Steps ethical evaluation ICLON research

March 2022; subject to changes

Introduction

For all ICLON research projects that include new data collection, or that use personal data for which originally no consent was given for further research, an application for approval by the ICLON Research Ethics Committee (IREC) has to be submitted. Final approval has to be gained before any data collection from people takes place. An ethical application is not needed when you do a literature review study only.

IREC will evaluate the application against current regulations of research ethics and scientific conduct, as valid for Leiden University and national bodies for social scientific research (KNWU, VOR). The evaluation considers aspects of research ethics, data management, and privacy.

It is best to apply for an ethical evaluation at the start of your PhD project or postdoc, or other research project, as soon as you have planned data collection. Note that you will have to submit a new application for every sub-study that was not included in former applications (this applies mainly to PhD projects).

Planning: IREC needs a maximum of 6 weeks to evaluate your application, from application to final approval; depending also on the quality of the application and responses to change requests.

DPIA

You are required to do a Data Protection Impact Assessment (DPIA) for your research project when you collect and process **personal data**.

A DPIA is a process designed to help you systematically analyse, identify and minimise the data protection risks of a research project. Under the GDPR (European data protection regulation) it is mandatory for research projects with sensitive personal data and/or large scale personal data collection. This applies to almost all research at ICLON. Filling out an DPIA form is part of the application steps.

Useful information about conducting research can be found as well on the Leiden University Research Support Portal: https://www.researchsupport.universiteitleiden.nl/en

Steps

Rule-of-thumb

Before I start my data collection, I have received ethical and data management approval

When	What	Who
At least 8 weeks before data collection	***Draft*** an *ethic application form*, including *data management plan* (DMP) (this draft has to be approved by supervisors) Use the latest forms; request them from irec@iclon.leidenuiv.nl	Researcher, supervisor(s)
	Email the draft ethics application form and DMP to the ***ICLON Privacy Officer***, Carla den Hartog, at privacy@iclon.leidenuniv.nl	Researcher, Privacy Officer
	The Privacy Officer schedules a (MS Teams) meeting to discuss and – if necessary - ***fill out the Data Protection Impact Assessment (DPIA) form*** together.	Researcher, Privacy Officer
	In case of uncertainty about issues, the Privacy Officer contacts the university's data protection officer (*functionaris gegevensbescherming*) for advice.	Privacy Officer
	Revise ethic application form and data management plan accordingly.	Researcher
At least 2 weeks before the next IREC meeting (only 6 meetings/year, so plan ahead)	Get ***signature from supervisor*** (and other researchers involved in the project) and ***submit*** the application and annexes to irec@iclon.leidenuniv.nl	Researcher, supervisor(s), co-researcher(s)
Within 1 week after submission	***IREC*** registers application form and notifies applicant	IREC
Until next IREC meeting	***Evaluation*** of the application; draft by 2 IREC members; final evaluation in IREC meeting	IREC
Within 2 weeks after IREC meeting	***Notification*** to applicant of either final approval, conditional approval, or request for information or changes	IREC
If applicable	Response to IREC request for information or changes	Researcher
If applicable	Re-evaluation of adjusted application	IREC
If applicable	Notification of final evaluation: approval or rejection	IREC
After final approval	***Data collection*** can start	Researcher
In case of: New (sub) study; Change in research plan	• New study: submit new application form; refer to former application (registration number, date) • Changed plan: send email to IREC with description of changes; attach application form with changes clearly marked.	Researcher