# DCU Research Ethics Committee Guideline Statement on conducting Research outside Ireland

The Research Ethics Committee of DCU already considers and evaluates any ethical considerations arising from research conducted by DCU researchers outside Ireland. The purpose of this document is to clarify the categories of ethical considerations which researchers should address when seeking ethical approval prior to conducting research outside Ireland. DCU researchers conducting research abroad, or as part of an international collaboration, should be aware of the different civil, legal, financial and cultural conditions when working overseas and are expected to refer to international guidelines and conform to relevant local regulations for the country or countries where the research is taking place.

The International Compilation of Human Research Standards listing, compiled by the Office for Human Research Protections, US Department of Health and Human Services provides details of research ethics committees, laws, regulations and guidelines for over 100 countries. See: International Compilation of Human Research Standards listing

DCU researchers are expected to be aware of and comply with all relevant laws and regulations at the local research site. Any exemption to the general requirement to comply with local laws requires detailed justification. Examples might be cases where compliance with local legal frameworks would risk harm to research participants, e.g. oppressive criminal law sanctions criminalizing those identifying as Lesbian, Gay, Bisexual, Transgender, Queer or Questioning, and Intersex (LGBTQI), or political dissents in dictatorships or authoritarian states. Only upon consultation with local partners and legal advisers on a case-by-case basis would DCU REC approve such an exemption. It is expected that the research will also comply with the DCU research ethics policies and guidelines as well as other relevant DCU policies and procedures, such as relating to insurance arrangements, and risk assessment, etc.

# **Research involving human participants**

Research involving human participants in other countries should involve local perspectives at all stages of the design, approval and conduct of the project. A local perspective is invaluable. It brings local and cultural considerations to bear that might not otherwise be appreciated by ethics committees outside that country/ies particularly around the issues of recruitment, consent, and implementation amongst others. It is the unexpected nuances when carrying out research overseas that can cause difficulties and need some local advice. For example, the risks might not be understood by an Irish researcher who is not aware of localized conflicts, or the challenges with finding competent researchers/data collectors in the location might not be understood.

Researchers should also be aware of the local formal and informal practices. Identification and response to all the ethical issues and sensitivities in another culture requires active engagement with members of that culture. Unless a strong justification to the contrary is offered, local researchers should play an active role in the research, not only for cultural reasons, but also as a contribution to local research capacity building. In some places, for example, where local researchers may not exist, getting views of the local community who will be (or provide) participants should be planned. Involving local perspectives could also involve getting the views of local health authorities or regulatory agencies.

Examples of ethical challenges arising in previously published research include: inaccurately translated research materials, using research tools that had not been validated for the research culture, lack of awareness of different cultural dynamics for children or genders. In conflict settings, participants may be placed at additional risk of harm from interacting with outside researchers. Researchers have obtained untrustworthy data after failing to build trust with the local community. Research has triggered problems within or between communities because of how subjects were selected. Participants have had unrealistic expectations for how the research will benefit them or their communities because of how the project was communicated. For these, and other reasons, researchers planning to conduct research overseas must pay particular attention to ethical issues and cultural sensitivities that may not arise in Ireland.

In particular, research (including that conducted by visiting researchers and affiliated academics) conducted overseas (including the rest of Europe) is expected to have the following ethical approvals, in addition to involvement of local perspectives throughout the preparation and conduct of the research:

- Approval by the DCU REC; see: <u>https://www4.dcu.ie/researchsupport/research\_ethics/guidelines.shtml</u>
- Local ethics approval in the study country(ies) in accordance with local requirements. However, if a local ethics committee does not exist, approval from the organization where the research will be conducted must be sought.
- ➤ NB: there might be contexts where institutional local approval is not possible, i.e. conducting research in authoritarian states or fragile/conflict contexts. In these exceptional situations, assessment through critical friends who are expert in particular regions/topics may be appropriate, but requires clear and strong justification. Research conducted in such contexts should be notified to the researcher's line manager who should perform an overall risk assessment (liaising with the Office of the Chief Operating Officer where necessary)

# Research using animals which is carried out overseas

The researcher should have ethical approval from DCU REC and must have regulatory approval from the relevant body in the country of research. For more details see <u>DCU Policy</u> on the Use of <u>Animals for Scientific or Educational Purposes</u>. In particular, research with animals is expected to have the following ethical approvals:

- Preapproval by the DCU Bioresource Advisory Group (BRAG). Please contact <u>brag@dcu.ie</u> with your application details.
- Applications involving animal subjects will be submitted to REC via BRAG with a supporting letter from the BRAG. REC will contact the researcher in due course with the REC review outcome.
- In the case of activities taking place outside Ireland but within the European Union, individuals must comply with Directive 2010/63/EU on the protection of animals used for scientific purposes and with local legislation and ethical requirements.

In the case of activities taking place **outside** the European Union, individuals should comply with the spirit of the Irish Regulations (SI 543 of 2012) and Directive 2010/63/EU, and must comply with local legislation and ethical requirements.

These requirements also apply to collaborative studies (any aspect of which uses animals outside Ireland).

#### Managing research data

#### Data collected overseas

Personal identifiable data collected and stored outside of the European Economic Area and where DCU will not be the data controller must comply with local data protection legislation. In addition, researchers should make every effort to ensure that data management processes comply with the Irish data protection principles in order to ensure that identifiable data is protected to the same extent that it would be in Ireland.

If the country where the research will be conducted does not have any data protection legislation, or this is known to be weaker than the Data Protection Legislation in Ireland, researchers should make every effort to comply with the Irish data protection principles. Also non-identifiable data should be handled, stored and reported to the same ethical standards as it would in Ireland.

If identifiable data is to be managed and stored in Ireland then the Irish Data Protection Legislation will apply to the data.

# Data transferred overseas

Levels of protection for the rights and freedoms of data subjects vary depending on the country the data is transferred to. It is important to note that data transfer also involves transient or unintentional transfers; where data is transferred to another recipient who is not the intended recipient.

This happens when a website or web application being used (either to store or collect data) is based outside Ireland; the data is first transferred to the website/application before being sent to the researcher/collaborator and therefore through the country in which the website/application is based.

Researchers are therefore strongly advised to check the terms and conditions of any web application or site that is being used to either transfer or store personal data to ascertain which country the website/applications is based in. Researchers should also ensure they are familiar with the DCU guidance on data protection including the guidance relating specifically to research. See: <a href="https://www4.dcu.ie/sites/default/files/research\_support/DCU%20Data%20Protection%20Training%20-%20Researchers.pdf">https://www4.dcu.ie/sites/default/files/research\_support/DCU%20Data%20Protection%20Training%20-%20Researchers.pdf</a>

#### **Student researchers**

Students are required to consult and comply with *Student Guidelines for Ethical Fieldwork Overseas*, a document developed by students for students with the support of the Development Studies Association of Ireland and Irish Forum for Global Health. See: <a href="http://globalhealth.ie/wp-content/uploads/2016/10/Student-Ethical-Guidelines\_draft.pdf">http://globalhealth.ie/wp-content/uploads/2016/10/Student-Ethical-Guidelines\_draft.pdf</a>

#### Proportionality of risks and benefits of the research

The expected benefits of the research should outweigh the risks that participants and researchers might be exposed to when doing research abroad. Therefore, risk assessment is pivotal. This is especially important for postgraduate students or early stage researchers who may feel pressured to conduct research in situations they may be uneasy about. The risks should also be reviewed regularly, especially with a longer-term project where the situation on the ground may change dramatically. An example is research in conflict zones.

#### **Travel safety**

You should check the Irish Department of Foreign Affairs and Trade website (see: <u>https://www.dfa.ie/travel/travel-advice/</u>) for travel advice for the country you are planning to travel to, both before and during your stay there as well as complete any necessary risk assessments and insurance forms.

# (This document has adapted content from guidelines provided by Univerity College London, available at:

https://www.ucl.ac.uk/research/integrity/research-ethics/outside-the-uk)