UNIVERSITY OF REDLANDS
INSTITUTIONAL REVIEW BOARD MANUAL

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1. INTRODUCTION

These policies and procedures have been developed to provide the University of Redlands research community with an overview of the federal regulations and institutional policies governing the use of human subjects in research.

Research involving human participants conducted within the University of Redlands community will:

- Safeguard the rights and welfare of research participants.
- Be consistent with the teaching and mission of the University.
- Obey laws and regulations as set forth in: *Federal Policy for Protection of Human Subjects* (known as the "Common Rule; 45 CFR 46, Subpart A).[1]

This policy applies to all research involving human subjects, including non-funded and funded research, regardless of the source of any funding.

This policy and these procedures shall be operative as of the date they are approved by a quorum of the Redlands IRB and shall be reviewed and revised as necessary by the IRB Administrative Coordinator (see Section 7). Revisions in statement of policy require approval of the University of Redlands institutional official.

2. INSTITUTIONAL REVIEW BOARD

2.1 PURPOSE OF THE INSTITUTIONAL REVIEW BOARD

The University of Redlands institutional review board is charged with the responsibility of determining:

1. Whether human subjects have volunteered for a research endeavor by means of informed consent, and;
2. Whether risks to these subjects are outweighed by potential benefits to them, and importance of the knowledge to be gained by the research.

In considering ethical issues and government guidelines, the evaluation of risk involves estimating the potential for injury to the subject by reason of direct application of an experimental procedure or circumstance, or by reason of the subject's exclusion from ordinary standards of practice of care. Rights of subjects regarding confidentiality and

[1] Code of Federal Regulations (CFR) Title 45, Subtitle A, Part 46 Protection of Human Subjects; "Common Rule" is subsequently referenced as: 45 CFR 46: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

access to professional care and counsel are included in IRB deliberations so that human dignity, rights, and physical, psychological, behavioral and social welfare are protected.

2.2 IRB SCOPE AND AUTHORITY

All human research authorized and conducted under the jurisdiction of the University of Redlands is subject to review by the IRB for risk, benefit, and informed consent without regard to the source of financial, physical (facilities) or logistical support. This review must be conducted before a project can be started. The IRB is responsible for any research activity that involves physical, psychological, behavioral or social welfare of human subjects that is conducted within, supported by, or otherwise the responsibility of University of Redlands.

The IRB shall have the authority to disapprove, discontinue, suspend or limit research involving human subjects and, by its recommendations to the Provost of the University, can effect action that withholds or withdraws financial or approved support from projects involving human subjects that are not in compliance with University policies or federal regulations. University administrators and/or supervisors (departmental chairs, deans, Provost) should remind prospective investigators of IRB requirements whenever a proposed activity involves human subjects.

2.3 ACTIVITIES REQUIRING IRB REVIEW AND APPROVAL

The HHS Office of Human Research Protections (OHRP) provides a decision chart for determining if an activity is research involving human subjects.

To determine if the proposed activity requires review by the Redlands IRB, answer the following questions:

- **Is the proposed activity research?** According to 45 CFR 46.102(l), research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:
    - Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

If, according to this definition, the proposed activity is not research, then IRB review is not required. If the proposed activity is research, continue with the next question.

- **Does it involve human subjects**? Research investigators must determine whether their proposed research will involve human subjects. Regulations define "human subject" as a living individual about whom an investigator (whether professional or student) conducting research 1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. If you determine that the research does not involve human subjects, then IRB review is not required. If you determine that the research does involve human subjects, IRB review is required. If it is not clear whether the research involves human subjects, seek assistance from the IRB Administrative Coordinator or Chair.
- **Will it be authorized and conducted under the jurisdiction of the University of Redlands**? All research involving human subjects regardless of the funding status or the source of any funding is under the jurisdiction of the University. In cooperative research projects involving one or more institutions in addition to University of Redlands, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with the individual IRB policies.
- **Is IRB review and approval required for when human subject research is not intended for publication and/or presentation**? Any activity qualifying as

research, as defined above, that also involves human subjects—regardless of whether intended for publication and/or presentation—requires IRB approval.

Additional activities requiring IRB review and approval include classroom instruction involving research activities with human subjects. (See section 5.1.3 for additional information.)

2.4 PRINCIPLES GOVERNING THE IRB

The IRB is guided by federal regulations and ethical principles regarding all research involving humans as subjects. DHHS (45 CFR 46 [*Protection of Human Subjects*]) and FDA (21 CFR 50 [*Protection of Human Subjects*], 56 [*Institutional Review Boards*], 312 [Investigational New Drug Application] and 812 [Investigational Device Exemptions]) are the primary agencies and regulations that guide the IRB. In addition, the IRB is guided by the *Belmont Report: Ethical Principles and Guidelines for The Protection of Human Subjects of Research* ("Report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research," 1979).

The IRB weighs risks to which research subjects may be exposed that may result in physical, psychological, social and economic harms:

- Physical harms: minor pain, discomfort, or injury.
- Psychological harms: stress, feelings of guilt or embarrassment caused by talking about sensitive subjects or being manipulated or deceived as part of the research.
- Social and economic harms: invasions of privacy and breaches of confidentiality.

2.5 SELECTION AND COMPOSITION OF THE IRB

IRB members are selected from the faculty and from the community-at-large to ensure representation of professional expertise and community attitudes. Members shall be diversified as to race, gender, cultural background and sensitivity to community attitudes (45 CFR 46.107).

The University institutional review board is a standing University faculty committee. The institutional review board reports to the Provost.

IRB Composition. Federal regulations require at least five members sit on an IRB, and fulfill three characteristics: a scientist, a non-scientist, and an unaffiliated member. Membership should reflect the diversity and range of human subjects research, with reference to the research activities conducted and categories of subjects studied commonly at the institution. University of Redlands IRB members shall be appointed to the following roles:

1. **Chairperson**. The IRB Chair should not be the non-scientist or unaffiliated member. A social scientist from the College of Arts and Sciences, Graduate School of Theology, School of Business, or School of Education should lead the IRB. The IRB Chair may have expertise in quantitative or qualitative research methods.
2. **School of Education Member**. The School of Education member may have expertise in quantitative or qualitative research methods. The methodological background of this member should reflect the research methods being used in the School of Education and complement the expertise of the Open members and the Chair (see Balanced and Complementary Expertise, below).
3. **Non-Scientist**. Appointed from the College of Arts and Sciences, School of Business, or Graduate School of Theology.
4. **Scientist**. Appointed from the College of Arts and Sciences, this member will typically be a natural scientist.
5. **Open**. The methodological expertise of the Open IRB member should complement social science expertise of the School of Education member and the Chair (see Balanced and Complementary Expertise, below). Accordingly, the Open IRB member should bring expertise in quantitative and/or qualitative social research methods depending on what is needed to bring methodological balance to the board.
6. **Unaffiliated**.
7. **Administrative Coordinator** (non-voting).

Balanced and Complementary Expertise. To ensure balanced, complementary expertise that reflects the kinds of human subjects research conducted at the University of Redlands, members of the IRB should have backgrounds in qualitative and quantitative social research methods. The methodological backgrounds should reflect the kinds of methods being used by faculty and students in all academic units of the university. These methods should include, but not be limited to, the following:

- Action research
- Archival research
- Case studies
- Clinical studies
- Content analysis
- Focus groups
- Ethnography
- Historical research
- Interviews

- Laboratory experiments
- Mixed methods research
- Participant observation
- Quantitative analysis
- Survey research

Balance should be achieved through appointment of individuals with appropriate expertise to serve as the IRB Chair, School of Education member, and Open member.

Prisoner's Advocate. The IRB will provide an *ad hoc* prisoner's advocate for any proposed research that wishes to use a prisoner population.

IRB Membership. Appointments to the IRB are made by the Provost, who acts as the University of Redlands Human Protections Administrator. Members are appointed on a staggered cycle for three-year terms. Members may serve a maximum of two consecutive terms. Member service is a year-round (12-month) commitment, with appropriate supplemental compensation.

IRB Chair. The Provost will appoint one of the IRB's faculty members to serve as Chair, who will:

1. Maintain records of IRB applications, continuation requests, end-of-project reports, IRB decisions, and any other IRB records;
2. Distribute applications for review;
3. Write the decision letters;
4. Correspond with applicants;
5. Answer questions from faculty, students, and administrators;
6. Prepare minutes of IRB meetings; and
7. Communicate with the Human Protections Administrator.

IRB Administrative Coordinator. The Provost will appoint an Administrative Coordinator who will:

1. Serve as an advisor to the IRB, attending meetings as a non-voting member and assisting in organizational and operational effectiveness.
2. Pre-review applications, deciding whether a project is human subjects research and identifying the type of IRB review necessary.
3. Field faculty concerns, acting as a neutral intermediary to receive faculty concerns, forwarding concerns to the IRB, and conveying resolutions back to the submitter.
4. Support best practices in IRB compliance, operationalizing IRB application development

into research design and methods classes for student researchers, as well as "boot camps" for student and faculty researchers.

5. Work with the IRB Chair to convene an annual open session where researchers can interact with the IRB.

IRB Member Training. All IRB members are required to document training associated with their roles in the committee. All IRB members are required to complete the CITI IRB Members - Basic/Refresher Course every three years. The Chair is also required to complete the CITI IRB Chair Basic/Refresher Course every three years. The IRB Administrative Coordinator is responsible for documenting all IRB members' training. Periodic training for all potential applicants is provided by the IRB Administrative Coordinator. Student PIs receive application development support from the Unit IRB Coordinators.

2.6 IRB MEETINGS

Except when an exempt or expedited review procedure is used, proposed research must be reviewed at convened meetings at which a majority of the members of the IRB are present (45 CFR 46.108). Monthly meetings of the full IRB will be scheduled for each semester prior to its start. These dates will be publicized, and proposals that require full-board review at the next meeting will be given a deadline of one week prior to each meeting. In addition to review of protocols, the agenda specifically routinely will include:

- Review of the administrative procedures for the institutional review board and human research protections policies, making additions and voting on revisions
- Consideration of changes to IRB forms and any additional information that generally should be sought from research investigators in the future

Prior to each meeting, an agenda will be sent to participating investigators and all IRB members (and consultants), notifying them of the date, time and place of the meeting. In addition to the regularly scheduled meetings, the IRB Chair may call emergency meetings of the IRB as necessary to review research protocols or address issues of noncompliance or serious and/or unexpected injury to research subject(s).

Meetings are conducted in accordance with Roberts Rules of Order and all action requires a voice or show-of-hands vote of the members present following discussion and the making and seconding of a motion. An IRB member may abstain from voting for any reason, without explanation.

2.6.1 Meeting Materials

The Chair shall provide each member of the board with an electronic or physical copy of the following materials prior to the regularly scheduled meeting:

- The agenda.
- The minutes from the previous meeting that include information on official IRB activities conducted through the IRB since the previous mailing of the minutes, such as protocols reviewed to determine exempt status, protocols reviewed by expedited review and adverse event reports received.
- The IRB application, protocol and informed consent document for each new project subject to full IRB review.
- Documents for those continuing research projects to be reviewed by the full board. If necessary, the documents should include an unsigned copy of the most recently approved consent/assent documents(s) for those projects in which subjects are still being enrolled.
- Any other information necessary for the meeting.

Except for a copy that must remain on file with the IRB, sensitive documents such as protocols and consent forms for approved applications are collected and destroyed after each meeting.

2.6.2 Quorum

A majority of members must be present, in person or via teleconference or web conference, to conduct business of the IRB, except for expedited or exempt reviews, and among this majority at least one member must be a non-scientist (45 CFR 46.107). No proxy votes will be accepted, all votes must be cast during the convened meeting. The final approval or disapproval of any research project application will require a majority vote of IRB members present and voting, with at least one member of a non-scientific area voting. If a quorum is lost at any time during the meeting, the meeting shall be adjourned and no further action taken until a quorum is attained.

IRB members with a conflict of interest in a particular research project cannot participate in the board's deliberations and voting concerning that project and shall not be present during initial or continuing IRB review of that project. When conflicted IRB members leave a meeting, the total needed to calculate quorum is reduced by the number who leave the meeting. Those with a conflict of interest may provide information requested by the IRB.

2.6.3 Attendance

Members are expected to attend a majority of convened IRB meetings. The IRB Administrative Coordinator will maintain records of attendance and members who attend less than 50% of meetings per year will be contacted and encouraged to increase their attendance. Anticipated absence from an IRB meeting should be communicated to the IRB Chair at least 24 hours prior to the meeting.

If requested, research investigators are required to attend IRB meetings at the date and time scheduled for full IRB review and discussion of their initial submission or of changes to a previously approved or disapproved research project if requested. Once scheduled, the PI should contact the IRB Chair to request a scheduling change if such a change is necessary.

Confidentiality. All members are expected to hold in confidence all matters coming before the IRB.

2.6.4 Minutes

Minutes of meetings shall include (45 CFR 46.115) the following information:

- Attendance of members and guests.
- Actions taken by the IRB on each research project reviewed including the level of risk as determined by the IRB, the approval period and any required modifications for IRB approval.
- Votes on these actions including the number of members voting for, against, and abstaining, and record of members who were not present during deliberations and voting when review involved projects on which they have a conflict of interest.
- The basis for requiring modifications or disapproving research.
- A written summary of the discussion and resolution of debated issues.

2.7 EDUCATION OF NEW IRB MEMBERS

All new members appointed to the IRB must complete the University of Redlands's *Human Subjects Research Tutorial and Certification* requirement. Initial certification fulfillment requires the following:

- Reading a copy of the most recent University of Redlands's Federal-Wide Assurance (FWA) of Protection for Human Subjects.
- Completion of the CITI IRB Members Basic/Refresher course

- Completion of onboarding training provided by the IRB Administrative Coordinator.

2.8 IRB RECORDS

All research protocols submitted to the IRB for review will receive an identifying number. The proposals received beginning at the onset of the calendar year will be sequentially identified using the following method:

EXAMPLE: 2022-001 "2022" designates the calendar year submitted, "001" representing the first protocol submitted, "002" to follow, etc.

The IRB shall retain and have accessible in a central location (45 CFR 46.115) the following records for at least three years after the completion of the research:

- All research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, required yearly, or other progress reports submitted by investigators, correspondence between the IRB and the investigators, and adverse event reports.
- Minutes of IRB meetings, detailed appropriately.
- Records of continuing review of previously approved research projects.
- Copies of all correspondence between the IRB and the investigators.
- List of IRB members, identified by name, earned degrees, representative capacity, indications of experience sufficient to describe each member's chief anticipated contributions and employment relationship (if any) with the institution and dates of service on the IRB.
- Written procedures for the IRB.
- Statements of significant new findings provided to subjects as required by either FDA or DHHS.
- The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.
- Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §46.103(e).

IRB records, as outlined above, shall be available for inspection and copying by the institutional official or his/her designees, affiliated entities, and designated federal and other agencies.

3. ADMINISTRATIVE ROLES AND RESPONSIBILITIES

3.1 THE INSTITUTIONAL OFFICIAL

The Provost of University of Redlands serves as the institutional official for the IRB. The Provost signs the institution's federal-wide assurance of protection for human subjects that is required by DHHS. The Provost may further review and/or disapprove research projects previously approved by the IRB, with the following exception: the Provost may not approve any research project that has been previously disapproved by the IRB.

3.2 THE IRB CHAIR

The IRB Chair ensures that the IRB carries out its responsibilities in accordance with federal requirements and these policies and procedures.

The Chair keeps the Provost informed of IRB activities as required and a letter will be prepared yearly summarizing the research approved, disapproved, and tabled actions taken on policy and program issues.

3.3 THE IRB ADMINISTRATIVE COORDINATOR

The IRB Administrative Coordinator serves as an advisor to the IRB, attending meetings as a non-voting member and assisting in organizational and operational effectiveness.

3.4 THE UNIT IRB COORDINATORS

The dean of each academic unit in the University of Redlands (College of Arts and Sciences, Graduate School of Theology, School of Business, and School of Education) will designate a faculty member to serve as an advisor to students completing IRB applications.

3.5 THE IRB

The IRB reviews and approves, requires modification in, or disapproves all research activities involving human subjects conducted under the jurisdiction of University of Redlands. The IRB conducts continuing review of previously approved research at appropriate intervals based on risk, but not less than once a year. The IRB has authority to suspend or terminate previously approved research that is not conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to research subjects. The IRB has authority to place any restrictions on an approved project as necessary to ensure protection of human subjects.

3.6 THE PRINCIPAL INVESTIGATOR (PI)

The Principal Investigator (PI) has the primary responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the University's FWA, federal laws and regulations, and the University's policies and procedures as set forth in this manual.

4. HUMAN SUBJECTS RESEARCH EDUCATION PROGRAM

The University of Redlands Human Subjects Research Education Program includes online training in human research ethics and responsibilities, mentoring by Unit IRB Coordinators and targeted workshops for student PIs, "boot camps" and other training for all PIs and human subjects research personnel, onboarding training for new IRB members, and an annual townhall for the university community.

4.1 PROGRAM OBJECTIVES

The program is designed to:

- Help investigators and staff understand the special requirements associated with the use of human subjects in research.
- Clarify the responsibilities of those involved in human subjects research and of the IRB.
- Increase recognition of the basic ethical principles for the use of human subjects: respect for persons, beneficence and justice.
- Provide education on the protection of human subjects as mandated by DHHS (OHRP) in Title 45 of The Code of Federal Regulations, Section 46 (45 CFR 46).
- Provide education on IRB review, informed consent, and policies and procedures applicable to human subjects research
- Assist PIs in completing human subjects research applications.
- Foster opportunities for the university community to provide feedback on IRB policies and procedures.

4.2 ONLINE CERTIFICATION AND RECERTIFICATION

Related to their roles in human subjects research at the University of Redlands, individuals must complete online courses offered by CITI Program. The training satisfies the National Institute of Health (NIH) *Human Subjects Training Requirement* for obtaining federal funds. Some courses require periodic recertification.

4.2.1 Investigators - Human Subjects (Basic) and Social and Behavioral Responsible Conduct of Research (Basic)

The following individuals must complete the CITI Human subjects (Basic) and Social and Behavioral Responsible Conduct of Research (Basic) courses offered by CITI Training. Recertification of the CITI Human Subjects course must be accomplished every three years by taking the refresher course. Mandatory certification (and recertification, if necessary) must be completed before IRB approval of any new project, revisions, or amendments to existing projects or renewals of existing projects. Failure to comply with these requirements may lead to a suspended protocol.

- University of Redlands faculty serving as PIs.
- Any Redlands project staff conducting the informed consent process.
- All Redlands project staff designated by the PI.
- University of Redlands faculty serving as teaching faculty to Redlands students who are involved in exempt or non-exempt research projects.
- Redlands students who are conducting non-exempt research (i.e., research that is subject to either expedited review or full IRB review; see section 5.2).
- PI's from non-Redlands facilities (working with a Redlands faculty member) who do not have certification of education from another institution's IRB and who are conducting research with the consent of the Redlands IRB or under the responsibility of the University.
- Project staff from non-Redlands facilities who are conducting the consent process either within Redlands or with the consent of the Redlands IRB and who do not have certification of education from another institution's IRB.
- Anyone serving as a PI in a non-exempt submission.

4.2.2 IRB Members (Basic) and Social and Behavioral Responsible Conduct of Research Course (Basic)

The following individuals must complete the IRB Members (Basic) and Social and Behavioral Responsible Conduct of Research (Basic) courses. Recertification of the CITI IRB Members course must be accomplished every three years by taking the refresher course. Current certification and/or recertification is required for all individuals serving in these roles.

- The University of Redlands Institutional Official (Provost of the University)
- IRB Chair
- IRB Members

- IRB Administrative Coordinator
- Unit IRB Coordinators

4.2.3 IRB Chair Basic/Refresher Course

The IRB Chair is required to complete the CITI IRB Chair Basic/Refresher Course every three years.

4.2.4 Individuals Who are Exempt from Completing CITI Human Subjects Research Courses

The following individuals are exempted from requirements to complete CITI Human Subjects Research courses:

- Research staff who perform standard of care procedures in connection with a protocol.
- Research staff who analyze data, if the data do not contain identifying information (e.g., name, social security number).

4.3 ADDITIONAL EDUCATION

The IRB and University will provide additional education as needed, addressing such issues as regulatory changes and issues identified through the current IRB internal monitoring process.

5. THE REVIEW PROCESS

Any research that involves human subjects and is authorized and conducted under the jurisdiction of University of Redlands is subject to review by the University of Redlands IRB. No new research project or changes to previously approved research projects may be initiated until approved by the IRB. The IRB reviews new projects, changes to existing projects and ongoing projects as follows:

- **Pre-Review and mentoring for student PIs**: Before submitting applications to the IRB, student PIs must first work with their advisor and the appropriate Unit IRB Coordinator. The Unit IRB Coordinator may request additional information about the research and/or request modifications to the application form, protocol, and/or informed consent documents prior to submission to the IRB. Signatures from a student PI's faculty research advisor and the relevant Unit IRB Coordinator are required for submission to the IRB.

- **Initial review**: All new research projects must be submitted for initial review. The three types of review (exempt, expedited, full board) are described in section 5.2 and submission requirements are described in Section 5.3.
- **Review of changes to previously approved protocols**: Any amendments, addenda, supplements or other changes to existing projects must be submitted to the IRB for either expedited or full board review.
- **Continuing review of approved research projects**: Continuing review of projects previously approved by full board review is conducted by the full board at its regular meetings. Continuing review of exempt or expedited projects is conducted by the IRB Chair or other appointed member.

5.1 WHEN IRB REVIEW IS REQUIRED

5.1.1 New Projects

To determine if the proposed activity requires review by the Redlands IRB, answer the following questions:

1. **Is the proposed activity research**? Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. If the proposed activity is research, continue with the next question.
2. **Does it involve human subjects**? Research investigators must determine whether their proposed research will involve human subjects. (See Section 2.3) Regulations define "human subject" a living individual about whom an investigator (whether professional or student) conducting research:
    - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or
    - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

    If you determine that the research does not involve human subjects, then IRB review is not required. If you determine that the research does involve human subjects, IRB review is required. If it is not clear whether the research involves human subjects, seek assistance from the IRB Chair, IRB Administrative Coordinator, or appropriate Unit IRB Coordinator.

3. **Will it be authorized and conducted under the jurisdiction of University of Redlands**? All research involving human subjects regardless of the funding status or the source of any funding is under the jurisdiction of the University. In cooperative research projects involving one or more institutions in addition to University of Redlands, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with the individual IRB policies.

5.1.2 Projects Generally Not Considered to be Human Subjects Research

Examples of activities that typically are not designed to create generalizable knowledge (and thus are not research) include:

- Biography research involving a living individual that is not generalizable beyond that individual.
- Oral history research designed solely to create a record of specific historical events
- Service or course evaluations, unless the data would be analyzed in a manner to create generalizable knowledge
- Classroom activities and simulations designed to teach research methods and course concepts, but have no intent to create generalizable knowledge
- Quality assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share the results beyond the University of Redlands community.
- Journalistic activities focused on collecting, verifying, reporting, and analyzing information or facts about current events, trends, issues or individuals involved in such events or issues.
- Information-gathering interviews where questions focus on things, products, or policies rather than people or their thoughts regarding themselves may not meet the definition of human subjects research.
- Projects that only document or report on events, situations, policies, institutions or systems without the intent to form hypotheses.
- Projects that only collect information about policies, practices or procedures.
- Interviews or surveys which do not collect information about a person, such as interviews on government or corporate policies.
- Production of creative arts, e.g., writing poetry and prose, painting, taking artistic photographs of people.
- Research using secondary data from publicly available sources.

See Section 2.3 for a list of activities that are specifically deemed not to be research by the common rule. Investigators should check with the IRB Chair, IRB Administrative Coordinator, and/or appropriate Unit IRB Coordinator before making a determination that their project is not subject to IRB review.

5.1.3 Student Classroom Research Projects

Many of our University courses require undergraduate and graduate students to engage in research activities as part of the regular academic experience. Where that research uses human subjects, the University of Redlands wants to ensure that all student researchers are cognizant of the need to protect human subjects from risk. While majority of student research falls into categories that in may not be construed as exposing subjects to more than minimal risk, the IRB, on behalf of the University, has a responsibility to students who may be subjects and to external research participants to ensure researcher awareness of possible risks. Nevertheless, classroom projects that meet certain criteria (see below) may not require IRB review. Faculty who require research projects of their students must certify that the projects being conducted in their courses would qualify for exempt status. The IRB Chair determines whether the projects meet the criteria.

Classroom curriculum projects in which students conduct research involving human subjects need not be reviewed by the IRB if all three of the following conditions are satisfied:

1. **The project (s) involve minimal risk to subjects**. A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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. For example, collecting a saliva sample from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.
2. **They do not involve vulnerable populations** (i.e., children younger than 18 years, those with intellectual disabilities, prisoners, pregnant women).
3. **Results will never be distributed outside the classroom and/or institutional setting** (e.g., disseminated at a conference, submitted for publication, posted on the world wide web, presented at a conference). If the researcher thinks that the data or the report/manuscript may be used in a future conference presentation, or related research project, IRB review is recommended. Data collected without IRB review may not be used in future presentations or research.

Instructors wishing to have students conduct research that meets the above criteria must do the following:

1. So that they may properly evaluate proposals and identify violations, instructors must

complete appropriate CITI training. (See 4.2.1).

2. Students conducting human subjects research for a class project must complete appropriate CITI training. (See 4.2.1).
3. Instructors must submit an application to the IRB providing a description of general research assignment information:
    - The types of research to be undertaken.
    - Nature of participants to be used.
    - Kinds of procedures to be used in the research projects.
4. Instructors must complete and submit to the IRB an Application to Use Human Subjects in Course Only Research found on the IRB website.

Instructors must require students to complete a proposal for the classroom assignment that addresses: the purpose of the project, description of participants, data collection methodology, and the consent process (see Requirements for Student Proposals).

Furthermore, instructors must submit a copy of the consent form used by each student, signed by the student conducting the research. Any research not within the described parameters proposed and submitted by the instructor to the IRB requires separate approval from the IRB. Furthermore, faculty and students should take note that any data collected for a classroom research project as described in this section will not be eligible for publication or presentation outside of the classroom and *post-hoc* reviews will not be conducted for the purpose of publication or presentation outside of the classroom.

5.1.3.1 Requirements for Student Proposals

1. **Overview of the Project**
    A. Purpose.
    B. Rationale/significance.
    C. General description of research strategy and design.
2. **Participants**
    A. Who (general sample/population information, not by name).
    B. Criteria for selection.
    C. How selected, e.g., volunteer or recruitment strategies.
    D. Risk factors for participants (be specific).
3. **Data Collection Methods**
    A. Specific steps to gather data.
    B. Instrumentation.

C. How the data will be recorded (describe steps for confidentiality).

D. Secure data storage.

E. Destruction of raw data.

4. Consent

A. Describe the consent process:

a. How the study will be explained to participants.

b. Implicit or explicit consent. If explicit consent is obtained, the copy of consent form should:

1. Identify the project as through University of Redlands.
2. Outline data collection procedures.
3. Describe how confidentiality will be ensured.
4. Explain the rights of the participant, e.g., to withdraw at any time with no penalty and what will happen with their data if they choose to withdraw.
5. Explain the risks to the participant.
6. Provide IRB, instructor, and researcher contact information.
7. Include date and signature line(s).

5.2 LEVELS OF REVIEW

There are three different levels of review for a submission to the IRB. While the investigator will submit to a specific level, the IRB Chair or IRB Administrative Coordinator may change the level of review required. The requirements for each level are explained in detail, below.

The IRB will evaluate all non-exempt research projects to ensure that the defined risks to the subject are outweighed by the potential benefits. The IRB will determine that the following criteria are satisfied:

- The research is significant, has scientific merit, contributes to knowledge and research and methods are appropriate.
- The investigator is qualified and research investigators have received education in human subjects protection and are certified by the University.
- Risks to subjects are minimized, procedures used are consistent with sound research design and do not necessarily expose subjects to risk.
- Risks to subjects are reasonable in relation to anticipated benefits.

- Selection of subjects is equitable.
- Informed consent will be sought and appropriately documented in accordance with and to the extent required by 45 CFR 46.116.
- Privacy is protected and confidentiality of data is maintained.
- Safeguards for those who are likely to be vulnerable to coercion or undue influence have been included to protect research subjects.
- Adequate provisions are made if special issues are a component of the research study.

5.2.1 Review for Determination of Exempt Status

Federal guidelines identify those research activities that are exempt and therefore do not require full IRB review. See the OHRP decision chart for guidance on whether human subjects research is eligible for exemption. If your proposed research falls under one of the exempt categories below, submit your application to the IRB Chair for determination of exempt status. (See section 5.3 for information on submission requirements and review process.)

The following information on exempt categories is from 45 CFR 46.104. Unless otherwise required by federal department or agency heads, research activities in which the only involvement of human subjects (with additional protections for pregnant women, human fetuses and neonates; prisoners; and children [see 45 CFR 46 104 (b)]) will be in one or more of the following categories are exempt :

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

    A. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects,

    B. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging

to the subjects' financial standing, employability, educational advancement, or reputation; or

C. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

3. Benign behavioral interventions.

A. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

B. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

C. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that they will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

A. The identifiable private information or identifiable biospecimens are publicly available;

B. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

C. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

D. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

   A. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or

demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies if:
    A. Wholesome foods without additives are consumed, or
    B. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level 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.
7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).
8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
    A. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);
    B. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;
    C. An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
    D. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

If you have any questions regarding the exempt categories defined above, please contact the IRB Chair for assistance.

5.2.2 Expedited Review

Federal guidelines identify those research activities eligible for expedited IRB review. See the OHRP decision chart for determining if an IRB review may be done by expedited procedures. If your proposed research meets the applicability requirements described below and falls under one of the expedited review categories identified below, submit your application to the IRB for expedited review (see section 5.3.2 for information on

submission requirements and review process). The following information on expedited review categories is from the federal register (63 FR 60364-60367, November 9, 1998).

5.2.2.1 Applicability

1. Research activities that (a) present no more than minimal risk to human subjects and (b) involve only procedures listed in one or more of the following categories may be reviewed by the IRB through expedited review. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
2. The categories listed herein apply regardless of the subject's age, except as noted.
3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of privacy and breach of confidentiality are no greater than minimal.
4. The expedited review procedure may not be used for classified research involving human subjects.

5.2.2.2 Research Categories for Expedited Review

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
    A. Research on drugs for which an investigational new drug application (21 CFR 312) is not required. Note: research on marketed drugs that significantly increases risk or decreases the acceptability of risks associated with the use of the product is not eligible for expedited review.
    B. Research on medical devices for which 1) an investigational device exemption (21 CFR 812) is not required; or 2) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared approved labeling.
2. Prospective collection of biological specimens for research purpose by noninvasive means. Examples include:
    A. Hair and nail clippings in a nondisfiguring manner;
    B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
    C. Permanent teeth if routine patient care indicates a need for extraction;
    D. Excretia and external secretions (including sweat);
    E. Uncannulated saliva collected either in an unstimulated fashion or stimulated

by chewing gum or by applying a dilute citric solution to the tongue;

F. Placenta removed at delivery;

G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic techniques;

I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washing;

J. Sputum collected after saline mist nebulization.

3. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples include:

   A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

   B. Weighing or testing sensory acuity;

   C. Magnetic resonance imaging;

   D. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;

   E. Moderate exercise, muscular strength testing, body composition assessment and flexibility testing where appropriate given the age, weight and health of the individual.

4. Research involving materials (data, documents, records or specimens) that have been collected solely for nonresearch purposes (such as medical treatment or diagnosis). Note: some research in this category may be exempt from the DHHS regulations for the protection of human subjects (see section 5.2.1, #4). This listing refers only to research that is not exempt.

5. Collection of data from voice, video, digital or image recordings made for research purposes.

6. 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 and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies. Note: some research in this category may be exempt

from the DHHS regulations for the protection of human subjects (see section 5.2.1, #2 and #3). This listing refers only to research that is not exempt.

5.2.3 Full Board Review

If your project involves human subjects and does not qualify for exempt status or expedited review, full board review is required. If funding support is requested from the federal government and human subject research is involved, full board review is required. All expedited reviews that are not approved will be subject to full board for final determination. In addition, the IRB can request a full board review of any protocol that has been approved through the expedited review process (see section 5.3.3 for information on submission requirements and review process).

5.3 SUBMISSION REQUIREMENTS AND REVIEW PROCESS

Once you have determined which type of review is required for your project (Section 5.2), prepare your submission to the IRB, accordingly, as described below. The review process for each type of IRB review is also described in this section.

Throughout the review process and subsequent administration of the project, research investigators are responsible for complying with all IRB decisions, conditions and requirements. If revisions in the proposed protocol or informed consent document are required by the IRB, these revisions must be submitted to and approved by the IRB before the research project can begin.

5.3.1 Determination of Exempt Status

5.3.1.1 Submission Requirements

Faculty, Administrators, and Staff. If your project qualifies for exempt status, send the completed and signed Application to use Human Subjects in Research to the IRB Chair.

Student PIs. As described in Section 5, before submitting an application for exempt status to the IRB, student PIs must first work with their advisor and the appropriate Unit IRB Coordinator. After the student's faculty research advisor and relevant Unit IRB Coordinator have signed the Application to use Human Subjects in Research, it may be submitted to the IRB.

5.3.1.2 Review Process

An IRB designate will determine whether a research protocol qualifies for exemption from coverage under 45 CFR 46.101 or 21 CFR 56.104. After you have submitted your application, your submission will be reviewed, and you will be notified in writing of the official determination within approximately fourteen (14) days. If it is determined that

your project does not qualify for exempt status, you will be asked to submit your protocol for either expedited or full board review, as appropriate.

Exempt research may be subject to continuing IRB review (see section **Error! Reference source not found.**)

5.3.2 Expedited Review

5.3.2.1 Submission Requirements

Faculty, Administrators, and Staff. If your project qualifies for expedited review, send the completed and signed Application to use Human Subjects in Research to the IRB Chair.

Student PIs. As described in Section 5, before submitting an application for expedited review to the IRB, student PIs must first work with their advisor and the appropriate Unit IRB Coordinator. After the student's faculty research advisor and relevant Unit IRB Coordinator have signed the Application to use Human Subjects in Research, it may be submitted to the IRB.

Include:

- A completed "application for expedited review" form.
- Protocol or study design, including list of references.
- Informed consent document.
- Assent document(s), if applicable.
- Parental consent document, if applicable.
- Questionnaires/surveys.
- Interview questions.
- Other material as needed to allow a thorough review.
- Advertising or information flyers, brochures or materials, if any.
- If the research project being submitted has been previously reviewed by a local or institutional IRB other than the University of Redlands IRB, a copy of the approval or disapproval notification from that IRB.

5.3.2.2 Review Process

After faculty have submitted their application for expedited review, the submission is reviewed by the IRB Chair and/or one or more experienced IRB members designated by the Chair. The reviewer(s) may exercise all of the authorities of the IRB except that the

reviewer(s) may not disapprove the research. The reviewer(s) will complete the review within 2-3 weeks and will make one of the following determinations:

- Approved.
- Approved pending modifications.
- Requires full board review

You will be notified in writing of the determination. If you are asked to make changes, allow one week for the IRB to respond once you have submitted the requested changes.

Activities approved through the expedited review process are recorded in the IRB meeting minutes, which are distributed to the full IRB prior to the next regularly scheduled IRB meeting. At a convened IRB meeting, any member may request that an activity that has been approved under the expedited review procedure be reviewed by the full IRB in accordance with full board review procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue. Full IRB decision shall supersede any expedited review decisions.

5.3.3 Full Board Review

5.3.3.1 Submission Requirements

Faculty, Administrators, and Staff. If your project is being submitted for full board review, send the completed and signed Application to use Human Subjects in Research to the IRB Chair.

Student PIs. As described in Section 5, before submitting an application for full board review to the IRB, student PIs must first work with their advisor and the appropriate Unit IRB Coordinator. After the student's faculty research advisor and relevant Unit IRB Coordinator have signed the Application to use Human Subjects in Research, it may be submitted to the IRB.

IRB meetings only occur monthly, so it is important to make submissions for full board review on time. Refer to the IRB website for a schedule of meetings and due dates.

The following materials must be included with the application:

- A completed "application for full board review" form.
- Protocol or study design, including list of references.
- Informed consent document.
- Assent document(s), if applicable.
- Parental consent document, if applicable.

- Questionnaires/surveys.
- Interview questions.
- Other material as needed to allow a thorough review.
- Advertising or information flyers, brochures or materials, if any.
- Any other documents that will be given to research subjects.
- If the research project being submitted has been previously reviewed by a local or institutional IRB other than the University of Redlands IRB, a copy of the approval or disapproval notification from that IRB.

5.3.3.2 Presenting to the IRB

PIs should contact the IRB Chair if they wish to personally present their proposal at the IRB meeting during which their application will be considered. In some cases, the Chair might invite a PI to attend the meeting to address questions or concerns about a proposal.

5.3.3.3 IRB Review Responsibilities

The IRB shall have the responsibility to review and authority to approve, require modification in, table, or disapprove all research activities. Each board member will study the protocol under review to ensure that no unnecessary or unacceptable risks are present and that adequate precautions are provided for research subjects. IRB members shall have access to all documents relating to the research protocol, including all information provided by the research investigator and others with a vested interest in the research (i.e., other institution, pharmaceutical company or corporation, etc., as applicable).

5.3.3.4 Presenting at the IRB Meeting

At the IRB meeting, the PI or co-PI may be asked to explain the purpose for, risks of, and alternatives to the proposed research, including subject selection and exclusion criteria. IRB members are then encouraged to ask clarifying questions concerning the protocol and consent process. The investigator is dismissed from the inquiry and any IRB members who have a conflict of interest with the project are excused from the meeting.

5.3.3.5 IRB Action

IRB members will make determinations regarding the category of risk, risk and benefit issues, and whether informed consent procedures are adequate. The IRB takes one of the following actions:

- **Approval**: the IRB informs the PI of its approval along with a copy of the approved informed consent document with the IRB date noted on each page. The PI may begin the research project upon receipt of IRB written approval.
- **Approval Subject to Modification**: the IRB shall provide written notice to the PI of its approval subject to modification, identifying specific areas of modification required. The PI must provide the IRB with a revised protocol and/or informed consent document incorporating the modifications. The IRB Chair or designated member of the IRB shall review the revised protocol and/or consent document within one week of receipt of the revised documents. The IRB reviewer will then provide written notice to the PI granting final approval of the protocol if the required modifications have been made. The notice of final approval will include a copy of the approved informed consent document with the IRB date noted on each page, if appropriate. The PI may begin the research project upon receipt of IRB written approval.
- **Tabled**: if the IRB requires additional information and has concerns regarding the proposed research project, the PI will be notified of the IRB decision and will be allowed to address the issue at the next regularly scheduled IRB meeting.
- **Disapproval**: if the IRB disapproves a research protocol, the IRB shall provide to the PI, in writing, the reasons for the IRB decision and an opportunity for the PI to appeal the decision.

5.3.3.6 Appeal Process

The appeal process consists of resubmitting the project to the IRB, with or without modification, accompanied by a letter from the PI indicating why they feel the project should be again considered by the IRB.

All actions taken are recorded in the minutes. Minutes of the IRB meetings are forwarded to IRB members and are available to the Provost or other institutional officials or administrators. Specific letters of instruction based on the IRB review are sent to each PI.

5.3.4 Changes to Previously Approved Projects

Research investigators are responsible for submitting for review by the IRB Chair all amendments, addenda, supplements, or other changes to previously approved projects, along with a copy of the original protocol, when:

- The research project proposes to involve or to change the involvement of human subjects and the involvement is significantly different from that which was originally approved by the IRB.
- The informed consent document is materially modified from that which was originally approved by the IRB.

The *Application for Continuation of Approval and/or to Revise an Approved Protocol* form found on the IRB website should be used to submit changes for IRB review. If the IRB Chair deems the changes to be significant, the changes will be brought to the full IRB for review.

5.3.4.1 Review Process

- **Expedited Review**. The IRB may use the expedited review procedure to review minor changes to previously approved research projects during the period for which approval was authorized. The Chair determines whether changes are minor.
- **Full Board Review**. Amendments, addenda, supplements, or other changes that do not qualify for expedited review shall be reviewed as set forth in the preceding explanation for full board review.

5.3.5 Continuing Review of Ongoing Projects

Approved IRB protocols have an expiration date indicated on the approval letter. For full board review projects and some projects approved under expedited review procedures, the expiration date is no more than one year from the date of IRB action (not from the date of project initiation).

5.3.5.1 Submission Requirements

If the approved human subjects research is to extend beyond the expiration date indicated on the approval letter, the research investigator must submit to the IRB Chair an *Application for Continuation of Approval and/or to Revise an Approved Protocol*. The research investigator is solely responsible for timely submission of continuing review materials. For projects previously approved by expedited or full board review, continuing review materials should be submitted at least one month prior to the expiration date keeping in mind the date scheduled for the next IRB convened meeting. The research investigator is responsible for submitting the following documents to the IRB for continuing review:

- A completed *Application for Continuation of Approval and/or to Revise an Approved Protocol* form.
- A clean copy of the current consent/assent document, if subjects are still enrolled in the study.
- If research subjects were enrolled in the last approval period, copies of assent/consent forms available for IRB review upon request.

Failure to complete and submit the continuing review form in the time stipulated will lead to corrective action resulting in the research project being closed. If this occurs, the

research investigator will have to resubmit a new application for full board review and receive IRB approval for that submission before continuing the research.

5.3.5.2 Review Process

The IRB uses the same criteria for continuing review as it does for initial review.

Continuing review of a research project may not be conducted through an expedited review unless:

- The project was eligible for, and initially reviewed by an expedited procedure, or
- The study has changed such that the only activities remaining are eligible for expedited review.

See the ORHP decision chart to determine whether IRB continuing review may be done by expedited procedures.

5.3.6 Submitting a Project Previously Reviewed by One IRB to a Different IRB

- **Previously disapproved by University of Redlands IRB**. If the University of Redlands IRB disapproves a research project that is subsequently submitted to one or more other IRBs, the Redlands IRB disapproval must be made known by the PI to the other IRB.
- **Previously reviewed by an IRB other than University of Redlands IRB**. If you are submitting a protocol to the University of Redlands IRB that has been reviewed by one or more other IRBs, then you must provide the Redlands IRB with copies of the approval or disapproval letter(s) along with your initial submission.

5.4 PROVOST REVIEW OPTION

The Institutional Official (the Provost of University of Redlands) may further review and/or disapprove research projects previously approved by the IRB, with the following exception: The Provost may not approve any research project that has been previously disapproved by the IRB.

5.5 IRB SUSPENSION OR TERMINATION OF A PROTOCOL

The IRB has the authority to suspend or terminate a protocol when (1) the protocol is not conducted in accordance with IRB requirements and/or (2) there is unexpected serious harm to subjects. The IRB shall promptly notify the PI, institutional official, and, if appropriate, DHHS and other involved federal department/agency heads or sponsor when it suspends or terminates a research project.

6. PREPARING FOR IRB REVIEW

6.1.1 PROTOCOL PREPARATION REQUIREMENTS

Research investigators shall prepare a protocol giving a complete description of the proposed research involving human subjects. All protocols shall contain provisions for the adequate protection and rights and welfare of prospective research subjects and for ensuring that pertinent laws and regulations are observed.

The protocol shall be detailed and include the following information:

- Describe the characteristics of the subject population, such as their anticipated number, age ranges, sex, ethnic background and/or health status. Identify the criteria for inclusion or exclusion.
- Explain the rationale for the use of special classes of subjects, such as children, pregnant women and fetuses, institutionalized mentally disabled persons, prisoners or others who are likely to be vulnerable (see section 9, vulnerable research populations).
- Describe the purpose of the study, results of previous related research, study design, procedures to be performed and, if appropriate, identity of the sponsor.
- Describe plans for the recruitment of subjects and the consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects and the method of documenting consent (see Section 7, Informed Consent).
- State if the IRB has authorized a modification or waiver of consent or of the requirement for documentation of consent.
- Describe any potential risks (physical, psychological, social, legal, or other) and assess their likelihood, seriousness, and management.
- Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring professional intervention in the case of adverse effects to the subjects and for monitoring the data collected to ensure the welfare of the subjects.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.
- Identify the costs to research subjects and/or any third-party payers. Where applicable, describe the compensation or benefit (i.e., extra credit for students) to be provided to research subjects for participation.

- Describe the timeline and procedure for disposing of or destroying any easily identifiable information received from research subjects.

6.2 SPECIAL RESEARCH ISSUES

This section presents an overview of research issues that require special consideration and must be addressed prior to IRB review.

6.2.1 Use of Protected Health Information for Research

The health insurance portability and accountability act (HIPAA) of 1996 ("Privacy Rule") establishes the conditions under which protected health information (PHI) may be used or disclosed by covered entities or their "business associates" for research purposes.

The privacy rule defines the means by which human research subjects are informed of how medical information (written, electronic or verbal) about them will be used or disclosed and their rights with regard to gaining access to information about themselves when such information is held by entities. Where research is concerned, the privacy rule protects the privacy of individually identifiable health information, while at the same time, ensuring that researchers continue to have access to medical information necessary to conduct research. Research information protected by the Privacy Rule includes:

- All research, regardless of funding source, involving/associated with treatment (because PHI is created).
- Medical records review.
- Medical registry review.
- Research of identifiable or coded data (i.e., research involving data that has been coded where researcher does the coding).

Although a research investigator who holds a Ph.D. as a general rule is not subject to HIPAA (not health care providers) there are exceptions (possible exception: a Ph.D. working out of a lab, who provides feedback to subjects regarding testing). Because of the ambiguity of such exceptions, the research investigator must, in addition to receiving informed consent from the human subject participants, provide written documentation to the IRB that:

- Use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research.
- No PHI is to be removed from the entity or the custody of the research investigator in the course of the review.
- The PHI for which use or access is sought is necessary for research purposes.

The Office for Civil Rights (OCR) is charged with enforcement of HIPAA and the review of all PHI compliance.

6.2.2 Gender Differences in Clinical Evaluation of Drugs

On July 22, 1993, FDA published in the federal register "guideline for the study and evaluation of gender differences in clinical evaluation of drugs." (58 FR 39406, July 22, 1993) this guideline presented two major changes in FDA regulations. First the guideline lifts the restriction on the participation of women of childbearing potential in early clinical trials, including clinical pharmacology studies and early therapeutic studies. Second, the guideline states that sponsors should collect gender-related data during research and development and should analyze the data for gender effects in addition to other variables such as age and race. In response to this guideline and to ensure adequate protection of women in research studies or early clinical trials, the IRB will consider the following in its review of both drug/biologic product and device protocols:

- Women of childbearing potential: women of childbearing potential may enter research studies or limited clinical trials. Clinical trial protocols should include provisions for testing for pregnancy as well as to medically acceptable methods of birth control.
- Pharmacokinetic issues: three specific pharmacokinetic issues that should be considered in such a protocol are:
    - Effect of menstrual status on the drug's pharmacokinetics, including both comparisons of pre-menopausal and postmenopausal subjects and continuation of within cycle changes.
    - Effect of exogenous hormonal therapy including oral contraception.
    - Effect of the test article on the pharmacokinetics of oral contraceptives

When preclinical teratology and reproductive toxicology studies have not been completed prior to initial human studies, subjects should be informed of this incomplete data in the informed consent document as well as the potential effects of the test article on conception and fetal development. Any new pertinent information arising from preclinical studies as well as any new clinical data that emerge regarding general safety and effectiveness (including gender differences) should be provided to subjects and the informed consent document should be updated, when appropriate.

6.2.3 Genetic Research

Because of the specific ethical, regulatory and public relations concerns associated with research with genetic material, research investigators should review and be familiar with all applicable regulations prior to submitting to the IRB any project involving

genetic research, including the collection and/or use of samples for DNA analysis or establishment of cell lines, with or without long-term storage. See Human Genome Research Institute, Human Subjects Research for guidance.

6.2.4 Studies Involving Investigational New Drugs

If the research study involves an investigational new drug, or a marketed drug that is being used for an indication not in the approved labeling, the research investigator must follow the requirements of FDA's investigational new drug application (IND) regulation (21 CFR 312). The IRB will not review any protocol involving an investigational new drug without authorization from FDA.

6.2.5 Use of Biohazardous Materials

Although not presently active at University of Redlands, any research involving the use of biohazardous materials (recombinant DNA and/or infectious biological agents) and human subjects must go through an institutional biosafety review conducted by the Environmental Health and Safety Manager and/or Provost prior to review by the IRB. A copy of any approval or exemption must be provided to the IRB before any review can begin.

6.2.6 Use of Radioisotopes, Radiation, and Radioactive Drugs

Although not presently active at University of Redlands, any research involving the use of radioisotopes, radiation and radioactive drugs and human subjects must be reviewed and approved by the Environmental Health and Safety Manager and/or Provost prior to review by the IRB. A copy of any approval or exemption must be provided to the IRB before any review can begin.

6.2.7 Studies Involving Investigational New Devices

Although not presently active at University of Redlands, any research involving an investigational new device, or a marketed device that is being used for an indication not in the approved labeling, and human subjects must follow the requirements of FDA's investigational exemption (IDE) regulation (21 CFR 812). The IDE regulation applies to all clinical investigations of devices to determine safety and effectiveness. The research must be reviewed and approved by the University environmental health and safety officer and/or Provost prior to review by the IRB. A copy of any approval or exemption must be provided to the IRB before any review can begin.

7. INFORMED CONSENT

7.1 GENERAL REQUIREMENTS

Research investigators shall ensure that no human subject will be involved in their research activity approved in the IRB protocol prior to obtaining informed consent from the subject or his/her legally authorized representative.

7.1.1 Obtaining Informed Consent

Research investigators shall obtain informed consent from the subject or the subject's parent, guardian, or other legally authorized representative (hereafter referred to as the legally authorized representative) in accordance with 45 CFR 46.116, 21 CFR 50.20 and these policies. This responsibility cannot be delegated to personnel who are not listed as investigators on the research protocol approved by the IRB. Research investigators shall ensure that no human subject will be involved in any research project prior to obtaining informed consent from the subject or his/her legally authorized representative. Informed consent must be obtained prior to any stage or procedure performed solely for the purpose of determining eligibility for the research project.

Informed consent must be obtained under circumstances that offer the subject or his/her legally authorized representative sufficient opportunity to consider whether the subject should or should not participate. The informed consent must not include exculpatory language through which the subject or the subject's legally authorized representative is made to waive or appear to waive any of the subject's legal rights or releases, or that appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.

- **In person consent**: The research investigator is responsible for providing informed consent in the presence of the human subject, his/her legally authorized representative if applicable, and an adult witness if the subject is a minor. The witness must be an adult person not involved in the research study and may be an adult relative of the human subject. The written informed consent document must be signed by the human subject, his/her legally authorized representative, if applicable, and the adult witness before the human subject can participate in the research. Each person who signs the written consent document shall be given a copy of the signed document.
- **Telephone consent**: The research investigator may obtain consent by telephone, as approved by the IRB. In such instances, the research investigator is responsible for providing informed consent to the human subject and his/her legally authorized representative, if applicable, over the telephone. If the subject is a minor, an adult witness must be present during the informed consent process. The research investigator shall document in the research record the

informed consent process. The written informed consent document shall be sent by mail or facsimile to the human subject and his/her legally authorized representative if applicable and the witness (if witnessed by an adult present with the human subject) for signature and returned before the human subject can participate in the research. If a witness is present with the research investigator, then he/she shall sign the informed consent document once the signed document has been received from the human subject. A facsimile of the signed informed consent document is as valid as the original. Each person who signs the written consent document shall be given a copy of the signed document.

- **Electronic consent**: The research investigator may obtain consent electronically. The informed consent must be presented prior to participation in the study. Diagrams, images, graphics, videos, and narration may be integrated into the informed consent material to aid in the subject's understanding of the material. Methods to assess subjects' understanding of the informed consent materials (e.g., questions and other tools to measure comprehension) may also be used. For minimal risk research, consent can be considered received if after the page with the informed consent is presented the participant clicks to continue on the electronic study, or by answering a question saying consent is given. Higher risk research may require verification of state-issued identification, use of personal questions, or visual methods (for detailed guidance, see 21 CFR part 11, Use of Electronic Informed Consent: Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors, and Part 11, Electronic Records; Electronic Signatures - Scope and Application: Guidance for Industry). A copy of the informed consent should be available to the participant upon request and all electronic informed consents must have written in them 'print for your records.'

7.1.2 Informed Consent Language

Informed consent must be obtained in language understandable to the subject and/or the subject's legally authorized representative. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

The research investigator should use language that the average person of the age of the proposed research subject is likely to understand. Technical and scientific terms should be adequately explained, or common terms substituted. Research investigators are urged to write the consent using the second person writing style (i.e., "you,", "I/we") as it helps communicate that there is a choice to be made by the prospective subject. In all cases, the writing style should be consistent throughout the written consent document. In cases where the study population includes non-English speaking people, the IRB will require that the informed consent document be written in each subject population's language and that an independently qualified translator be available during the consent process for those subject populations that do not understand English. If any member of the research population is illiterate, then the research investigator is responsible for having the informed consent document explained in the research subject's native language by an individual fluent in that research subject's native language.

7.2 EXCEPTIONS FROM INFORMED CONSENT REQUIREMENTS

7.2.1 Emergency Use of a Test Article

A test article is defined as a drug, biological product, medical device, food additive, color additive, electronic product, or any other article subject to regulation by FDA 21 CFR 56.101 or under sections 351 or 354-360F of the Public Health Service Act. Single emergency use of a test article is exempted from prospective IRB review (21 CFR 50.23) and informed consent requirements provided that written certification of such use, as outlined in all of the criteria below, is reported to the IRB within five working days after use.

- The subject is confronted by a life-threatening situation.
- Informed consent cannot be obtained from the subject due to an "inability to communicate" subject's inability to speak a particular language would not be considered an "inability to communicate."
- Time is insufficient to obtain consent from the subject's legally authorized representative.
- No alternative method is available that provides an equal or greater likelihood of saving the subject's life.

7.2.2 Emergency Research Consent Waiver (FDA studies only)

In very limited emergency research situations, the IRB may approve FDA-regulated research without requiring prior informed consent from the research subject. A protocol that clearly is identified as one that may include subjects who are unable to consent because of their life-threatening medical condition and who do not have a legally authorized representative.

In both situations listed above the PI is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject or his/her legally authorized and the IRB. If the IRB determines that it cannot approve the research because the research fails to meet the criteria for waiver of informed consent or because of other ethical concerns, the IRB must document its findings and provide them in writing to the PI and any sponsor. For additional information, see Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research.

7.3 ELEMENTS OF INFORMED CONSENT

FDA 21 CFR 50.25(a) and DHHS 45 CFR 46.116(a) both require that the following basic information be provided to subjects asked to participate in a research project:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

- A statement that a copy of the consent form will be given to the subject.
- The date that the consent form was approved by the IRB [21 CFR50.27(a)]
- A statement explaining procedure for study participants to be provided results of research study, if appropriate.

7.4 DOCUMENTATION OF INFORMED CONSENT

The informed consent document must be prepared in at least a 12-point easily readable font with adequate margins on the sides, top and bottom.

Research investigators are responsible for ensuring that informed consent is documented by the use of the written consent document most recently approved by the IRB. Research investigators shall also be responsible for ensuring that the most recently IRB-approved consent document is used to enroll each research subject and is signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB. The IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

7.5 ASSENT OF MINORS AND CONSENT OF PARENT(S)/ GUARDIAN(S)

7.5.1 Minor's Assent

Assent is defined as a child's affirmative agreement to participate in a research project. Assent is not granted by a child's passive resignation to an intervention procedure. When a research study involves minors as research subjects, both FDA and DHHS require that the research investigator obtain and document the minors' assent (where the minors are capable of providing assent) prior to initiating the research project. For research studies involving minors aged 7-17, the research investigator shall prepare and submit an informed assent document for IRB approval, which outlines the study in simplified language. A separate assent document outlining the key aspects of the research in very simple terms should be prepared for minors aged 7-12. The assent document for minors aged 13-17 may be more comprehensive, but must still use simplified, age-appropriate language.

Research investigators are responsible for obtaining each minor's assent and for ensuring that assent is documented by use of a written document recently approved by the IRB, as indicated by the dated bottom page of the assent document. The research investigator is responsible for ensuring that the minor signs the most age-appropriate assent document and that a copy of the assent is given to the minor and their parent(s)/guardian(s). Once a minor subject turns 18 years of age, the research investigator must re-consent the subject with a more recently approved adult consent document.

7.5.2 Consent of Parent(s)/Guardian(s)

Research investigators are responsible for obtaining parental consent from the parents or guardians of each minor subject enrolled in a research project. Parental consent should be obtained using the parental consent document most recently approved by the IRB, as indicated by the date entered at the bottom of the consent document. If the parents of a potential subject are minors themselves, they are not allowed to consent to their child's participation as a research subject unless the IRB has granted a waiver to this requirement. The IRB may grant waivers for projects that include no invasive procedures and present no more than minimal risk to the minor subjects. In rare instances, waivers may also be granted in situations where parent/guardian consent does not provide reasonable protection to the subjects (e.g., neglected or abused children). However, an adequate mechanism to protect the children as research subjects must be in place and accurately documented.

7.6 RETENTION OF SIGNED CONSENT DOCUMENTS

Research investigators are responsible for retaining all consent and assent documents signed by human subjects or the subjects' legally authorized representatives. These documents shall be maintained by the research investigator for a minimum of three (3) years after completion of the research project.

7.7 CALIFORNIA LAW

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed for informed consent to be legally effective. For information about state requirements, refer to the California Informed Consent Guidelines maintained on the Attorney General's Research Advisory Panel webpage.

8. RECRUITING RESEARCH SUBJECTS

The IRB is responsible for ensuring the equitable selection of research subjects [45 CFR 46.111(a)(3) and 21 CFR 56.111(a)(3)]. In fulfilling this responsibility, the IRB shall review the methods that investigators use to recruit subjects.

University of Redlands IRB follows the reimbursement model when considering payments made to research subjects. This model allows payments to be made to research subjects for direct expenses incurred while participating in a particular research project. However, this payment must not be lucrative enough to serve as an inducement or provide coercion for participation in the study. A payment is reimbursement when it is meant to directly offset the out-of-pocket costs that a subject may incur. This could include reimbursement for expenses such as gas, parking, travel expenses, childcare, food, lost wages, and other expenses that the subject may incur while participating in the study. Modest enticements to participate in the research project will be considered on a case by case basis, but could impede the approval of a proposal. The researcher should justify any payments and enticements to research subjects in their application materials.

8.1 ADVERTISING FOR RESEARCH SUBJECTS

When advertising is to be used to recruit human subjects for research that is to be conducted within, supported by, or under the responsibility of University of Redlands, the IRB shall review the information contained in the advertisement and the mode of its communication to determine if the procedure for recruiting subjects affords adequate protection. The following are not included in this requirement for IRB review:

- Peer communication intended to be seen or heard by other educators.
- News stories.
- Publicity intended for other audiences, but including reference to the research project.

Advertisements used to recruit human subjects should be seen as an extension of the informed consent and subject selection processes. IRB review is necessary to ensure that information is not misleading to subjects, especially when a study will involve persons with physical or mental illness or persons who are economically or educationally disadvantaged.

Generally, any advertisement to recruit subjects should be limited to:

- Name and address of the research investigator.
- Purpose of the research and eligibility criteria that will be used to admit subjects into the study.
- Description of the benefits (e.g., compensation or credit) to the subject for participation in the study.
- Time or other commitment required of subjects.
- Location of the research and the person to contact for further information.

Advertisements may not be directed to minors. Advertisements intended to recruit minor subjects must be directed to minors' parents or guardians and must be sent to the IRB for prior review.

8.2 FINDER'S FEES

The University of Redlands IRB considers it unethical for investigators to provide "finder's fees" to those who refer subjects to them for possible involvement in research studies. The IRB will not approve research proposals that involve such payments.

9. VULNERABLE RESEARCH POPULATIONS

The regulations specify additional protections for certain classes of human research involving children (45 CFR 46.401, and 21 CFR 50.50 and 56.111), pregnant women, human fetuses, and human in vitro fertilization (45 CFR 46.201) and prisoners (45 CFR 46.301 and 21 CFR 56.111 21 CFR 56.107). In addition, other vulnerable populations, such as members of Native American tribes, the mentally disabled, immigrant, and economically or educationally disadvantaged persons may require special protections and procedures as set forth in this policy or as required by the IRB.

9.1 RESEARCH INVOLVING CHILDREN

9.1.1 Categories of Research

There are four basic categories of research that may be conducted on minors. In all cases adequate provisions must be made for soliciting the assent of the minor subjects and permission of their parents or guardians (see section 7.5). The four categories of research are based on the level of risk and benefit, as follows:

1. Research involving minimal risk. (§46.404)
2. Research involving greater than minimal risk that presents the prospect of direct benefit to individual minor research subjects. The IRB may approve the research only if the following conditions are met (§46.405):
   - The risk is justified by the anticipated benefit;
   - The relation of the anticipated benefit to the risk is at least as favorable to the minor subjects as that presented by available alternative approaches; and
   - Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at § 46.408.

1. Research involving greater than minimal risk with no prospect of direct benefit to minor subjects, but likely to yield generalizable knowledge about the minor subject. The IRB may approve such research only if all the following conditions are met (§46.406):
   - The risk represents a minor increase over minimal risk;
   - The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
   - The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
   - Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

2. Research not otherwise approvable by the IRB that the IRB determines presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children. The IRB may approve such research only if the secretary of DHHS (or the FDA commissioner for FDA-regulated research), after consultation with a panel of experts, determines that the research meets defined criteria [45 CFR 46.407(b)].

When planning a research project that will involve minors as subjects, the PI is responsible for making the initial determination regarding which of the above categories applies to his/her research. The IRB shall make the final determination regarding the category of research prior to approval of the research.

9.1.2 Research Involving Minor Students

9.1.2.1 Family Educational Rights and Privacy Act (FERPA)

Administered by the U.S. Department of Education, (ED), The Family Educational Rights and Privacy Act (FERPA) (34 CFR Part 99) protects the privacy of a student's education records at all public elementary and secondary schools and virtually all public and private postsecondary institutions.

Student education records are confidential and cannot be released to third parties without written consent from the student unless disclosure is allowed under one of FERPA's exceptions for signed consent.

Student education records include a range of information about a student that is maintained in schools in any recorded way, such as handwriting, print, computer media, video or audio tape, film, microfilm, and microfiche (NCES).

- Date and place of birth, parent(s) and/or guardian addresses, and where parents can be contacted in emergencies;
- Grades, test scores, courses taken, academic specializations and activities, and official letters regarding a student's status in school;
- Special education records;
- Disciplinary records;
- Medical and health records that the school creates or collects and maintains;
- Documentation of attendance, schools attended, courses taken, awards conferred, and degrees earned;
- Personal information such as a student's identification code, social security number, picture, or other information that would make it easy to identify or locate a student.

Personal notes made by teachers and other school officials that are not shared with others are not considered education records. Additionally, law enforcement records created and maintained by a school or district's law enforcement unit are not education records.

Part of the education record, known as **directory information**, includes personal information about a student that can be made public according to a school system's

student records policy. Directory information may include a student's name, address, and telephone number, and other information typically found in school yearbooks or athletic programs. Other examples are names and pictures of participants in various extracurricular activities or recipients of awards, pictures of students, and height and weight of athletes.

Each year schools must give parents public notice of the types of information designated as directory information. By a specified time after parents are notified of their review rights, parents may ask to remove all or part of the information on their child that they do not wish to be available to the public without their consent.

Generally, schools must obtain written permission from the parent or eligible student in order to release any information from a student's education record. FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when they reach the age of 18 or attend a school beyond the high school level. Accordingly, researchers desiring access to student education records should obtain signed releases that (ED):

- Specify the records that may be disclosed
- State the purpose of the disclosure, and
- Identify the party or class of parties to whom the disclosure may be made.

PIs using FERPA-protected education records should follow all protections normally afforded to research data, including used of the data only for approved purposes, confidentiality, and security from unauthorized access

9.1.2.2 Protection of Pupil Rights Amendment (PPRA)

The U.S. Department of Education (ED) issued guidelines under the Protection of Pupil Rights Amendment (PPRA) regarding research involving minor students. Here and throughout this document, a "minor" is defined to be a person under eighteen years of age. The amendment applies to programs that receive funding from ED, and it is intended to protect the rights of parents and students in the following ways:

- It seeks to ensure that schools and contractors make instructional materials available for inspection by parents if those materials will be used in connection with an ED-funded survey, analysis or evaluation in which their children participate.
- It seeks to ensure that schools and contractors obtain written parental informed consent before minor students are required to participate in any ED-funded survey, analysis or evaluation that reveals information concerning:
    - Political affiliations.

- Mental and psychological problems potentially embarrassing to the student or his/her family.
- Sexual behavior and attitudes.
- Illegal, anti-social, self-incriminating and demeaning behavior.
- Critical appraisals of other individuals with whom the respondents have close family relationships.
- Legally recognized privileged or analogous relationships, such as those of lawyers, physicians and ministers.
- Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such programs).

9.2 RESEARCH INVOLVING PREGNANT WOMEN, FETUSES OR NEONATES

DHHS has established certain criteria that must be met before pregnant women, fetuses or neonates can be involved as subjects in research. According to DHHS criteria, "fetus" and "neonate" are defined as follows: fetus means the product of conception from implantation until delivery and neonate means a newborn.

9.2.1 Pregnant Women or Fetuses

DHHS has established the following criteria (45 CFR 46.201, § 46.204) that must be met prior to conducting research activities that involve pregnant women or fetuses as research subjects:

- Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- Any risk is the least possible for achieving the objectives of the research;
- If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means,

her consent is obtained in accord with the informed consent provisions of section 7;

- If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of section 7, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- Each individual providing consent under the preceding two criteria is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- For children as defined in § 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of section 7;
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- Individuals engaged in the research will have no part in determining the viability of a neonate.

9.2.2 Neonates

DHHS has established the following criteria (45 CFR 46.201, 45 CFR 46.205) that must be met prior to conducting research activities that involve neonates:

- Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:
  - Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates
  - Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the neonate.
  - Individuals engaged in the research will have no part in determining the viability of the neonate.
  - The requirements set forth below have been met as applicable.
- Neonates of uncertain viability may not be involved in research unless the following additional conditions are met:
  - The research must hold out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or;

- The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research, and;
- Informed consent of either parent or either parent's legally authorized representative is obtained, unless altered or waived by the IRB as allowed under the regulation.

- Nonviable neonates may not be involved in research unless the following additional conditions are met:
  - Vital functions of the neonate will not be artificially maintained.
  - The research will not terminate the heartbeat or respiration of the neonate.
  - There will be no added risk to the neonate resulting from the research.
  - The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means, and;
  - Informed consent of both parents is obtained, unless one parent is unable to consent because of unavailability, incompetence or temporary incapacity, in which case the consent of one parent is sufficient. The consent of a legally authorized representative cannot be substituted for parental consent and informed consent cannot be waived or altered.
  - Viable neonates may be included in research only to the extent permitted by and in accord with informed consent requirements, IRB approval and requirements for research involving children (see section 9.1).

9.2.3 Research involving After Delivery, the Placenta, the Dead Fetus or Fetal Material (CFR 45 46.206)

- Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.
- If information associated with the placenta, the dead fetus or fetal material is recorded for research purposes in a manner such that living individuals can be identified, then those individuals are research subjects and all pertinent consents and IRB approval requirements apply and research must be conducted in accordance with any applicable federal or local laws regarding such activities.

9.2.4 Research Not Otherwise Approvable by the IRB

If the IRB determines that the research presents a reasonable opportunity to further the understanding, prevention of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates, the IRB may approve the research only if the

secretary of DHHS, in consultation with experts, determines that certain criteria (45 CFR 46.207) are met.

9.3 RESEARCH INVOLVING PRISONERS

Involvement of prisoners in behavioral or biomedical research requires additional safeguards (45 CFR 46.301), as prisoners may be unduly influenced to participate as subjects in research because of their incarceration. The following must be met as specific requirements for prisoner research (45 CFR 46.304):

- A majority of the IRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from membership on the board.
- The IRB must have at least one member who has a background in prisoner matters (e.g., a former prisoner, social worker).

9.4 RESEARCH INVOLVING OTHER VULNERABLE POPULATIONS

9.4.1 Members of Native American Tribes

The research investigator is responsible for obtaining approval from the appropriate tribal counsel(s) for research involving members of Native American tribes prior to submitting the protocol to the IRB for review and approval. Also adapt language from Guiding Principles for Engaging in Research with Native American Communities?

9.4.2 Mentally Disabled Persons or Economically/Educationally Disadvantaged Persons

Involvement of persons in research who are mentally disabled or economically / educationally disadvantaged requires additional safeguards as those individuals may, because of their conditions, be susceptible to undue influence during the enrollment process or be unable to understand the informed consent process. The IRB will review each case where research may involve mentally disabled or economically/ educationally disadvantaged persons and may require additional safeguards to protect these vulnerable segments of the population.

10. PROCEDURES FOR REPORTING AND RESPONDING TO CONCERNS INVOLVING HUMAN PARTICIPANT RESEARCH

10.1 ADVERSE EVENT REPORTING

If during the course of a research study, an adverse reaction (including unexpected events) does occur, the PI must immediately take action to ameliorate the adverse event and cease research. A full board of the IRB must review these adverse events and reassess the balance between the risks and benefits to the subjects. The PI has the primary responsibility of evaluating each adverse event for severity, likelihood of occurrence and relationship, if any, to the study.

10.1.1 Serious adverse events

- Serious adverse events include the following (FDA):
  - death,
  - a life-threatening adverse event,
  - inpatient hospitalization (initial or prolonged)
  - a significant disability or permanent damage,
  - a congenital anomaly/birth defect, and
  - any medical event that requires treatment.
- Unexpected adverse events: an unexpected adverse event is any adverse event the specificity or severity of which is not consistent with the consent document or protocol. Unexpected refers to an adverse event that has not been previously observed, rather than from the perspective of such experience not being anticipated (21 CFR 312.32).

10.1.2 Reporting Requirements

It is the responsibility of the PI to report serious adverse events and unexpected adverse events that occur during the course of the research to the IRB, the sponsor and federal monitoring agencies, if applicable and appropriate.

10.1.3 IRB Review of Adverse Event Reports

The IRB Chair shall review all serious adverse events that occur under the jurisdiction of the IRB within one business day of receipt. All other reports of adverse events shall be initially reviewed by a member of the IRB within five business days of receipt by the IRB Chair. After initial review, the adverse event shall be reported to the IRB members at a scheduled meeting and the IRB shall take one of the following actions:

- Note the occurrence of the adverse event but take no action.
- Request additional information.
- Require modifications to the protocol or consent document.
- Revise the continuing review timetable, or;
- Suspend the project.

The PI will be immediately notified in writing if his/her protocol is suspended. The PI will also be contacted should additional information be required at any stage of the IRB review process or if changes need to be made to the protocol or informed consent document.

It is the responsibility of the PI to inform subjects participating in an ongoing study of the occurrence of any adverse events related to the research that were unknown at the time the original informed consent document was signed. The IRB may make a determination as to whether or not subjects need be informed. The PI must notify the IRB of when and how subjects are to be informed. Modifications to the consent document that include this new information must be approved by the IRB.

10.2 NOTIFICATION OF PROCEDURES PERFORMED IN VARIANCE WITH THE PROTOCOL

The PI must submit a written report to the IRB within five working days of any activity that is conducted in variance with the protocol. The IRB Chair shall review the deviations that occur under the jurisdiction of the IRB. After initial review, the deviation shall be reported to the IRB members at a scheduled meeting and the IRB shall take one of the following actions:

- Note the occurrence of the variance but take no action.
- Request additional information.
- Require modifications to the protocol or consent document.
- Revise the continuing review timetable, or;
- Suspend the project.

The PI will be immediately notified in writing if his/her protocol is suspended. The PI will also be contacted should additional information be required at any stage of the IRB review process or if changes need to be made to the protocol or informed consent document.

10.3 PROTECTION FOR WHISTLEBLOWERS

Retaliation against whistleblowers is considered scientific misconduct. Therefore, it is the policy of University of Redlands that persons expressing concerns or making allegations about a protocol involving human subjects will not be subject to retaliation, disciplinary action or other actions by the University if they act in good faith. This protection holds even if the concerns or allegations are found, upon investigation, to be without merit. Individuals wishing to report misconduct or violations related to University of Redlands IRB policy should use the procedures outlined on the Ethics Reporting website.

11. CONCLUSION OF RESEARCH PROJECT

11.1 NOTIFICATION OF CONCLUSION OF RESEARCH PROJECT

The research investigator is responsible for notifying the IRB that a research project has been concluded at which point the IRB will close its file. The PI should submit a completed *Final Report* form noting that the research project has been completed and should be closed.

11.2 RETENTION OF RECORDS

11.2.1 PI

Depending on the project and University of Redlands policy, research data may belong to the university, the funder, or the PI (HHS Office of Research Integrity (ORI)). Research data should be retained for at least 3 years after completion of the project or longer if specified by a sponsor. Individually identifiable data should be safeguarded by the research investigator and destroyed in the period defined under the approved protocol. Individually identifiable data will not be relinquished to any sponsor or outside entity. Summarized research results remain the property of the research investigator.

11.2.2 IRB

Protocols and approved informed consent forms will be retained by the IRB in a central accessible location for at least 3 years after completion of the project. All minutes and IRB documentation of discussion will also be held for at least 3 years after project completion.

ABBREVIATIONS

DHHS: Department of Health and Human Services

ED: United States Department of Education

EPA: Environmental Protection Agency

FDA: Federal Drug Administration

FWA: Federal Wide Assurance

HIPAA: Health Insurance Portability and Accountability Act

IDE: Investigational Exemption

IND: Investigational New Drug Application

IRB: Institutional Review Board

NIH: National Institutes of Health

OHRP: Office of Human Research Protections

ORI: Office of Research Integrity

PHI: Protected Health Information

PI: Principal Investigator

USDA: United States Department of Agriculture