# Q&A ARIA ethics section

Please note that eligibility criteria and submission guidelines are available here. This Q&A only relates to the ethics section of the ARIA platform to submit your application.

## HUMAN SAMPLES AND DATA

### My proposed research concerns research on embryo/foetus. Can I apply?

EASI-Genomics does not accept projects involving human embryos nor human embryonic stem cells. hiPSC derived from such materials could nevertheless qualify.

### My proposed research concerns research on humans or on human samples. Which documents will I need to provide?

You will be expected to provide:

1. the ethics approval for the research in humans (or other relevant documents e.g. a national authority declaration/authorization);
2. the templates of informed consent (or assent) forms for research participation including information sheets;
3. the authorization or relevant documents for human cell/tissues collection and use
4. Information about possible harm to the environment related to the use of the material (e.g. biosecurity, biosafety levels and instructions for recipient Facilities)

### I did not take into account sex/gender, ethnicity and diversity aspects in the design of my study, can this be a potential blocker to my EASI Genomics application?

Taking into account, in the analysis but most of all in the design of the research, gender, ethnicity or diversity aspects is essential in research for a more equitable representation and share of research benefits. Those aspects are thus part of the evaluation of a quality application but are not the only criteria. If these aspects have not been taken into account, the applicant should justify why in the dedicated section.

### My research project involves processing of human data. Which documents will I need to provide?

If you are processing personal data, you will be expected to provide a declaration/authorization from your national competent authority for collecting and processing personal data.

Alternatively, you will be expected to provide a statement from your Data Protection Officer statement (a simple email from him or her is sufficient) confirming either that the data processed

for your research project is not “personal data” according to your national law; or (if your national law does not require a declaration/authorization) that the personal data processing in your research project will be compliant with your national law and with GDPR.

### The data in my research project originates from non-EU/EEA countries, can I still apply?

Yes. However, you will be expected to provide copies of necessary authorisations in your country allowing processing within the EU, or a statement from designated Data Protection Officer (DPO) confirming compliance with applicable laws and Chapter V of GDPR.

If your institution does not have a DPO because it is not based in an EU country, such a statement can come from a data protection authority, a DPO equivalent in your institution or simply the legal department.

## NON-HUMAN SAMPLES AND/OR ANCIENT DNA

### My project concerns research involving the use of genetic resources of non-human origin or ancient DNA (including human). Which documents do I need to provide?

If the proposed research involves the use of local resources and might of benefit to local communities, or of it involves the use of animal samples, of vegetal samples or of other genetic resources (fungi, bacteria, protists, etc), you will be expected to:

1. Check whether bio-resource used in your project needs a declaration of utilization as imposed by the EU ABS Regulation (EU Regulation 511/2014) and in compliance with your national implementing law. Note: The ABS Clearing House website helps you find information about ratifying countries' framework and contacts of Focal National Contact Points.
2. Provide copies of relevant declaration/authorisation required under National laws implementing the EU ABS Regulation or, if not applicable, a short explanation.

### My project concerns research on animals or on animal samples. Which further documents do I need to provide?

You will be expected to provide copies of relevant authorizations for animal experiments regarding compliance with procedures for animal welfare and adherence to the three Rs principles.

You will also be expected to provide information about possible harm to the environment (e.g. biosecurity, biosafety levels and instructions for recipient Facilities)

### My proposed research concerns research on plants. Which further information do I need to provide?

You will be expected to provide information about possible harm to the environment (e.g. biosecurity, biosafety levels and instructions for recipient Facilities), especially (but not only) if the research involves genetically modified organisms, genetically edited plants, or toxic plants.

## OTHER ASPECTS

### My proposed research concerns research has direct military use or potential for terrorist abuse. Can I apply?

Yes, but please provide copies of export licenses for concerned goods and information used and produced in your research.

Note: For cross-border transfers of dual-use materials, technologies and information, you must observe the EU Export Control Regulation No 428/2009. If you have any doubts, you should consult the relevant national export control authority to clarify whether transfer licenses are needed.

### I don't have every document that is asked for in the ethics check on the ARIA platform, can I still apply?

EASI Genomics only accepts projects that have the necessary legal and ethical authorisations, depending on the bioresource, to start the research activities. However, in exceptional cases EASI Genomics may grant a further delay to provide the necessary documentation if the situation justifies it. EASI Genomics holds the right to assess which situation justifies it or not, and will retain the possibility to reject the application at any time if the further delay is not respected.

### Is the open access requirement regarding sequencing data negotiable?

Supporting open science is at the heart of EASI-Genomics services in order to improve data sharing and potential benefits which could arise from their FAIRness. A minimum level of openness of the sequencing data generated in TNA is expected. EGA and ENA are recognised open-controlled databases providing solutions and support which are available to any users of EASI-Genomics services. The Facilities can help in the implementation of the process.

However, there can be an embargo period, as foreseen in EGA and ENA.