Research Ethics Office: Frequently Asked Questions (FAQs)

Part I: GENERAL QUESTIONS

Q: What is research ethics?

Research ethics plays a key role throughout the research process. Ethical issues must be examined and addressed in the design, conduct, and dissemination of scientific research –especially when individuals are engaged as research participants. Research ethics outlines ethical principles and guidelines to help ensure the responsible conduct of research. The primary goal of research ethics is to protect the rights, welfare, and dignity of research participants or subjects.

Q: What is the research ethics review?

A research ethics review is a process that was established to ensure the ethical and responsible conduct of research. These reviews are conducted by a research ethics committee.

The committee may review technical aspects of the research, but their primary focus will be on the methodology of the research. Specifically, committees look into how data will be gathered and they check if there are sufficient procedures in place to ensure the safety of research participants.

The research ethics review process does not end with the approval or disapproval of research. The review process also provides a mechanism that helps researchers respond to issues that arise from unfavorable / unforeseen events that may occur in the conduct of the study.

Q: Why do I have to have my research reviewed?

All research projects require some form of ethics review to ensure that it complies with existing ethical standards and requirements. A research ethics review helps ensure that the proposed research upholds the ethical principles articulated in the Belmont Code National Ethical Guidelines (prepared by the Philippine Health Research Ethics Board), and De La Salle University Code of Research Ethics and Guide to Responsible Conduct of Research.

Research ethics clearance is often a requirement for publication in reputable, peer-reviewed journals. In many disciplines, the absence of research ethics clearance may make it difficult to publish papers.

In addition, many grant-giving agencies require proponents to obtain ethical clearance before data-gathering activities commence. In some cases, the release of funding may also be dependent on obtaining ethics clearance.

It's important to note that there are no mechanisms that will allow for retroactive clearance of research projects.

Q: Who does the review?

The research ethics review committee in DLSU is called the University Research Ethics Committee (U-REC), and this committee oversees Research Ethics Review Panels (RERPs) that are usually made up of:

- At least three scientific members who have been trained in research ethics review and have expertise regarding the type of research being reviewed;
- At least one scientific member who is not affiliated with the institution that established the committee or the funding agency of the project; and
- At least one lay member who is a non-scientist / not engaged in research.

(Source: DLSU Research Ethics Governance approved by the Academic Council on February 10, 2023)

Q: What aspects of the research proposal are reviewed?

The committee's primary task is to ensure the ethical and responsible conduct of research projects. They need to determine if the benefits of the proposed research outweighs the risk of harm to the prospective participants.

Therefore, committees must review the entire proposal – including the objectives and rationale of the study. They also closely assess the proposed methodology and relevant supporting documents. The committee looks at how data will be collected and the measures in place to minimize and manage risk amongst those affected by the research's activities.

Q: What are the types of review?

There are four types of reviews (1) Exempted from Review, (2) Expedited Review, (3) Full Review, and (4) Continuing Review. The table below presents the different types of reviews and describes the proposals that would qualify for each type.

Type of Review	Description
Exempted	Proposals are usually exempted from review when they:[1] (1) do not pose more than minimal risk to study participants, (2) are categorized under institutional quality assurance, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests, and (3) rely exclusively on information that is publicly available and therefore will not involve any interaction between the researcher and the individuals who provided the data. In addition, proposals that will utilize survey procedures, interview procedures, or observation of public behavior (including visual or audio recordings) may also be exempted from review when they meet the following criteria: (1) There will be no disclosure of the participants' responses outside the research which could reasonably place participants at risk of criminal liability or be damaging to their reputation, employability, or financial standing. (2) Information obtained from participants are recorded in a way where the identity of the participants cannot be directly or indirectly known through any identifiers linked to the participant.

Expedited Review	Proposals usually undergo an expedited review when they: (1) do not pose more than minimal risk to the study participants, (2) do not have participants in the vulnerable group, and (3) do not generate vulnerability. (Source: DLSU SOP 4)
Full Review	Proposals usually undergo a full review when they: (1) involve more than minimal risk to study participants, (2) when the study participants belong to vulnerable groups or (3) when a study generates vulnerability to the participants. (Source: DLSU SOP 5)
Continuing Review	Proposals undergo a continuing review when the period allotted in ethics clearance has lapsed and the research is still on-going. Committees need to conduct a continuing review to extend ethics clearance. (Source: DLSU SOP 12)

[1] Philippine Health Research Ethics Board. (2022b). *National Ethical Guidelines For Research Involving Human Participants 2022*. Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=154:national-ethical-guidelines-for-research-involving-human-participants-2022

Q: What is minimal risk?

The Philippine Health Research Ethics Board defines minimal risk as: "*a classification of risk in research where the probability and magnitude of harm or discomfort anticipated in the proposed research* ***are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.***" [2]

Q: What is an informed consent?

Informed consent is a process that provides individuals the opportunity to willingly participate in research. It is not just a form appended to a research proposal. It's a fully articulated process that details *how* informed consent will be obtained, *when* informed consent will be obtained, and *who* will be facilitating the process.

In general, the following requirements are recommended when obtaining informed consent:[3]

1. Consent must be obtained by the investigator or a designated individual.
2. Consent must be obtained **before** any research-related procedures are performed on the participant.
3. Consent must be given voluntarily. The participant or their legal representative must not be forced to participate or, if they wish to withdraw, to continue to participate.
4. Consent is documented by having the participant or their legal representative sign the informed consent form (with date). The signature indicates that informed consent documents have been adequately discussed and the participant or their legal representative is freely giving their informed consent.

It's important to note that the informed consent process is not a singular event. Researchers must ensure that participants are adequately informed and continue to provide their consent throughout their participation. Therefore, informed consent is an ongoing process. In some cases, research ethics committees may recommend including an expiry date for informed consent and will require researchers to renew consent with their participants.[4]

Q: What are the essential components of an informed consent form (ICF)?

Informed consent forms (ICF) are often used to facilitate the informed consent process. Please see our Guide to Designing an ICF.

Q: How is an ICF assessed?

Research ethics committees assess the ICF together with the **informed consent procedures** described in the methodology/procedures section of the research protocol.

For ICFs, at the minimum, research ethics committees check for the following components:

- Research Statement
- Description of participants' involvement
- Statement of risks
- Statement of benefits
- Description of confidentiality procedures
- Information regarding compensation
- Statement of voluntary participation and right to withdrawal
- Information regarding contact persons

Apart from these components, committees also check the language used in the ICF. Information should be presented in non-technical language and in a manner that is easily understood by their prospective participants.

Having an ICF with all of these components is not enough. Researchers need to ensure voluntary consent of participants by describing the informed consent process in their protocol.

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[1] Philippine Health Research Ethics Board. (2022b). *National Ethical Guidelines For Research Involving Human Participants 2022*. Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=154:national-ethical-guidelines-for-research-involving-human-participants-2022

[2] Philippine Health Research Ethics Board. (2022b). *National Ethical Guidelines For Research Involving Human Participants 2022*. Philippine Council for Health Research and Development. https://ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg?download=154:national-ethical-guidelines-for-research-involving-human-participants-2022

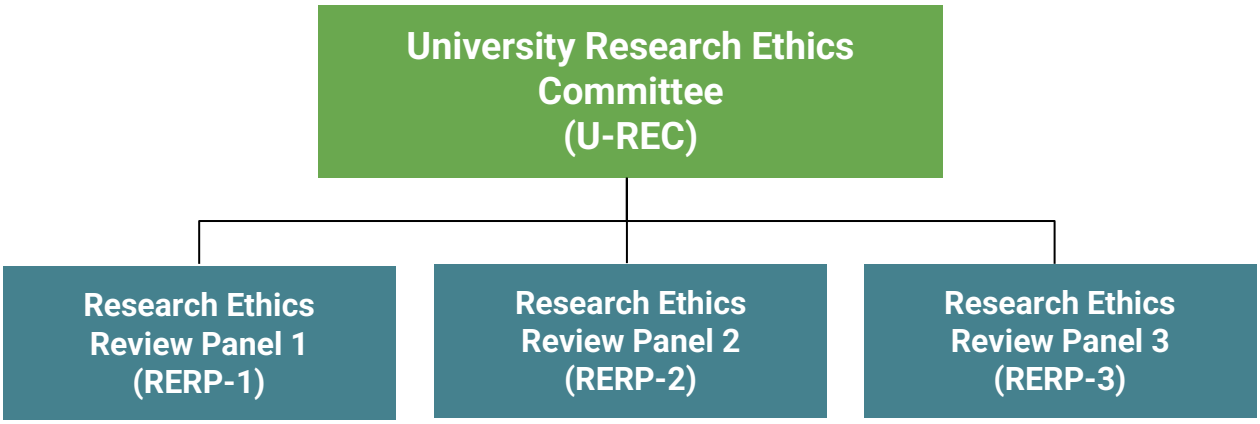
[3] Nijhawan, L. P., Janodia, M., Muddukrishna, B., Bhat, K., Bairy, K., Udupa, N., & Musmade, P. B. (2013). Informed consent: Issues and challenges. *Journal of Advanced Pharmaceutical Technology & Research*, *4*(3), 134. https://doi.org/10.4103/2231-4040.116779

[4] Helgesson, G., & Eriksson, S. (2011). Does informed consent have an expiry date? A critical reappraisal of informed consent as a process. *Cambridge Quarterly of Healthcare Ethics*, *20*(1), 85–92. https://doi.org/10.1017/s0963180110000642

Part II: DLSU Ethics Review Governance System & Process

Q: Who conducts the research ethics review in DLSU?

Depending on the stage of the review process, reviews are conducted by the University Research Ethics Committee (UREC) and the Research Ethics Review Panels (RERP).



Q: Who are the members of the U-REC and RERP?

The University Research Ethics Committee (U-REC) is composed of:

- A Chairperson
- A Vice-chairperson
- A Member Secretary
- Committee members

The RERP is a multidisciplinary panel composed of:

- The RERP Chair Designate
- RERP members
- One lay member
- One non-affiliated scientific member

There are multiple RERPs working under the supervision of the UREC.

Q: What are the roles of the U-REC and the RERP?

The U-REC oversees the RERP and they are responsible for the following:

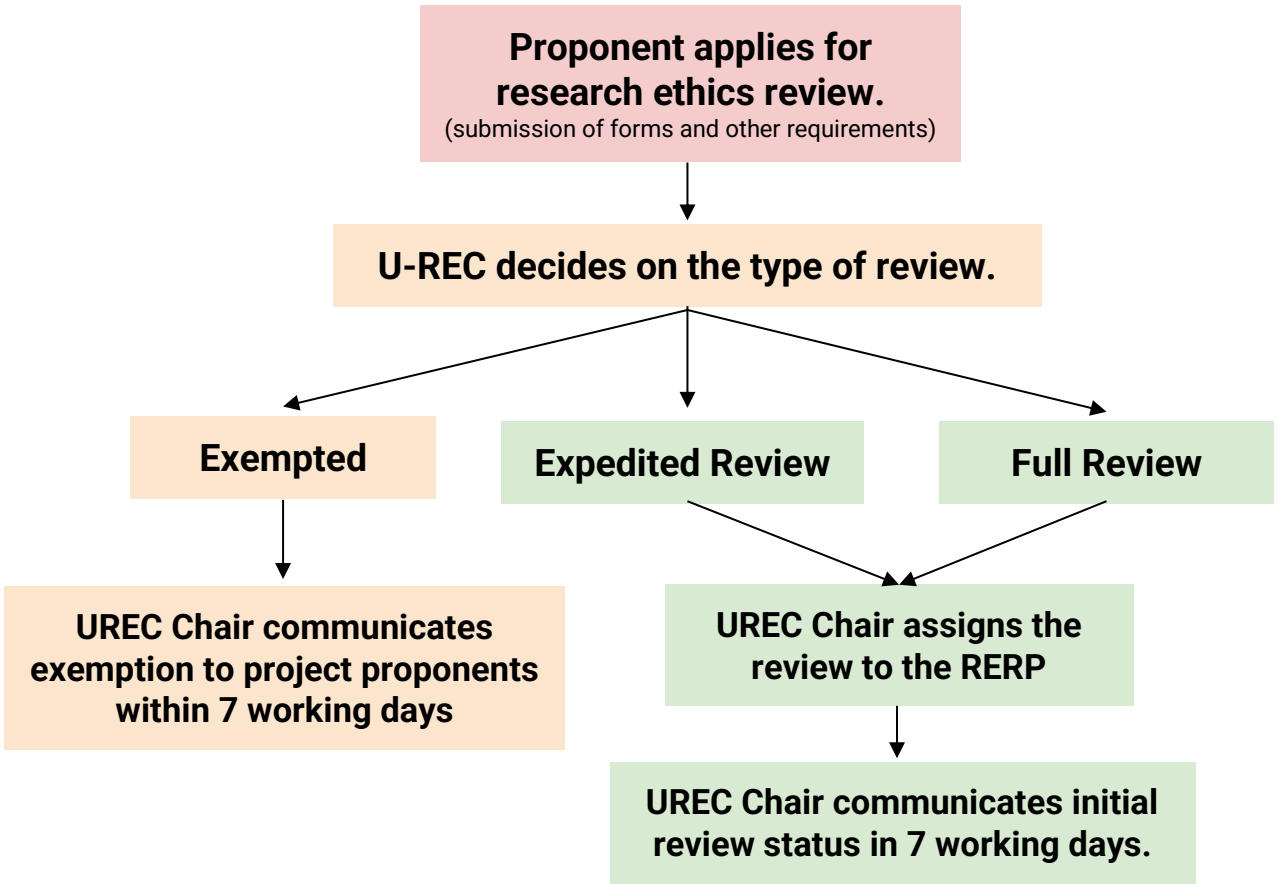
- Carries out administrative tasks (ex: noting certificate of clearance issued by the RERP, writing reports, etc.)

- Determines the type of review each submission will undergo (i.e. exempted from review, expedited review, or full review)
- Notifies project proponents of exemptions from the review process.
- Convenes once a month to conduct an overview of RERP reviews

RERPs are tapped by the U-REC if submissions need to undergo an expedited or full review. The RERP conducts these reviews and endorses the results for either revisions or approval, in which the U-REC will issue a certificate of clearance.

Q: What is the research ethics review process in DLSU?

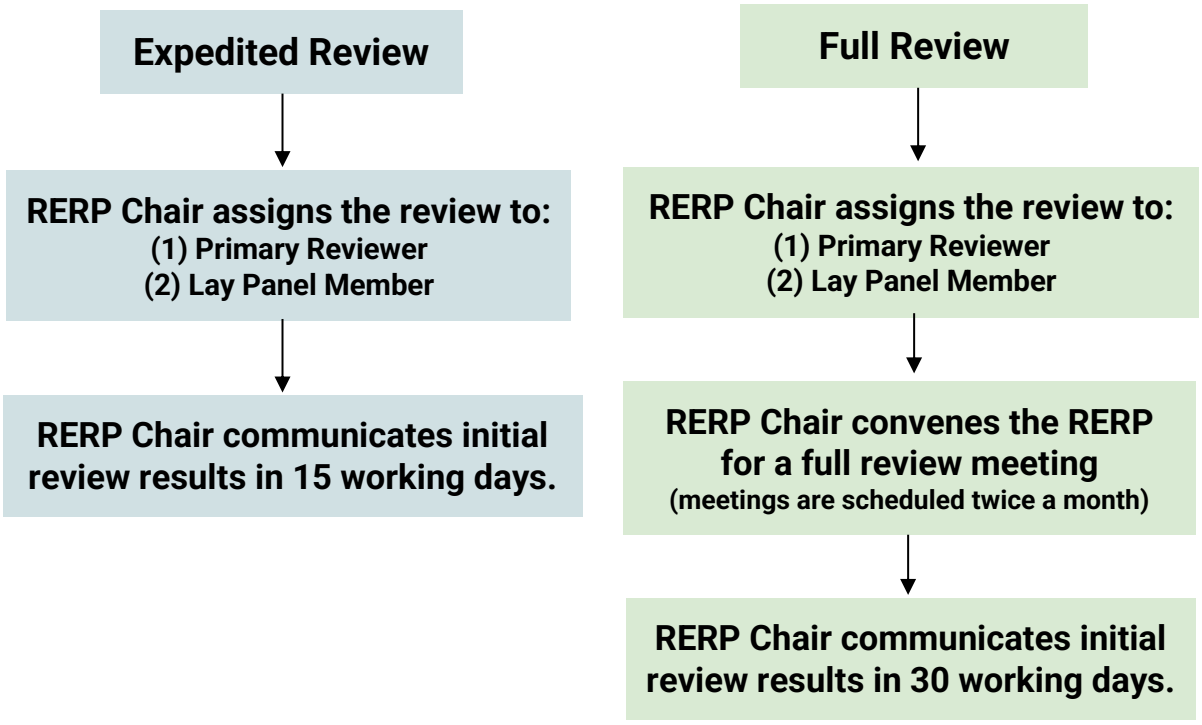
The first stage of the ethics review process is conducted by the U-REC. The U-REC will first ensure that the submission is complete. Once they verify the completeness of the submission, they will then determine what kind of ethics review is required (exempted from review, expedited review, or full review).



This first stage of the ethics review process takes 7 working days after the proponent makes a complete submission. When the RERC categorizes a submission as expedited or full review, the U-REC will assign it to the appropriate RERP.

If the submission is **not** exempted from the review process it will proceed to the second stage of the ethics review process which will be conducted by the RERP.

If a research does not pose more than minimal risk, it will undergo an **Expedited Review**. However, if a research poses more than minimal risk, it will undergo a **Full Review**.



After receiving the initial review status, proponents will have the results of the expedited review in 15 working days and the results of a full review in 30 working days.

If the expedited or full review results include recommended revisions prior to approval, proponents are given 7 working days to respond to the committee's recommendations. Once the proponent submits their revisions/response, the RERP will review the submission and will respond within 7 working days.

Q: How do I apply for Ethics Review?

Kindly follow the following steps to process the review of your proposal:

1. Fill out RERC Form 6A and attach the corresponding files needed. You may download the files here: Application Packet for Ethics Review
2. Label your files accordingly:
    - Proposal, version #, date submitted: **Proposal, version 1, 01 January 2024**
    - Informed Consent Form, version #, date submitted: **Informed Consent Form, version 1, 01 January 2024**
    - Data Gathering Materials, version #, date submitted, **Questionnaire, version 1, 01 January 2024**
3. Kindly include also a **Certificate or Approval** signed by **BOTH thesis adviser and Panel members,** if your submission is your thesis/course requirement.
4. Submit the files through the Application for Ethics Review Submission Page
5. For concerns or clarifications, you may contact rerc-staff@dlsu.edu.ph.