the control group in the medical experiment? See point 2.3;
- can participants opt out of the study at any time before or during the experiment?
- 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.

b) provide information concerning:

- the selection of study subjects and the mode of their recruitment;
- the characteristics of the study group, i.e. group size, place of residence (origin), age, sex, along with a justification for such choice; where relevant, describe how the gender dimension, i.e. sex and/or gender analysis is taken into account in the project's content. Please note that this question does not refer to gender balance in the teams in charge of carrying out the project but to the content of the planned research and innovation activities. Sex and gender analysis refer to biological characteristics and social/cultural factors respectively;
- the informed consent, obtained or pending, of study subjects to their participation in the project (including minors over the age of sixteen);
- the consent, obtained or pending, of the statutory representative of the study participant;
- the approval, obtained or pending, of a designated bioethics committee.

2.2. Will 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 without direct interference with brain function, using, for instance, techniques such as 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 (e.g. abortion, in vitro fertilisation, death penalty) or topics that require particular tact and caution (e.g. religious and political beliefs, attitudes toward minority groups)?
- is the study long, tiring and physically or mentally taxing?
- will the study use biological material taken from organs removed from the human body or medical waste tissue (e.g. amputated limbs, placenta)? See points 3 and 10.

b) provide information concerning:
- the kind of medical intervention;
- the kind of sampled biological material;
- the psychological intervention method;
- the ways to minimise study risk.

2.3. Is the study a medical experiment within the understanding of the Act of 5 December 1996 on the profession of physician and dentist (Journal of Laws of 2018, item 617, as amended)?

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;
- can enough patients be recruited in a single centre?
- is it a multicentre trial?
- is there a need to recruit healthy subjects?
- who will be in charge of their recruitment?
- how is the study going to guarantee the principle of voluntary participation?
- is the study a medical experiment with the use of biological material taken from living persons, within the understanding of the Act of 5 December 1996 on the profession of physician and dentist? 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 points 3 and 10.

b) provide information concerning:
- the experiment: briefly describe the experiment, including the subject inclusion and exclusion criteria;
- the study centres (in the case of 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 Act of 5 December 1996 on the profession of physician and dentist (applicable to medical experiments with human subjects or research on human genetic material).

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.

2.4. Will the study use human genetic material?

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:

c) 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, 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?
   - are the proposed genetic tests reimbursed by the National Health Fund?

d) provide information concerning:
   - the approval, obtained or pending, of a bioethics committee, in accordance with the Act of 5 December 1996 on the profession of physician and dentist;
   - the informed consent, obtained or pending, of all study participants.

2.5. Does the research project constitute one or several non-commercial clinical trials that must be registered in the Central Register of Clinical Trials (https://www.clinicaltrialsregister.eu/), in accordance with the Act of 6 September 2001 – Pharmaceutical Law (Journal of Laws of 2017, item 2211, as amended) and the Act of 20 May 2010 on medical products (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?
   - do healthy subjects need to be recruited?
   - will the trial involve minors? See point 10;
   - who will be in charge of recruitment?
   - will the study involve cluster randomisation?
   - how will the principle of informed consent be respected in the trial? How is the study going to guarantee the principle of voluntary participation?

b) provide information concerning:
   - the non-commercial nature of the trial;
   - the study centres (for multicentre trials);
   - the characteristics of the clinical trial, along with subject inclusion and exclusion criteria;
   - the approval, obtained or pending, of a bioethics committee, in accordance with the Act of 5 December 1996 on the profession of physician and dentist;
   - the informed consent, obtained or pending, of all study participants;
   - registration of the study in the Central Register of Clinical Trials.

At this juncture, please justify in detail the non-commercial nature of research involving a clinical trial with the use of a medicinal or medical product [in English]

We recommend that you familiarise yourself with the following legal acts and publications:

- Act of 5 December 1996 on the profession of physician and dentist (Journal of Laws of 1997, no. 28, item 152);
- Act of 1 July 2005 on the procurement, preservation and transplantation of cells, tissue and organs (Journal of Laws of 2005, no. 169, item 1411);
- Act of 14 December 2012 on waste (Journal of Laws of 2018, item 992);
- Act of 31 January 1959 on cemeteries and burial of the dead (Journal of Laws of 2017, item 912);
- Act of 6 September 2001 – Pharmaceutical Law (Journal of Laws of 2008, no. 45, item 271, as amended);
- Act of 25 June 2015 on infertility treatment (Journal of Laws of 2015, item 1087);
- Regulation of the Minister of Health of 2 May 2012 on Good Clinical Practice (Journal of Laws of 2012, item 489);
- Regulation of the Minister of Health of 30 April 2004 on the conduct of clinical research on children and adolescents (Journal of Laws of 2004, no. 104, item 1108);
- Regulation of the Minister of Health and Social Welfare of 11 May 1999 concerning detailed rules of appointment, financing and mode of operation of ethics committees (Journal of Laws of 1999, no. 47, item 480);
- Regulation of the Minister of Health of 5 October 2017 on the detailed method of dealing with medical waste (Journal of Laws of 2017, item 1975);
- Regulation of the Minister of Health of 23 November 2016 on the requirements and methods for the disposal of medical and veterinary waste (Journal of Laws of 2016, item 1819);
- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjectshttp://www.nil.org.pl/__data/assets/pdf_file/0010/93097/Deklaracja-Helsinska-przyjeta-na-64-ZO-WMA_-pazdziernik-2013_pelny-tekst.pdf;
- The Belmont Report. Ethical principles and guidelines for the protection of human subjects of research;
- *Świadoma zgoda na udział w eksperymencie medycznym. Poradnik badacza [Informed Consent to Participation in Medical Research. A Guidebook for Researchers]*, published by the Centre of Bioethics of the Supreme Medical Council, ed. Marek Czarkowski, Joanna Różyńska, Warsaw, 2009;

- *Realizacja zasady informed consent w kontekście relacji lekarz-pacjent. Wyzwania i bariery rozwojowe w Polsce: materiały z seminarium ekspertów zorganizowanego przez Biuro Rzecznika Praw Obywatelskich we współpracy z Centrum Ekologii Człowieka i Bioetyki Uniwersytetu Kardynała Stefana Wyszyńskiego w Warszawie dnia 12 marca 2011 r. [Implementation of the Principle of Informed Consent in the Context of the Doctor-Patient Relationship. Challenges and Development Barriers in Poland: Materials from an Expert Seminar Organised by the Office of the Commissioner for Human Rights (Ombudsman) in Cooperation with the Institute of Ecology and Bioethics at the Cardinal Stefan Wyszyński University in Warsaw on 12 March 2011]*, ed. Wojciech Bołoz, Romuald Krajewski, Warsaw 2012;
- *Eksperyment medyczny na organizmie ludzkim w prawie międzynarodowym i europejskim [Medical Experiments on the Human Body in International and EU Law]*, Agata Wnukiewicz-Kozłowska, Dom Wydawniczy ABC, Warsaw 2004, pp. 28–37;
- *Research Ethics in Ethnography/Anthropology*, Ron Iphofen, AcSS, 2013; http://ec.europa.eu/research/participants/data/ref/h2020/other/hi/ethics-guide-ethnog-anthrop_en.pdf
- *Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research*, 2010; http://ec.europa.eu/research/participants/data/ref/fp7/89867/social-sciences-humanities_en.pdf
- For guidance on methods of sex/gender analysis and the issues to be taken into account, please refer to http://ec.europa.eu/research/swafs/gendered-innovations/index_en.cfm?pg=home

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.

3.1. Will 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 those indicated in point 1?
   - 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 foreign biobanks?
   - will the project use human cell lines, including genetically modified cell lines, purchased in a cell bank such as ATCC, ECACC?
   - will the cells (cell lines) or tissues used in the study be purchased within the framework of the project?

- are the researchers involved in the research project already in possession of the cells (cell lines) or tissues to be used in the study?
- how will the cells or tissues be stored?
- have the researchers obtained certificates attesting to the purity and authenticity of cell lines to be used in the study? If not, do they plan to conduct tests to confirm their authenticity?

b) provide information concerning:
- the characteristics of the cells (cell lines) or tissues;
- the source of cells (cell lines) or tissues (name of provider);
- authenticity certificates or methods for confirming the authenticity of cells (cell lines) or tissues.

3.2. Will the research project use human biological samples taken within the framework of the project or received from non-commercial sources?

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 the project use cell lines sourced from other labs in Poland or abroad? See point 4;
- will the project create new cell lines? See point 4;
- will the project procure stem cells? If so, where from? 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)? See points 4 and 10;
- will the study use biological material taken from human remains? See points 4 and 10;
- what information should be acquired from cells or tissue donors?
- 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 type of cells or tissues;
- the origin of cells or tissues, e.g. directly from the donor, from the entity's own repositories;
- 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 country of origin of biological material (if applicable);
- 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 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, 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).

Where cells or tissues are to be transferred from a non-EU country, please indicate the legal basis for such transfer. See point 6.

We recommend that you familiarise yourself with the following legal acts and publications:

- Act of 14 December 2012 on waste (Journal of Laws of 2016, item 1987 and 1954, and of 2017, item 785 and 1566);
- Act of 1 July 2005 on the procurement, preservation and transplantation of cells, tissue and organs (Journal of Laws of 2005, no. 169, item 1411, as amended);
- Regulation of the Minister of Health of 5 October 2017 on the detailed method of dealing with medical waste (Journal of Laws of 2017, item 1975);
- *Recommendation Rec (2006)4 of the Committee of Ministers to member states on research on biological materials of human origin*, passed on 15 March 2006;
- *European Agreement concerning the International Carriage of Dangerous Goods by Road* (commonly known as the ADR treaty) (Journal of Laws of 2005, no. 178, item 1481);
- http://www.bbmri.pl/pl/psb/55-polska-siec-biobankow;
- *OECD Recommendation on Human Biobanks and Genetic Research Databases of 2009*;
- 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).

[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.*

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"). This means that the identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as:

- 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 Act on data protection 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. Will the research involve the processing of personal data?

If the answer is "YES", please...

a) consider the following issues:
   - will the personal data be collected from persons from non-EU countries?
   - 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]?
   - will the personal data be pseudonymised[3]?

b) provide information concerning:

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[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.

[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 understanding of GDPR provisions.

- 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 compliance of personal data collection with the domestic law in force in the country where the data were acquired;
- the personal data risk assessment.

4.2. Will the research involve further processing of previously collected personal data (secondary use) or data 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:
   - the kind of personal data collected;
   - the origin of personal data (country, institution);
   - justification for the processing of personal data obtained from outside the research entity;
   - 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 type of exported or imported personal data.

Personal data processing requires the free and informed consent of study participants. In accordance with the principle of minimising the use of personal data, no data should be collected that is not necessary for the proper documentation of the research project.

The best way to protect personal data is to have them anonymised or pseudonymised. 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).

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 or GMMs should be attached to the annual report covering the period during which the animal research project was launched.

5.1. Will the research use animal biological material (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:

- the animal species;
- the number, age and sex of research animals, including the relevant justification;
- 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).

5.2. Will the research use commercially available animal tissues or cells (e.g. cell lines)?

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

- the animal species;
- the characteristics 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 (cell lines).

We recommend that you familiarise yourself with the following legal acts and publications:

- Act of 15 January 2015 on the protection of animals used for scientific and educational purposes (Journal of Laws of 2015, item 266);
- Act of 22 June 2001 on genetically modified organisms (Journal of Laws of 2001, no. 76, item 811);
- Regulation of the Minister of Environment of 11 April 2016 on the classification of microorganisms and organisms employed in the contained use of GMMs and GMOs (Journal of Laws of 2019, item 624);
- Decision no. 14/2016 of the National Ethics Committee for Animal Testing of 17 June 2016 on animal tagging and identification;
- *The ARRIVE Guidelines Checklist Animal Research*: Reporting in vivo Experiments https://nc3rs.org.uk/sites/default/files/documents/Guidelines/NC3Rs%20ARRIVE%20Guidelines%20Checklist%20%28fillable%29.pdf.

5.3. Will the research use vertebrates or live cephalopods?

If the answer is "YES",

a) consider the following issues:
   - will the research project use adult specimens?
   - will the research project use larvae?
   - will the research project use embryonic forms of mammals?
   - will the research project use primates?
   - will the research project use free-living 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;
   - are the research animals commercially available?
   - were the research animals bred in the entity's own breeding centre?

b) provide information concerning:
   - the species of animals used in research;
   - the number, age and sex of animals used in research, along with the relevant justification;
   - the way in which animals were assigned to the study and control groups;
   - the animal tagging and identification method;
   - the origin of animals, e.g. name of their provider or donor;
   - the place and manner of animal storage that meets high ethical standards;
   - the approval, obtained or pending, of the local animal research ethics committee;
   - the researcher who designed and is in charge of the experiments.

5.4. Will the research use genetically modified organisms or microorganisms?

If the answer is "YES", please...

a) consider the following issues:
   - does the research entity run a Genetic Engineering Lab where the contained use of GMMs or GMOs will be performed?
   - are the genetically modified microorganisms commercially available?
   - are the genetically modified organisms commercially available?
   - does the project involve the genetic modification of organisms or microorganisms?
   - will the project use GMOs or GMMs acquired from other institutions within the framework of research cooperation?
   - will the project breed GMM cells or GMO cultures?
   - what category of contained use do the GMMs or GMOs used in the project belong to?
   - what group do the microorganisms used in research belong to?
   - do researchers possess authenticity and purity certificates for the GMOs and GMMs to be used in the project? If not, do they plan to conduct tests to confirm their authenticity?

b) provide information concerning:
   - the characteristics of the type of GMMs or GMOs used in the project;
   - 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;
   - the approval, obtained or pending, of a local animal research ethics committee;
   - the place of storage of the GMOs or GMMs during the project;
   - the researcher in charge of the contained use of GMMs or GMOs;
   - the agreement, signed or pending, on the transfer of GMOs or GMMs between institutions (e.g. a *Material Transfer Agreement*) (if applicable);
   - authenticity certificates or methods for confirming the authenticity of the GMOs and GMMs used in the project;
   - the breeding conditions (for GMO cultures) that minimise animal suffering.

6. Research cooperation 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 the Republic of Poland.

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 World Bank). 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.

6.1. If the research project is conducted in cooperation with non-EU countries, may it raise potential ethics issues?

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

- the risk and benefit analysis concerning the cooperation;
- the ethical dilemmas involved in the implementation of the research project in non-EU countries;
- 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, etc.?

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

- the type of local resources to be used in the research project;
- 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 approval, acquired or pending, of an appropriate ethics committee, 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.

6.3. Will the research require to import any material from outside the EU?

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

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

- the kind of imported material;
- the agreement, 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, of appropriate authorities for the importation of the materials in question (e.g. human remains, artefacts) to Poland (if applicable).

6.4. Will the research require to export any material from the EU to non-EU countries?

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

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

- the kind of exported material;
- the method for securing the permission for the export of the material to non-EU countries;

6.5. If the research involves low- or medium-income countries, does it provide for the distribution of project benefits?

If the answer is "YES", please...

a) consider the following issues:
   - will the cooperation contribute to the development of local specialist knowledge?
   - will the cooperation contribute to the development of research infrastructure in the country?
   - will the cooperation contribute to the distribution of results, data access, technology transfer or publication in the country?
   - will the cooperation potentially benefit the local community (property resources, equipment)?

b) provide information concerning:
   - the cooperating institution/institutions;
   - prior research cooperation with the foreign institution (if applicable);
   - direct benefits for research participants or the local community if the research is conducted in low- or medium-income countries.

6.6. Could the situation in the country in question expose research participants to risk?

If the answer is "YES", please...

c) 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 politically unstable countries, e.g. involved in military action, riots, etc?

d) provide information concerning:
   - the sources of potential risk;
   - the measures taken to eliminate the risk.

We recommend that you familiarise yourself with the following documents:

- *Convention on Biological Diversity* Rio de Janeiro 1992 https://www.cbd.int/doc/world/pl/pl-nbsap-v3-pl.pdf;
- *The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*: https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf
- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects http://www.nil.org.pl/__data/assets/pdf_file/0010/93097/Deklaracja-Helsinska-przyjeta-na-64-ZO-WMA_-pazdziernik-2013_pelny-tekst.pdf;
- *Global code of conduct for research in resource-poor settings* http://www.globalcodeofconduct.org/wp-content/uploads/2018/05/Global-Code-of-Conduct-Brochure.pdf

7. Environment, health, safety

This section covers research that may have a potentially negative impact on the natural environment, plants, animals, as well as the health and safety of researchers involved in the project. This may be caused by adverse events arising as a consequence of inappropriate research methods or technologies.

7.1. Will the research involve the handling of elements that may pose a hazard to the environment, animals or plants?

If the answer is "YES", please:

e) consider the following issues:
   - does the research project use genetically modified microorganisms?
   - does the research project involve plant or animal species that, if released into the environment, may pose a threat to endemic species or natural habitats?

f) provide information concerning:
   - factors that may pose a hazard to the environment, animals, plants and humans;

- in the case of the contained use of class IV GMMs, please describe the risk assessment and the potential effects on human health and the environment.

7.2. Will the research involve protected animal or plant species 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?
   - will the research project involve catching fish or other water organisms in protected areas?
   - will the research project involve plants or animals that could, if released into the environment, pose a threat to endemic species or natural habitats?

b) provide information concerning:
   - the exemption, obtained or pending, from the bans reffered to in art. 15 paragraph 1 of the Act of 16 April 2004 on environmental protection (if applicable);
   - the consent, obtained or pending, of the director of the national park or protected area to research activity (if applicable);
   - potential research-related hazards to the environment, plants or animals;
   - the lack of alternative solutions to the research project.

7.3. Will the research project require the use of factors or conditions that may be hazardous to humans, including the research staff?

If the answer is "YES", please...

a) consider the following issues:
   - will the research project use hazardous chemicals, e.g. carcinogens, liquid nitrogen?
   - will the research project use hazardous physical factors, e.g. radioactive reagents, UV radiation?
   - will the research project involve biological material that may be hazardous for the research team, e.g. pathogens (retroviruses, viruses, bacteria, fungi, mycoplasma)?
   - 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, e.g. arachnids, snakes?

- will the research project be conducted in countries with a high risk of tropical diseases, such as malaria, viral haemorrhagic fever?
- will the research project be conducted under difficult climatic or geographical conditions, e.g. prolonged sunshine, high altitude, etc.?
- will the research project be conducted in countries that are politically unstable, e.g. involved in military action, riots, etc.?

b) provide information concerning:
- the 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.

We recommend that you familiarise yourself with the following legal acts:

- Act of 16 April 2004 on environmental protection (Journal of Laws of 2004, no. 92, item 880, as amended);
- Regulation of the Minister of Environment of 28 September 2004 on protected wild animal species (Journal of Laws of 2004, no. 220, item 2237, as amended);
- Regulation of the Minister of Environment of 9 September 2011 on the list of foreign plant animal species that may threaten endemic species or natural habitats in the event of their release into the environment;
- Regulation of the Minister of Environment of 3 August 2011 on animal species dangerous to human life and health;
- Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds (annex IV);
- Council Directive 92/43/EEC of 21 May 1992 on the protection of natural habitats and wild fauna and flora (annex VI);
- Convention on the Conservation of European Wildlife and Natural Habitats, Bern, 19 September 1979 (annex IV) – ratified by Poland on 12 July 1995.

8. Dual use

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.

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

If the answer is "YES", please...

a) consider the following issues:
- will 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?

- will the project results belong to any of the ten categories of goods placed on the checklist annexed to the Council Regulation (EC) No. 428/2009?

b) provide information concerning:
   - 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. Misuse

Some research projects generate knowledge, materials or technologies that may be used by others in unethical ways. The researchers may have good intentions and conduct their research in accordance with ethical standards, but their results may be hijacked by others to potentially harm people, animals or the natural environment.

9.1. Can the research project be a potential source of misuse, crime, terrorism?

If the answer is "YES", please...

a) consider the following issues:
   - what would happen if the materials, methods, technologies or knowledge resulting from the project fell into the wrong hands?
   - can the materials, methods, technologies or knowledge resulting from the project be used for purposes other than their intended application? If so, would such use be unethical?
   - 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 for the purposes of criminal or terrorist activity?
   - is caution recommended during their publication or dissemination?

b) provide the following information:
   - the risk assessment of the misuse of research results;
   - the measures taken to prevent the unethical use of research results.

10. Other ethical aspects

10.1. Are there any other ethical aspects of the research project, which should be taken into account and have not been mentioned above?

If the answer is "YES", please...

a) consider the following issues:
   - does the research project include individuals deprived of liberty? Will the research directly benefit the participants?

- does the research project involve individuals incapable of granting independent consent? Is the research legal?
- will the research project use biological material taken from organs removed from the human body or medical waste tissue (e.g. amputated limbs, placenta)?

b) provide information concerning:
- the benefits to study participants;
- the informed consent, obtained or pending, of participants to voluntary participation in the study;
- reasons why the participant is unable to grant such consent;
- the approval, obtained or pending, of the statutory representative of the study participant;
- the approval, obtained or pending, of an appropriate bioethics committee.

10.2. Will the research project involve vulnerable social groups, such as people with disabilities, children?

If the answer is "YES", please...

c) consider the following issues:
- will the study with minors bring direct benefits for their own therapy or the therapy of their peers?
- does the study include minors over the age of 16 or under the age of 16, as long as they are capable of expressing an informed opinion on their participation in the medical experiment?
- is the researcher experienced in handling minors and able to provide them with intelligible information concerning the study?

d) provide information concerning:
- the consent, obtained or pending, of the statutory representative and the minor, in accordance with the principles laid down in Article 25 of the Act on the profession of physician and dentist, concerning the requirement of obtaining consent for the medical experiment from the subject.

10.3. Will the research project involve handling samples taken from human remains?

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

- 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;
- the consent, obtained or pending, of medical staff or the deceased person's family members to the sampling of biological material from the remains, as reflecting the wish of the deceased person that their biological material be used for research purposes;
- 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 above-

mentioned Act of 31 January 1959 on cemeteries and the burial of the dead (Journal of Laws of 1959, no. 11, item 62, as amended) (if applicable).

Research on biological material taken from human remains is conditional on the consent of the deceased person, as expressed during lifetime.

We recommend that you familiarise yourself with the following legal acts and publications:

- Act of 31 January 1959 on cemeteries and the burial of the dead (Journal of Laws of 2011, no. 118, item 687, as amended);
- Act of 1 July 2005 on the procurement, preservation and transplantation of cells, tissue and organs (Journal of Laws of 2005, no. 169, item 1411);
- Act of 14 December 2012 on waste (Journal of Laws of 2018, item 992);
- Regulation of the Minister of Justice of 30 October 2007 on the method and mode of obtaining information from the prosecutor or the decision of the family court not to object to the sampling of cells, tissues and organs (Journal of Laws of 2007, no. 210, item 1532);
- Regulation of the Minister of Health of 30 April 2004 on the conduct of clinical research on children and adolescents (Journal of Laws of 2004, no. 104, item 1108);
- Regulation of the Minister of Justice of 7 July 2010 on the method of handling the remains of persons deprived of liberty in correctional facilities and remand centres (Journal of Laws of 2010, no. 123, item 839);
- Regulation of the Minister of Internal Affairs and Administration of 26 October 2010 on the handling of the remains of foreign citizens placed in guarded centres or rigorous detention centres ahead of deportation (Journal of Laws of 2010, no. 213, item 1405);
- Regulation of the Minister of Health of 5 October 2017 on the detailed method of dealing with medical waste (Journal of Laws of 2017, item 1975);
- Regulation of the Minister of Health of 23 November 2016 on the requirements and methods for the disposal of medical and veterinary waste (Journal of Laws of 2016, item 1819);
- Regulation of the Minister of Health of 30 July 2009 on the mode and conditions of donating human remains for research purposes (Journal of Laws of 2009, no. 129, item 1067).

Please 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].