6. Non-EU countries

This section concerns projects with activities involving non-EU countries.

This is the case where:

- activities are conducted, partially or wholly, in a non-EU country
- participants or resources come from a non-EU country
- material is imported from or exported to a non-EU country.

Being outside the reach of European laws and standards, such activities can raise specific ethical issues *(particularly in developing countries)*, such as:

- exploitation of participants
- exploitation of local resources
- risks to project teams and staff
- activities (especially research) that is prohibited in the EU.

⚠ For Horizon Europe, funding cannot be granted for activities carried out outside the EU if they are prohibited in all Member States.[6]

6.1 Ethics issues checklist

Section 6: THIRD COUNTRIES	YES/ NO		Information to be provided in the proposal	Documents to be provided on request
Will some of the activities be carried out in non-EU countries? *Specify the countries*	☐	☐	1) Countries involved. 2) Risk-benefit analysis. 3) Details on activities are carried out in non-EU countries.	
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues? *Specify the countries*	☐	☐	1) Details on the materials and the countries involved.	1) Copies of ethics approvals and other authorisations or notifications (if required). 2) Confirmation that the activity could have been legally carried out in an EU country (for instance, an opinion from an appropriate

[6] *See Article 18(2) of the Horizon Europe Framework Programme and Rules for Participation Regulation YYYY/NN (OJ L XXXX).*

				ethics structure in an EU country).
Is it planned to use local resources *(e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)***?**	☐	☐	1) Details on the type of local resources to be used and modalities for their use.	1) For human resources: copies of ethics approvals. 2) For animals, plants, micro-organisms and associated traditional knowledge: documentation showing compliance with the *UN Convention on Biological Diversity (e.g. access permit and benefit sharing agreement)*.
Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? *For data imports, see section 4.* *For imports of human cells or tissues, see section 3.* *Specify the material and countries involved*	☐	☐	1) Countries involved. 2) Details on the type of materials to be imported.	1) Copies of import licences / Material Transfer Agreement (MTA).
Is it planned to export any material (other than data) from the EU to non-EU countries? *For data exports, see section 4.* *Specify the material and countries involved*	☐	☐	1) Countries involved. 2) Details of the type of materials to be exported.	1) Copies of export licences / Material Transfer Agreement (MTA).
Does your activity involve low and/or lower-middle income countries, are any benefit-sharing actions planned?	☐	☐	1) Details on the benefit sharing measures. 2) Details on the responsiveness to local research needs. 3) Details on the procedures to facilitate effective capacity building.	
Could the situation in the country put the individuals taking part in the activity at risk?	☐	☐	1) Details of the safety measures you intend to take, including training for staff and insurance cover.	1) Insurance coverage (if relevant)

6.2 How do I deal with the issues?

Your activities must comply with the ethics provisions set out in the Grant Agreement, and notably:

- highest ethical standards
- applicable international, EU and national law.

Research carried out in a non-EU country — For activities carried out outside the EU, it is not enough for that the activity to be accepted and comply with the legal obligations of a non-EU country.

For Horizon Europe, the activities must ALSO be allowed in at least one Member State.[7]

⚠ Beneficiaries must confirm in the ethics self-assessment section of their proposal that this condition is met.

Resources from a non-EU country — Any use of local resources *(especially animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, fossils)* must show respect for cultural traditions and share benefits *(i.e. also benefit local participants and their communities, involve local stakeholders — as equal partners — and respond to local needs)*.

This is particularly important for research projects in **low income and lower-middle income countries** *(see Convention on Biological Diversity and Declaration of Helsinki and follow the Global code of conduct for research in resource-poor settings)*. For access to **genetic resources**, you must also comply with the Nagoya Protocol on Access and Benefit Sharing and EU Regulation 511/2014 which implements this Protocol.

Import/export of material — If genetic resources are transferred across borders, it may be mandatory under the law of the provider country to obtain an authorisation for the transfer. In addition, you must use an agreement which describes the conditions for the export and the terms of utilisation and, if applicable, relevant benefit-sharing measures. *For transfers of human cells or tissues, see section 3; for data transfers, see section 4.*

Sending project teams to a non-EU country — Non-EU countries are not necessarily less safe than EU countries. Nevertheless, a risk assessment must be undertaken when sending project teams abroad and appropriate safety measures must be taken. These may include insurance cover or health and safety measures, *such as no lone working, contact points via phone, counselling support, etc. (see also section 7.2)*.

6.3 What do you need to provide?

If your proposal raises one of the issues listed in the ethics issue checklist above, you must complete the **ethics self-assessment** in **Part A** of your proposal.

Your grant proposal must include the **information** referred to in the ethics issues checklist and any of the **documents** already available. Documents that are not

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[7] *See Article 18(2) of the Horizon Europe Framework Programme and Rules for Participation Regulation YYYY/NN .*

submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the granting authority.

Background documents & further reading

Human resources

Declaration of Helsinki

Flora and fauna

Convention on Biological Diversity

Genetic resources

Nagoya Protocol on Access and Benefit Sharing

EU Regulation 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the fair and equitable sharing of benefits arising from their utilization in the Union (ABS Regulation) (OJ L 150, 20.5.2014, p. 59)

EU Regulation 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices (OJ L 275, 20.10.2015, p. 4)

Developing countries and lower income settings

FP 7: Developing countries

Global code of conduct for research in resource-poor settings