

Educational Research Requests at

Laredo College

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# Overview of Process and Documents for Research Requests

1. Research is being conducted if the following is being done:
	1. Is data being collected?
	2. Is the data going to be used for generalizable knowledge (e.g., presentations, publications)?
		1. As defined by Code 45 CFR 46.102f, research is gathering information or data to draw generalizable conclusions or to add to the body of knowledge. Research adds to the body of knowledge if it is shared publicly such as conference presentations or other publications.
	3. Is the data about living people?
		1. As defined by Code 45 CFR 46.102d, a human subject is a living individual about whom data is obtained either through interaction or by way of identifiable private information. If data is gathered from or about live people, it is considered human subjects research. Data is not considered human subjects research if gathering data from people who are deceased or by way of secondary data.

## Required Documents:

All required forms should be submitted to the Institutional Effectiveness and Assessment Office for review by the Research Review Committee.

1. Include copy of approved request from the requesting institution’s review board.
2. Certificate of Completion for the NIH or CITI training course on Protecting Human Research Participants.
3. Include a copy of the instrument/questions and procedures to be used for data collection, based on type of research being conducted (e.g., Survey, Interview, Observation, Case study, etc.)

NOTE: All forms are expected to be developed in a professional manner. Application or revision will be due on the first of the month for consideration in that month’s meeting. Applications or revision received after the first of the month will be considered at the next month’s meeting. The Research Review Committee has the authority to audit the research study. Continued approval of the study is based on compliance with the established criteria.

# Approval Process

The Research Review Committee will convene monthly on the first Tuesday of the month to review submitted applications. Only complete applications will be reviewed.

Committee

* Reviews applications
* Meets as scheduled to discuss submitted requests.
* Approves or denies requests.

If approved by committee

* Committee Chair will inform the researcher to proceed.

If not approved by committee

* Request will be returned with comments to the researcher for review and re-submittal by the first of the next month. The revised request will be reviewed at the next monthly meeting.

# Institutional Review Board (IRB) Research Categories

The Research Review Committee has jurisdiction over all research conducted at Laredo College. The [Federal Policy for the Protection of Human Subjects (Common Rule)](http://www.hhs.gov/ohrp/humansubjects/commonrule/) defines research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

The Research Review Committee reviews and approves research under three distinctive categories specified Exempt, Expedited, and Full Review.

## Exempt Research Review

Exemptions can be granted for very low risk studies.  **If you believe that you might qualify for an exemption, you must still complete the standard IRB application and request the exemption.** Failure to request the exemption, even if it turns out that you are entitled to the exemption, would be considered noncompliance. No data collection can begin until the Research Review Committee officially grants the exemption.

The [Code of Federal Regulations (45 CFR 46.101 b)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101%28b%29) sets out the following situations where research may be exempted from regular IRB review:

**Categories for Exempt Review**

1. Research will be conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless the subjects can be identified directly or through identifiers linked to the subjects and disclosure of responses could reasonably place the subjects at risk or criminal or civil liability or be damaging to the subjects’ financial standing, employability or reputation.
3. Research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under item (2) above, if (a) the subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) that the confidentiality or other personally identifiable information will be maintained throughout the research and thereafter.
4. Research will involve the collection or study of existing data, documents, records, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of federal agency sponsoring the research, and which are designed to study, evaluate or otherwise examine (a) public benefit or service programs, (b) procedures for obtaining benefits or services under those programs, (c) possible changes in or alternatives to those programs or procedures, or (d) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed, or if (b) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

## Expedited Research Review

If you do not qualify for an exemption, it may still be possible to have your review expedited. It is important to note that the standard for expedited review and the materials that you will submit are the same as for regular review.

Expedited review is available for studies that involve minimal risk meaning that 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 or psychological examinations or tests. Categories for expedited review include:

1. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
2. Collection of data from voice, video, digital, or image recordings made for research purposes.
3. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language communication, cultural beliefs or practices, social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

## Full Research Review

Research protocols that are not eligible for either an exemption or expedited review will be placed on the agenda for the next convened meeting of the Research Review Committee. A quorum of committee members must be present in order for the committee to vote. All committee members review each request placed on the agenda for the convened meeting unless a member has a conflict of interest. The committee then discusses the protocol and votes for approval, modification, deferral pending the receipt of additional information, or disapproval.

NOTE: This list is not exhaustive. The final decision as to whether an application is reviewed by the Research Review Committee at a convened meeting is that of the Committee chair and/or the Committee membership.

## Definitions

**Minimal Risk**

Minimal risk means that the probability and magnitude of the 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 or psychological examinations or tests.

**Vulnerable Populations**

Individuals whose willingness to volunteer in a study or clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces (i.e., ROTC or Corps of Cadets), and persons kept in prison or detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

# Application for Review of Research Requests

## Part I: General Information

Please note that college resources cannot be used for independent research without prior approval through the Research Review Committee. Approval to conduct education research of students or staff data requires prior consent to the following conditions:

* The proposed research will not violate the individual’s confidentiality of personal information on file with Laredo College. Information gathered on study subjects will not be released in personally identifiable form.
* Students or staff participation in survey research is voluntary.
* An employee of Laredo College acting as an independent researcher will conduct all research activities through a personal email account.
* The proposed research will not interfere with assigned personnel job responsibilities.
* Research reports prepared for publication will be previewed by the Institutional Research and Planning Department prior to submission to verify accuracy of information about the institution.
* A copy of the final report will be submitted to the Research Review Committee and the Institutional Research and Planning Department.
* The proposed research will be coordinated through the Research Review Committee. The Research Review Committee has the authority to audit the research study. Continued approval of the study is based on compliance with the established criteria.

## Part II: Researcher Information

After the form is completed, please save it to your computer and send it as an attachment to the following e-mail address: irb@laredo.edu.

|  |  |
| --- | --- |
| Researcher Name:  |  |
|  |  |
| Researcher Email:  |  |
|  |  |
| Institutional Affiliation: |  |
|  |  |
| Liaison Name: |  |
|  |  |
| Liaison Address: |  |
|  |  |
| Liaison Phone: |  |
|  |  |
| Liaison Email: |  |
|  |  |
| Project Title: |  |
|  |  |
| Duration of Project: |  |
|  |  |
| Start Date: |  |
|  |  |
| End Date: |  |

## Part III: Purpose of Research:

[ ] To fulfill requirements related to courses/degree program at a college/university

[ ] Course project

[ ] Thesis (attach Summary of Proposal made to institution)

[ ] Dissertation (attach Summary of Proposal made to institution)

[ ] Other

[ ] As part of externally funded project. Funding Agency:

[ ] Other Please describe:

## Part IV: Elements of the Proposed Study

Answer the questions below:

1. In 1-2 pages, summarize the proposed research project (provide statement of the problem and purpose of the study).

Please provide answers to the following items. Indicate “none” or “Not applicable” as appropriate.

1. Why are you interested in using Laredo College (LC) as a basis for your research?
2. What benefits are expected to be gained from conducting this study?
3. During the course of the study, how will it be made clear that LC’s involvement does not imply endorsement of the project?
4. Will you be requesting access to any existing LC data or resources? If so, please identify.
5. How will you maintain confidentiality of any individually identifiable data to which you have access regardless of methods used to obtain information? Describe where and how long the data files will be maintained (including storage and coding of records).
6. How will individually identifiable data collected be protected after your research is completed?
7. Explain how research findings will be used.
8. Explain how the results of this research will be disseminated.
9. Will Laredo College or its employees be identified during the dissemination process of the research results? If so, how will this be accomplished?

If the Research involves human subjects, including surveys, please answer the following:

1. Provide copies of any survey instruments or questions to be asked as part of interview process.
2. Describe the characteristics of the sample population including the sample size, ethnic background, sex, age, and/or state of health.
3. Provide step by step procedures for selecting subjects.
4. Are there risks such as risk of criminal or civil liability, damage to employability or to financial standing, or undue embarrassment, associated with participating in research project to which subjects may be exposed?
	1. If so, provide a description of safeguards to counter these risks.
	2. How will the subjects be informed of the risks to which they will be subjected?
	3. Will all subjects be free to withdraw at any time without penalty?
5. How will Informed Consent be obtained? Provide a copy of the document to be used.
6. In which office (Liaison’s name, campus building and room number) or format will the Informed Consent forms be kept?
7. If deception is involved, explain why it is necessary and how subjects will be debriefed.
8. Will participants receive any compensation (monetary, course credit) for their participation? If students are to receive any form of course credit, explain the opportunities non-participants will be afforded.

I certify that the research procedures used in this project and the method of consent (if any) will be followed as approved by the Research Review Committee. Any future changes will be submitted for review and approval prior to implementation.

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Researcher Signature Date

*DISCLAIMER: The Research Review Committee reserves the right to request additional information or clarification throughout the review process including but not limited to copies of all recruiting materials, data collection instruments, informed consent forms, and any other information related to conducting the study at the site.*

# Action Taken by Research Review Committee

**Name of person making research request:**

Project Title:

**Are rights and welfare of subjects adequately protected?**

[ ]  YES [ ]  NO [ ]  N/A

## Recommendation

[ ]  Approved (as indicated below):

[ ]  Exempt

[ ]  Expedited

[ ]  Full Review

[ ]  Defer pending further revisions (See below)

[ ]  Not Approved (See below)

Signature of Review Committee Chair: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Summary of Issues and/or Resolutions To Be Addressed By Researcher:

**Informed Consent issues:**

Questionnaire/survey issues:

Protocol application issues: