

Research Ethics Office

Research Ethics Review Process

Background

- In line with its goal of becoming a **leading learner-centered and research university**, De La Salle University has, since 2008, established an ethical review mechanism guided by the **DLSU Code for the Responsible Conduct of Research**.
- Ethics review procedures were implemented and **checklists for different research categories** were used.
- **College Research Ethics Committees (RECs)** were constituted to conduct the ethical review of faculty researches.
- Since 2011, **expedited and full ethics reviews** were carried out for research proposals of faculty members.

The Rationale for an Institutional Ethical Review System/Mechanism

- International guidelines prescribe independent ethics committee review for research
- The performance of an ethical review is essential for publication
- External funding institutions require the conduct of ethical reviews on proposals.
- Demonstrates our concern for the consequences of our research on society and on the environment
- A governance structure will provide the needed guidance to address these emerging concerns regarding the effects of globalization on research.

DLSU Research Ethics Office (DLSU-REO)

- Mandated to develop, implement and evaluate policy and procedures related to the **research governance** in De La Salle University
- Has the specific responsibility to ensure the high **quality of research output** and that research in the University **adheres to international and disciplinary ethical standards.**

Step 1:

Submission of Documents to REO

Proponents are requested to submit **soft copies** of the following:

- ✓ Proposal
- ✓ Accomplished General Checklist
- ✓ Accomplished Specific Checklists (human participants, animal subjects, wildlife, infections agents, and toxic substances)
- ✓ Other pertinent attachments (consent/assent forms, data-gathering instruments, procedures for chemical waste disposal etc.)
- ✓ Accomplished Research Ethics Review application form (only proposals that will be submitted for external funding, for non-DLSU researchers, for student proposals seeking REC review, for DLSU researchers not availing of URCO support)

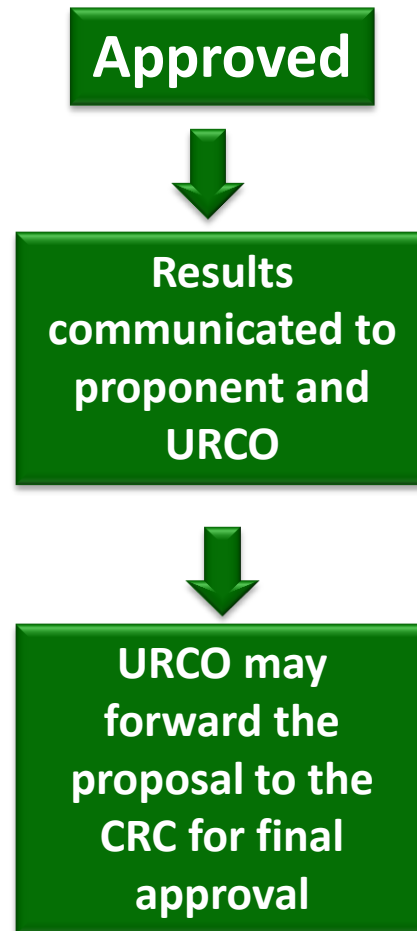
The REO will only forward the documents to the RASD once they are complete.

Step 2: Initial Review

The college RASD (or an REC representative in cases with conflict of interest issues) and the REO Director will review the documents submitted and will determine the type of review required.

Type of Review	Persons Involved	Possible Outcomes
Exempted	RASD and REO Director	<input type="checkbox"/> Approved
Expedited Review	RASD and REO Director	<input type="checkbox"/> Approved <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Resubmit Proposal
Full Review	Research Ethics Council	<input type="checkbox"/> Approved <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Disapprove

Exempted Reviews



Expedited Reviews

Approved



**Results
communicated to
proponent and
URCO**



**URCO may
forward the
proposal to the
CRC for final
approval**

**Conditionally
Approved**



**RASD and REO Director
asks questions/requests
for missing documents**



**Adequate response
provided by proponent
and requested documents
are submitted**



Approved

**Resubmit proposal
because substantial
revisions are required**



**RASD and REO Director
provides a rationale for this
decision and they also
provide
comments/suggestions to
the proponent**



Return to STEP 1
(submission of documents)

Approved

Full Reviews

REC is convened

Approved

REC transforms
into CRC to
approve the
proposal for
funding

Results are
communicated to
the proponent.

Conditionally
Approved

REC asks
questions/requests for
missing documents

Adequate response
provided by proponent
and requested documents
are submitted

Approved

Areas of the study are deemed
unethical and the ethical Issue
cannot be resolved.

Disapprove

REC provides a rationale for this
decision and they also provide
comments/suggestions

Results are communicated
to proponent

Proponent
may revise
and resubmit
(STEP 1)

Proponent
may appeal

Research subjected to Review

- Proposals submitted for University grants (i.e., **URCO grants or Challenge grants**)
- Proposals submitted for **external grants managed by Research Centers**

Applications for review

- **Non-DLSU** faculty members or students
- Principal research investigators who are **not affiliated with the University** and who wish to conduct studies that involve the collection of data with University faculty, administrative staff, or students as participants
- **Student researchers who need to have an ethics review** done by the REC on their project proposals
- **Faculty whose researches will not be funded** through University or external grants and who intend to publish their researches.

Types of Reviews

Exempted Reviews

- Projects which involve the collection data from **public available databases** or public documents are **exempted from review**.

Expedited Reviews

Projects qualifying for expedited review are those that involve:

- ✓ Research involving **minor changes** in previously approved research projects
- ✓ Research involving analysis of information **without interaction** with subjects

Expedited Reviews

Projects qualifying for expedited review are those that involve:

- ✓ 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

Full Reviews

- Research projects which pose a more than “minimal risk” to research participants or subjects are subjected to a full review by the REC.
- 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*” (U.S. Department of Health and Human Services, 1994, p.6, as cited by Hadjistavropoulos, & Smythe, 2001).

Full Reviews

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

Full Reviews

Projects that require a full review are those that involve:

- ✓ 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

Student Research

- The ethics review of student projects are **conducted by the research ethics committees of academic departments.**
- Ethics review is undertaken for the **purpose of educating students** in research approaches and methodologies, and on the scientific and ethical principles of research (WHO, 2000)
- **Academic departments provide students with instruction on the ethical principles and guidelines** in methods courses. Instruction is based on the University Code for the Responsible Conduct of Research and guidelines which apply to research conducted in their disciplines.

Thank you!