FAQs for the Research Ethics Review of Student Research

<u>Part 1: THE USUAL QUESTIONS</u>

1.1 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. This review focuses both on the methodology than the technical aspect 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. Most higher education institutions and non-profit organizations around the world have their own identified bodies to conduct a research ethics review. This body sometimes goes by the name of Research Ethics Review Committee, Research Ethics Review Board, Institutional Research Board, Ethics Review Committee, among others.
c. 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.
d. 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.

1.2 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.
b. Ethics reviews help assure the safety and respect of those involved and those who might be affected by the research's activities.
c. Ethics review committees provide mechanisms that help address issues and respond to unfavorable events related to safety occurring in approved studies.
d. Some grant agencies or donors require institutional ethical clearance before releasing funds to a research proponent.
e. Some national and international scholarly journals require institutional ethical clearance before accepting a research paper for publication.

1.3 I am a student currently enrolled in thesis writing/research methods class. Does my research need to be reviewed for research ethics?

a. If you are doing your thesis, you need to have your proposal reviewed for ethical review. The review will be conducted by your adviser and your thesis panel, or by your adviser alone.
b. 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*[1].

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[1] 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/*

c. The adviser and/or panel for your thesis project will be filling out the *Student Research Ethics Clearance Form*[2] indicating that the ethical issues pertinent to your research have been addressed in your study. The filled-out form is an attachment to your thesis proposal and final research report you will be submitting to the department.
d. Any research-related non-thesis project you will do for your courses (e.g. conducting interviews or undertaking a short survey) will be assessed of possible ethical considerations together with your course teacher. The ethics review here is for the purpose of educating you about the responsibilities we all need to consider in conducting our researches.
e. If your Faculty Adviser, your Department Chair, or the College Dean recommends that the ethical issues relevant to your research should be assessed carefully by an independent body other than your thesis and/or your thesis panel, they will have to send a letter to the Research Ethics Office (REO) recommending that your proposal undergo a research ethics review by the University Research Ethics Review Committee (RERC). The REO will then request you to fill out a Research Ethics Review Application Form to initiate the ethics review process. The Research Ethics Review Application which is downloadable at REO website.
f. If your thesis project is funded by an external funding agency (e.g. the CHED or DOST), you may need to have your research reviewed by the RERC. You will need to fill out the Research Ethics Review Application which is downloadable at the REO website.

1.4 My thesis/research project will employ data collection methods that involve invasive procedures (needles, blood extraction, skin sample collection), sensitive items in a questionnaire/interview (questions that ask about depression, mental health, meaning in life, homesickness, etc.), animal experiments, experiments that involve the use of toxic substances, heavy metals, and/or infectious agents. Does my thesis/research project have to undergo research ethics review by the DLSU RERC?

a. No. Even for research projects that pose minimal risk or more than minimal risk to participants, the ethics review is still done by the student's academic department.
b. However, in very special cases, if your thesis adviser/department chairperson insists that your research proposal needs to undergo an ethics review by the Univeresity Research Ethics Review Committee, your thesis adviser or department chairperson can write a formal request to the Research Ethics Office.
c. If the REO grants the request, you, the student, should submit the application form and pertinent documents needed for research ethics review. The Research Ethics Review Application Form is downloadable at the REO website.

1.5 My thesis/research project will involve data collection at other institutions (schools, universities, hospitals) and these places require some form of research ethics clearance. Where can I get this?

a. Ethics review for students is reflected in the Students Ethics Clearance Form. This is signed by the department chairperson, the student's thesis adviser, and/or the thesis panel.
b. This form can serve as an endorsement that your thesis received ethical clearance from your academic department.

[2] Students Research Ethics Clearance Form can be downloaded at *http://www.dlsu.edu.ph/offices/reo/forms.asp*

c. This form should be attached to the students' final proposal and final manuscript.

1.6 Are there documents available to help me determine the ethical issues I need to consider in my research?

a. You can start with the *University Code for the Responsible Conduct of Research*. This is downloadable from the intranet.
    - The Code contains the ethical principles all members of the University community should abide by.
    - The Code also presents you with the areas of ethical concern, explains these areas, and how ethical conduct can be done under these areas.
b. There are the *Research Ethics Checklists* you can get from the REO. These are also downloadable from the intranet.
    - The checklists provide you with the questions that alert you to the possible issues relevant to research ethics.
    - They also provide you with steps you can undertake to address these issues.
    - There are checklists for different categories of research, for example, for research involving human participants, research involving toxic substances, etc. These checklists are downloadable at the REO website.
c. Additionally, there are *research ethics guidelines* in your specific disciplines you can look up to guide you. You can get more detailed information from your teachers.
d. Finally, there are *international guidelines* that provide you with a more comprehensive understanding of research ethics. These guidelines were crafted to tackle the most significant ethical concerns for research in a period in our human history. The most prominent of these guidelines are listed below. These are all downloadable from the internet.

- The Nuremberg Code ((1947), *https://www.ushmm.org/information/exhibitions/online-exhibitions/special-focus/doctors-trial/nuremberg-code*

- The Belmont Report (1979), http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/

- International Ethical Guidelines for Biomedical Research Involving Human Subjects by the Council for International Organizations of Medical Sciences (CIOMS, 2002), *http://www.cioms.ch/publications/layout_guide2002.pdf*

- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants by the World Health Organization (WHO, 2011), *http://www.who.int/ethics/research/en/*

- National Ethical Guidelines for Health Research by the Philippine Health Research Ethics Board (2011), *http://www.ethics.healthresearch.ph/index.php/phoca-downloads/category/4-neg*

- Declaration of Helsinki (2013), *http://www.wma.net/en/20activities/10ethics/10helsinki/index.html*

1.7 What documents do I need to submit to the Research Ethics Office if my research needs to be reviewed by the University Research Ethics Review Committee?

a. Project proposal – this should include background (why are they carrying out the research, what is already known), research aims, methodology, details of recruitment (where and how).
b. Informed Consent Form for the participants (A Template for Creating an Informed Consent Form is available at the REO website.)
c. Any questionnaires/surveys that may be used in the study
d. It may also be appropriate to include:
    - Advertisement for recruitment (this could include posters, email messages intended to be sent, etc.)
    - Letters to/from other parties (government agencies, school principals)
    - Information sheet for children (simplified version)
    - Interview schedule (even if semi-structured)

1.8 If an ethics review gets elevated to the University Research Ethics Review Committee (as formally requested from the academic department), how long will the review process take?

a. Initial feedback is usually given within 7-10 working days after submission. Ethics reviews done by the Research Ethics Review Committee only begin once the researcher has submitted complete documents. After which, the documents immediately get forwarded to the reviewer. The reviewer determines provides comments that help the researcher address the ethical issues in his/her proposal.
b. On average, the overall process of receiving approval can take 2 weeks up to 1 month, depending on the ethical issues that need to be addressed in the research and the promptness of the researcher's response to the Reviewer's comments.

1.9 What should I write in the Informed Consent Form?

a. The REO has developed a Template for Creating an Informed Consent Form. It is uploaded on the Downloadable Forms section of the REO webpage.

1.10 Do the same ethics guidelines apply to both student and faculty?

a. All of the guidance applies to faculty and students. However, students cannot be named as principal or lead investigators (PI) – your mentor should be listed as the PI, but your details can be included on the paperwork. The REO will make an effort to copy you into all correspondence between your PI and the RERC and the REO.

1.11 I want to administer my questionnaires/surveys online in order to easily reach my participants and gain a wider reach of referred participants. How do I gain consent?

a. If you will be transmitting soft copies of survey questionnaires via email, we recommend that the participant sign the consent form and send you back a soft copy of the signed consent form. They may either attach an e-signature onto the form or print the consent section, sign it, and email you back the scanned copy.

b. In cases where this is not possible, such as mass data collection from participants overseas, consent is still required prior to answering the questionnaire/survey. All the key elements should be there so that the participant can make an informed decision before participating. The REO has developed a Template for Creating an Informed Consent Form, which contains the key elements that should be present in informed consent. In lieu of a signature, the consent section of an online administered form should say *"If you agree to participate and have no further questions/clarifications, please proceed to the next page to answer the survey."*

1.12 I want to collect data from a public database (public posts on Twitter, Facebook, and other social networking sites). Do I still need to gain consent from the user?

a. If these posts are considered "public" by their content providers (e.g. Facebook, Twitter). Users, by default, post public content, and will have to configure their account to make their posts private. For Twitter, public data can be automatically culled from the site. For Facebook, researchers can either (a) gather the data from their friends and all public profiles (e.g. companies, organizations) without the consent of the owner as the data is public, or (b) ask the user for access via Facebook's authentication interface like the one below:

In this case, waiving of consent is allowed under the condition that all users whose content were gathered will be anonymized and personal identifiers will be omitted (personal details include school attended, workplace, etc.).

b. However, in cases where the research involves inferring part of the user's profile (e.g. using your posts/tweets to determine your age/gender), informed consent is required. This is because the researchers will need to collect other profile information, aside from public posts. Following the example of determining your age/gender from your posts/tweets, the researchers will ask consent to gather the participant's posts/tweets and their actual age/gender (for ground-truth).

Part 2: THE COMMON PROBLEMS

2.1 What should I do if I uncover something during the course of my study that may compromise the ethical conduct of my research?

a. You should be aware in advance what problems might arise in the collection of data. For example, if you are carrying out a survey or interview about a sensitive topic, you may uncover signs of depression or anxiety. For projects of this nature, it may be advisable to issue all participants with a help sheet at the onset of the project containing contact information of professionals they can approach or contact for help, if needed. It is their choice if they wish to seek help, and who to approach. If you believe the participant is suicidal, then some form of intervention is required. The University has a number of clinical psychologists who can advise on this matter. You can consult the Chair or the Vice-Chair of the Department of Psychology about professional psychologists you can approach for some guidance.

2.2 I need to recruit a specific cohort of participants, and I know someone who has access to their contact details. Can I use this information to contact potential participants?

a. You cannot directly use a list of names of people that has been given to you unless the participants or those who have custody of the data have agreed to have their data shared in this way. For example, you need to use the GPA of students as data for your study. You will have to request permission to use these data from the University Registrar, who has custody of the data.

2.3 Do I need to gain written consent (adults)?

a. In most cases written consent should be obtained. This is to protect the researcher and the University. However, there are some cases where consent may not be needed. If you are issuing an anonymous survey, then you may be able to assume consent be completion of the questionnaire. This should be stated in the information given to participants before they complete the questionnaire (e.g. “consent to take part in this research project is assumed by completion of this questionnaire”). However, if there may be a need to contact the participant again (perhaps because the results have shown a medical problem or possible signs of abuse) then you will need to obtain consent, but could use ***keyed anonymity.*** This is where the questionnaire is labelled with a number, and a file containing who that number relates to is kept separately. If you want to give people the option of withdrawing their answers from a project, then you will also need to have a way to identify which questionnaire is theirs.
b. If your participants are illiterate, obtaining consent can be difficult. An Information Sheet should be read aloud to them and they should be given the chance to ask questions. A consent form can also be read out to them, the researcher can complete their name for them, and they can indicate their consent with a cross or a thumb print. If your research is taking place in a country that has political sensitivities and participants will be reluctant to sign any documentation, then please speak to the REO for advice.

2.4 Do I need to gain written consent (children)?

a. If the child is fairly young, then consent will need to be gained from a parent or guardian. Children should be given a simplified Information Sheet, perhaps with pictures if appropriate, and should be involved in an assent process. The research should be explained to them and they should be given the choice not to take part or to stop at any time.
b. If you are doing research with teenagers (younger than 18 years), then you may also want to consider consent from both teenager and parent/guardian. If your research is invasive, consent should be obtained from both; however, if you are issuing a simple survey asking teenagers about their progression routes, it is probably sufficient to gain consent from the teenager only. Be careful if your cohort is older teenagers – this age group in particular may take affront to having to get parental consent to take part in a research study. Please consult the REO when such situations apply.

2.5 What about deception?

a. If your research involves not revealing to your participants the true nature or objectives of the research, then your research will be considered as involving procedures posing more than minimal risk. 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" (Code of Federal Regulations, 2009)[3]
b. Where possible, information sheets should give all details upfront. However, there are occasions where a level of deception can be acceptable (in order not to bias the results of the research). Whether this level of deception is acceptable is the decision of your Thesis Panel or the Departmental Research Ethics Committee (if there is one in your Department), or the University Research Ethics Review Committee. Projects with a level of deception should include a debrief sheet or similar in order to inform people after data collection what the deception was and why it was necessary. You need to inform the participants that they may choose to have data provided by them removed if they were not in favor of having been deceived.

2.6 I am conducting a study that involves usability tests and this requires that the sample users test out the software/program/product before it is released. This is a standard practice in my field. Do I still need to gain the consent of the users? *Usability tests normally include gathering the following:*

- amount of time it took the user to complete a task on the software
- satisfaction of the user when performing a task
- probability that the user will continue using the software
- actions the user took to complete a task
- feedback/suggestion for improvements on the software

[3] *Federal regulation definition of minimal risk used across almost all international guidelines Basic Health and Human Services Policy for Protection of Human Research Subjects, 46 CFR §.102 (2009)*

a. Yes, consent from the users is still needed. A detailed and comprehensive explanation should be given before the participant uses the software/program/product. Whether you choose to attain written, recorded, verbal, or online consent, there are certain key elements that any participant must be informed of prior to participating in any kind of study. The REO has developed a Template for Creating an Informed Consent Form containing these key elements.

2.7 At what point in the thesis process should the Students' Ethics Clearance Form be signed by my mentor and/or the thesis panel members?

a. The review of ethical issues should be a precursor to the approval of the research proposal and the final manuscript. This can be done during the proposal defense, during the final defense, or the academic department/thesis panel can have a separate meeting for this (the practices vary among the different academic departments).
b. Before a student is given approval to collect data, and before a student is given a final grade for their research project, they should have been granted ethical clearance as reflected in the Students' Ethics Clearance Form. The Students' Ethics Clearance form should be attached to the Appendix section of the proposal and final manuscript.

2.8 How should I attach the ethics clearance for to my thesis proposal and my completed thesis once it has been signed by my mentor and/or the thesis panel members?

a. The Students Ethics Clearance form should be attached in the Appendix section of the submitted thesis proposal and completed thesis.

2.9 Do all student theses and thesis proposals have to be reviewed for ethics?

a. Yes. However, the departments are given enough time to fully implement the ethics clearance procedure for undergraduate and graduate student theses.

Part 3. OBTAINING ETHICAL CLEARANCE AT THE ACADEMIC DEPARTMENT

NOTE: As a standard rule, ethical review of all student theses and research projects will be conducted by the students' respective academic departments. In special cases where the academic department feels that ethical expertise is needed to examine the issues in the research, the department can formally request the Research Ethics Review Committee (through the Research Ethics Office) to conduct a review of the proposal. In which case, approval from the RERC is required prior to any data collection.

3.1 Who conducts the ethics review for students' thesis?

Ethics reviewers can vary for each department. Some departments delegate this task to the thesis panel, where ethical issues are discussed during the student's proposal/final defense. In which case, the thesis panel chair/members are asked to sign the Student's Research Ethics Clearance Form. Other departments delegate this task to the thesis adviser, where the adviser discussed ethical issues involved in the paper educates the student by providing ways in which these issues can be addressed. **We encourage you to consult with your department's thesis coordinator on the appropriate time to submit the necessary forms.**

3.2 Do coursework requirements involving research projects/activities require a Student's Ethics Clearance Form?

The coursework professor discusses ethical issues related of the project with the students. If you wish, you may refer to the research ethics checklists at http://www.dlsu.edu.ph/offices/reo/forms.asp and other research ethics materials online. No clearance form is required to be submitted to the REO.

3.3 What do I need to submit to my academic department?

Students are to append a copy of the filled out and signed Students' Research Ethics Clearance Form to the approved thesis proposal and the final thesis report, and whatever other documents the department requires. In addition, students are also to submit a scanned version of the filled out and signed Students' Research Ethics Clearance Form with the file name in the format below (see STEP 3 of the PROCEDURE) to the academic department.

PROCEDURE:

STEP 1: During the thesis proposal writing stage, engage in a discussion with your thesis mentor regarding the ethical issues that could arise in your research. The REO has ethics checklists that can guide faculty and students in identifying what ethical issues may be present in the study. It also provides recommended actions that help address the issues.

STEP 2: Append the signed Students Research Ethics Clearance form to the approved thesis proposal and the approved completed thesis report when you submit your thesis to your academic department.

STEP 3: Scan a copy of the signed Student's Research Ethics Clearance Form and submit to your academic department with the filename in the format below:

1. For approved thesis proposal students research ethics clearance forms:
   Surname.STUD.ProgramCode.THProposal.Term.AcademicYear
   For example: Albaniel.STUD.AB-PSM.THProposal.T3.AY2015-2016

2. For completed thesis students research ethics clearance forms:
   Surname.STUD.ProgramCode.THComplete.Term.AcademicYear
   For example: Albaniel.STUD.AB-PSM.THComplete.T1.AY2016-2017

If including all surnames makes the filename too long, you 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

What is important is that all names of students appear on the actual document when the file is opened.

It is the student's responsibility to submit the scanned version of the signed Student's Research Ethics Clearance Form in the file name format above to the academic department.

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

Please contact the REO Director at local 513 or at email REO@dlsu.edu.ph for advice.