



INSTITUTIONAL REVIEW BOARD APPLICATION REVIEW PROCESS

Purpose

In accordance with the College's [Institutional Review Board Charter](#), the Institutional Review Board (IRB) ensures the protection and welfare of human subjects involved in research supported by, conducted at, or associated with the College. Specifically, the IRB (1) ensures all human subject research conducted at the College is administered in accordance with federal regulations and the College's established human subject research procedures and guidelines; (2) reviews and approves proposals for research involving human subjects supported by, conducted at, or associated with the College; (3) confirms that the required elements of informed consent are included in research proposals; (4) conducts continuing review of all approved research at least once annually; and (5) maintains a master list of all open research projects.

Guidelines and Procedures

- 1) [Delgado Institutional Review Board \(IRB\)](#) approval is required before human subject research can begin, including approval for participant recruitment.
- 2) The Delgado IRB does not have the authority to grant access to student records or personal student information, and therefore, IRB approval does not obligate the College or its employees to release such information to the researcher.
- 3) Applications should be submitted to the [current IRB Chair](#) at least four (4) weeks before the end of the fall or spring semesters only; generally, applications will not be accepted between semesters or during the summer session. Applicants should expect the approval process to take at least one month from the date the completed application is submitted.
- 4) Applicants doing research as a requirement of a graduate program must submit IRB full approval, without conditions, from the college/university with which they are affiliated, in order for their application to be reviewed by the Delgado IRB.
- 5) Studies that are determined by the Chair to require review by the full IRB will be reviewed by all members of the IRB. The majority of IRB members must approve the research before final approval of the research is granted. The Primary Investigator of the study may be required to meet with the IRB.
- 6) Studies that qualify for approval under expedited review are thoroughly reviewed by *either* the IRB Chair and two other IRB members *or* three experienced IRB members designated by the Chair. See "*Expedited Review*" Section for specific procedures.
- 7) Researchers are required to notify the IRB Chair in writing when the research has been completed. Any research that continues beyond one year since original approval must be resubmitted for approval before the end of each year.

Application for Research

The following must be included in the Research Application:

A. Face page -

1. Title of Research Study
2. Principal Investigator with Contact Information
3. Co-Investigators with Contact Information, if applicable
4. Name of Faculty Advisor, if applicable

B. Full IRB Approval without Conditions from University/College -

(For Applicants Doing Research as a Requirement of a Graduate Program only)

C. Project Description -

1. Brief description of the purpose, background, and methodological design of the study
2. Estimate of how much time will be requested of each participant
3. Description of inclusion and exclusion criteria for subjects
4. Description of instances in which confidentiality will or may be broken

D. Data Collection -

1. Description of the setting or location where the research will be conducted
2. If applicable, attach letters of support or agreement showing permission to conduct research at this location
3. Copies of all surveys, instruments or measures, questionnaires, interview schedules, focus group questions, screening questions or other materials used to collect data as applicable

E. Risks to Participants -

1. Description of any potential benefits for participating (including incentives of any type)
2. Description of steps to be taken if the participant becomes upset or distressed as a result of his/her participation in the research
3. Description of any potential risks to the participants as a result of participation in the research

F. Informed Consent -

Include all forms used to document informed consent and agreement to participate in research

G. Advertisements/Recruitment Letter(s)/Telephone Scripts/Instructions to Participants

Include copies of any of these listed above, if applicable

H. Debriefing Script

(Applicable if Deception is Used)

I. Copy of [NIH Office of Extramural Research](#) Online Human Subjects Certification

J. Reporting Requirements

Include signed statement that the Principal Investigator will: 1) report to the IRB Chair in writing when the research has been completed and 2) resubmit for approval any research that continues beyond one year since original approval before the end of each year

K. Funding Source

Description of any potential financial or professional interest by a funding source in the outcome of the research

Expedited Review Procedure

The College may use the expedited review procedure to approve certain protocols that involve no more than minimal risk to the human subjects and the only involvement of the subjects will be in one or more of the following categories:

1. The study of existing data, documents, or records; and/or
2. Research on individual or group behavior or characteristics of individuals where the research investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

Studies that qualify for approval under expedited review are thoroughly reviewed by *either* the IRB Chair and two other IRB members *or* three experienced IRB members designated by the Chair to conduct the review. The IRB members conducting the expedited review may exercise all of the authorities of the IRB except to disapprove the research. As deemed necessary, the reviewers may refer any study to the full IRB for review. The reviewers may also refer other research protocols to the full IRB whenever the reviewers believe a full IRB review is warranted.

When the expedited review procedures are used, the IRB Chair or members conducting the review shall inform IRB members of studies that have been approved under the provisions of the expedited review procedure. Any member may request that a study that has been approved through the expedited procedure be reviewed by the entire IRB. A vote of the members will be taken concerning the request, and the majority will decide the issue.

Reference:

Policy and Procedures Memorandum, [Charter: Institutional Review Board](#)

Policy Review and Approval:

Institutional Review Board 5/7/14

Academic Affairs Council 11/6/14

Procedural Update - Vice Chancellor for Academic Affairs Approval 12/1/16