

FAQs for the Ethics Review of Research Studies

NOTE: For the ethics review of student researches, please refer to the FAQs for the Research Ethics Review of Student Projects, downloadable on the REO webpage of the DLSU website.

PART I: THE USUAL QUESTIONS

1. *What is research?*

- a. Research is defined as a systematic investigation to develop or contribute to generalizable knowledge.¹

2. *What is research ethics?*

- a. Research ethics focuses on the analysis of ethical issues during the conduct of research. Research ethics govern the standards of conduct for scientific researchers.
- b. The three (3) universal principles² are:
 - i. Respect for Persons
 - ii. Beneficence
 - iii. Justice

3. *What is a research ethics review?*

- a. A research ethics review is a process that is undertaken to ensure the ethical and responsible conduct of a research project. Specifically, reviewers look at how data will be collected and the measures undertaken to assure the safety of the research participants and those who might be affected by the research's activities.
- b. In DLSU, the Research Ethics Review Committee (RERC) is composed of appointed faculty members and non-affiliated members who possess the expertise and skills to assess the ethical issues in a research proposal.
- c. The DLSU-Research Ethics Office (REO) has the mandate to ensure that proper research ethics governance is in place in the University. The REO provides assistance to the RERC for its reviews.

4. *Why does a research project need an ethics review?*

- a. All research projects require some form of ethics review to ensure that research conducted complies with existing ethical standards and requirements. Ethics reviews help assure the safety and respect of those involved and those who might be affected by the research's activities.
- b. Ethics review committees provide mechanisms that help address issues and respond to unfavorable events related to safety occurring in approved studies.
- c. Some grant-giving agencies or donors require institutional ethical clearance before releasing funds to a research proponent.
- d. A number of national and international scholarly journals and conferences require institutional ethical clearance before accepting a research paper for publication and dissemination.

¹ Garfinkel, S. L. (2008). IRBs and Security Research: Myths, Facts and Mission Creep. In Proceedings of the USENIX Workshop on Usability, Psychology, and Security, 8, 1-5.

Kass, N. E., Faden, R. R., Goodman, S. N., Pronovost, P., Tunis, S., & Beauchamp, T. L. (2013). The research-treatment distinction: a problematic approach for determining which activities should have ethical oversight. Hastings Center Report, 43(s1), S4-S15.

Thabane, L., Thomas, T., Ye, C., & Paul, J. (2009). Posing the research question: not so simple Poser la question de recherche: pas si simple!. Can J Anesth/J Can Anesth, 56, 71-79.

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- e. The conduct of the review should help you understand the risks in your research that may violate the ethical principles of *respect, beneficence and justice*².
- f. In DLSU, the University Research Coordination Office (URCO) will only release funds if a project has been granted ethical approval from the Research Ethics Review Committee.

5. **What does the research ethics review committee look at when reviewing my research proposal?**

- a. In order to conduct an adequate review, the RERC will need the complete research protocol. This includes:
 - i. Research Proposal
 - 1. Introduction/Background of the study
 - 2. Research objectives/questions
 - 3. Review of related literature
 - 4. Study Design, methodology, data collection protocol
 - 5. Plans for Data Analysis
 - ii. Data Collection Tools (including informed consent forms, informed consent process scripts, letters of invitation to institutions, interview schedule, FGD guide, surveys, questionnaires)
 - iii. Experimental procedures
 - iv. Safety procedures (including personal protective equipment, procedures for handling, storage, and disposal of chemicals or samples, etc.)
 - v. Material Safety Data Sheets

PART II: APPLYING FOR RESEARCH ETHICS REVIEW

1. **At what stage of my project should I obtain ethical review?**

- a. Ethical clearance is applied for and granted at the proposal stage, prior to any data collection or experimentation.

2. **What do I need to submit in order for my study to undergo research ethics review?**

- a. All proponents need to submit the following documents:
 - a. **Application for Research Ethics Review** (only for proposals that will be submitted for external funding, commissioned projects, or proposals that will be funded by the researchers' personal funds)
 - b. **Research Proposal**
 - c. **General Checklist** (depending on the answers in the General Checklist, proponents will need to submit a specific checklist relevant to his/her research proposal. Specific Checklists NOT relevant to the research proposal SHOULD NOT be filled out)
 - d. **Checklist A** – Research Ethics Checklist for Investigations involving Human Participants
 - e. **Checklist B** – Research Ethics Checklist for Investigations Involving Animals
 - f. **Checklist C** – Research Ethics Checklist for Investigations Involving Animal Subjects – Research Ethics Checklist for Research on Wildlife
 - g. **Checklist D** – Research Ethics Checklist on the Use of Infectious Agents
 - h. **Checklist E** – Research Ethics Checklist on the Use of Toxic Substances
 - i. **Checklist F** – Research Ethics Checklist for Investigators conducting Action Research
 - j. **Checklist G** – Research Ethics Checklist for Investigators conducting Internet Research

² Definitions of each principle and how these principles are applied in the research process can be viewed in the Belmont Report (1979) at <http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/>

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- k. **Checklist H** – Research Ethics Checklist for Investigators conducting Community Research
 - l. **Documents stipulated in each relevant checklist (including the data collection protocol, informed consent forms, letters to institutions/community leaders, data collection tools, surveys, interview/FGD guides, material safety data sheets, permits to purchase certain chemicals, etc.)**
 - b. The above documents need to be signed and submitted via email to REO@dlsu.edu.ph. Researchers may attach their e-signature and submit the documents in PDF format or submit clearly scanned copies. Hard copies submitted to the Research Ethics Office will also be accepted.
 - c. The review process can only begin when complete documents have been submitted.
- 3. How do I submit my application for research ethics review?**
- a. If you are applying for an URCO grant, research ethics clearance is a requirement and thus, the review is automatic. You will receive an email from the Research Ethics Office requesting you to submit complete documents (see item 6).
 - b. If your project is externally funded, institutional, or using personal funds, researchers must apply for ethics review by filling out the Application Form (see item 6) and submitting it along with the other required documents.
- 4. Can I submit a paper copy of the application or submit the application by email?**
- a. While paper copies are accepted, the REO prefers that soft copies are submitted for more efficient document transmission. Documents can be sent via email to REO@dlsu.edu.ph
 - b. Please make sure that the application form and checklists have been carefully read, completely filled out and signed by the principal investigator/lead researcher. Investigators may choose to attach their e-signatures and send the forms in PDF, or submit clearly scanned copies.
- 5. What happens after I submit complete documents to the Research Ethics Office?**
- a. After submitting complete documents, the REO will conduct an initial review by going over the documents submitted and communicating to the researcher if there are additional documents needed or revisions that need to be made. Initial feedback is given within two (2) weeks after complete documents have been submitted.
 - b. After the investigator has submitted revised document, the REO immediately forwards the documents to the RERC and recommends a type of review for the approval. The RERC considers the recommendation of the REO and makes a final decision.

PART III: WHAT ARE THE TYPES OF REVIEW?

- 1. There are three (3) types of research ethics reviews:**
- a. **Exempted from review**
 - i. Projects which involve the collection data from public available databases or public documents are exempted from review
 - b. **Expedited Review**
 - i. Projects posing minimal risk to research subjects go through expedited review. Risk is minimal when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life

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or during the performance of routine physical examinations or tests.³ Projects that go through expedited review include:

- Research involving minor changes in previously approved research projects;
- Research involving analysis of information without interaction with subjects;
- Research where informed consent is needed from the subjects and the informed consent process will be correctly and appropriately applied, and that the researchers will be taken appropriate measures to protect the privacy of the subjects;
- Research which is a local portion of a multi-center or multi-national research project has already received a full review from another research ethics committee or institutional review board

c. Full Review

i. Research projects which pose a more than “minimal risk” to research participants or subjects are subjected to a full review by the RERC. Risk is minimal when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical examinations or tests.³ Projects that require a full review are those that involve:

- Research involving vulnerable groups, such as the elderly, youth-at-risk, special children, or individuals who are in inequitable relationships;
- Research involving sensitive topics, such as substance use, sexual behaviors, or criminal or politically sensitive behaviors;
- Research with groups which necessitate permission to acquire access to them, such as research with indigenous communities;
- Research which will require deception or which will be conducted without the participants’ full and informed consent at the time data are to be collected;
- Research that will require access to personal and confidential information of identifiable individuals, such as genetic or biological information, medical records, or psychological assessment records;
- Research that will cause physical and/or psychological harm or pain, or will cause humiliation, stress or anxiety;
- Research that will involve intrusive interventions, such as hypnotherapy, drug administration, or vigorous exercise, which may cause participants to reveal information about themselves they otherwise would not normally want revealed in their everyday lives.
Research involving respondents through the internet
- Research involving deceased persons, body parts or other human elements

PART IV: THE REVIEW PROCESS

1. What happens if a project is deemed exempted by the RERC?

- a. Projects that are exempted from review are granted ethical clearance. The approval will be communicated to the proponent in a Decision Letter.

2. What happens if a project is expedited by the RERC?

³ U.S. Department of Health and Human Services, 1994, p.6, as cited by Hadjistavropoulos, & Smythe, 2001

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- a. There are four (4) possible outcomes of an expedited review:
 - a. Approved
 - b. Minor modifications required
 - c. Major modifications required
 - d. Disapproved
- b. The results of an expedited review will be communicated to the proponent(s) within 2 weeks of resubmission.
- c. If the proposal is recommended for approval, it will be granted clearance from the RERC and the approval will be communicated to the proponent.
 - d. When modifications are required, proponents are asked to resubmit their proposal and documents if substantial revisions are required. The RERC will provide a rationale for this decision and he/she will also provide comments/suggestions to help the proponent revise his/her proposal.

3. *What happens if the RERC determines that a project needs to undergo Full Review?*

- a. Research projects which pose more than “minimal risk” to research participants or subjects are subjected to a full review by the Research Ethics Review Committee (RERC).
- b. A full review entails a formal face-to-face meeting among RERC members to discuss the ethical issues and to arrive at decisions regarding the ethics of a research project. The RERC may request for the proponent/s to attend the RERC Full Review meeting.
- c. The RERC convenes at the end of each academic term to conduct the full review of research proposals.
- d. Once the RERC has been convened, there are four possible outcomes from a Full Review:
 - a. Approved
 - b. Minor modifications required
 - c. Major modifications required
 - d. Disapproved
- e. The results of a full board review will be communicated to the proponent within ten (10) working days following the full review meeting.
- f. If the proposal is approved, it will be granted clearance from the RERC and the approval will be communicated to the proponent.
- g. If the proposal requires minor or major modifications, the RERC will send their comments/suggestions/questions through the REO and REO will send it to the proponent. The proponent will be asked to address the comments of the RERC by submitting revised or additional documents to the REO. The reviewer will then review the proponent’s submission and, if he/she adequately addresses the concerns of the reviewer, the proposal will be approved and granted clearance by the RERC.

4. *Does a full review mean my project might not be approved?*

- a. Of course not. A full review is a venue for the RERC to come up with recommendations that will best prepare researchers to address all risks posed in their research protocol.

5. *What does a disapproval from the RERC mean?*

- a. The submitted research proposal and all other protocol documents have not been given ethical clearance. This could be due to the lack of expertise and measures to ensure the ethical conduct of the study or the unfavourable risk-benefit ratio.
- b. The researchers are not given ethical clearance to pursue the research activities.

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- c. Proposals are disapproved when there are aspects of the study that are deemed unethical or when the ethical issues cannot be resolved. The RERC will provide a rationale for this decision. The decision will be communicated to the proponent. The proponent has the option of (1) revising and resubmitting his/her proposal and (2) appeal the RERC's decision.
 - d. If you disagree with the RERC's decision, you may appeal by writing a formal letter to the Research Ethics Review Committee, sent through the REO. This letter should contain justifications for the appeal that would merit reconsideration and approval.
6. ***There is a comment from the Review Results that is not clear to me and I'm not sure how to address it. Who can I talk to in order to better understand the comment?***
- a. Please feel free to schedule an appointment with the Director of the Research Ethics Office. Appointments can be made by calling the office at 524-4611 loc. 513.

PART V: POST-APPROVAL

1. ***How long is the ethical clearance for my study valid?***
 - a. Ethical clearance is valid for one (1) year. Approximately one year after the issuance of clearance the REO will request for a progress report in order to facilitate a Continuing Review.
 - b. A Continuing Review is undertaken annually by the RERC to assure that the rights, well-being and safety of those involved in the research or those who might be affected by the research activities are protected. This is simply a continuation of the ethics review process that needs to be documented.
2. ***My project has been approved and I have started it, but now I wish to make an amendment. What do I need to do?***
 - a. Any amendments need to be approved by the Research Ethics Review Committee prior to implementation. This can be done by filling out the Amendment Request Form and submitting it to the Research Ethics Office. This will then be forwarded to the RERC for their approval.
 - b. Researchers will be informed of their request for an amendment has been approved by the RERC.
3. ***I have received a request for a progress report from the Research Ethics Review Committee about my project that was granted ethical clearance last year. How do I access the format of the Progress Report?***
 - a. Please email REO@dlsu.edu.ph and you will be provided a template for the progress report. For your convenience, REO will fill out the parts of the report we already have information on.
4. ***I have received ethical approval for my study, but while carrying out the research a problem has arisen that was not anticipated. Do I need to tell anyone?***
 - a. An incident reporting procedure in human interventional studies is in place at the University, which outlines the appropriate course of action depending on the severity of the incident. With the exception of minor incidents, these should be reported to the University Research Ethics Review Committee. Should a problem arise in the conduct of your research, please contact the REO at 524-4611 loc. 513 as soon as possible and you will be advised on what to do.
5. ***My research is an experiment that involves the use of chemicals and agents. Is there anything I need to do to ensure the safe conduct of my research?***

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- a. Disclose in the research proposal and ethics checklists what kind of chemicals and agents will be used in the research. Provide safety measures for transport, handling, and disposal.
- b. Coordinate with the University Campus Sustainability Office for the proper disposal of wastes generated from the research experiments. The Campus Sustainability Office is located at Room 407, Henry Sy Sr. Hall. You can contact them by calling (632) 524-4611 local 272 or emailing green@dlsu.edu.ph.

6. *What If I disagree with the results of the review?*

- a. You may appeal by writing a formal letter to the Research Ethics Review Committee, sent through the REO. This letter should contain justifications for the appeal that would merit reconsideration and approval.

PART VI: THE COMMON QUERIES

1. *I completed a research paper before the REO and RERCs inception. Can I obtain ethical clearance so that I can publish this paper?*

- a. The RERC does not issue retroactive ethical clearances. Research ethics clearance is given during the research proposal stage to assure that ethical issues in the research were addressed prior to the collection of data.

2. *Is there a university template for informed consent forms?*

- a. No. However, REO has adapted a Guide to Designing an Informed Consent Form from the World Health Organization. It is uploaded on the Downloadable Forms section of the REO webpage. It contains compulsory elements of informed consent. Please note that this is a guide, not a template. Researchers are encouraged to develop consent forms that best suit the design of their studies while using this as a guide. The REO's guide provides the standard elements that should be present in the informed consent process.

3. *Do you need an actual form to get informed consent?*

- a. Informed consent is a process that involves more than just obtaining the signature of a participant. Researchers must explain the nature of participation very clearly so that participants will be well informed before conceding to participate.

4. *What happens when you cannot disclose the true nature of your study at the beginning of data gathering?*

- a. Some studies require deception so as not to bias the responses of the participants. A rational argument for deception needs to be clearly argued in the research proposal and checklists when documents are submitted for review.
- b. Researchers need to debrief participants after data has been gathered. Participants must also be given the option to withdraw their data.

5. *How do you get informed consent from minors?*

- a. Minors are legally defined as individuals younger than 18 years old.
- b. Obtaining consent from minors also involves obtaining parental consent. This is reflected in a Parental Consent Form similar to the Informed Consent Form.
- c. After obtaining parental consent, the minors themselves need to assent to participate. An assent form is essentially an informed consent form written in the language appropriate for the age of the participant:

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- i. For ages 0-7, minors cannot yet provide assent and consent will primarily be obtained from the parents.
- ii. For ages 7-12, minors can provide verbal assent.
- iii. For ages 12- under 15, minors can provide assent by signing an Assent Form.
- iv. For ages 15-under 18, minors can co-sign the informed consent form with parents/legal guardians.

6. *What if I want to waive informed consent?*

- a. Waiving informed consent must be applied for by writing a formal letter to the RERC through the REO seeking approval for the waiver. This is subject to approval by the Research Ethics Review Committee.

7. *I am a faculty member advising a student thesis group. Do my students' thesis need to undergo ethics review by the research ethics review committee?*

- a. Ethical reviews of students' thesis and coursework-related research projects are primarily done by the academic department.
- b. An ethics review for students' work is educational in nature, in such a way that there is a discussion between student and faculty member on the ethical issues present in their research and how these ethical issues can be addressed.
- c. If you would like assistance in identifying the ethical issues in research, please refer to our General Checklist and Specific Checklists uploaded on the REO website.
- d. There are instances where a student's academic department feels that the ethical issues in the study require the expert examination and review in order to ensure ethical conduct is adhered to. In special cases like this, the academic department (Thesis Mentor/Coursework Professor through the Department Chairperson) can formally request the Research Ethics Review Committee to conduct a review of a student's proposal. This letter can be sent through the REO. After the department has submitted the formal request, the student can apply for ethics review. The application for ethics review and ethics checklists can be downloaded at <http://www.dlsu.edu.ph/offices/reo/forms.asp>. It is the student's responsibility to submit the necessary forms and documents, under the supervision of the Thesis Mentor.

8. *Do our students need to submit their thesis proposals and completed theses to the Research Ethics Office?*

- a. No. REO only requests for a copy of the accomplished Students Ethics Clearance Form, available on the downloadable forms section of our webpage.
- b. Only the Student Research Ethics Clearance Form needs to be attached to thesis/dissertation proposals and final reports. This attachment will have to be scanned by the student researcher(s) and emailed to the department coordinator in charge of thesis programs. All ethics checklists downloadable from the REO webpage **need not** be attached to the proposals and final reports. The checklists can be used to guide/alert the student proponent(s) about the ethical issues that may have to be addressed in their research(es).
- c. Students Ethics Clearance Forms of approved thesis/dissertation proposals and final thesis reports need to be scanned and stored by the academic department. After which, please provide scanned copies of these to the Research Ethics Office at the end of every academic term. Please see the format below for the proper file naming of scanned Students Ethics Clearance Forms:

- i. ***For approved thesis proposal students ethics clearance forms:***

Surname.STUD.ProgramCode.THProposal.Term.AcademicYear

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For example: Albaniel.STUD.AB-PSM.THProposal.T3.AY2015-2016

ii. ***For completed thesis students ethics clearance forms:***

Surname.STUD.ProgramCode.THComplete.Term.AcademicYear

For example: Albaniel.STUD.AB-PSM.THComplete.T1.AY2016-2017

- d. If putting all surnames makes the filename too long, the students can put the surname of whoever's name appears first on the title page followed by GROUP. For example: AlbanielGROUP.STUD.AB-PSM.THProposal.T3.AY2015-2016
- e. What is important is that all names of students appear on the actual document when the file is opened.
- f. At the end of each academic term, please provide the REO with scanned copies of the Student Research Ethics Forms in the filename format shown above.

9. *Our program has a research methods/research-related course. Do student research projects in coursework have to use the Students Ethics Clearance Form?*

- a. No. However, we encourage the coursework professor/subject teacher to use the ethics checklists as tools for identifying and addressing ethical issues in the research projects of students.
- b. Research ethics for students should be an educational experience where they are involved in the discussion of ethical issues as part of the training to be responsible researchers and graduates.

10. *Do I have to seek permission from the Chancellor or Vice Chancellor to collect data from the University?*

- a. If your study will undergo ethics review for an URCO grant or an externally funded grant that is managed by any of the University's research centers, then you do not need to seek permission from the University's approving authorities.
- b. Only requests to collect data for non-affiliated researches need to seek permission from the University's approving authorities. All non-affiliated requests must write a formal request to the Office of the Chancellor. The REO helps facilitate the process.
- c. As approved by the University Research Council, all non-affiliated requests must also provide the following documents:
 - i. Complete research proposal and data collection protocol
 - ii. Data collection tools (e.g. informed consent forms, interview/FGD guides, surveys, etc.)
 - iii. Certification that the research underwent ethics review was granted ethical clearance. This clearance may have been issued by a research ethics committee at another institution.
- d. An affiliated research is defined as:
 - i. Researches where the principal investigator/lead researcher is currently enrolled or employed at De La Salle University.
 - ii. The funding for the research is from the University (URCO, Challenge Grants, or Institutional projects)
 - iii. The funding for the research is being managed by a University research center.
 - iv. The affiliated researcher is using his/her own personal funds for the research project.
- e. A non-affiliated research refers to research conducted by researcher(s) not affiliated with DLSU, or by DLSU-affiliated researchers whose proposed studies are funded and managed by other agencies or institutions, or are conducted to fulfill course requirements in an institution other than those under De La Salle Philippines.

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- f. Approval of non-affiliated requests are granted by the University Chancellor or the Vice Chancellor for Academics. While this approval grants permission for non-affiliated researchers, the standard principles of free and voluntary consent still apply.

11. I am an affiliated member of the University. Should I obtain permission from the Chancellor of the Vice Chancellor in order to collect data from the University? (e.g. conduct interviews with faculty, administrators, students, or use data managed by the University)

- a. No, you do not need permission from the University's approving authorities.
- b. However, if you will be collecting data that is managed by the University, you must obtain formal permission from the custodian of the dataset, i.e. the unit head, in addition to the documents required for research ethics review. The document indicating approval must be attached to your research protocol.
- c. For interviews with students, faculty and administrators, you do not need permission from the University's approving authorities. The approval letter indicating ethical clearance will suffice, but the standard principles of free and voluntary consent are applied.

12. I can't find an answer to my query.

- a. Please contact the REO Director for advice.

FOR ALL DOWNLOADABLE REO FORMS, please visit <http://www.dlsu.edu.ph/offices/reo/forms.asp>

If you would like MS Word versions of the application form and checklists, please email REO@dlsu.edu.ph and someone from our office will send you copies.

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3rd Floor, Henry Sy Sr. Hall
(632) 524-4611 loc. 513
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