FREQUENTLY ASKED QUESTIONS ABOUT THE UNIVERSITY OF REDLANDS IRB

1. What is the IRB?

IRB is the acronym for Institutional Review Board for Human Participants. Any institution that receives federal funding to conduct research with human participants is required to establish an IRB to review all research that directly or indirectly involves human participants, and to set forth institutional policy governing such research. The University of Redlands IRB operates under a charge.

The IRB has the responsibility to review, approve, disapprove or require changes in research or related activities involving human participants. Research reviewed by the IRB may also be subject to other review and approval or disapproval by officials at the University of Redlands, such as the Provost. However, those officials may not approve research that has not been approved by the IRB. The IRB primary role is to ensure the protection of human participants as subjects of research.

2. Who makes up the IRB?

The IRB is a board appointed by President of the University of Redlands.
The composition consists of representatives from the natural sciences, social sciences, humanities, School of Business, School of Education, an at large position, and the broader Redlands community. This last member cannot be affiliated with the University of Redlands --meaning that s/he does not work at the University or have any immediate family member who currently attends or works at the University.

3. How do I know if I am conducting research with human participants?

According to IRB Policy, research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Activities which meet this definition constitute research for this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human subjects are "living individuals about whom an investigator (whether professional or student) conducting research obtains:

- data through intervention or interaction with the individual,
- identifiable private information."

Intervention includes both physical procedures by which data are gathered (e.g., hormone assay) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g., providing stimuli to gauge reaction and response).

Interaction includes communication or interpersonal contact between investigator and subject (for example, surveys and interviews).

Private information includes

- information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and
- information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

If you are unsure if your project involves research with human subjects, please consult with IRB members who can provide guidance in making this determination.

4. When am I required to submit a proposal involving research with human participants to the IRB?

All research projects that will involve human participants must be submitted for review and approval before beginning the study, even if you believe it might be exempt. This includes proposed research involving existing data and previously collected human fluid and tissue samples, as well as any advertising or other recruitment procedures.

5. I am just doing a simple survey; do I need to submit my proposal to the IRB?

Yes, if the study meets the definition for research with human participants, as explained above. The University of Redlands' Federal Wide Assurance (FWA) with the U.S. Department of Health and Human Services states that all research being conducted under the auspices of this institution is subject to review and approval by the IRB. Written approval from the IRB must be in place before any interventions or interactions with human participants (e.g., recruitment) actually begin.

6. I am not collecting any identifying information in my human participant research project. Do I need to submit my proposal to the IRB for review?

Yes, if your research project involves active data collection. Federal regulations and University of Redlands policy require that **ALL** research involving intervention or interaction with human participants, regardless of whether or not identifying information is being collected, must be submitted for review prior to beginning the research study.

7. Do research projects conducted by Redlands students need IRB approval?

Yes. Projects conducted by Redlands undergraduate and graduate students need IRB approval, if the project fits the definitions of "research" and "human participants" as described above. If the project is to be used in classroom setting only to teach research methods, the project may be submitted under the Course Research umbrella with its shorter form (see the IRB website to download the IRB Application for Course Projects form). However, this means that at no point during or after the conclusion of the course can the results or the data be used for publication, presentation or other research purposes. Therefore, students should discuss these limitations with their instructor or faculty advisor so that they can determine whether IRB review is necessary.

8. If I have students doing research as part of a course project, do I need to complete IRB forms and if so, which ones?

Yes, research done as part of a class still requires IRB review. There is a specific form for courses that include research on the IRB website. If you have questions about completing it, please contact the IRB chair as indicated on the IRB website.

9. What is meant by "exempt" protocol? What are the requirements?

Under certain circumstances, human participant research activities may be granted exempt status. Technically, exemption means that all the research activities fall under one or more of the exemption categories specified by the federal regulations.

The significance of exempt status is that the research activity is not monitored by the IRB. Assuming the project does not change, it also is not subject to continuing IRB oversight. Exempt status does not, however, lessen the ethical obligations to subjects as articulated in the Belmont Report and in disciplinary codes of professional conduct. Thus, investigators performing exempt studies still need to make provisions to obtain informed consent, protect confidentiality, minimize risks, and address problems or complaints.

In order to have a research project recognized as exempt, investigators will need to submit their IRB application, along with other study related materials (e.g., consent forms, surveys, questionnaires, interview scripts/outlines, etc.) to the IRB chair. If the project is eligible, the chair will contact investigators with the appropriate documentation.

Please note that for each change that is proposed or occurs during the execution of the research activity, the investigator may need to consult with the IRB to determine if the change affects the eligibility of the research activity to continue to be exempt from IRB review and approval.

10. If my research qualifies as exempt, does this mean that I don't have to submit a protocol for review?

No. The Federal Regulations do make certain categories of research exempt from IRB review. However, University of Redlands policy does not allow investigators to self-exempt their human participant research projects. Instead, determining if a project is exempt from IRB review is an administrative review process handled by the IRB.

11. I will be collaborating with another institution. Do I need to submit to Redlands' IRB and the other institution?

If you are a member of the University of Redlands faculty or staff, or student, and you are the person responsible for the conduct of the study (PI), you must get Redlands IRB approval to conduct your research regardless of where the research takes place. Investigators should contact the IRB office whenever collaborative research is occurring. Separate applications for each institution may be necessary; **however**, in order to avoid duplicate review, an IRB Authorization Agreement may be arranged with the other institution to establish one IRB as the designated IRB to review and approve the research. If it has already been approved at another university and you are going to collect data here, please submit your application as an expedited review with the other institutions FWA number included.

12. My research will be conducted in another country. Do I have to obtain IRB review and approval from Redlands?

Yes. If you are a member of the University of Redlands faculty or staff, or a student, and you are the person responsible for the conduct of the study (PI), you must get Redlands IRB approval to conduct your research regardless of where the research takes place. You should also be aware that your project may need local IRB approval (or the equivalent ethical review) in addition to ours.

13. How long will it take for me to obtain approval to do my study?

That depends on the nature of your study and the characteristics of the people you intend to recruit. Research projects that involve only minimal risks are eligible for expedited review, for which you should allow at least 3 weeks. However, many if not most projects involve more than minimal risk (and amount of risk is determined by the chair of the IRB, not the investigator).

Research projects that involve greater than minimal risk to participants will need to go to the full board for review, which is scheduled for the third Friday of every month (excepting June/July/August). For applications requiring full board review. The IRB needs completed applications at least 1 week in advance of a meeting. Applicants are notified by email of the

outcome of the IRB's decision within 1 week after the IRB meets, often sooner. If you do not hear back from the IRB within a week after we meet, then you should assume that we never received your application. A rough estimate for a majority of applications is 6-8 weeks from completed draft to approved project. Do not forget to give your supervisor time to read your application and provide feedback before submitting it.

14. Can the IRB approve a project "retroactively?"

No. There is no provision in the federal regulations that allow for IRB approval of research that has already been conducted. If data was collected for purposes that the IRB determines to be non-research (e.g., program evaluations for library or educational programs not initially intended to be used for research), IRB approval can be sought for the data analysis going forward.

15. Who can I talk to if I have a question about my research project involving human participants?

The IRB chair, currently Catherine Salmon (Catherine_salmon@redlands.edu) is able to answer questions with regard to your project and IRB review. You can also explore the IRB website for detailed information about the IRB Standard Operating Procedures, policies and procedures (in the IRB manual), application forms, templates, sample applications, CITI Training, meeting schedule and other important information.

16. Where can I download application forms and guidelines?

Log-in and then navigate through the myRedlands portal (documents and forms -> miscellaneous -> Institutional Review Board) or log-in directly at http://sites.redlands.edu/irb

- Note that you are also required to take the CITI on-line training https://www.citiprogram.org before conducting research on human subjects. Go to the website, there is a link to it on the main IRB page, and register. Completion of the CITI Collaborative Institutional Training Initiative modules must be completed and a copy of the certificates attached to your completed IRB application.

17. What CITI modules do I need to complete?

Researchers (and their supervisors and/or anyone else who may have access to the data, if applicable) need to complete the Investigators - Human Subjects basic course module and the Social and Behavioral Responsible Conduct of Research basic course module.

18. How many copies of completed applications are required?

One electronic copy submitted as an email attachment to catherine_salmon@redlands.edu and a single, signed, hard copy of all materials sent to Catherine Salmon, Department of Psychology (Larsen Hall 135).

19. What are the most common reasons for not approving an application?

Applicants fail to provide information, such as a signed letter of Agreement from a gatekeeper, that they have permission to recruit participants in the manner they describe. For example, if you plan to recruit students from the University's dorms or the library, then you need a signed letter of agreement from Student Life stating that you can recruit participants in the manner you describe. Or, if you plan to use students who are attending a local school, then you need permission from the school principal and/or school district supervisor stating that you can recruit the students in your project. Different organizations will have different authority figures who are responsible for giving a researcher permission to recruit participants at a particular site. Gatekeeper letters need to be included with applications submitted to the IRB. If you are unsure from whom you need to obtain permission, ask your faculty sponsor or email the Chair of the IRB.

The application is incomplete. Please answer all questions.

Questionnaires, surveys, or sample interview questions were not included with the application. Please include these materials.

Applicants have not made a compelling case for their research project. Do not resort to hyperbole (e.g., "My goal is to invalidate the SAT using 5 volunteers from the University of Redlands"). Be honest about what you can accomplish with your project. In many cases, it may be nothing more than replicating a study to see whether you can get the same result. This is the same reason, for example, why students in biology, chemistry, and physics have lab components for their courses. Students in courses with labs are not trying to discover something new; they are trying to learn basic lab skills.

The project has no chance whatsoever of meeting its stated objective. The University of Redlands' guidelines state that the IRB cannot approve a project that is a waste of participants' time. A project that is overtly flawed that it cannot achieve its objective is a project that will waste participants' time. Projects of this sort are misleading (because they cannot achieve their objective) and thus unethical.

The IRB cannot approve that which we cannot understand. Write for a lay audience. At best, one member of the IRB might be familiar with your discipline and its jargon. Assume that the

members of the IRB are educated, but not steeped in the traditions and vocabulary of your discipline. Explain things clearly in everyday language.

20. I need my application evaluated over the summer. How does the IRB handle applications submitted during June, July, and August?

Follow the same procedure as during the traditional academic calendar. If your project meets the criteria for expedited review, the IRB chair will handle it. But be aware that the wait time may be longer.