University of California, Riverside Policies and Procedures for Protection of Human Participants in Research
(also referred to as the Standard Operating Procedures, or SOPs)

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The University of California, Riverside, Policies and Procedures for the Protection of Human Participants in Research, was adapted from SOPs supplied by Dr. Jeffrey M. Cohen, Ph.D., CIP, President, HRP Associates, Inc.
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FOREWORD

The University of California, Riverside (UCR), *Policies and Procedures for Human Research Protection* (also referred to as the *Standard Operating Procedures*, or SOPs) detail the policies and regulations governing research with human participants and the requirements for submitting research proposals for review by the UCR Institutional Review Board¹ (IRB).

These policies and procedures also detail:

1) Written procedures which the IRB must follow for:
   a) conducting its initial and continuing review of research and for reporting its findings and actions to the principal investigator (PI) and the institution;
   b) determining which projects require review more often than annually and which projects need verification from sources other than the PIs that no material changes have occurred since previous IRB review; and
   c) ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the participant.

2) Written procedures for ensuring prompt reporting to the IRB, appropriate IOs, and the federal Department or Agency head of any unanticipated problems involving risks to participants or others, or any serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB suspension or termination of IRB approval.

These policies and procedures present the most current information for reference by potential PIs and their staff. However, this is not a static document. The policies and procedures are subject to annual review and revision by the Director, the HRRB, and University counsel. The Director will keep the University research community apprised of new information that may affect the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues on its website, through campus electronic mailing lists, and via regular campus-wide seminars.

These policies and procedures are available on the Office of Research Integrity’s IRB website, a public website that also houses FAQs and community reference information for participants or potential participants. This website is updated on a continuing basis.

¹ The IRB is also known as the Human Research Review Board (HRRB) at the University of California, Riverside. For the purposes of this document, however, IRB, an internationally recognized title, will be used.
1 Mission

The University of California, Riverside (UCR) fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the University. In the review and conduct of research, actions by UCR will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (often referred to as the Belmont Report) and will be performed in accordance with the Department of Health and Human Services (DHHS) policy, and regulations at 45 CFR 46 (also known as the “Common Rule”). The actions of UCR will also conform to all other applicable federal, State, and local laws and regulations.

To conduct this responsibility effectively, the University maintains an Institutional Review Board (referred to as the Human Research Review Board (HRRB) at the institution, though hereafter referred to as “IRB” in this document) to review research protocols involving human participants and to evaluate both the risk to and protection of participants. It is the function of the IRB to 1) determine and certify that all projects reviewed by the IRB conform to the policies and procedures in this document and the regulations and policies set forth under the Common Rule regarding the health, welfare, safety, rights, and privileges of human participants; and 2) assist the principal investigator (PI) in complying with federal and state regulations.

1.1 Introduction

These policies and procedures apply to all research involving human participants that requires use of UCR facilities and/or is under the supervision of UCR agents, regardless of sponsorship and where the research is conducted. UCR adopts the definition of “agent” as defined by the Office of Human Research Protection (OHRP): “agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility.” The following are examples of agents of the university:

- UCR faculty members conducting research involving human participants at another institution while on sabbatical;
- UCR students taking classes at another institution and conducting research involving human participants at that institution; and
- persons from another organization or institution that come to UCR to recruit participants for a research project (see Section 4.3: IRB Relationships).

When determining whether a researcher is an agent of the university, the IRB will consider the proposed facilities, resources, and participants to be used for the research. If, for example, a UCR student is working as a research assistant at another institution or organization and conducting human participant research as part of his or her job, this student will not be subject to UCR IRB oversight because he or she is not using UCR facilities, resources, or participants.

The UCR Institutional Review Board has written procedures for determining whether or not studies meet the regulatory definitions of human research. That information, along with other relevant information (including information about the “Common Rule,” the criteria for determining human subjects use) can be found on the IRB website under the “Frequently Asked Questions” section.

UCR is guided by the ethical principles regarding all research involving humans as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled: Ethical Principles and Guidelines for the Protection of Human Subjects of
Research, often referred to as the Belmont Report (National Commissions for the Protection of Human Subjects of Biomedical and Behavioral Research, April 1979).

All domestic or foreign institutional and non-institutional performance sites for UCR will be obligated to conform to ethical principles which are at least equivalent to those of UCR, as cited in the previous paragraph or as may be determined by the DHHS Secretary.

1.2 Ethical Principles: The Belmont Report

The Belmont Report

It is the duty of UCR IRB to review and make decisions on all protocols for research involving human participants. The primary responsibility of the IRB is the protection of research participants from undue risk and from deprivation of personal rights and dignity. This protection is best assured by consideration of three principles, which are the touchstones of ethical research:

1) that voluntary participation by the participants, indicated by free and informed consent, is assured;

2) that an appropriate balance exists between the potential benefits of the research to the participant or to society and the risks assumed by the participant; and

3) that there are fair procedures and outcomes in the selection of research participants.

These principles are summarized as respect for persons, beneficence, and justice.

Respect for Persons: Voluntary Participation and Informed Consent. One of the most important elements in any research involving human research participants is the assurance of voluntary informed consent. Any person who is to be a research participant, whether designed for his/her own direct benefit or for the advancement of scientific knowledge in general, must understand as completely as possible what is to be done and what the potential risks and benefits are. The person must give his/her consent freely, without pressure or inappropriate inducement. The IRB at UCR strives to ensure voluntary informed consent of research participants through careful review of the recruitment and consent process, and of the consent form or information sheet to be used with participants. The informed consent concept is extended to those studies in which the participants are not able to give personal consent for themselves. Here the consent document is addressed to those who have been designated responsible for the research participant’s well-being (e.g., parents of children). The IRB’s concern is to verify that the consent process and document are likely to assist these persons to make an informed decision, which is in the best interest of the research participant. The capacity for truly informed and voluntary participation in research varies widely among study populations. At one extreme there may be ample understanding and manifest freedom from coercion; at the other, there may be degrees of understanding and freedom that affect the consent of potential participants. The IRB will exercise special care when considering participants whose ability to give free and informed consent may be compromised in any way.

Beneficence: The Risk-Benefit Ratio. For any proposed activity which falls under its jurisdiction, the IRB is charged with deciding whether “[t]he risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept (those) risks” (Federal Register, May 30, 1974).

The assessment of the risk/benefit relation is a complex task. There are risks of injury or discomfort to the individual that can be physical, psychological and/or social. There can be potential benefits to the individual, to a group to which the individual belongs, and/or to society. When reviewing applications, the IRB will carefully assess the types and degrees of both risks and benefits for a given participant population, as well as the PI’s communication of these risks and benefits in the consent process and
form. While the IRB is not charged with reviewing scientific design per se, it must sometimes do so in order to assess the risk/benefit ratio. If a study design does not seem adequate to attain the stated aim of the investigation, then no benefit can be anticipated from conducting the study, and there is no justification for placing any research participant at risk, however minimal. Thus the design of the study must be sound, and the nature and likelihood of all risks and benefits must be made clear in any application to the IRB.

Justice: The Fair Selection of Research Participants. Both the risks and the potential benefits of research should be spread fairly among potential individual research participants and research participant groups. Study design and selection of participants should avoid bias for or against particular social, racial, sexual, or ethnic groups.

Sharing Research Risks. The guiding principle in the ethical selection of research participant groups is that any risks of the research should fall upon the groups who might benefit from the research. If the results of a risky protocol might benefit the general population, it would be unethical to focus participant recruitment on vulnerable or disadvantaged groups (e.g., institutionalized people or prisoners; patients at free clinics primarily patronized by people unable to afford other medical care) simply because they are easily accessible or can be persuaded to participate. An undue share of research risks should not also burden groups already burdened by other factors. Rather, attempts should be made to include a fair sampling of the populations who might benefit from the study. When research involves persons whose autonomy is compromised, it is expected that the research bear some direct relationship to the conditions or circumstances of the research participant population. In addition, groups fully able to consider research risks and informed consent should be asked to face research risks before more vulnerable populations. Investigational drugs are usually tested in adults before they are tested in children. Certain investigational drugs and procedures may be tested in healthy volunteers before being tested in patients.

Sharing Research Benefits. In recent years, increasing attention has been paid to the rights of various groups to be included in research. As individuals and through advocacy groups, many patients have come to insist on having access to experimental treatments as these experimental treatments may potentially provide the best medical care available. In addition, researchers, ethicists, and public officials have recognized that because many clinical trials focus primarily on white middle-class research participant groups, the results of some trials were of questionable value for members of other social, racial, sexual, and ethnic groups. As a result, both the National Institutes of Health and the Food and Drug Administration now require that study design include as broad a range of research participants as feasible and the data be analyzed to uncover responses that differ between groups. Where women of child-bearing potential and pregnant and nursing women previously were routinely excluded from new drug trials, it is now required that whenever possible these women be asked to make their own choices after being fully informed of the risks of the research.

2 Definitions

Research – A methodical planned inquiry to obtain or ascertain facts. This includes research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.

For the purposes of this policy, a “systematic investigation” is an activity that involves a prospective methodical planned inquiry which incorporates data collection, both quantitative and qualitative, and
data analysis to answer a research question. Investigations designed to develop or contribute to **generalizable knowledge** are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

**Human Participants Research** – For the purposes of this policy “human subject research” is any activity that meets the DHHS definition of research and involves human participants as defined by DHHS.

**Human participant** – a living individual about whom a PI (whether professional or student) conducting research obtains

1) data through intervention\(^a\) or interaction\(^b\) with the individual, or

2) identifiable private information\(^c\).

\(^a\)Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant’s environment that are performed for research purposes.

\(^b\)Interaction includes communication or interpersonal contact between a PI and participant.

\(^c\)Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the PI or associated with the information) in order for obtaining the information to constitute research involving human participants.]

**IRB approval** – the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

### 3 Institutional Authority

The Chancellor of UCR has designated the Vice Chancellor for Research as the Institutional Official (IO) for carrying out the University’s human research protections program.

The UCR IRB has jurisdiction over all human participant research (as defined below) conducted under the auspices of the institution (see **Section 1.1: Introduction**).

As authorized by a Memorandum of Understanding negotiated among the campuses, all UC campuses may rely on each other’s IRBs.

#### 3.1 Assurance of Compliance

UCR holds a Federal-wide Assurance (FWA), FWA00001965. As part of its FWA, UCR has agreed to protect the welfare of all human participants involved in research, whether or not the research is conducted or supported by a federal department or agency.

#### 3.2 UCR IRB Office

The UCR IRB is supervised by the Director of the UCR Office of Research Integrity (Director) who reports directly to the IO. The Director has expert knowledge in regulatory issues regarding human
participants and serves as the Human Protections Administrator, the sole point of contact at UCR for the Office for Human Research Protections, DHHS.

The duties and responsibilities for all staff are found in their respective job descriptions, and their performance is evaluated on an annual basis.

3.3 Applicable Laws

The UCR IRB relies on the Campus Counsel and the UC Office of the General Counsel for the interpretations and applications of relevant laws of any jurisdiction wherever research is conducted (including transnational research) as they apply to human participants research. All policies and procedures described in these Policies and Procedures, which are applicable to research conducted domestically, also apply to research conducted in other countries, as appropriate. For research being conducted outside the United States, the IRB provides access to the most recent version of OHRP’s “International Compilation of Human Research Protections” to assist researchers in complying with local laws and taking into account cultural context. It is the PI’s responsibility to comply with these laws (see Section 13.3: Transnational Research).

4 UCR Institutional Review Board

The UCR IRB is an administrative body established to protect the rights and welfare of human research participants recruited to participate in research activities conducted under the auspices of this institution in accord with and for the purposes expressed in this policy.

4.1 Authority of the IRB

The IRB reviews and has the authority to approve, require modifications in, or disapprove all research activities conducted under the auspices of UCR. The IRB will ensure that appropriate safeguards exist to protect the rights and welfare of research participants [45 CFR 46.111]. In fulfilling these responsibilities, the IRB reviews all the research documents and activities that bear directly on the rights and welfare of the participants of the proposed research. The UCR Application for Approval to Use Human Subjects and consent/assent document(s) are examples of documents that the IRB reviews. The IRB also reviews the methods and material(s) that PIs propose to use to recruit participants.

Before any human participant is involved in research in relationship to this institution, an IRB will give proper consideration to:

1) the risks to the participants,
2) the anticipated benefits to the participants and others,
3) the importance of the knowledge that may reasonably be expected to result, and
4) the informed consent process to be employed

The IRB has the authority to suspend, place restrictions, or terminate approval of research activities that fall within its jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with unexpected adverse events (see Section 11: Non-Compliance, Suspension, or Termination of IRB Approval or Research). The IRB has the authority to observe or have a third party observe the consent process and the research if the IRB determines it to be indicated (see Section 7.5.8: Consent Monitoring).
4.2 Jurisdiction of the IRB

UCR, as part of its Federal-wide Assurance (FWA), has agreed to protect the welfare of all human participants involved in research, whether or not the research is conducted or supported by a federal department or agency. Therefore, the UCR IRB has jurisdiction over all human participant research conducted at this institution, regardless of funding, as described in Section 1.1: Introduction, except if the only involvement of human participants is in one or more exempt categories (see Attachment A – Exempt Categories of Review).

4.3 IRB Relationships

The IRB functions independently of, but in coordination with, other institutional regulatory committees. The IRB, however, makes its independent determination whether to approve or disapprove a protocol based upon whether or not human participants are adequately protected. The IRB has review jurisdiction over all research involving human participants conducted, supported, or otherwise participant to regulation by any federal department or agency that has adopted the human participants regulations.

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of UCR. However, those officials may NOT approve research if it has not been approved by the IRB.

IRB members and staff are encouraged to report any attempts to or suspicions of undue influence of IRB determinations to the ORI Director or IO via email, telephone, or in person. The IRB member or staff may also report undue influence to the UCR designated official, per UCOP’s Whistleblower Policy. The ORI Director, IO, and/or designated official will investigate the allegations, make conclusions based on the findings, and take appropriate actions.

Relationships with other institutions:
In the conduct of cooperative research projects, UCR acknowledges that each institution is responsible for safeguarding the rights and welfare of human participants and for complying with applicable federal regulations. The particular characteristics of each institution’s local research context must be considered, either (i) through knowledge of its local research context by the UCR IRB or (ii) through subsequent review by the appropriate designated IOs, such as the Chairperson and/or other IRB members at cooperating institutions.

PIs from a different institution (non-UCR PIs) who express a desire to conduct a study at UCR will be guided to the policy 529-002, “Policy for Research Being Conducted by a Non-UCR Principal Investigators Accessing UCR Facilities, Patients or Personnel.” All Non-UCR PIs must complete and submit the Non-UCR Principal Investigators Accessing UCR Facilities, Patients or Personnel form before the UCR determines to take one of the following methods of review:

1) Enter into a joint review and approval arrangement with the other institution. The non-UCR PI will be asked to submit the pending or approved protocol from his/her own institution. This protocol will be subject to the standard UCR protocol review process as described in Section 7: IRB Review Process.

2) Rely on the review of another qualified IRB. Before UCR relies on the IRB of another institution, UCR may take the following actions: request copies of that institution’s assurance, the approved protocol and consent documents, and the approval notice. UCR may also review the other institution’s IRB web site and, if necessary, discuss the protocol with the other institution’s IRB staff or Chair.

UCR may also choose, on a case-by-case basis, to provide human research protection oversight for another institution. In order for the University to provide this oversight, a formal relationship must be
established between the University and the other institution through either a Cooperative Agreement or a Memorandum of Understanding. This relationship must be formalized before the University will accept any human research proposals from the other institution.

When UCR is the coordinating center for a multi-center protocol, the IRB will require the UCR PI to ensure that IRB approval has been obtained at each participating site prior to initiation of the research at that site. At the time of initial review, the IRB will assess the procedures for dissemination of protocol information (e.g., unanticipated problems involving risks to participants or others, protocol modifications, interim findings) to all participating sites.

4.4 Roles and Responsibilities

4.4.1 Chairperson of the IRB

The UCR IO, in consultation and approval with the IRB members, and the Director, appoints a Chair and Vice Chair of the IRB to serve for renewable three-year terms. Any change in appointment, including reappointment or removal, requires written notification.

IRB Chair should be a highly respected individual, from within or outside the University, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of the Chair. The IRB must be perceived to be fair, impartial, and immune to pressure by the institution’s administration, the PIs whose protocols are brought before it, and other professional and nonprofessional sources.

The duties of the IRB Chair include:

- conducting the meetings and serving as a signatory for correspondence generated by the IRB;
- designating other IRB members (e.g., the Vice Chair and Director) to perform duties, as appropriate, for review, signature authority, and other IRB functions; and
- advising the IO and the Director about IRB member performance and competence.

The performance of IRB Chair will be reviewed on an annual basis by the Director in consultation with the IO. If the Chair is not acting in accordance with the IRB’s mission, following these policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the Chair, he/she will be removed from the position of IRB Chair.

4.4.2 Vice Chair of the IRB

The Vice Chair serves as the Chair of the IRB in the absence of the Chair and has the same qualifications, authority, and duties as Chair.

4.4.3 Subcommittees of the IRB

The Chair, in consultation with the Director, may designate one or more IRB members to serve on a subcommittee to perform appropriate duties, which may include review, signature authority, and other IRB functions.

For IRB members to serve as designees to the IRB Chair for expedited review, they must have

- received the appropriate training as described in Section 5.3: Training/Ongoing Education of Chair and IRB Members in Regulations and Procedures
- the appropriate disciplinary expertise, and
• attended at least one Committee meeting.

Duties of a subcommittee may include the following:

1) Serve as designees by the IRB Chair for the review of new or continuing protocols, and/or modifications of continuing protocols.

2) Review and approve non-substantive revisions submitted by PIs for a protocol given provisional approval, i.e., “Approval Pending Revisions,” by the convened IRB.

3) Conduct an inquiry into allegations of non-compliance (see Section 11.2.4: Inquiry Procedures).

4) Conduct on-site review or audit of research that requires additional supervision as determined by the IRB (for example, for a PI who is performing particularly risky research, or for a PI who has recently had a protocol suspended by the IRB due to regulatory concerns).

4.5 Resources for IRB

UCR provides for the appropriate number of IRBs for the volume and types of research that are currently conducted at UCR. UCR will review the resources and activity of the IRB on an annual basis and make a determination as to the appropriate number of IRBs for the institution.

UCR provides its IRB(s) with adequate resources, including adequate meeting and office space, and staff, to review protocols in a thorough and timely manner and has time for thoughtful discussions commensurate with the level of risk involved. Office equipment and supplies, including technical support, file cabinets, computers, internet access, and copy machines, will be made available to the IRB and staff. UCR also provides resources that are necessary to protect the participants recruited for such studies. This includes an adequate and qualified staff, adequate facilities, and the availability of a counseling center that participants may need as a consequence of the research. The resources provided for the IRB and IRB Office will be reviewed during the annual budget review process.

4.6 Conduct of Quality Assurance/Quality Improvement Activities for IRB Operation

The IRB is subject to audit by the UCR Audit and Advisory Services (AAS) per AAS’s annual schedule or “for cause.” If an IRB chair, member, or staff person feels that the IRB has been unduly influenced by any party, he/she may make a confidential report to the IO, depending on the circumstances. The institution will conduct a thorough investigation and corrective action will be taken to prevent additional occurrences.

The IRB Office staff takes all complaints, unanticipated problem or adverse event reports, or allegations of non-compliance seriously. Complaints, unanticipated problems, or adverse event will be logged into a database and responded to within 3 business days after the staff receives the report; a plan of action must be agreed upon between the PI and IRB Staff and/or members within 15 business days after the report, or the PI will be considered to be in non-compliance. If more than 5 complaints a year, or 3 unanticipated problems or adverse events a year, are reported for a single protocol or PI, the IRB staff and/or members will conduct an investigation and audit of the PI and protocol(s) in question. If any single complaint, unanticipated problem, or adverse event is deemed serious by the IRB Staff and/or members, an audit will automatically take place. Some possible results of these investigations include mandating additional training, or, if necessary, suspension or termination of the research.

For allegations of non-compliance, a plan of action will be determined by the IRB Chair (or designee) and Director within 7 business days. Resolutions for such allegations will depend on the type of non-compliance (e.g., minor, serious, continuing, etc.). (See Section 11: Non-Compliance, Suspension,
or Termination of IRB Approval of Research for a detailed discussion of investigations and audits.)

In addition, the staff will conduct “for cause” and “not for cause” audits of research. Some examples of “not for cause” audits are the continuing review process and annual lab inspections to ensure that data are stored and protected as described and approved in a researcher’s protocol. Annual lab inspections will be scheduled in advance with the researcher to accommodate the researcher’s schedule. Labs participating in the annual inspections will be randomly selected by the staff and will vary each year.

The IRB has a Quality Improvement (QI) plan to ensure that the rights and welfare of human participants in research are adequately protected while providing timely service to PI's and their research staff. Measures of the quality, efficiency, and/or the effectiveness of the QI plan include assessing, on a monthly and annual basis, the number of visitors to key IRB websites such as the Community Reference page, the Frequently Asked Questions page, the forms and training pages, and these SOPs. Additionally, all approval or determination emails will include a link to a brief, anonymous online survey for researchers to rate their experience with the IRB and its staff. These surveys will be stored and reviewed every 3-4 months to monitor the campus’ satisfaction with the IRB and take into consideration any suggestions for improvement.

In addition, the support by the university administration of the IRB is assessed regularly, primarily through the annual campus budget planning process, so that continued financial support (including adequate staffing levels and operating funds) for the IRB is maintained.

5 IRB Membership

5.1 Composition of the IRB

UCR adheres to the Federal Regulations, 45 CFR 46.107, regarding the composition of the IRB which requires at least five men and women who are

- professionally competent
- qualified through experience and expertise,
- of diverse races, cultural backgrounds, and professions, and
- with sensitivity to such issues as community attitudes to safeguard the rights and welfare of human participants of research activities commonly conducted by the institution.

The IRB must also include

- one or more individuals who are knowledgeable about and experienced in working with vulnerable populations that are commonly recruited as UCR research participants (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons);
- at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
- at least one member who represents the perspective of research participants; and
- at least one member who is not affiliated with UCR and who is not part of the immediate family of a person who is affiliated with UCR.

In addition, UCR graduate students and the Director the UCR Office of Research Integrity may serve as voting member of the IRB.
One member may satisfy more than one membership category.

Individuals with potential competing business interests cannot serve on the IRB or be involved in the day-to-day operations of the review process. For example, the Director of Sponsored Projects, the Associate Vice Chancellor for Research or others who are responsible for raising funds or garnering support for research cannot serve on the IRB or be involved in the daily operations of the review process.

5.2 Appointment of Members to the IRB

When the need for a new or replacement member is identified by the IRB Chair, Vice Chair, and/or the Director may nominate candidates qualified for membership based on the prospective member's knowledge, skills, and abilities appropriate to their respective roles. The names of the nominees may be communicated to the IRB Chair and Staff or the IO. The IO or the Director may contact the appropriate Department Chairs or Program Directors to solicit nominees. All nominees will be contacted by the Director.

The final decision in selecting a new or replacement member is made by the IO and the Director.

Appointments are made for a renewable three-year period of service. Any change in appointment, including reappointment or removal, requires written notification. Members may resign by written notification to the IO.

The IRB Chair and the Director reviews the membership and composition of the IRB on an annual basis to determine if it continues to meet regulatory and institutional requirements.

Alternate members. The appointment and function of alternate members is the same as that for primary IRB members. The alternate’s expertise and perspective must be comparable to those of the primary member. The IRB roster identifies the primary member(s) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The IRB minutes will document when an alternate member replaces a primary member.

5.3 Training/Ongoing Education of Chair and IRB Members in Regulations and Procedures

A vital component of a comprehensive human research protection program is an education program for the IRB Chair and the IRB members. UCR is committed to providing training and an on-going educational process for IRB members and the staff of the IRB Office related to ethical concerns and regulatory and institutional requirements for the protection of human participants and to improve their qualifications and expertise for protecting the rights and welfare of research participants. This is accomplished by having mandated training at every convened IRB meeting that addresses current, relative issues related to human participants research.

Orientation. New IRB members, including alternate members, will meet with the IRB Chair and Director for an informal orientation session. At the session, the new member will be given an IRB Handbook (binder) that includes:

- Federal and international regulations relevant to the IRB;
- UCR Policies and Procedures for Human Research Protection;
- The Belmont Report.
Initial Education. IRB members and office staff are required to complete the UCR online tutorial. IRB members must complete the tutorial before they may serve as Primary Reviewer.

Continuing Education. To ensure that oversight of human research is ethically grounded and the decisions made by the IRB is consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB. The Office of Research Integrity will provide continuing education at each regularly scheduled, convened IRB meeting and via email. Educational activities include, but are not limited to:

- In-service training at IRB meetings, such as reviewing the UCR IRB SOPs;
- Regular training workshops;
- Copies of appropriate publications;
- Identification and dissemination by the Chair, IRB members, Director, and UCR ORI staff of new information that might have affected the human research protection program, including laws, regulations, policies, procedures, and emerging ethical and scientific issues to IRB members via email, mail, or during IRB meetings;
- Unlimited access to the IRB Office resource library.

The IO will provide support for the Chair, Vice Chair and as many members of the IRB as possible to attend the annual PRIM&R/ARENA conference on human research protections.

The IRB administrators will be expected to become Certified IRB Professionals (CIP-certified).

5.4 Duties of IRB Members

Regarding convened IRB meetings, members are required to review all documents, including the agenda, minutes, and protocols and their related materials, prior to the convened meetings. All copies of the convened meeting materials, including protocols and their related materials, must be returned to the IRB staff at the conclusion of the meeting for professional document disposal.

Members are also required to serve as designated reviewers for protocols undergoing expedited review procedures. Members assigned to review protocols in this manner are asked to respond within 5 business days with the Expedited or Full Review Checklist and any additional comments and recommendations. The designated reviewer(s) may determine that any specific protocol requires full committee review and, in this event, the protocol will be placed on the next agenda as the schedule of meetings reasonably allows. Designated reviewer(s) may also suggest that a protocol is exempt from review, and in that event, the Chair or Vice-Chair will review the protocol and the reviewer(s) recommendations and proceed as determined.

IRB members are expected to treat the research proposals, protocols, and supporting data with confidentiality.

5.5 UCR Expectations of IRB Members

The UCR IRB is committed to fostering professional and collegial relationships between the UCR research community and the IRB, including its members and staff. As a result, great consideration is given when choosing members who can positively represent the IRB. IRB members are expected to be familiar with the 45 CFR 46 and related documents as set forth in the “UCR Human Research Review Board Policies, Rules & Regulations” manual given to each member.

In addition, during convened IRB meetings, IRB members are expected to:
• Carry out their duties in a spirit of collegiality. This entails mutual respect in the deliberations during the convened IRB meetings by listening carefully and courteously to fellow IRB members and guests (such as external consultants and/or the PI).
• Provide constructive criticism and critique.
• Focus on the protection of human participants, rather than administrative issues; members are encouraged to submit administrative requests for revisions (e.g., grammatical errors in the protocol) to the IRB staff before or after the convened meeting.
• Be mindful of the amount of time spent on a protocol or other agenda items. It is understood that weightier issues require more discussion, and administrative and/or non-substantive issues require less discussion. The length of a discussion should be appropriate given the issues at stake.
• Express their concerns, without expecting others to agree with them; a “groupthink” mentality is strongly discouraged.

Members will be evaluated on an annual basis as described in Section 5.8: Review of IRB Member Performance.

5.6 Attendance Requirements

Members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should inform the IRB Chair, Vice Chair, or an IRB Office staff member. If the inability to attend will be prolonged, a request for an alternate to be assigned may be submitted to the Chair or the Director.

If the member has a designated alternate (See Section 5.4: Duties of IRB Members), the alternate can serve during the primary member’s absence, provided the IRB has been notified in advance.

If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he/she must notify the IRB at least 30 days in advance so that an appropriate replacement can be obtained. The replacement can be temporary, for the period of absence, or permanent if the member is not returning to the IRB.

5.7 Member Self-Disclosure of Conflict of Interest

IRB members and consultants will not participate in any IRB action taken, including the initial and continuing review of any project, in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members are expected to self-identify conflicting interests. A primary reviewer or expedited reviewer with a conflict of interest must notify the IRB staff, who will then re-assign the protocol to another reviewer.

An IRB member is considered to have a conflicting interest when the IRB member or an immediate family member of the IRB member:

1) is the PI of the research project;
2) is a member of the research team;
3) is the program director of the program under which the study is being run;
4) has a financial interest in the research whose value cannot be readily determined or whose value may be affected by the outcome of the research;
5) has a financial interest in the research with value that exceeds the specified monetary threshold in the California Fair Political Practices Commission Conflict of Interest Policy 700-U Form and/or the Federal thresholds as contained the UC Federal Financial Disclosure Form;
6) has received or will receive any compensation whose value may be affected by the outcome of the study;
7) has a proprietary interest in the research (property or other financial interest in the research including, but not limited to, a patent, trademark, copyright or licensing agreement);
8) is an executive or director of the agency/company sponsoring the research; and/or
9) any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

Except when requested by the IRB to be present to provide information, the IRB member will absent himself or herself from the meeting room before the IRB reviews research in which he/she has a conflicting interest. The absent member is not counted toward the quorum and his/her absence and the reason for the absence during the discussion and vote on the protocol will be noted in the IRB meeting minutes.

All IRB members will submit a “Disclosure of Potential Conflict of Interest” form annually to the IRB staff for review by the Chair and staff. The IRB staff will maintain this documentation as proof that these individuals are aware of and committed to compliance with the IRB policy regarding conflicts of interest.

If the Conflict of Interest status of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chair and/or Director.

All conflicts of interest are managed according to the University’s Conflict of Interest Policy.

5.8 Review of IRB Member Performance

The IRB members’ performance will be reviewed on an annual basis by the Chair and Director, and recommendations will be made to the IO concerning any issues that require remediation, e.g., members who are not acting in accordance with the IRB’s mission or policies and procedures or who have an undue number of absences either of which may result in the member being removed from the IRB. After the determination is made concerning the members’ performance, the IO will send every member a letter to communicate this determination; the letter may confirm a member’s continued service on the IRB, excuse a member from further service, or request a meeting with a member for whom re-appointment is in question in order to determine if the person should continue serving on the IRB. If the IO determines that the member in question is unsuitable for re-appointment, the IO will inform the member of this determination via a letter excusing them from the IRB.

HRRB members may request to meet with the Chair, Director, and/or IO during this evaluation period. At that meeting, members can discuss if they would like additional education/training, concerns about procedures, concerns related to IRB staff and/or other HRRB members, recommend areas requiring improvement, goals and expectations for the coming year, and other topics they deem necessary.

In addition, if at any time there is evidence that a member is not acting in accordance with the IRB’s mission or policies and procedures, has an undue number of absences from convened IRB meetings, or has an undue number of declinations to requests for review, the member may be removed from the IRB for cause.

The IRB staff members are evaluated annually by the Director of the Office of Research Integrity as part of the University’s mandatory performance evaluation process. This includes the submission of a Self-Appraisal Form by the staff member to the Director and the solicitation by the Director of comments from extra-departmental persons who have interacted with the IRB staff, e.g., the IRB chair and vice chair and other committee members as well as non-IRB clients. The Director reviews the
Self-Appraisal Form and comments from extra-department persons and completes a Performance Appraisal Form for each staff member. This Form is also reviewed by the Institutional Official. After such review, the Director meets with each staff member to discuss the Performance Appraisal, including areas requiring improvement, the plan for the remediation of these issues and the development of action plans, training, and development goals or expectations for the coming year.

5.9 Liability Coverage for IRB Members

The University’s insurance coverage applies to employees and any other person authorized to act on behalf of the University for acts or commissions within the scope of their employment or authorized activity.

5.10 Use of Consultants (Outside Reviewers)

When necessary, the IRB Chair or the Director may solicit individuals from the University or the community with competence in special areas to assist in the review of issues or protocols that require appropriate scientific or scholarly expertise beyond or in addition to that available to the IRB. Prior to committing to review, consultants will be informed of the IRB conflict of interest policy either by phone or letter from the Director. Consultants must verbally confirm to the Director that they do not have a conflict of interest prior to review. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation.

The consultant’s findings will be presented to the full board for consideration either in person or in writing. If in attendance, these individuals will provide consultation but will not participate in or observe the vote. Reports and comments provided by consultants will be recorded in the IRB minutes and kept with the PI’s file that was reviewed.

Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher’s confidentiality and is in compliance with the IRB conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular PI and research protocol).

6 IRB Records

The IRB will prepare and maintain adequate documentation of its activities including copies of all items reviewed, such as
- research proposals and recruitment materials,
- scientific evaluations (if any) that accompany the proposals,
- the description of action taken by the reviewer,
- any findings required under the regulations,
- approved consent documents,
- the specific category of exemption or expedited review,
- the frequency for the next continuing review,
- any proposed amendments and the IRB action on each amendment,
- progress reports submitted by PIs,
- reports of injuries to participants and serious and unexpected adverse events,
- documentation of protocol violations, and
- documentation of non-compliance with applicable regulations.

The IRB will also maintain the HRRB Reviewer’s Checklist, which supports determinations for
- waiver or alteration of the consent process;
• research involving pregnant women, fetuses, and neonates;
• research involving prisoners; and
• research involving children.

IRB records will also include copies of all correspondence between the IRB and PIs. Statements of significant new findings provided to participants will be maintained with the related research proposal and, when reviewed at an IRB meeting, will be documented in the minutes, unless they are already documented in the records.

6.1 Minutes of an IRB Meeting
Proceedings will be available for review by the next regularly scheduled IRB meeting date. Once approved by the members at a subsequent IRB meeting, the minutes may not be altered by anyone, including a higher authority. Minutes of IRB meetings will contain sufficient detail to show:

1) The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area (see Section 7.4.2: Quorum);
2) When an IRB member was not present (and that the quorum was maintained) during the deliberations or voting on proposal with which the member has a real or potential conflict of interest, as defined by University policy (see Section 5.7: Member Self-Disclosure of Conflict of Interest);
3) Actions and votes taken by the IRB related to the previous meeting’s Minutes;
4) Actions taken by the IRB related to protocols requiring review by the convened IRB, including
   a. a summary of the discussion of controverted issues and their resolution;
   b. key information provided by consultants will be documented in the minutes or in a report provided by the consultant
   c. documentation indicating the approval of a waiver or alteration of the HIPAA Authorization, as required by 45 CFR 164.512(i)(2), if applicable;
   d. the basis for requiring changes in or disapproving research;
   e. determinations regarding the level of risk;
   f. determinations that the proposed consent procedures meet the criteria set forth by the applicable regulations for informed consent, the waiver or alteration of informed consent, or the waiver or alteration of the documentation of informed consent (45 CFR 46.116-117);
   g. determinations related to the use of and protection of the vulnerable populations represented by the 45 CFR 46 Subparts B, C, and/or D, if applicable;
   h. the approval period for initial and continuing review;
   i. the frequency of continuing review; and
   j. the vote on actions, including the number of members voting for, against, and abstaining;
5) Separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB;
6) Separate deliberations, actions, and votes for each modification to a protocol undergoing review by the convened IRB;
7) Protocols that have been approved via expedited procedures;
8) Protocols that have been determined to be exempt from Federal regulations; and
9) Any announcements and continuing education topics that were covered at that meeting.
6.2 Membership Rosters

A current membership list of IRB members is maintained by the IRB staff. The list contains information such as a member’s name; earned degrees; representative capacities in terms of the vulnerable populations that each member is knowledgeable about or experienced in working with, if any; affiliated or non-affiliated status (whether the member or any of his/her immediate family members are affiliated with UCR); status as scientist (scientist or non-scientist); voting status (e.g., member, alternate, Chair, or Vice-Chair); and qualifications as member including indications of experience sufficient to describe each IRB member's chief anticipated contributions. A résumé for the IRB member will be maintained.

Changes in IRB membership are promptly report to the Office for Human Research Protections (OHRP), Departments of Health and Human Services.

6.3 Records Retention Requirements

The above detailed records are stored securely in the IRB Office and retained for at least three years after completion of the research unless otherwise specified. After that time the records are destroyed. If a protocol is cancelled without participant enrollment, IRB records are maintained for at least three years after cancellation.

Records pertaining to research involving children as participants are stored securely for at least seven years after the children turn 21, unless otherwise specified. After that time the records are destroyed.

All records must be accessible for inspection and copying by authorized representatives of the OHRP, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

Currently, the IRB forms are paper and those records are maintained in two alarmed IRB offices (the active records) and also in the locked office conference room (the retired records). The staff tracks these records on a database. The forms are available daily to the IRB office staff and to the IRB Chair and the IRB members upon request. When records are required to be destroyed, the IRB office staff places them in a box labeled “Shredding,” taping it closed and contacts the main office who provides a work order for Physical Plant to pick up all material that requires shredding and take them to the campus’ shredding facility. Digital records are maintained on secured servers.

7 IRB Review Process

These procedures and guidelines apply to all research involving human participants conducted under the auspices of UCR, regardless of sponsorship and performance site.

On an annual basis, the Chair will designate a list of experienced IRB members (as defined above) eligible to conduct reviews and the Chair or the IRB Office will select reviewers from that list.

7.1 Human Participants Research Determination

If a PI is conducting research as defined in Section 2: Definitions, an IRB protocol must be filed. The responsibility for determining whether an activity constitutes human participants research rests with the PI. The University will hold PIs in noncompliance (see Section 11.2: Noncompliance) if the determination is not correct. Therefore, PIs are urged to request a confirmation from the IRB Office whether an activity constitutes human participants research by submitting the UCR HRRB Request for Determination of Non-Human Subjects Research form. The IRB staff and Chair will review and return the form with a response indicated on the last page of the form. The IRB’s response to the submission will be based on 45 CFR 46.102(d-f), and references will be made available to the PI. Both the PI and the IRB Office will retain documentation of such a decision.
7.2 Exempt Research

All research using human participants must be reviewed by the ORI. The IRB requires all PIs proposing to use human participants in their research to submit a complete protocol for IRB review before a final determination as to the category of review is made. These determinations are communicated via e-mail to the PI when the review process is completed.

Upon review, the ORI may determine that the proposed research falls into the exempt categories of research. This means that the research is exempt from Federal regulations. However, exempt research is still subject to institutional review and must be approved by a qualified ORI staff or IRB member.

Not all research is eligible for exemption. Exemptions do not apply if the research specifically recruits vulnerable populations such as prisoners or persons who are cognitively impaired.

Research specifically involving children and persons who are economically or educationally disadvantaged, or pregnant women, human fetuses, and/or neonates may be eligible for exempt review on a case-by-case basis.

For categories of research permissible for Exemption, please refer to the 45 CFR 46.101(b), which is also posted as Attachment A – Exempt Categories of Review on the IRB Website.

7.2.1 Additional Protections

Although exempt research is not covered by the federal regulations, this research is not exempt from the ethical guidelines of the Belmont Report because some exempt research raises ethical concerns. Additionally, the individual making the determination of exemption may require additional protections for participants in keeping with the guidelines of the Belmont Report.

To determine if exempt research adequately protects participants, the individual making the determination of exemption uses the HRRB Exempt Protocol Reviewer’s Checklist. This checklist ensures that all applicability criteria are met and is kept with the file to document the reviewer’s determinations, including justifications for exempting the protocol from Federal regulations.

7.3 Expedited Review of Research

For categories of research that may undergo an Expedited review procedure, please refer to the Categories of Research published by OHRP, which is also posted as Attachment B - Expedited Categories of Review on the IRB Website.

The IRB may use the expedited review procedure to review:

1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk, and/or

2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

A minor change is one which, in the judgment of the IRB reviewer, all added procedures involve no more than minimal risk and fall into categories (1)-(7) of research that could be reviewed using the expedited procedure, makes no substantial alteration in

(i) the level of risks to participants;

(ii) the research design or methodology;
(iii) the number of participants enrolled in the research (no greater than 10% of the total requested);

(iv) the qualifications of the research team;

(v) the facilities available to support safe conduct of the research; or

(vi) any other part of the research that would otherwise warrant review of the proposed changes by the convened IRB.

Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more reviewers (e.g., a subcommittee of the IRB) designated by the Chair, in consultation with the IRB staff, from among members of the IRB.

If a subcommittee is asked to conduct a review using the expedited procedure, the subcommittee submits its majority vote to the IRB staff, who then communicates this vote to the IRB Chair for the final determination of the status of the protocol.

When reviewing research under an expedited initial or continuing review procedure, the IRB Chair, or designated IRB member(s), will receive and review all documentation that would normally be submitted for a full-board review (see Section 7.5.2: Materials Received by the IRB), including the complete protocol, and determine the regulatory criteria for use of such a review procedure by using the Expedited Review Checklist, which includes the nine Expedited categories of review. This checklist ensures that all applicability criteria are met and represents one or more approvable categories or research, and is kept with the file to document the reviewer’s determinations, including justifications for using the expedited procedure.

If modifications are proposed to previously approved research, reviewers evaluate whether these changes represent “minor” modifications.

In reviewing the research, the reviewers will follow the review procedures described in Section 7.5: Review Process and may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth below.

The criteria for approval using the expedited procedures are the same as those for review by a convened IRB.

7.3.1 Informing the IRB

All members of the IRB are apprised of all expedited review approvals of new protocols, as well as of protocols undergoing continuing review and modifications to previously approved protocols, by means of the agenda for the next scheduled meeting. Copies of the expedited review approvals will be made available for any optional review at the request of any IRB member.

7.4 Convened IRB Meetings

Except when an expedited review procedure is used, the IRB will review proposed research at convened meetings at which a quorum is present (see Section 7.4.2: Quorum).

7.4.1 Schedule of IRB Meetings

The IRB meets on a regular monthly basis throughout the year. The meeting schedule may vary due to lack of business, holidays, or lack of quorum. However, if important business necessitates an immediate response, special meetings may be arranged to meet that need.
7.4.2 Quorum

A quorum consists of a simple majority of the voting membership, including at least one member whose primary concern is in a non-scientific area and at least one member unaffiliated with UCR. If there is a research protocol involving prisoners or participants vulnerable to coercion or undue influence, a representative for each group must be present and included in the quorum. The IRB Chair, with the assistance of the IRB staff, will confirm that an appropriate quorum is present before calling the meeting to order. The IRB Chair will be responsible to ensure that the meetings remain appropriately convened.

A quorum must be maintained for each vote to occur. If a quorum is not maintained, the proposal must be tabled or the meeting must be terminated. All members present at a convened meeting have full voting rights, except in the case of a conflict of interest (see below). In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting.

IRB members are strongly recommended to be physically present at the meeting. If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. In this case the member must have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions.

Opinions of absent members that are transmitted by mail, telephone, facsimile or e-mail may be considered by the attending IRB members but may not be counted as votes or to satisfy the quorum for convened meetings.

7.4.3 Pre-Meeting Distribution of Documents

Place and time of meeting is set forth on the agenda cover sheet distributed to all IRB members.

The agenda, with review assignments, and all protocols and supporting documentation to be reviewed are provided to all IRB members approximately one week prior to each meeting.

7.4.4 Guests

At the discretion of the IRB, the PI may be invited to the IRB meeting to answer questions about their proposed or ongoing research. The PI may not be present for the discussion or vote on their research.

Other guests may be permitted to attend IRB meetings at the discretion of the IRB Chair and the Director. Guests must sign a confidentiality agreement and may not participate in the deliberations unless requested by the IRB.

7.4.5 Primary Reviewers

The IRB Office staff assigns a Primary Reviewer from the members of the appropriate IRB for all protocols requiring full IRB review. Reviewers are assigned protocols based on related expertise. When making reviewer assignments, IRB staff takes into consideration the vulnerable populations involved in the research and assign the protocol to at least one individual who has experience with this population. If the IRB Staff cannot identify a primary reviewer with appropriate expertise, the IRB Chair or the Director will solicit one or more consultants from the University or the community with competence in special areas to assist in the review of issues or protocols, which require appropriate scientific or scholarly expertise beyond or in addition to that available on the IRB (see Section 5.10: Use of Consultants (Outside Reviewers)).

Before the meeting, each protocol application (including background information, project protocol, and informed consent) must be carefully reviewed by the Primary Reviewer.
At the meeting, the Primary Reviewer presents a brief overview of the protocol application, with specific attention paid to the Risk/Benefit Ratio of the research and the adequacy of the consent form in addressing participants’ concerns. The Primary Reviewer will present any problems, questions, or concerns related to the research. Other IRB members are then invited to introduce other areas of concerns. The IRB may request to speak to with an external consultant as described in Section 5.10: Use of Consultants (Outside Reviewers), or the PI via conference call or in person (previous arrangements would have been made by the IRB Staff to facilitate this). The Committee then makes a determination via majority vote regarding the PI’s immediate responses (if applicable), the review that will be sent back to the PI, and the substantive or non-substantive nature of the review, and IRB actions (e.g., approval determinations).

### 7.4.6 Administration of a Convened Meeting

While a convened IRB meeting differs depending on the issues at hand, each meeting has a general structure that must be followed in order to meet the goals of these meetings. Below is a description of the normal courses of action that must take place during a convened meeting:

1) The Chair begins each meeting by reminding members to declare a conflict of interest on any issue before the Committee; submit a minority opinion for the next convened meeting’s Minutes, if they voted in the minority; keep the discussions of the Committee confidential; and leave all hard copies of protocol-related documents with the staff for professional disposal.

2) The Committee reviews and votes on the Minutes from the most recent convened meeting.

3) The Committee reviews and votes on any previously tabled IRB protocols, new IRB protocols or amendments that were requested by an IRB member to be reviewed by the convened IRB, and Applications to Extend Approval for protocols that were reviewed and approved by the convened IRB within the last 12 months.

4) The Chair updates members of the progress of protocols that were reviewed by the convened IRB and deferred to Chair and Staff for non-substantive issues.

5) The Chair draws the members’ attention to a list of expedited approvals, exempt determinations, retired/withdrawn protocols, and other protocol-specific determinations that were made after the last convened meeting.

6) The Staff conducts a mini-training session on a selected IRB policy or a current IRB issue.

7) The IRB Chair, members, and staff are invited to make any Committee-related announcements before the meeting is adjourned.

The IRB Chair has the responsibility of ensuring that the above points are followed as closely as possible during the course of the convened IRB meetings.

For details related to the documentation of any determinations made during the convened meeting, see Section 6.1: Minutes of an IRB Meeting.

### 7.5 Review Process

#### 7.5.1 New Protocol Applications

The Protocol Application must include enough information for reviewers to make determinations based upon the Criteria for IRB approval of Research [45 CFR 46.111]. The UCR HRRB Application
for Approval to Use Human Participants consists of questions to help the PI meet Federal requirements.

Applications are screened by the IRB Office staff for completeness and regulatory compliance prior to assigning them to a Primary Reviewer for expedited review or review by the convened IRB.

7.5.2 Materials received by the IRB

For review of research by a convened IRB, each IRB member receives the following documentation, as applicable:

1) Complete Protocol Application form
2) Recruitment materials, including access letters, the proposed consent, parental permission, and or assent form(s) (translated if necessary)
3) Research questions, such as surveys and questionnaires (translated if necessary)
4) If the research specifically involves children; prisoners, probationers, parolees; pregnant women, fetuses, and neonates; cognitively impaired participants (see Section 10: Vulnerable Populations for more information related to the use of these populations for research purposes); deception (see Section 15.4 Deception for more information related to the use of deception for research purposes); the internet; physiological processes; a request to waive the consent procedures or the documentation of consent (see Sections 9.3: Waiver of Informed Consent and 9.5 Waiver of Documentation of Informed Consent for more information); or the researcher or any research staff have a conflict of interest related to the study, the appropriate appendices must be completed.

The primary reviewer of the protocol will also receive the Expedited or Full Review Checklist as a guide to completing their review and any other materials as requested by the reviewer.

For Sponsored Research only, the IRB staff will compare grant awards with existing protocols to determine if procedures in the protocol match those in the grant. If modifications to the protocol are necessary, the IRB staff will obtain an amendment and/or a revised protocol from the PI for review by the IRB.

7.5.3 Review of PI Responses

PI submissions and responses to any questions, comments, or reviews are first reviewed by the IRB staff and Chair. PI responses may be forwarded to the full IRB committee or a designated sub-committee of the IRB if required or requested. Approval of protocols occurs only when the PI’s responses are deemed satisfactory to all members of the sub-committee or a majority of full committee reviewers of the protocol.

7.5.4 Possible IRB Actions Taken by Vote

Approval – the study is approved as submitted. Official UCR notification that a research project or activity involving human participants has been reviewed and approved by an IRB in accordance with an approved assurance will be sent to the PI and his/her department.

Deferred for non-substantive issues – the protocol and/or its related submissions require minor revisions, such as wording changes with replacement language provided. The revisions are presented to the PI for incorporation by simple concurrence. The IRB Chair and members determine how these types of revisions are reviewed and approved but typically, the IRB Chair, Vice Chair, a subcommittee of the IRB, or the Director may approve the study upon receipt and approval of the revisions without further action by the IRB.
Note: Approval of the protocol application will not be granted and certification will not be issued until all deficiencies, if any, are corrected to the satisfaction of the IRB.

Deferred for substantive issues – substantial modification or clarification is required, or insufficient information is provided to judge the protocol application adequately (e.g., the risks and benefits cannot be assessed with the information provided). IRB approval of the proposed research will not occur until the PI submits the requested new or revised material(s), and this material is reviewed by the assigned sub-committee or at the next convened IRB meeting.

If the application is deferred the following will occur:

1) The IRB Office will inform the PI in writing of the IRB’s decision, questions, and concerns.

2) When the IRB Office receives the PI’s responses, the Office will forward the submission to the previously assigned sub-committee or place it on the agenda for review at the next convened IRB meeting. The Office will provide the IRB with the PI’s response and the revised protocol.

3) The outcome of the IRB’s deliberations will once again be communicated to the PI in writing.

4) The IRB’s determination concerning the subsequent amended submission will be documented in the minutes of that meeting.

Disapproved – questions are of such significance that the IRB feels approval of the study is unwarranted. Approval of a previously disapproved protocol requires full IRB review.

Approval in Principle [45 CFR 46.118] – There are two circumstances in which the IRB may grant approval required by a sponsoring agency without having reviewed all of the study procedures and consent documents. One is if study procedures are to be developed during the course of the research, but human participants research approval is required by the sponsoring agency. The other is if the involvement of human participants depends on the outcomes of work with animal subjects. The IRB may then grant approval without having reviewed the as yet undeveloped recruitment, consent, and intervention materials. However, if the proposal is funded, the PI must submit such materials for approval at least 60 days before recruiting human participants into the study, or into any pilot studies or pre-tests. Approval in principle is granted to satisfy sponsoring agency requirements or to allow PIs to have access to funding to begin aspects of the project that do not involve human participants.

7.5.5 Determination of Risk

At the time of initial and continuing review, the IRB will make a determination regarding the risks associated with the research protocols. Risks associated with the research will be classified as either “minimal” or “greater than minimal” based on the “absolute” interpretation of minimal risk. Minimal risk is defined in 45 CFR 46.102(i) as risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The meeting minutes will reflect the Committee’s determination regarding risk levels.

7.5.6 Period of Approval

At the time of initial review and at continuing review, the IRB will make a determination regarding the frequency of review of the research protocols. All protocols will be reviewed by the IRB at intervals appropriate to the degree of risk but no less than once per year. In some circumstances, a shorter review interval (e.g., biannually, quarterly, or after accrual of a specific number of participants) may be required. The meeting minutes will reflect the IRB’s determination regarding review frequency. This determination governs the approval period and expiration date of the protocol.
Research that meets any of the following criteria will require review more often than annually:

1) Significant risk to research participants (e.g., death, permanent or long lasting disability or morbidity, severe toxicity) without the possibility of direct benefit to the participants;
2) The involvement of especially vulnerable populations likely to be subject to coercion (e.g., institutionalized psychiatric patients, incarcerated minors); or
3) A history of serious or continuing non-compliance on the part of the PI.

The following factors will also be considered when determining which studies require review more frequently than on an annual basis:

1) The probability and magnitude of anticipated risks to participants;
2) The likely medical condition of the proposed participants;
3) The overall qualifications of the PI and other members of the research team, including their specific experiences in conducting similar research;
4) The nature and frequency of adverse events observed in similar research at this and other institutions;
5) The novelty of the research, making unanticipated adverse events more likely; and
6) Any other factors that the IRB deems relevant.

In specifying an approval period of less than one year, the IRB may define the period with either a time interval or a maximum number of participants either studied or enrolled. If a maximum number of participants studied or enrolled is used to define the approval period, it is understood that the approval period can in no case exceed 1 year and that the number of participants studied or enrolled determines the approval period only when that number of participants is studied or enrolled in less than one (1) year.

7.5.7 Independent Verification Regarding Material Changes

Protecting the rights and welfare of participants sometimes requires that the IRB verify independently (utilizing sources other than the PI) information about various aspects of the study including but not limited to adverse event reporting, information in the scientific literature, reports of drug toxicity, drug approval status, and that no material changes occurred during the IRB-designated approval period.

The IRB will determine the need for verification from outside sources on a case-by-case basis and according to the following criteria:

1) Protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources;
2) Protocols conducted by PIs who have previously failed to comply with Federal regulations and/or the requirements or determinations of the IRB;
3) Protocols randomly selected for internal audit; and
4) Whenever else the IRB deems verification from outside sources is relevant.

The following factors will also be considered when determining which studies require independent verification:

1) The probability and magnitude of anticipated risks to participants;
2) The likely medical condition of the proposed participants; and
3) The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed.

In making determinations about independent verification, the IRB may prospectively require that such verification take place at predetermined intervals during the approval period, retrospectively require such verification at the time of continuing review, or require such verification at any time during the approval period in the light of new information.

7.5.8 Consent Monitoring

In reviewing the adequacy of informed consent procedures for proposed research, the IRB may determine that special monitoring of the consent process by an impartial observer (consent monitor) designated by the IRB is required in order to reduce the possibility of coercion and undue influence. Such monitoring may be particularly warranted where the research presents significant risks to participants, or if participants are likely to have difficulty understanding the information to be provided. Monitoring may also be appropriate as a corrective action where the IRB has identified problems associated with a particular PI or a research project.

The consent monitor has five principal duties:

1) **Listen** to the consent process and the exchange between the PI, the participant, and the participant’s family, if applicable.
2) **Closely observe** the communication between the PI and the participant.
3) **Ask questions** in order to facilitate the participant’s comprehension. Questions should elicit a response from the participant that requires some deliberation and thought about the research, rather than yes/no questions, to confirm that the participant fully comprehends the research and is making a knowledgeable decision about participation.
4) **Document** the interactions, questions, answers, and the decision-making process.
5) **Decide** with the PI and the participant whether the participant should be enrolled in the research, provided additional time to consider participation in the research, or should not be enrolled. The consent monitor may determine that a participant does not understand the consent process or the research and request that the PI re-review the materials with the participant. If the monitor does not think the participant understands the research or all items of the consent document, then the participant should not be enrolled.

When the IRB determines that a consent monitor must be present during the consent process, the PI or designee must provide a copy of the current approved informed consent document to the consent monitor in advance. When a consent session with a potential subject is scheduled, the PI or designee must contact the designated consent monitor in advance.

During the consent session, the PI will introduce the consent monitor to the potential participant and provide an explanation for the consent monitor’s presence. The consent monitor will utilize a copy of the approved informed consent document and complete the “Consent Monitoring Checklist” during the consent process to ensure that all required and appropriate elements of the consent document are addressed by the PI. At any time during the consent session, the consent monitor may request that the PI review or clarify information for the potential participant and/or seek clarification of comprehension from the potential participant. At the end of the consent session, the consent monitor will utilize the “Evaluation to Sign a Consent Form for Research” document to assess the potential participant’s comprehension of the consent process. The potential participant will be asked the questions on the evaluation form by the consent monitor. The consent monitor may ask additional
questions, as necessary and also inform the participant that he/she may ask any questions concerning the consent process.

After the consent session, the consent monitor will prepare the “Summary of Consent Monitoring for Research” document for IRB review and approval. This document will be submitted to the IRB staff and maintained in the specific IRB research protocol file(s). It will be reviewed by the IRB at an identified interval (e.g., every five subjects) as determined by the IRB.

7.5.9 PI Conflicts of Interest

The UCR ORI has several methods for identifying conflicts of interest:

- The UCR COI website, which provides information to researchers about COI policies and disclosure requirements;
- The IRB Application form, which is specific to human subjects research and includes a mandatory disclosure of any conflicts of interest; and
- The electronic Campus Approval Form (eCaf), which is required for all UCR researchers who have received funding for their research.

The University Conflict of Interest Policies

- uses thresholds that comply with PHS and NSF conflict of interest policies and State of California policies, as appropriate;
- includes all PIs and research staff members (i.e., those who are involved in the design, conduct, or reporting of research);
- defines immediate family members (spouse or registered domestic partner, or dependent children);
- includes a time frame for reporting changes in financial interests;
- has a process for determining whether financial interests require management and approving management plans;
- has appropriate documentation; and
- involves the IRB in the review of management plans for human participants research.

For more information and the required forms, please go to the UCR Conflict of Interest Website as well as Policy 529-601 at the UCR Office of Research Policies website.

7.5.9.1 Conflict of Interest Management – General Disclosure

All PIs and research staff must follow the UCR Conflict of Interest Policies and disclose any conflicts of interest for themselves and their immediate family members. A conflict management plan must also be submitted for review by the convened IRB. Based on the significance of the conflict and the potential for adverse effects on the protection of participants, conflict management plans can include:

- Disclosure to participants through the consent process,
- Modifications in the research plan,
- Monitoring by independent reviewers,
- Divestiture of financial interests,
- Appointment of a non-conflicted PI, and/or
• Prohibition of the conduct of the research at the University.

The convened IRB will determine if the conflict will adversely affect the protection of human participants and if the management plan is adequate. Researchers will be informed whether the convened IRB

1) Accepts the management plan and recommend approval, or
2) Recommends changes in the management plan.

A copy of the final, approved conflict management plan will be filed in the IRB Office.

7.5.9.2 Conflict of Interest Management – Protocol-Specific Disclosure

The UCR HRRB Application for Approval to Use Human Participants asks protocol-specific questions regarding conflict of interest for the PIs, research staff, and immediate family members. For any potential or actual conflict of interest, the PI must complete and submit HRRB Appendix H: Research Involving Conflicts of Interest for review by the IRB.

As part of its review process, the IRB will make a determination as to whether the conflict adversely affects the protection of human participants. If the answer is “yes” and an approved conflict management plan exists, the IRB will review the plan to determine if it adequately protects the human participants in that protocol.

If no approved conflict management plan exists, the IRB will forward the conflict information to the University Conflict of Interest Committee (COIC) and an appropriate conflict management plan will be developed according to the procedures described above.

Review of conflict management plans are documented in the IRB minutes in the protocol file for expedited review. If a conflict of interest exists, final IRB approval cannot be given until an approved conflict management plan that adequately protects the human participants in the protocol is in place.

If the conflict of interest status of a PI changes during the course of a study, the individual is required to notify the IRB Office within ten (10) working days of the change. The IRB will review the change as a modification to the protocol.

At the time of continuing review, the PI will be asked whether there has been any change in the conflict of interest status relating to the research. The IRB will review conflict of interest as part of its continuing review.

7.5.10 Other Committee Approvals

In the protocol application the PI will be asked specific questions to determine if the research requires approval from other pertinent research compliance committees (Institutional Biosafety Committee, Radiation Safety Committee, etc.). If the PI answers “yes” to any of the questions, then he or she will be requested to provide documentation of approval from the other committees. Final approval from the IRB will be contingent on receipt of the required documentation.

7.5.11 Reporting IRB Actions

All IRB actions are communicated to the PI, or designated primary contact person for the protocol, in writing within ten (10) working days by the IRB Office and/or the Chair of the IRB. PIs and the institution in writing of IRB decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity.
For proposed research, a notification must be sent to the PI, which includes the determination of the IRB regarding approval or disapproval, along with:

1) an analysis of risk and benefits of the research reviewed, and
2) an assessment of proposed informed consent documents.

For approved research:

1) The IRB will send the PI the “IRB Approval Notice” and “IRB Approval Memo” which is signed by the IRB Chair, Vice-Chair, or designee.

2) Along with written notification of approval, PIs are informed that:
   a. modifications of approved projects must be reviewed and approved by the appropriate IRB before they are initiated;
   b. problems listed in Section 7.9: Unanticipated Problems and Adverse Events must be reported to the IRB within ten (10) working days of becoming aware of the problem;
   c. monitoring may occur; the nature and frequency of monitoring will be determined by the IRB at the time of initial or continuing review, and PIs will be so informed; and
   d. the protocol will expire on a date determined by the IRB, unless renewed prior to that date; the period of approval will not exceed one year and there is no provision for a grace period on or after the expiration date.

3) Certification (approval) letters are signed by the IRB Chair or the Director. Along with written notification of approval, a copy of the approved consent form containing the stamped approval with the dates of the approval and expiration on each sheet will be sent to the PI and must be filed in the protocol files maintained by the IRB.

4) For PIs who receive IRB approval for applications sponsored by federal departments or agencies adopting the Common Rule (45 CFR 46), if requested by either the Agency or the sponsored program officer, the IRB Staff will provide the PI with a completed and signed “Protection of Human Subjects, Assurance Identification/Certification/Declaration of Exemption” (Common Rule) form.

If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision and give the PI an opportunity to respond in person or in writing.

The IRB reports its findings and actions to the institution in the form of its minutes, which are reviewed by UCR IO upon request, and are stored permanently and securely in the IRB Office. They are available to the public via a formal Freedom of Information Act (FOIA) request or a formal California Public Records Act (CPRA) request.

7.6 Continuing Review of Active Protocols (Renewals)

DHHS regulations at 45 CFR 46.108(b) and 109(e) require, respectively, that:

1) except when an expedited review procedure is used, the IRB must review proposed research at convened meetings at which a majority of the members of the IRB is present, including at least one member whose primary concerns are in nonscientific areas; and

2) an IRB must conduct continuing review of research at intervals appropriate to the degree of risk, but not less frequently than once per year. The IRB should decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research participants. A continuing review must take place before the approval expiration date, which is the last date for which the protocol was approved.
The approval date and the termination (expiration) date are clearly noted on all IRB certifications sent to the PI and must be strictly adhered to. PIs should allow sufficient time for review of renewal submissions.

7.6.1 Continuing review process

In accordance with DHHS regulations at 45 CFR 46.108(b), continuing review by the convened IRB, with a recorded vote on each study, is required unless the research is otherwise appropriate for expedited review under Section 46.110 (see below). Furthermore, DHHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied in order for the IRB to approve research. These criteria include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human participants. The IRB must ensure that these criteria are satisfied at the time of both initial and continuing review. The procedures for continuing review by the convened IRB may include a primary reviewer system.

In conducting continuing review of research not eligible for expedited review, all IRB members will at least receive and review a complete protocol and a status report on the progress of the research, including the following information from the past year (cumulative data must also be included after the first renewal):

- the number of participants enrolled;
- number of participants who withdrew prematurely and reason(s) for their withdrawal;
- a summary of adverse events and any unanticipated problems involving risks to participants or others and any withdrawal of participants from the research or complaints about the research since the last IRB review, if applicable;
- summary of any amendments or modifications to the research since the last review;
- any other relevant information, especially new information about risks associated with the research;
- a copy of the current informed consent document and any newly proposed consent document; and
- a copy of the current HIPAA Authorization document, if applicable.

When a full review protocol undergoes continuing review, the IRB will be provided with and review the Application to Extend Approval form, the full protocol, the current consent document, and any modifications previously approved by the IRB prior to a convened IRB meeting. In addition, any IRB member can request access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting.

When reviewing the current informed consent document(s), the IRB will ensure the following:

- The currently approved or proposed consent document is still accurate and complete; and
- Any significant new findings that may relate to the participant’s willingness to continue participation are provided to the participant in accordance with DHHS regulations at 45 CFR 46.116(b)(5).

Review of currently approved or newly proposed consent documents will occur during the scheduled continuing review of research by the IRB, but informed consent documents that would require modification should be reviewed whenever new information becomes available.

7.6.2 Expedited Review of Continuing Review
Generally, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories (8) and (9) at 63 FR 60364-60367 (see Attachment B - Expedited Categories of Review). It is also possible that research activities that previously qualified for expedited review in accordance with 45 CFR 46.110, have changed or will change, such that expedited IRB review would no longer be permitted for continuing review.

However, if a study was approved by the convened IRB but the PI either unable to recruit or enroll participants, the continuing review may be conducted using expedited review procedures as described in Section 7.3: Expedited Review of Research. If the study is finally canceled without participant enrollment, records will be maintained for at least three years after cancellation.

7.6.3 How is the Continuing Review Date Determined?

At UCR, determination of the review interval and the need for additional supervision and/or participation is made by the IRB on a protocol-by-protocol basis. For example, for a PI who is performing particularly risky research, or for a PI who has recently had a protocol suspended by the IRB due to regulatory concerns, an on-site review by a subcommittee of the IRB might occur or approval might be subject to an audit of study performance after a few months of enrollment, or after enrollment of the first several participants.

IRB approval is considered to have lapsed at midnight on the last day of the approval period.

Several scenarios for determining the date of continuing review apply for protocols reviewed by the IRB at a convened meeting. The date by which continuing review must occur depends on the date of the convened meeting at which IRB approval occurs (these examples presume the IRB has determined that it will conduct continuing review no sooner than within 1 year).

Scenario 1: The IRB reviewed and approved a protocol without any conditions at a convened meeting on October 1, 2006. Continuing review must occur within 1 year of the date of the meeting, that is, by midnight of September 30, 2007.

Scenario 2: The IRB reviewed a protocol at a convened meeting on October 1, 2006, and defers the protocol for non-substantive issues (see Section 7.5.4: Possible IRB Actions Taken by Vote) which can be approved by the IRB Chair or designee. On October 31, 2006, the IRB chair or designee confirms that the required minor changes were made and approves the protocol. Continuing review must occur within 1 year of the date of the convened meeting at which the IRB reviewed the protocol, that is, by midnight of September 30, 2007.

Scenario 3: The IRB reviews a study at a convened meeting on October 1, 2006, and defers the protocol for substantive issues (see Section 7.5.4: Possible IRB Actions Taken by Vote) that requires IRB review of the study at subsequent convened meetings on October 15 and October 29, 2006. At their October 29, 2006 meeting, the IRB completes its review and approves the study. Continuing review must occur within 1 year of the date of the convened meeting at which the IRB reviewed and approved the protocol, that is, by midnight of October 28, 2007.

For a study approved under expedited review, continuing review will occur within 1 year of the date the IRB Chair or IRB member(s) designated by the Chair gives final approval to the protocol.

Review of a change in a protocol ordinarily does not alter the date by which continuing review will occur. This is because continuing review is review of the full protocol, not simply a change to it.
The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research will occur by midnight of the date when IRB approval expires.

When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. This would be, for example, October 1, 2006, in the above Scenarios 1 and 2, and October 29, 2007, in Scenario 3, even if the continuing reviews took place up to 30 days prior to these dates.

If continuing review is conducted earlier than 30 days prior to the approval expiration date (e.g., due to the scheduled IRB meeting date), the protocol will be assigned a new approval date – that of the early continuing review. The approval expiration date will be based upon the new approval date for the purposes of future continuing reviews.

7.6.4 What Occurs if There is a Lapse in Continuing Review?

The IRB and PIs must plan ahead to meet required continuing review dates. To assist PIs, the IRB Staff will send PIs the Application to Extend Approval form at least two months and one month in advance of the expiration date. However, it is ultimately the PI’s responsibility to initiate a renewal application, allowing sufficient time for the review and re-approval process to be completed before the current approval expires. Turning in this form does not guarantee an extension of approval. Additional information may be requested, and if that information is not received and approved by the expiration date, the full protocol expires.

By federal regulation, no extension to that date can be granted.

If a PI has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the end of the approval period specified by the IRB, the research must stop, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private, identifiable information. If the research is DHHS-sponsored, the funding Agency will be notified. The continuation of research after expiration of IRB approval is a violation of the regulations. Retrospective approval for work done after the expiration date cannot be granted.

Interventions and interactions on current participants may continue only when the IRB Chair finds an overriding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating in the research interventions or interactions. Enrollment of new participants cannot occur after the expiration of IRB approval.

7.7 Modification of an Approved Protocol

PIs may wish to modify or amend their approved applications. PIs must seek IRB approval before making any changes in approved research – even if the changes are planned for the period for which IRB approval has already been given – unless the change is necessary to eliminate an immediate hazard to the participant (in which case the IRB must then be notified at once).

Modifications may be approved if they are within the scope of what the IRB originally authorized. For example, if a researcher wishes to add a population to an existing study, but not alter the study procedures or purpose, a modification request is usually appropriate. Likewise, modifying a procedure without changing the study’s purpose or study population may also be appropriate. If, however, the researcher wishes to add a population and revise study procedures, he or she will need to submit a new application for approval of human participants research.
PIs must submit documentation to the IRB to report proposed changes in the research study. This documentation must include, but is not necessarily limited to:

- the completed Request for Amendment to an Approved Protocol form;
- the revised or additional recruitment materials, such as recruitment materials, consent documents, and/or measures; and
- any other relevant documents provided by the PI.

IRB Staff will determine whether the proposed changes may be approved through an expedited review process, if the changes are minor, or whether the modification warrants review by the convened IRB.

### 7.7.1 Expedited Review of Protocol Modifications

An IRB may use expedited review procedures to review minor changes in ongoing previously-approved research during the period for which approval is authorized [45 CFR 46.110; 63 FR 60364-60367, November 9, 1998, and 63 FR 60353-60356, November 9, 1998; 21 CFR 56.110(b)]. An expedited review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the IRB Chair from among members of the IRB.

### 7.7.2 Full Board Review of Protocol Modifications

When a proposed change in a research study is not minor (e.g., procedures involving increased risk or discomfort are to be added), then the IRB must review and approve the proposed change at a convened meeting before the change can be implemented. All IRB members (including alternate members) receive and review all of the bullet point items listed in Section 7.7: Modification of an Approved Protocol; the Primary Reviewer will receive and complete the reviewer’s checklist. The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects. In such a case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with ensuring the participants’ continued welfare.

When the IRB reviews modifications to previously approved research, the IRB will consider if the modification meets the regulatory criteria for approval, including whether information about those modifications might relate to participants' willingness to continue to take part in the research and if so, whether to provide that information to participants.

### 7.8 Closure of Protocols

The completion or termination of the study is a change in activity and must be reported to the IRB on the Extension of Approval form. This form requests that the PI provide information that may be used by the IRB in the evaluation and approval of related studies.

The IRB staff will notify the IRB of protocols that have been closed on the following month’s agenda.

### 7.9 Unanticipated Problems and Adverse Events

#### 7.9.1 Definitions

Federal regulations require procedures for the prompt reporting to the IRB (within ten (10) working days) of unanticipated problems involving risks to participants or others (referred to as "unanticipated problems" in this policy). Unanticipated problems involving risks to participants or others are defined as problems that
1) are not expected given the nature of the research procedures and the participant population being studied; and

2) suggest that the research places participants or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.

Not all unanticipated problems involving risks to participants or others involve direct harm to participants. Events can occur which are unexpected and result in new circumstances that increase the risk of harm to participants without directly harming them. In addition, the event may have presented unanticipated risks to others (e.g., the sexual partners of the participants, individuals the participant may come in contact with, family members, research personnel, etc.) in addition to the participants. In each case, while the event may not have caused any detectable harm or adverse effect to participants or others, it nevertheless represents a reportable problem as defined below and should be promptly reported.

PIs must report to the IRB the following problems within ten (10) working days of becoming aware of the problem:

- Any harm experienced by a participant that was unexpected and caused by the research procedures;
- Any change to the protocol without prior IRB review to eliminate apparent immediate hazard to a research participant;
- Any deviation from the protocol (protocol violation) that is related to participant safety or findings that indicate a new risk of harm;
- Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research;
- Any complaint of a participant that indicates an unanticipated risk or which cannot be resolved by the research staff;
- A breach of confidentiality of research data;
- A breach of privacy, confidentiality, data security, loss of study data, or destruction of study data due to noncompliance; and/or
- Any event that requires prompt reporting according to the sponsor.

PIs may report an unanticipated problem to the IRB via telephone or email correspondence first; however, the IRB staff will require the formal submission of the Unanticipated Problems Report in order to document the problem and its resolution.

7.9.2 IRB Review of Reported Problems

1) Reported problems will be reviewed by the IRB Chair and/or other experienced member(s) designated by the Chair. The Chair (or designee) will make the final determination as to whether the event is to be regarded as an unanticipated problem involving risks to participants or others.

All events determined to be unanticipated problems will be reported to the relevant regulatory agencies and IOs according to the procedures in Section 12: Reporting to Regulatory Agencies and Institutional Officials.

2) Unanticipated problems involving no more than minimal risk to participants or others may be handled by the IRB Chair, staff, or designee (with notification to the Chair and IRB) and reported to the full committee.

3) Unanticipated problems involving more than minimal risk to participants or others shall be reported to the full IRB committee at a convened meeting. All reviewers shall receive the
report of the event as well as a copy of the current consent form(s) and the Protocol Application. In addition, the reviewers shall have access to the full protocol.

The IRB or the IRB Chair (or designee) has authority to require submission of more detailed contextual information by the PI, the sponsor, the study coordinating center, or DSMB/DMC about any adverse event occurring in a research protocol as a condition of the continuation of the IRB’s approval of the research.

4) Unanticipated problems for which no modifications to the protocol or informed consent process/documents are needed, as determined by the IRB or the IRB Chair (or designee), may be:
   a) filed in the IRB records without further review by the convened IRB or,
   b) at the discretion of the IRB Chair (or designee), referred to the rest of the IRB members for review and further action, as appropriate, at a convened meeting.

5) If an unanticipated problem requires modifications to the protocol and/or informed consent process/documents, either as requested by the PI or determined by the IRB or the IRB Chair (or designee), the PI must submit these modifications as an amendment for review and approval by the IRB chairperson (or designee) under an expedited review procedure. The related report of the unanticipated problem involving risks to participants or others may be: (i) filed in the IRB records without further review by the convened IRB, or (ii) at the discretion of the IRB Chair (or designee), referred to the rest of the IRB members for review and further action, as appropriate, at a convened meeting.

When the convened IRB reviews an unanticipated problem involving risks to participants or others, the IRB will consider:

- Requesting for a modification of the protocol,
- Requesting for a modification of the information disclosed during the consent process,
- Requesting that additional information be provided to past participants,
- Requesting that current participants re-consent to participation,
- Modifying the continuing review schedule,
- Monitoring the research,
- Monitoring the consent process, and/or
- Referring to other organizational entities.

If the convened IRB determines that modifications are not adequate to reduce the risk to participants, the convened IRB may require:

- Suspension of the research,
- Termination of the research, and/or
- Notification of current participants when such information may relate to participants’ willingness to continue to take part in the research.

### 7.10 Further Review/Approval of IRB Actions by Others within the Institution

Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution; however, those officials may not approve research if it has been not been approved by the IRB [45 CFR 46.112]. There are no required institutional reviews after the IRB grants approval, but the institution reserves the right to subject research reviewed by the IRB to further review.
7.11 Appeal of IRB Decisions

If the IRB makes a decision that the PI believes to be unduly restrictive on the proposed research, the PI should first discuss the matter with the Chair of the relevant IRB or the Director, taking care to explain the reasons for believing that the proposed procedures are in compliance with University policy and with Federal regulations. If the issue cannot be resolved satisfactorily by negotiation, the PI may appeal the decision in writing to a convened meeting of the IRB. The convened IRB will reconsider the appeal based upon the new information provided and will continue to re-review the protocol as long as the PI wishes to appeal. However, if no resolution can be reached at the local level, the PI may appeal to OHRP.

7.12 Sponsored Research Contracts

The Office of Sponsored Programs Administration (SPA) will review contracts and the IRB and SPA will share contract and study information as necessary for each sponsored protocol to ensure that the protocol, consent(s), and contract language are consistent. For contracts that are not reviewed by SPA, but are reviewed by another entity to which the PI reports, the IRB application requests a copy of the contract to ensure that the protocol, consent(s), and contract are consistent.

Contracts will be reviewed for the following by both the SPA and the IRB:

1) All sponsored contracts, in accordance with the University’s internal contract negotiation guide, must indicate that UCR will follow the protocol, applicable regulations, and its ethical standards.

2) All sponsored contracts, in accordance with the University’s internal contract negotiation guide, must define who will be responsible for research related injuries.

3) If the sponsor will monitor the conduct of the research, the contract must state that if the study monitor uncovers information that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB’s approval to continue the study, the sponsor will make sure that the information is communicated to the IRB. Additionally, if the sponsor discovers results that could affect the safety or medical care of participants, the sponsor will make sure the IRB is notified.

4) All sponsor contracts, in accordance with the University’s internal contract negotiation guidelines, must indicate that the University owns or is able to control dissemination of the results of research since open publication of results is essential to the research mission of the University (UC Memo Operating Guidance #93-11, issued July 1993). In addition, the UC Academic Senate has affirmed that the freedom of the PI to disseminate the results of research is an essential part of academic freedom. Unless otherwise approved by the Chancellor, the campuses of the University will undertake research projects only if the scientific results can be published or otherwise promptly disseminated. The policy also precludes placing an unreasonably long or unlimited delay on the publication or dissemination of information (UC Faculty Handbook).

8 Criteria for IRB Approval of Research

In accordance with 45 CFR 46.111 and 21 CFR 56.111, in order to approve research, the IRB must determine that all of the following requirements are satisfied as described in the following subsections.

8.1 Risk/Benefit Assessment

Scientific Merit. In order to assess the risks and benefits of the proposed research, the IRB must determine that:

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• The research uses procedures consistent with sound research design;
• The research design is sound enough to reasonably expect the research to answer its proposed question; and
• The knowledge expected to result from this research is sufficiently important to justify the risk.

In making this determination, the IRB may draw on its own knowledge and disciplinary expertise, or on the knowledge and disciplinary expertise of others, such as reviews by a funding agency or departmental review.

The scientific review conducted by the IRB is completed by reviewers whose knowledge and disciplinary expertise are matched to the protocol they receive. The reviewers certify this on the reviewer’s checklist. If deemed necessary by the Committee, Chair, or Staff, expert external consultants are employed to provide information regarding protocol to the IRB.

Departmental scientific review is documented by the signature of the administrative official responsible for the PI’s research unit on new protocol applications.

Goal. The goal of the assessment is to ensure that the risks to research participants posed by participation in the research are justified by the anticipated benefits to the participants or society.

Risks to participants must be minimized (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk; and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

The assessment of the risks and benefits of proposed research – one of the major responsibilities of the IRB – involves a series of steps:

1) **Identify the risks** associated with the research, as distinguished from the risks of therapies the participants would receive even if not participating in research.

2) **Determine whether the risks will be minimized** to the extent possible.

3) **Identify the probable benefits** to be derived from the research.

4) **Determine whether the risks are reasonable in relation to the benefits** to participants, if any, and assess the importance of the knowledge to be gained. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research – as distinguished from risks and benefits of therapies participants would receive even if not participating in the research. **Risks to participants must be reasonable in relation to anticipated benefits**, if any, and to the importance of the knowledge that may reasonably be expected to result. The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

5) **Ensuring that potential participants will be provided with an accurate and fair description** of the risks or discomforts and the anticipated benefits.

The IRB will judge whether the anticipated benefit, either of new knowledge or of improved health for the research participants, justifies asking any person to undertake the risks. If risks are judged unreasonable in relation to the anticipated benefits, the research will not be approved.
8.2 Selection of participants is equitable

The IRB will review the inclusion/exclusion criteria for the research to ensure equitable selection of participants. In making this assessment the IRB takes into account the purposes of the research and the setting in which the research will be conducted, and is particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, fetuses, pregnant women, human in vitro fertilization, persons who are cognitively impaired, or persons who are economically or educationally disadvantaged (see Section 10: Vulnerable Populations).

8.2.1 Recruitment of Participant

The IRB will review all recruitment procedures, materials, and advertisements to ensure that they are consistent with the protocol, accurate, and non-coercive. When participants are being paid, IRB will review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence. Payment to participants should not be considered a benefit to participation.

For additional information, please see Section 13.13: Payment to Participants and review Attachment D, “Payment to Research Participants.”

8.2.2 Review of Advertisements

All advertisements to recruit participants must be reviewed by the IRB. The IRB will review the information contained in the advertisement and the mode of its communication. Advertisements must not:

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol;
- Include exculpatory language;
- Emphasize the payment or the amount to be paid, by such means as larger or bold type;
- Promise “free treatment” when the intent is only to say participants will not be charged for taking part in the investigation.

For additional information, please see Section 13.12: Participant Recruitment and review Attachment C, “Advertising for Research Participants.”

Once the advertisements are finalized, the final copy of the printed, audio-taped, and/or video-taped advertisements must be submitted to and given a stamp of approval by the IRB before they may be utilized.

8.3 Informed Consent

The IRB will ensure that informed consent will be sought from each prospective participant or the participant’s legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116 and 21 CFR 50.20. In addition, the Committee will ensure that informed consent will be appropriately documented in accordance with, and to the extent required by 45 CFR 46.117 and 21 CFR 50.27. See Section 9: Informed Consent below for detailed policies on informed consent.

8.4 Data Safety Monitoring

The IRB will review the data safety monitoring plan for protocols involving more than minimal risk during initial review and at continuing review. These plans may include, but are not limited to data format (hard copy or computer files) and data storage (locked file cabinet, locked office, password-protected hard drive, stand-alone computer, encryption of data). If data is identifiable by name, voice,
or image or if individual participants can be identified by use of multiple variables (for example, the combination of race, gender, age, organizational unit, etc.), the PI will be asked to explain the nature of the data and justify retaining these identifiers.

### 8.5 Privacy and Confidentiality

The IRB will determine whether adequate procedures are in place to protect the privacy of participants and to maintain the confidentiality of the data.

**Privacy** refers to how much an individual has control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

The IRB must determine whether the activities in the research constitute an invasion of privacy. In order to make that determination, the IRB must obtain information regarding how the PIs are getting access to participants or participants’ information and the participants’ expectations of privacy in the situation. PIs must have appropriate authorization to access the participants or the participants’ information.

**Confidentiality** refers to the methods used to ensure that information obtained by researchers about their participants is not improperly divulged.

Confidentiality and anonymity are not the same. If anyone, including the PI, can readily ascertain the identity of the participants from the data, then the research is not anonymous and the IRB must determine if appropriate protections are in place to minimize the likelihood that the information will be inappropriately divulged. The level of the protection of confidentiality should be commensurate with the potential of harm from inappropriate disclosure.

### 8.6 Vulnerable Populations

The IRB determines if appropriate additional safeguards are in place to protect the rights and welfare of participants if they are likely to be members of a vulnerable population (e.g., persons with diminished autonomy). See **Section 10: Vulnerable Populations** below for detailed policies on vulnerable populations.

### 9 Informed Consent

#### 9.1 Informed Consent Process

No PI may involve a human being as a participant in research without obtaining the legally effective informed consent of the participant or the participant’s legally authorized representative unless a waiver of consent has been approved by the IRB in accordance with **Section 9.3: Waiver of Informed Consent** or **9.5: Waiver of Documentation of Informed Consent** of this policy. In general, the IRB considers individuals who are unable to consent for their own clinical care to be unable to consent for research participation. It is expected that the PIs will assess the comprehension and capacity of the participants to understand the consent language by asking a series of follow-up questions that may include, but are not limited, to the following:

1) In your own words, what do you see as the risks of being in this study?

2) How will we protect the confidentiality of the information we collect from you?

3) What are the limits of confidentiality? When are we required by law to reveal information about you or your child?
4) What is your understanding of the honorarium that you would receive for participating? What will your child receive for participating?

5) What will we be asking your child to do for the study?

6) Do you have any concerns about any part of this study? What part?

7) How can you let us know in the future if you have questions or concerns?

8) What is your understanding of how you can withdraw from this study now or later or anytime in the middle?

PIs must obtain consent prior to entering a participant into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB.

Consent must always be sought under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence.

The IRB will consider where the consent process will take place and the individual who will be obtaining consent (e.g., the PI, collaborator, or qualified designee) in its determination regarding the appropriateness of the consent process. When the potential participant’s understanding of the research may be impaired due to the timing, location, or individuals participating in the proposed consent process, the IRB will require an alternative process.

The information that is given to the participant or the representative must be in language understandable to the participant or the representative.

No informed consent, whether oral or written, may include exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant’s legal rights, nor to release or appear to release the PI, sponsor, institution, or its agents from liability for negligence.

A person knowledgeable about the consenting process and the research (i.e., a member of the project’s research team) to be conducted must obtain the informed consent.

If someone other than the PI conducts the interview and obtains consent, the PI needs to formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity.

**9.2 Basic Elements of Informed Consent [45 CFR 46.116]**

The basic elements of informed consent are:

1) a statement that the **study involves research**;

2) an explanation of the **purposes** of the research and the expected **duration** of the participant’s participation;

3) the approximate **number of participants** involved in the study;

4) a description of the research **procedures** to be followed;

5) a description of any reasonably **foreseeable risks** or discomforts to the participant;

6) a statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently **unforeseeable**;
7) any additional costs to the participant that may result from participation in the research;
8) a description of any benefits to the participant or to others which may reasonably be expected from the research;
9) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
10) a statement describing the extent, if any, to which confidentiality of records identifying the participant must be maintained;
11) for research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available;
12) the consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant;
13) anticipated circumstances under which the participant’s participation may be terminated by the PI without regard to the participant’s consent;
14) a statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation must be provided to the participant;
15) an explanation of whom to contact for answers to pertinent questions about the research and research participants’ rights, and whom to contact in the event of a research-related injury to the participant; and
16) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

The IRB has a Consent Writer program to assist PIs with the composition of an informed consent document that includes all elements listed above. After the PI answers a series of questions about their research, the program generates an editable Microsoft Word document, which the PI may continue to revise as he/she sees fit. The Consent Writer program provides detailed instructions about the program once the PI logs in.

9.3 Waiver of Informed Consent [45 CFR 46.116(d)(1-4)]

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement for informed consent provided the IRB finds and documents that:

1) the research involves no more than minimal risk to the participants;
2) the waiver or alteration will not adversely affect the rights and welfare of the participants;
3) the research could not practically be carried out without the waiver or alteration; and
4) whenever appropriate, the participants must be provided with additional pertinent information after participation;

or

1) the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
2) public benefit or service programs;
3) procedures for obtaining benefits or services under those programs;
4) possible changes in or alternatives to those programs or procedures; or
5) possible changes in methods or levels of payment for benefits or services under those programs; and
6) the research could not practicably be carried out without the waiver or alteration.

PIs may request a waiver of informed consent on the general IRB protocol application and UCR Appendix I: Waiver of Consent.

9.4 Documentation of Informed Consent (Signed Consent)

Informed consent must be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

1) Informed consent is documented by the use of a written consent form approved by the IRB and signed and dated by the participant or the participant’s legally authorized representative at the time of consent.

2) A copy of the signed and dated consent form must be given to the person signing the form.

3) The consent form may be either of the following:
   a) written consent document that embodies the elements of informed consent may be read to the participant or the participant’s legally authorized representative, but the participant or representative must be given adequate opportunity to read it before it is signed; or
   b) short form written consent document stating that the elements of informed consent have been presented orally to the participant or the participant’s legally authorized representative.

When this method is used:
1. there must be a witness to the oral presentation;
2. the IRB must approve a written summary of what is to be signed by the participant or representative;
3. for participants who do not speak English, the witness must be conversant in both English and the language of the participant;
4. the participant or the participant’s legally authorized representative must sign the consent document;
5. the witness must sign both the short form and a copy of the summary;
6. the person actually obtaining consent must sign a copy of the summary; and
7. a copy of the summary must be given to the participant or representative, in addition to a copy of the short form.

9.5 Waiver of Documentation of Informed Consent [45 CFR 46.117(c)(1-2)]

The IRB may waive the requirement for the PI to obtain a signed consent form for some or all participants if it finds either that the:

1) only record linking the participant and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality (Note: Participants must be asked whether they want documentation linking them with the research, and their wishes must govern. (Example: domestic violence research where the primary risk is discovery by the abuser that the participant is talking to researchers)), or
2) research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. Procedures such as non-sensitive surveys, questionnaires, and interviews generally do not require written consent when conducted by non-researchers.

PIs may request a waiver of documentation of informed consent on the general IRB protocol application and UCR Appendix I: Waiver of Consent. In cases in which the documentation requirement is waived, the IRB has to review a written script of the information to be provided to participants to be sure that this includes all required and appropriate additional elements of consent disclosures. The IRB will consider whether to require the PI to provide participants with a written statement regarding the research.

**9.6 Review and Approval of the Informed Consent Form**

The IRB is responsible for the review and approval of the informed consent form prepared by the PI. The wording on the informed consent form must contain all of the required elements and meet all other requirements as described in this section. If the wording of the informed consent has been initially prepared by an external entity (e.g., a pharmaceutical company or a cooperative study group, including National Cancer Institute (NCI) groups) other than by a University PI, the IRB needs to ensure that the wording of the consent meets all the requirements of, or has been reviewed by, the appropriate University committees and subcommittees such as the Institutional Biosafety Committee. IRB approval of the wording of all forms of consent must be documented through the use of a certification stamp on each page of the official, finalized consent document(s) that indicates the date of the most recent IRB approval of the document and the expiration date. If the consent is amended during the protocol approval period, it must bear the approval date of the amendment rather than the date of the approved protocol.

**9.7 Parental Permission and Assent**

See Section 10.1.3: Parental Permission and Assent for policies on parental permission and assent in research involving children.

**9.8 Surrogate Consent**

This policy is designed to protect human participants from exploitation and harm and, at the same time, make it possible to conduct essential research on problems that are unique to persons who are incompetent, or who have an impaired decision-making capacity. Regulations generally require that the PI obtain informed consent from participants. Under appropriate conditions, PIs also may obtain informed consent from a legally authorized representative of a participant (surrogate consent).

A legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant’s participation in the procedure(s) involved in the research [45 CFR 46.102(c)]. For research conducted in California, the IRB consults with legal counsel and/or California law to decide which individuals are “legally authorized representatives.” When the research is conducted outside of California, the IRB consults with legal counsel.

Such consent may be requested and accepted only when the prospective research participant is incompetent or has an impaired decision-making capacity. The PI must provide the IRB the procedures that will help make this determination.

If feasible, the PI must explain the proposed research to the prospective research participant even when the surrogate gives consent. Under no circumstances may a participant be forced or coerced to participate in a research study.
9.9 Consent and Language Barriers

Regulations require the researcher to submit translated consent forms for protocols that include non-English-speaking participants. The IRB may require a “back-translation” into English or consult with language experts. The translation should be accompanied by documentation to verify the accuracy of the translation and back-translation.

If the researcher meets a non-English-speaking person who expresses interest in the study, the researcher may not orally translate the approved English consent form or statement. The researcher must submit the appropriate translated consent documents via an amendment requesting approval to recruit non-English speaking participants.

Sometimes a participant understands English but does not read or write English. The IRB may request that the PI use a short form consent to document that an impartial witness was present during the consent process and this witness certifies that the participant understood the research and consented to participate voluntarily. For more information about the short form consent, please see Section 9.4: Documentation of Informed Consent (Signed Consent).

10 Vulnerable Populations

When some or all of the participants in a protocol are likely to be vulnerable to coercion or undue influence, the IRB will include additional safeguards to protect the rights and welfare of these participants. Some examples of vulnerable populations are children, pregnant women, fetuses, neonates, prisoners, adults who lack the ability to consent (e.g., physically or psychologically incapable), students, employees, or homeless persons.

45 CFR 46 has additional subparts designed to provide extra protections for vulnerable populations which also have additional requirements for IRBs:

- **Subpart B** – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
- **Subpart C** – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Participants
- **Subpart D** – Additional Protections for Children Involved as Participants in Research

DHHS-funded research that involves any of these populations must comply with the requirements of the relevant subparts. Research funded by other federal agencies may or may not be covered by the subparts. Researchers must check with the IRB to determine applicability of the subparts.

The following policies and procedures, which are based on the subparts, apply to non-federally funded research.

10.1 Research Involving Children [45 CFR 46.401-409 (Subpart D)]

For studies that involve the use of children (as defined below), UCR Appendix A: Research Involving the Use of Children must be submitted for IRB review and approval.

10.1.1 Definitions

Children – persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
Both common speech and California law define “children” and “minors” inconsistently. In the great majority of cases people who are “minors” under California law are also “children” under the federal human research regulations. Nevertheless, occasionally the difference is significant, and these guidelines attempt to use the terms consistently as described below.

**Federal Regulations Regarding “Children:”** Federal regulations state that “‘Children’ are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” In other words, who qualifies as a “child” depends on local laws for consent (and not necessarily on local definitions of the word “child”). In California, 18 is the usual age at which people can consent to treatments or procedures, but there are important exceptions, such as when seeking medical care related to the prevention or treatment of pregnancy (see below for limitations).

**Important Note:** Only “children” under the federal regulations are covered by the additional protections described in Subpart D of 45 CFR 46 and 21 CFR 50 (for example, the requirement for permission of one or two parents in addition to assent from the “child.”)

**California Law and “Minors:”** For research conducted in California, people considered minors or children by California law are usually also considered “children” in the applicable Federal regulations. California law uses both terms to refer to people who are under 18 years of age. For example, California Family Code (CFC) 6500 defines “minor” as “an individual who is under 18 years of age” and CFC 3402 says a “child” is “an individual who has not attained 18 years of age.” For clarity, these guidelines use “child” for people who meet the federal definition and “minor” for those who are under 18.

**“Minors” Who Are Not “Children:”** In California, certain people under 18 years of age are legally able to consent for treatments or procedures involved in research. In the terms used in these guidelines, they are minors but not children.

For example, CFC 6925 says, “A minor may consent to medical care related to the prevention or treatment of pregnancy.” The minors in a study involving prevention of pregnancy are of legal age to consent to the treatment or procedures involved in the study. Therefore they are not “children” as defined in federal regulations. They can sign their own consent form as if they were adults, and parental permission is not required.

Other examples of people under 18 able to consent to treatment or procedures in California include self-sufficient minors and emancipated minors.

**Parent** – a child’s biological or adoptive parent.

**Guardian:** An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care. [In California, a guardian may be a parent, a legally appointed guardian, a guardian ad litem as appointed by a court (this is an individual who may have no relationship to the minor who is appointed by the court to protect and represent the interests of the minor before the court), or others as consistent with an order of a court having jurisdiction over the minor. For wards of a court, usually an order from the judge is required in addition to permission from the person charged with care of the child.] **NOTE:** For research conducted outside of California, the research must comply with the laws regarding the legal age of consent in all relevant jurisdictions. The University Office of the General Counsel will provide assistance with regard to the laws in other jurisdictions.
Permission – the agreement of parent(s) or legal guardian to the participation of their child or ward in research.

Assent – a child’s affirmative agreement to participate in research. Mere failure to object, without a definite affirmative agreement, should not be construed as assent.

10.1.2 Allowable Categories

Research on children will be reviewed and categorized by the IRB into one of the following groups:

1) Research not involving physical or emotional risk greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk) [45 CFR 46.404].
   - The permissions of both parents are required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, unless the IRB finds that the permission of one parent is sufficient, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

2) Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participant [45 CFR 46.405 and 45 CFR 46.408].
   - The risk is justified by the anticipated benefit to the participants and this benefit is at least as favorable to the participants as that presented by available alternative approaches;
   - The permission of both parents are required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, unless the IRB finds that the permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child;
   - Requires assent of the child.

3) Research involving greater than minimal risk and no reasonable prospect of direct benefit to the individual participant, but likely to yield generalizable knowledge about the participant’s disorder or condition [45 CFR 46.406 and 45 CFR 46.408].
   - The risk represents a minor increase over minimal risk;
   - The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
   - Permission of both parents or the legal guardian is required – unless one parent is deceased, unknown, incompetent, or not reasonably available; or only one parent has legal responsibility for the care and custody of the child;
   - Requires assent of the child.

4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children [45 CFR 46.407].
   - Federally-funded research in this category must be approved by the Secretary of Health and Human Services, and requires consent of both parents or the legal guardian.
   - For non-federally-funded research, IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). Based on the recommendation of the panel, the IRB may approve the research based on either:
     a) That the research in fact satisfies the conditions of the previous categories, as applicable; or
     b) The following:
        i. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
ii. The research will be conducted in accord with sound ethical principles; and
iii. Informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this manual.

10.1.3 Parental Permission and Assent

10.1.3.1 Parental Permission

In accordance with 45 CFR 46.408(b) the IRB will determine that adequate provisions have been made for soliciting the permission of each child’s parent or guardian.

Parents or guardians must be provided with the basic elements of consent as stated in 45 CFR 46.116(a)(1-8) and any additional elements the IRB deems necessary.

The IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 or 45 CFR 46.405. The IRB’s determination of whether consent must be obtained from one or both parents will be documented in the consent checklist when a protocol receives expedited review, and in meeting minutes when reviewed by the convened committee.

Consent from both parents is required for research to be conducted under 45 CFR 46.406 and 45 CFR 46.407 unless

- One parent is deceased, unknown, incompetent, or not reasonably available; or
- Only one parent has legal responsibility for the care and custody of the child.

The IRB may waive the requirement for obtaining consent from a parent or legal guardian if:

- The research meets the provisions for waiver in 45 CFR 46.116(d)(1-4) and if the IRB determines that the research protocol is designed for conditions or a participant population for which parental or guardian permission is not a reasonable requirements to protect the participants (for example, neglected or abused children).
- An appropriate mechanism for protecting the children who will participate as participants in the research is substituted, and that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research participants, and their age, maturity, status, and condition.

Permission from parents or legal guardians must be documented in accordance with and to the extent required by 45 CFR 46.117.

10.1.3.2 Assent from Children

Because “assent” means a child’s affirmative agreement to participate in research [45 CFR 46.402(b)], the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. The IRB has the discretion to judge all of the children’s capacity to assent, or on an individual basis.

The IRB will take into account the nature of the proposed research activity and the age, maturity, and psychological state of the children involved when reviewing the proposed assent procedure and the form and content of the information conveyed to the prospective participants. For research activities involving adolescents whose capacity to understand resembles that of adults, the assent procedure should include information similar to what would be provided for informed consent by adults or for parental permission. For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in
research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (e.g., what the experience will be, how long it will take, whether it might involve any pain or discomfort). The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.

The IRB presumes that children ages 7 and older should be given an opportunity to provide assent. Generally, oral assent through the use of a script may be obtained from children 7-11 years of age. Written assent using a written document for the children to sign may be sought for older children.

At times there may be inconsistency between parent permission and child assent. Usually a “no” from the child overrides a “yes” from a parent, but a child typically cannot decide to be in research over the objections of a parent. Obviously, there are individual exceptions to these guidelines (such as when the use of an experimental treatment for a life threatening disease is being considered). The general idea, however, is that children should not be forced to be research participants, even when their parents consent to it.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted and that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

Even when the IRB determines that the participants are capable of assenting, the IRB may still waive the assent requirement under circumstances detailed in Section 9.3: Waiver of Informed Consent of this SOP.

The Assent Form

Researchers should try to draft a form that is age appropriate and study specific, taking into account the typical child’s experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The assent form should:

1) tell why the research is being conducted;
2) describe what will happen and for how long and how often;
3) say it’s up to the child to participate and that it’s okay to say no;
4) explain if it will hurt, and if so, for how long and how often;
5) say what the child’s other choices are;
6) describe any good things that might happen;
7) say whether there is any compensation for participating; and
8) ask for questions.

For younger children, the document should be limited to one page if possible. Illustrations might be helpful, and larger type makes a form easier for young children to read. Studies involving older children or adolescents may include more information and use more complex language.

10.1.3.3 Children Who are Wards

Children who are wards of the State or any other agency, institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to individual participants (45 CFR 46.406), but likely to yield generalizable knowledge about the participant’s disorder or condition, only if such research is:
1) related to their status as wards; or
2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.

If the research meets the condition(s) above, the IRB must affirm that an advocate has been or will be appointed for each child who is a ward (one individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or in loco parentis.

The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child’s participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the PI(s), or the guardian organization.

10.2 Research Involving Pregnant Women, Human Fetuses, and Neonates [45 CFR 46.201-207 (Subpart B)]

Most social and behavioral research does not involve neonates. However, any study that involves the use of pregnant women, human fetuses, and neonates (as defined below) must be described in the general IRB protocol application as well as the UCR Appendix C: Research Involving the Use of Pregnant Women, Human Fetuses, and Neonates for IRB review and approval. For research not funded by DHHS and that is also determined by the IRB to have no more than minimal risk to the pregnant woman or fetus, there are no additional restrictions on the involvement of the pregnant women of fetuses in the research (see 45 CFR 46 Subpart B for restrictions on DHHS-funded research).

For research that involves neonates and/or more than minimal risk to pregnant woman or fetuses or which involves neonates, the following subsections to 10.2 apply:

10.2.1 Definitions

Dead fetus – a fetus that does not exhibit heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord.

Delivery – complete separation of the fetus from the woman by expulsion or extraction or any other means.

Fetus – the product of conception from implantation until delivery.

Neonate – a newborn.

Nonviable neonate – a neonate after delivery that, although living, is not viable.

Pregnancy – the period of time from implantation until delivery. A woman is assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Viable – as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

10.2.2 Research Involving Pregnant Women or Fetuses

Pregnant women or fetuses may be involved in research involving more than minimal risk to fetuses if all of the following conditions are met:
1) Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

2) 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 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;

3) Any risk is the least possible for achieving the objectives of the research;

4) 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, then the consent of the pregnant woman is obtained in accord with the provisions for informed consent;

5) 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 provisions for informed consent, 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.

6) Each individual providing consent under paragraph 4 or 5 of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

7) For children who are pregnant, assent and permission are obtained in accord with the provisions of permission and assent;

8) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

9) 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

10) Individuals engaged in the research will have no part in determining the viability of a neonate.

10.2.3 Research involving Neonates

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

2) Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

3) Individuals engaged in the research will have no part in determining the viability of a neonate.

4) The requirements of Neonates of Uncertain Viability or Nonviable Neonates (see below in this section) have been met as applicable.

Neonates of Uncertain Viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:

The IRB determines that:

1) The research holds 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

2) 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
3) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative is obtained in accord with the provisions of permission and assent, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

**Nonviable Neonates.** After delivery, nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met:

1) Vital functions of the neonate will not be artificially maintained;
2) The research will not terminate the heartbeat or respiration of the neonate;
3) There will be no added risk to the neonate resulting from the research;
4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
5) The legally effective informed consent of both parents of the neonate is obtained in accord with the provisions of permission and assent, except that the waiver and alteration of the provisions of permission and assent do not apply.
6) However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

**Viable Neonates.** A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of IRB Review Process and Research Involving Children.

**10.2.4 Research Involving, After Delivery, the Placenta, the Dead Fetus, or Fetal Material**

Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, must be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

If information associated with material described above in this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and all pertinent sections of this manual are applicable.

**10.2.5 Research Not Otherwise Approvable**

If the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates, and the research is not approvable under the above provisions, then the IRB will consult with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law). Based on the recommendation of the panel, the IRB may approve the research based on either:

1) That the research in fact satisfies the conditions of [Section 10.2.2: Research Involving Pregnant Women or Fetuses](#), as applicable; or
2) The following:
a) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
b) The research will be conducted in accord with sound ethical principles; and
c) Informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this manual.

10.3 Research Involving Prisoners [45 CFR 46.301-306 (Subpart C)]

Prisoners are another of the three classes that are deemed so vulnerable to exploitation in research that there are special rules protecting them. In the past, prisoners were viewed as a convenient research population. They are housed in a single location, constitute a large and relatively stable population, and live a routine life. Unfortunately, all the things that make a prison and prisoners a convenient research population also make prisoners ripe for exploitation.

The concern Subpart C and this policy based on Subpart C attempt to address is whether prisoners have any real choice in participation in research, or whether incarceration prohibits free choice.

Any study that involves the use of prisoners must be described in the general IRB protocol application as well as the UCR Appendix B: Research Involving the Use of Prisoners for IRB review and approval. If federally funded, OHRP must also review the protocol and provide certification that it agrees with the approval category determined by the IRB before the study may commence. (See Section 10.3.5 Additional Duties of the IRB [45 CFR 46.306] for the approval categories.)

10.3.1 Applicability

This policy applies to all biomedical and behavioral research conducted under the auspices of UCR involving prisoners as participants. Even though a University IRB may approve a research protocol involving prisoners as participants according to this policy, PIs are still participant to the Administrative Regulations of any other applicable State or local law [45 CFR 46.301].

10.3.2 Purpose

Because prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as participants in research, it is the purpose of this policy to provide additional safeguards for the protection of prisoners involved in research activities to which this subpart is applicable [45 CFR 46.302].

10.3.3 Definitions [According to 45 CFR 46.303]

Prisoner – any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Minimal Risk – the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

10.3.4 Composition of the IRB [45 CFR 46.304]
In addition to satisfying the general requirements detailed in Section 5: IRB Membership of this manual, when reviewing research involving prisoners, the IRB must also meet the following requirements:

1) A majority of the IRB (exclusive of prisoner members) must have no association with the prison(s) involved, apart from their membership on the IRB.

2) At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

10.3.5 Additional Duties of the IRB [45 CFR 46.306]

In addition to all other responsibilities prescribed for the IRB in Section 7: IRB Review Process of this manual, the IRB will review research involving prisoners and approve such research only if it finds that:

1) the research falls into one of the following permitted categories [45 CFR 46.306]:
   a) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
   b) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the participants;
   c) research on conditions particularly affecting prisoners as a class (for example, research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); for DHHS-funded research, OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research;
   d) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant; for DHHS-funded research which requires the assignment of prisoners in a manner consistent with protocols approved by the IRB in control groups which may not benefit from the research, the study may proceed only after OHRP has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of its intent to approve such research.

2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

3) the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

4) procedures for the selection of participants within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the PI provides to the IRB justification in writing for following some other procedures, control participants must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

5) the information is presented in language which is understandable to the participant population;

6) adequate assurance exists that any law enforcement agency or entity will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each
prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

7) where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing participants of this fact.

### 10.3.6 Waiver for Epidemiology Research

In June 2003, the Secretary of DHHS waived the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or supported by DHHS as long as

1) The sole purposes of the research are
   a) To describe the prevalence or incidence of a disease by identifying all cases, or
   b) To study potential risk factor associations for a disease, and

2) The IRB has approved the research and fulfilled its duties under 45 CFR 46.305(a)(2-7) and determined and documented that
   a) The research presents no more than minimal risk and no more than an inconvenience to the prisoner-participants, and
   b) Prisoners are not a particular focus of the research.

The waiver would apply to research related to chronic diseases, injuries, and environmental health that uses epidemiologic methods (such as interviews and collection of biologic specimens) that generally entail no more than minimal risk to the participants.

In order for a study to be approved under this waiver, the IRB would need to ensure that, among other things, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of the data.

For more information about this waiver, please see 68 FR 36929.

### 10.4 Persons with Mental Disabilities or Persons with Impaired Decision-Making Capacity

Although not specifically covered in the Common Rule, research involving participants who are mentally ill or participants with impaired decision-making capacity warrants special attention. Research involving these populations may present greater than minimal risk; may not offer direct medical benefit to the participant; and may include a research design that calls for washout, placebo, or symptom provocation. In addition, these populations are considered to be vulnerable to coercion.

Any study that involves the use of persons with mental disabilities or impaired decision-making capacity must be described in the general IRB protocol application as well as the UCR Appendix D: Research Involving Cognitively Impaired Participants for IRB review and approval.

### 10.4.1 IRB composition

The IRB membership must include at least one member who is an expert in the area of the research. Consideration may be given to adding another member who is a member of the population, a family member of such a person or a representative of an advocacy group for that population.

### 10.4.2 Definitions
Disability – a developmental disability (as defined in 42 USC 15002(8)), a mental illness (as defined in 42 USC Section 10802(4)), a disability within the meaning of the Americans with Disabilities Act of 1990, or a disability within the meaning of the California Fair Employment and Housing Act.

The State of California defines any disabilities that originate before an individual attains age 18 years, continues, or can be expected to continue indefinitely and constitutes a substantial disability for that individual as “developmental disability.” As defined by the Director of Developmental Services, in consultation with the Superintendent of Public Instruction, this term shall include mental retardation, cerebral palsy, epilepsy, and autism. This term shall also include disabling conditions found to be closely related to mental retardation or to require treatment similar to that required for individuals with mental retardation, but shall not include other handicapping conditions that are solely physical in nature.

Legally Authorized Representative – an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant for participation in the procedure(s) involved in the research [45 CFR 46.102(c)].

According to the California Health and Safety Code section 24178(c), the State of California uses “legally authorized representative” synonymously with “surrogate decision-maker.” In determining the disabled person’s best interest, the decision-maker shall consider the person’s personal values and his or her best estimation of what the person would have chosen if he or she were capable of making a decision. For the purpose of clarity, these guidelines will use the term “surrogate decision-maker” hereafter.

10.4.3 Approval Criteria
Research involving persons with impaired decision-making capability may only be approved when the following conditions apply:

1) The PI must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as participants. *Incompetent persons or persons with impaired decision-making capacity must not be participants in research simply because they are readily available.*

2) The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant. Incompetent people or persons with impaired decision-making capacity are not to be participants of research that imposes a risk of injury, unless that research is intended to benefit that participant and the probability of benefit is greater than the probability of harm.

3) Procedures have been devised to ensure that a participant’s surrogate decision-maker is well informed regarding his/her roles and obligations to protect incompetent participants or persons with impaired decision making capacity. Health care agents [appointed under Durable Power of Attorney for Health Care (DPAHC)] or the surrogate decision-maker must be given descriptions of both proposed research studies and the obligations of the person’s representatives. They must be told that their obligation is to try to determine what the participant would do if competent, or if the participant’s wishes cannot be determined, what they think is in the incompetent person’s best interest.

10.4.4 Additional Concerns
Both PIs and IRB members must be aware that for some participants, their decision-making capacity may fluctuate. For participants with fluctuating decision-making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary.
It is the responsibility of PIs to monitor the decision-making capacity of participants enrolled in research studies and to determine if surrogate consent must be re-obtained.

The IRB will require PIs to conduct a **competency assessment** whenever there is a possibility of either impaired mental status or decision-making capacity in prospective participants.

Although incompetent to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may participants be forced or coerced to participate.

### 11 Non-Compliance, Suspension, or Termination of IRB Approval of Research

#### 11.1 Complaints, Concerns, and Appeals

UCR provides a variety of safe, confidential, and reliable channels for current, prospective, or past research participants or their designated representatives, to file a complaint, appeal, or express a concern to an informed individual who is unaffiliated with the specific research study in which they participated, such as an IRB Staff member, IO, or Chair, via walk-in, email, or phone call. These persons will promptly handle and, if necessary, investigate all complaints, concerns, and appeals.

#### 11.2 Non-compliance

All members of the University community involved in human participant research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional and IRB policies governing the conduct of research involving human participants.

#### 11.2.1 Definitions

**Non-compliance** – the failure to comply with any of the regulations and policies mentioned and described in this document and failure to follow the determinations of the IRB. Non-compliance may be minor or sporadic, serious, or continuing.

**Minor or sporadic non-compliance** – the failure to comply with IRB policies, which in the opinion of the IRB Chair and Director (or designee), are administrative in nature.

**Serious non-compliance** – the failure to follow any of the regulations and policies described in this document or failure to follow the determinations of the IRB and which, in the judgment of either the IRB Chair or the convened IRB, increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. Research being conducted without prior IRB approval is considered serious noncompliance.

**Continuing non-compliance** – a pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

**Allegation of Non-Compliance** – an unproved assertion of non-compliance.

**Finding of Non-Compliance** – an allegation of non-compliance that is proven true or a report of non-compliance that is clearly true. For example, a finding on an audit of an unsigned consent document, or an admission of a PI that the protocol was willfully not followed would represent reports of non-
compliance that would require no further action to determine their truth and would therefore represent findings of non-compliance.

**Suspension** – the temporary or permanent withdrawal of IRB approval for some or all research procedures short of permanent withdrawal of approval of all research procedures. This includes mandatory cessation of the recruitment, use of participants, or the use of data (including publication) collected from participants pending a review by the IRB of the suspected or alleged non-compliance. Suspended research must undergo continuing review.

**Termination** – the permanent withdrawal of IRB approval for all research procedures. The demands related to suspension as described above, apply. Additionally, terminated research is closed and does not require continuing review.

### 11.2.2 Review of Allegations of Non-compliance

All allegations of non-compliance will be reviewed by the IRB Chair and Director. They will review:

1. All documents relevant to the allegation;
2. The last approval letter from the IRB;
3. The last approved IRB application and protocol;
4. The last approved consent document;
5. The grant, if applicable; and
6. Any other pertinent information (e.g., questionnaires, DSMB reports, etc.).

The IRB Chair and Director will then make a determination as to the truthfulness of the allegation and determine a plan of action within 7 business days after the allegation is made. They may request additional information or an audit of the research in question by the UCR Audit and Advisory Services.

If in the judgment of the IRB Chair and Director, the reported allegation of non-compliance is not true, no further action will be taken and this decision will be documented in the research file. If in the judgment of the IRB Chair and Director, the reported allegation of non-compliance is true, the non-compliance will be processed according to **Section 11.2.3: Review of Findings of Non-compliance**.

If in the judgment of the IRB Chair and Director, any allegation or findings of non-compliance warrants suspension or termination of the research on an urgent basis before completion of any review or investigation to ensure protection of the rights and welfare of currently enrolled participants, the IRB Chair may terminate or suspend the research as described below with subsequent review by the IRB.

### 11.2.3 Review of Findings of Non-compliance

Once the IRB Chair and Director determine that the reported allegation of non-compliance is true, they will then make a determination as to whether the non-compliance is serious or continuing. If, in the judgment of the IRB Chair and Director, the reported finding of non-compliance is not serious, not continuing, and the proposed corrective action plan seems adequate, no further action will be required and the IRB will be informed at the next convened meeting.

If, in the judgment of the IRB Chair and Director, the reported finding of non-compliance may be serious or continuing, the matter will be presented to the IRB at a convened meeting with a recommendation that a formal inquiry will be held (see **Section 11.2.4: Inquiry Procedures**). All IRB members will receive:

1. All documents relevant to the allegation;
2) The last approval letter from the IRB;
3) The last approved IRB application; and
4) The last approved consent document.

The convened IRB may:
1) Find that there is no issue of non-compliance;
2) Find that there is noncompliance that is neither serious nor continuing and an adequate corrective action plan is in place;
3) Find that there may be serious or continuing non-compliance and direct that a formal inquiry be held (see Section 11.2.4: Inquiry Procedures); or
4) Request additional information before making a determination.

11.2.4 Inquiry Procedures
The IRB may request that a formal inquiry be held based on several issues that may include but are not limited to the:
1) Participants’ complaints that rights were violated;
2) Report(s) that the PI is not following the protocol as approved by the IRB;
3) Unusual and/or unexplained adverse events in a study; and/or
4) Repeated failure of the PI to report required information to the IRB.

A subcommittee will be appointed consisting of IRB members and non-members, if appropriate, to ensure fairness and expertise. The subcommittee will:
1) Review the protocol(s) in question;
2) Review the sponsor audit report of the PI, if appropriate;
3) Review any relevant documentation, including consent documents, case report forms, participants’ investigational and/or medical files etc., as they relate to the PI's execution of his/her study involving human participants;
4) Interview appropriate personnel, if necessary;
5) Prepare either a written or oral report of the findings to be presented to the convened IRB at its next meeting; and/or
6) Recommend actions, if appropriate.

11.2.5 Final Review
The results of the inquiry will be reviewed at a convened IRB meeting where the IRB will receive a report from the subcommittee. If the results of the inquiry substantiate the finding of serious or continuing non-compliance, the IRB’s possible actions could include, but are not limited to:
1) Requiring a corrective action plan from the PI;
2) Verifying that participant selection is appropriate;
3) Observing the actual informed consent;
4) Increasing the data and safety monitoring of the research activity;
5) Requesting a directed audit of targeted areas of concern;
6) Requesting a status report after each participant receives the intervention;
7) Modifying the continuing review cycle;
8) Requesting additional PI and staff education;
9) Notifying current participants if the information about the non-compliance might affect their willingness to continue participation;
10) Suspending the study (see Section 11.3: Suspension or Termination); or
11) Terminating the study (see Section 11.3: Suspension or Termination).

The PI will be informed of the IRB determination and the basis for the determination in writing and will be given a chance to respond. If the IRB determines that the non-compliance was serious or continuing, the results of the final review will be reported as described in Section 11.4: Reporting.

11.2.6 Additional Actions

A finding of serious or continuing non-compliance may also result in the following sanctions, among others:

1) Suspension or termination of IRB approval of specific research protocols or of all research involving human participants in which the PI participates.

2) Sponsor actions. In making decisions about supporting or approving applications or proposals covered by this policy, the DHHS or Agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension as described above, and whether the applicant or the person(s) who would direct or has directed the scientific and technical aspects of an activity has, in the judgment of the DHHS or Agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human participants.

3) Institutional or individual action by OHRP. OHRP may
   • withhold approval of all new UCR studies by the IRB;
   • direct that no new participants be added to any ongoing studies;
   • terminate all ongoing studies, unless doing so would endanger the participants; and/or
   • notify relevant state, federal, and other interested parties of the violations.

4) Individual disciplinary action of the PI or other personnel involved in a study, up to and including dismissal, pursuant to University policies and procedures.

Failure to secure necessary UCR IRB approval before commencing human participant research must be reported to the IO and the appropriate Dean for disciplinary action.

PIs should also be aware that, in general, UCR indemnifies them from liability for adverse events that may occur in UCR studies approved by the UCR IRB. Failure to follow approved procedures may compromise this indemnification and make the PI personally liable in such cases.

11.3 Suspension or Termination

An IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to participants. The IRB Chair and Director are authorized to suspend or terminate research on an urgent basis, and these suspensions and terminations are promptly reported to and reviewed by the convened IRB. When the IRB suspends or terminates its approval it will include a statement of its reasons in writing and report the suspension or termination promptly to the PI and as described in Section 12: Reporting to Regulatory Agencies and Institutional Officials.
When study approval is suspended or terminated by the IRB, IRB Chair, and/or Director, in addition to stopping all research activities, the IRB will notify any participants currently participating that the study has been terminated. The IRB will consider whether procedures for withdrawal of enrolled participants are necessary to protect their rights and welfare of participants. If follow-up of participants for safety reasons is permitted/required by the IRB, the IRB will require that the participants should be so informed and that any adverse events/outcomes be reported to the IRB and the sponsor.

11.4 Reporting

Serious or continuing noncompliance with regulations or the requirements or determinations of the IRB, and suspensions or terminations of IRB approval will be reported to the appropriate regulatory agencies and IOs according to the procedures in Section 12: Reporting to Regulatory Agencies and Institutional Officials.

12 Reporting to Regulatory Agencies and Institutional Officials

1) The IRB office will report cases of serious or continuing noncompliance, and suspensions or terminations of IRB approval to regulatory agencies and institutional officials as soon as it:
   a) Determines that an event may be considered an unanticipated problem involving risks to participants or others;
   b) Determines that non-compliance was serious or continuing; and/or
   c) Suspends or terminates approval of research.

2) The Director or designee will submit a report via a letter that contains the following information:
   a) The nature of the event (e.g., unanticipated problem involving risks to participants or others, serious or continuing non-compliance, and/or suspension or termination of approval of research);
   b) The name of the institution conducting the research;
   c) The title of the research project and/or grant proposal in which the problem occurred;
   d) The name of the PI on the protocol;
   e) The research project number assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
   f) A detailed description of the problem including the findings of the organization and the reasons for the IRB’s decision;
   g) Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend participant enrollment, terminate the research, revise the informed consent document, inform enrolled participants, increase monitoring of participants, etc.);
   h) Plans, if any, to send a follow-up or final report by the earlier of
      1. A specific date, or
      2. When an investigation has been completed or a corrective action plan has been implemented;

3) This letter will be reviewed and modified as needed by the IRB Chair and the IO.

4) The IO will sign the final letter and return it to the Director or designee.

5) The Director or designee will send a copy of the report to:
a) The IRB by including the letter in the next agenda packet as an information item
b) The IO
c) OHRP, if the study is subject to DHHS regulations or a DHHS federal-wide assurance
d) OHRP or the head of the agency as required by the agency, if the study is conducted or funded by any Federal Agency other than DHHS that is subject to “The Common Rule”
   1. Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization, and the agency has been notified of the event by the PI, sponsor, another organization, or other mechanisms.

e) The PI
f) The sponsor, if applicable
g) The contract research organization, if applicable
h) The chair or supervisor of the PI
i) The Privacy Officer of a covered entity, if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information from that covered entity
j) The Information Security Officer of an organization if the event involved violations of information security requirements of that organization
k) The Office of Risk Management
l) Others as deemed appropriate by the IO

The Director ensures that all steps of this policy are completed within 30 days of the initiating action. For more serious actions, the Director will expedite reporting.

13 PI Responsibilities

PIs are ultimately responsible for the conduct of research. PIs may delegate research responsibility; however, they must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

In order to satisfy the requirements of this policy, PIs who conduct research involving human participants must:

- develop and conduct research that is in accordance with the ethical principles in the Belmont Report;
- develop a research plan that is scientifically sound and minimizes risk to the participants;
- have sufficient resources necessary to protect human participants, including supervision, a sufficient number of appropriately trained staff, and appropriate support services;
- protect the rights and welfare of prospective participants;
- have plans to monitor the data collected for the safety of research participants;
- have a procedure to receive complaints or requests for additional information from participants and respond appropriately;
- ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating faculty and research staff, including those laws, regulations, and procedures that apply in any foreign entity where the research will take place;
• obtain and document informed consent as required by the IRB and ensure that no human participant is involved in the research prior to obtaining their consent;
• ensure that all research involving human participants receives IRB review and approval in writing before commencement of the research;
• comply with all IRB decisions, conditions, and requirements;
• report the problems listed in Section 7.9: Unanticipated Problems and Adverse Events to the IRB within ten (10) working days of becoming aware of the problem;
• obtain IRB review and approval in writing before changes are made to approved protocols or consent forms;

seek IRB assistance when in doubt about whether proposed research requires IRB review.

13.1 PIs
UCR faculty, students, and staff members may serve as the PI on a research project involving human participants. Students must have a faculty sponsor who will serve as faculty advisor on the study.

UCR allows for non-UCR persons to serve as PIs as long as they submit and have approved the “UCR HRRB Administrative Review for Human Research Studies Being Conducted by Non-UCR Principal Investigators Accessing UCR Facilities, Patients or Personnel” form.

The IRB recognizes one PI for each study. The PI has ultimate responsibility for the research activities.

Protocols that require skills beyond those held by the PI must be modified to meet the PI’s skills or have one or more additional qualified faculty as Co-PI(s).

Research Team
The research team consists of the PI and other individuals, also known as key personnel, who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol. The PI has ultimate responsibility for the actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.

13.2 Protocol Development
When developing a protocol, the PI or a member of the research team may contact the IRB Office by telephone or email for a determination whether the proposed project constitutes human participants research, and if so, what level of review would be required. The IRB staff may ask the PI to complete and submit the “UC Riverside Human Research Review Board (HRRB) Request for Determination of Non-Human Subjects Research” if they require more information or to document the IRB’s determination that a proposed project does not constitute human participant research. The IRB staff may also ask the PI to complete and submit the UCR HRRB “Application for Approval to Use Human Participants” if it is apparent that the proposed project does constitute human participants research. The IRB Office will respond to the PI or member of the research team by phone, letter, or email.

If a PI is asked to submit the UCR HRRB “Application for Approval to Use Human Participants,” it is the PI’s responsibility to submit the form and all attachments to appropriate institutional regulatory committee offices (e.g., Radiation Safety Committee, etc.) and the department IRB reviewer (if applicable) for review and sign-off.
If research is DHHS-sponsored, materials delivered to the departmental IRB reviewer must include the entire sponsoring application; if there is a significant variation between the DHHS application and the IRB protocol, the PI must identify and justify the discordance.

If applicable, the PI must make any changes recommended by the department reviewer. The intent is to address problems prior to review by the IRB, thus avoiding delays in receiving approval for the research study.

Following departmental review and sign-off by Department Chairs or other appropriate IO, the PI must submit all the required materials to UCR IRB Office.

**Note:** PIs who have other individuals write their protocols and responses to the IRB must recognize that the ultimate responsibility of any study lies with the PI. It is incumbent upon the PI to check all material that is submitted to the IRB for review.

### 13.3 Transnational Research

PIs are encouraged to conduct studies in other countries. Doing so, however, involves greater responsibilities. For example, it is the PI’s responsibility to ensure that they and their research staff are qualified to conduct research in another country. Research personnel must be sensitive to and respectful of that country’s culture and local laws.

If an international institution or agency will be assisting the researcher with the study, such as with recruitment of participants, a letter of access from the international institution or agency must be submitted. The institution or agency may be a university, government entity, community leader, etc. This letter should be written in or translated into English; the original language of the letter (if applicable) and the translation must both be submitted to the IRB. This letter of access should explain that the institution or agency understands and supports the purpose and procedures of the research. It may also need to include language about respecting participant confidentiality.

If a letter of access *cannot* be obtained (because, for example, participants will not be affiliated with any institution or agency), a formal letter from an expert on the political climate and/or culture of that country or region will need to be submitted with the protocol application. This letter must describe the writer’s qualifications for writing the letter and indicate that it would be acceptable, according to the culture of the local peoples in that country or region, to conduct the proposed research there. This letter may NOT be written by the PI or the project’s research personnel.

The IRB will assist the PI by finding such an expert if the PI is unable to do so. This expert may or may not be affiliated with UCR.

Some researchers conducting transnational research enlist the assistance of local peoples who may not have access to the internet and/or may not understand English well. In such cases, these local assistants are unable to take the UCR Human Subjects Tutorial. The IRB may then request a protocol-specific training schedule or completion certificate of such training for all research personnel, including the PI.

It is also the PI’s responsibility to coordinate and communicate with local IRBs, if available. OHRP’s “International Compilation of Human Research Protections” is a helpful resource for...
finding international IRB websites. The UCR IRB may request written documentation of another local IRB’s determinations.

If the participants in the proposed country’s official language(s) does not include English, the consent and research questions (i.e., surveys, interviews) must be translated to their language and approved by the UCR IRB and a local IRB in that country (see Section 9.9: Consent and Language Barriers for policies and procedures related to translations).

13.4 Adherence to Terms of Approved Protocols

Once the IRB has reviewed the protocol and approved a protocol (with the PI responding to any questions, comments, or concerns that were raised), the protocol is approved for the time frame suitable to the research and its participants, the PI and its staff must follow the requirements of the research protocol or plan and adhere to the policies and procedures set forth in said protocol and must also follow any requirements placed upon it by the IRB. Failure to do so may result in a finding of noncompliance that may lead to the suspension or termination of the protocol.

13.5 Withdrawal of Participants from Research

The UCR IRB follows the recommendations as set forth in the OHRP “Guidance on Withdrawal of Subjects from Research: Data Retention and Other Related Issues.” This guidance explains that:

- Participants have the right to withdraw from (i.e., discontinue participation in) research at any time (45 CFR 46.116(a)(8)). If a participant decides to withdraw from all components of a research study, the PI must discontinue all activities involving that participant’s participation in that study (45 CFR 46.116(a)(8)).
- PIs are allowed to retain and analyze already collected data from a participant who chooses to withdraw from a research study or whose participation is terminated by a PI without regard to the participant’s consent, provided that such analysis falls within the scope of the analysis described in the IRB-approved protocol.
- For research not subject to regulation and review by FDA, PIs, in consultation with the funding agency, can choose to honor a research participant’s request that the PI destroy the participant’s data or that the PI exclude the participant’s data from any analysis.
- Participants must be fully informed about whether their data will be retained and analyzed even if they choose to withdraw from the research.
- PIs and IRBs consider whether and how the withdrawal of a participant for a research study should be documented.

The complete guidance is available on the OHRP website.

13.6 Changes to Approved Research

PIs must seek IRB approval before making any changes in approved research – even though the changes are planned for the period for which IRB approval has already been given – unless the change is necessary to eliminate an immediate hazard to the participant (in which case the IRB must then be notified at once).

Minor changes (i.e., changes that do not involve increased risk or discomfort) may be authorized by the IRB Chair or his/her designee. A letter specifying the changes requested, a revised consent form (if applicable), and a copy of the approved protocol with the proposed changes highlighted, should be sent directly to IRB Office. The IRB Chair or Director must sign and return a letter to indicate approval.

Note: IRB approved amendments to ongoing research do NOT extend the original approval expiration date.
13.7 Continuing Review after Protocol Approval

Ongoing research studies must be reviewed by the IRB at least annually, or more often, if the IRB finds that the degree of risk to participants warrants more frequent review. **This renewal must take place prior to the end of the approval period noted on the approved protocol;** otherwise, participant recruitment/enrollment must be suspended and, if the research is DHHS-sponsored, the Agency must be notified.

It is the responsibility of the PI to submit a timely continuing review application. As a courtesy, the UCR IRB Office will send a “Continuing Review Form for Approval of the Human Participants Protocol” to the PI two months and one month prior to the expiration of each approved protocol. The PI should allow sufficient time for development and review of renewal submissions.

**Note:** The “approval date” and the “approval expiration date” are listed on all IRB certifications.

In addition to the usual protocol submissions to the IRB, a progress report must be included with the request for continuation including the following information from the past year (cumulative data must also be included after the first renewal):

1) progress of the research;
2) the number of participants enrolled;
3) number of participants who withdrew prematurely and reason(s) for their withdrawal;
4) a summary of adverse events and any unanticipated problems involving risks to participants or others and any withdrawal of participants from the research or complaints about the research since the last IRB review;
5) summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
6) any relevant multi-center trial reports;
7) any other relevant information, especially information about risks associated with the research; and
8) a copy of the current informed consent document and any newly proposed consent document.

13.8 Required Reports to the IRB

Researchers and research staff must follow reporting requirements in according with the policies and procedures described in **Section 7.9: Unanticipated Problems and Adverse Events.** The UCR IRB is responsible for reporting to appropriate State and Federal agencies as required.

13.8.1 Unanticipated Problems

Prompt reporting to the IRB chairperson through the IRB Office is required when any **problem** listed in **Section 7.9: Unanticipated Problems and Adverse Events** occurs.

PIs should be aware that some sponsors often use more inclusive definitions of adverse events and these definitions should be used if called for by the sponsor.

13.8.2 Complaints, Non-compliance, and Protocol Deviations

PIs must report all **complaints and concerns, non-compliance by the research staff,** and any **protocol deviations** listed in **Section 7.9: Unanticipated Problems and Adverse Events** to the IRB within ten (10) working days.
13.8.3 Progress Reports

PIs must **report the progress of the research** to the IRB in the manner and frequency prescribed by the IRB, but no less than once a year.

When an approved research project is completed, the PI must promptly notify the IRB and file with the IRB a “Notice of Closure” which should include a final progress report, which includes the information listed above for continuing review of protocols for the last research project period.

Once data collection has been completed and the research is closed at either the University or other sites, the PI is not required to submit any further reports of the research to the IRB.

13.9 PI-Required Record Keeping

PIs must retain copies of approved IRB documents, and implement a system to comply with approval expiration dates.

In addition to providing a copy of the signed and dated consent form to each participant, a copy must be stored securely by the PI and placed in the participant’s medical record (if the participant is a patient and this requirement has not been waived by the IRB), and a copy must be retained by the PI for a **minimum of 5 years after completion of the research**.

13.10 Conflict of Interest – PIs

All PIs and research staff members (i.e., those who are involved in the design, conduct, or reporting of research) must follow the UCR Conflict of Interest Policy. For more details, please see **Section 7.5.9: PI Conflicts of Interest**.

13.11 Training/Ongoing Education of PI and Research Team

One component of a comprehensive human research protection program is an education program for all **domestic and foreign** individuals involved with research participants. UCR is committed to providing training and an on-going educational process for PIs and members of their research team (also known as “key personnel”) related to ethical concerns and regulatory and institutional requirements for the protection of human participants and to improve their qualifications and expertise for protecting the rights and welfare of research participants. This is accomplished by having mandated quarterly training seminars that address current, relative issues related to human participants research. UCR (under its Federal-wide Assurance with the DHHS Office of Human Research Protections and these SOPs) requires proof of the completion of a training course for all those members of the research team in a protocol that is reviewed and approved by the UCR HRRB.

A research team consists of anyone involved in data collection and analyses related to that research, including the PI. The following are additional examples of members of a research team:

- undergraduate and graduate research assistants;
- a collaborator at another institution that is relying on the review of the UCR IRB; and
- a collaborator at another institution involved in a contractual relationship with UCR (e.g., being paid via a subcontract when UCR is the prime grant holder.)

**Orientation**

All PIs and key personnel must review core training documentation, including the “UCR Policies and Procedures for Human Research Protection,” and the “Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.”

**Initial Education Requirement**
All PIs and key personnel must meet UCR’s initial education requirement. There are no exceptions to this requirement. PIs will be required to complete the online tutorial that discusses the Common Rule and its application to research using human participants.

New research protocols and applications for continuing review will not be accepted from PIs who have not completed the initial education requirement (or the continuing education requirement once the initial education requirement has been satisfied).

While research protocols and applications for continuing review will be accepted and reviewed as long as the PI holds a current certification of training, final approval will not be granted until all key personnel have completed the initial education requirement (or the continuing education requirement once the initial education requirement has been satisfied).

Waiver of Initial Education
If PIs and their key personnel can verify that they have successfully completed human participants research training equivalent to that required by the University, they may request a waiver of the requirement for Initial Education. However, all PIs or members of their research team must complete the requirements of Continuing Education.

Continuing Education and Recertification
All PIs and key personnel must complete an online training that discusses the Common Rule and its application to research using human participants every five (5) years after they receive certification of Initial Education for as long as they are involved in human participant research. There are no exceptions to this requirement.

PIs who are also the IRB Chair, IRB members, or IRB Office staff will satisfy the training requirements for IRB members and staff described in this policy under Section 5.3: Training / Ongoing Education of Chair and IRB Members in Regulations and Procedures.

Additional Resources

1) Human research protection information will be made available on the IRB Office website on an ongoing basis to ensure that the University research community remains apprised of current regulatory and policy requirements and training opportunities.

2) Federal Office for Human Research Protections

13.12 Participant Recruitment

PIs are responsible for recruiting research participants in a manner that is fair, ethical, and equitable. IRB approval of the wording and format of all recruitment material(s) must be documented through the use of a certification stamp on all official, finalized recruitment material(s) that indicates the date of the most recent IRB approval of the document and the expiration date. If the recruitment material(s) is amended during the protocol approval period, it must bear the approval date of the amendment rather than the date of the approved protocol.

IRB approval is required for all recruitment procedures and materials. Recruitment materials must be consistent with the approved IRB protocol, accurate, and not coercive.

13.13 Payment to Participants

Payment to research participants may be an incentive for participation or a way to reimburse a participant for travel and other experiences incurred due to participation. However, payment for participation is not considered a research benefit. Regardless of the form of remuneration, PIs must take care to avoid coercion of participants. Payments should reflect the degree of risk,
inconvenience, or discomfort associated with participation. The amount of compensation must be proportional to the risks and inconveniences posed by participation in the study.

The IRB will review both the amount of payment and the proposed method of disbursement to assure that neither entails problems of coercion or undue influence. PIs may allow payment accrual as the study progresses. Payment can be contingent upon the participant completing the entire study but this fact needs to be made known to the participant at the beginning of the study. If a bonus will be given for completion of the study, the bonus must be reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn; this also must be disclosed at the beginning of the study.

The PI may also offer a “finder’s fee” to participants who refer other potential participants to the study. The PI may not offer a “finder’s fee” to individuals such as professors or supervisors to refer prospective participants when those individuals have a power relationship over the prospective participant. “Bonus payments” used to accelerate recruitment that is tied to the rate or timing of enrollment may not be paid to or accepted by PIs or research staff.

The consent form must describe the terms of payment and the conditions under which participants would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed).

If the monies in any form (e.g., cash, coupons, gift cards or certificates, vouchers) for payment are administered through the University, the expenditures of funds for this purpose must fall within all applicable Federal, State and University costing guidelines.

13.14 PI and Research Staff Concerns

PIs and research staff who have concerns, questions, or suggestions regarding UCR’s human research protection program may access the UCR HRRB FAQ to obtain answers to their questions or the most current UCR HRRB contact information. PIs and staff may also convey concerns or suggestions by telephone or email to the IO or other responsible parties (e.g., college dean, departmental Chair) regarding the issue, when appropriate. The IO will research the issue, and when deemed necessary, convene the parties involved to form a response or make necessary procedural or policy modifications, as warranted. In addition, the Chair of the IRB or the Director will be available to address PI or staff’s questions, concerns, and suggestions.

14 Health Insurance Portability and Accountability Act (HIPAA)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the creation of a Privacy Rule for identifiable health information. The resulting Privacy Rule, finalized in August 2002, set a compliance date of April 14, 2003. While the main impact of the Privacy Rule will be on the routine provision of, and billing for, health care, the Rule will also affect the conduct and oversight of research. Researchers, IRB staff, and members as well as research administration must be aware of these changes.

14.1 Historical Background

HIPAA is an expansive federal law, only part of which is intended to protect the privacy of health care information. HIPAA required Congress to enact a health information privacy law by August 1999 and stated that if it did not act by then, which it did not, the U.S. DHHS must develop privacy regulations. The final Privacy Rule was published on August 14, 2002.
The objective of the rule is to protect the privacy of an individual’s health care information. It creates a federal “floor” of protection so that every person in this country has at least the same basic rights and protections, though some may have additional rights depending on state law.

14.2 Effects of HIPAA on Research

The final Privacy Rule published on August 14, 2002 included a number of changes in how the Rule applies to research. See the NIH HIPAA Privacy Rule Booklet for Research and the NIH fact sheet on Institutional Review Boards and HIPAA for more information on how HIPPA applies to research. See also Impact of the Privacy Rule on Academic Research, a white paper published by the American Council on Education.

UCR is not a covered entity under HIPAA. However, researchers who are working with “protected health information” (PHI) from other institutions that are covered entities will need to comply with the rules on HIPAA.

14.3 Research under HIPAA

HIPAA defines research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” This definition is identical with the one used in the Common Rule, separate federal legislation designed to protect human participants involved in research. HIPAA describes privacy standards for protecting PHI and so only applies to research that involves humans’ (not animals’) health information.

14.4 HIPAA and New Documentation Requirements

New research documents include a HIPAA authorization form, a waiver of authorization form, and a de-identification form. These documents must be used whenever PHI of a covered entity is being utilized in the research.

14.5 Patient Rights and Research

Under HIPAA, patients have certain new rights. Those that may affect research include the right to receive a Notice of Privacy Practices, the right to access, inspect, and receive a copy of one’s own PHI, the right to request an amendment to one’s own PHI, and the right to an accounting of certain disclosures of PHI that occur outside the scope of treatment, payment and health care operations that have not been authorized.

14.6 HIPAA and Existing Studies

Any research participant enrolled in a study that uses PHI from a covered entity must sign a HIPAA-compliant authorization form. This form is in addition to the existing Informed Consent document, and is federally required. In a few cases, the Informed Consent document may be combined with a HIPAA authorization.

14.7 Waivers to HIPAA consent form

In some cases an IRB may approve a waiver to use the HIPPA authorization form. This may occur when the IRB finds that the research could not be practically done without the waiver, and not without access to and use of the PHI, and that disclosure poses minimal risk to privacy. This waiver would generally come from the IRB of the covered entity that has “ownership” of the PHI.

15 Special Topics
15.1 Student Research

Students may serve as PIs. They must have a faculty sponsor who fulfills the PI eligibility criteria and who will serve as faculty advisor on the study.

15.1.1 Class projects

The UCR IRB is frequently asked if research activities carried out as part of a class assignment or project are subject to the review and approval of the IRB. The short answer to this question is “no.” Although the IRB has reviewed some protocols covering research in classroom settings in the past, it will no longer do so unless the activity meets the definition of “Human Participants Research” as defined in Section 2: Definitions.

However, the one exception to this policy is for classes where there may be a high likelihood that data from course-related activities could produce generalizable results that are to be published or presented outside of the class for which it was assigned. Such presented or published presentations may be considered human participants research, and therefore must be submitted to the IRB before collection of data to determine whether prior review and approval of the IRB is required.

In these cases, the following steps should be taken to assure appropriate IRB review:

1) Instructors of courses in qualitative methods file a general protocol before the instructional term, listing themselves as PI, and enrolled students as “other project personnel.”

2) Other project personnel (i.e., the students) complete the online tutorial before collecting any data.

3) The instructor in the course provides the IRB with updates on the sub-projects being pursued by their students in the form of amendments when there are changes in the participants being used, the methods employed, or the research questions pursued.

4) The instructor informs the student researchers that they need to prepare and file a separate protocol with the IRB if, and as soon as, it becomes apparent that the work begun for instructional purposes may ultimately be used for research purposes, i.e., to contribute to generalizable knowledge, as defined in Section 2: Definitions.

5) Students who wish to use data collected in the course for subsequent research file with the IRB as independent researchers by the end of the course.

15.1.2 Independent Study, Theses, and Dissertations

These research activities are considered to meet the federal definition of human participants research and must be independently submitted to the IRB by the student-researcher. However, when students conduct research as part of a course of study, a faculty member ultimately is responsible for the protection of the participants, even if the student is the primary researcher and actually directs the project. Advisers assume the responsibility for students engaged in independent research, and instructors are responsible for research that is conducted as part of a course.

15.2 Department Subject Pools

In conducting research, PIs sometimes rely on entities not under their direct supervision, such as department subject pools. The department must designate a faculty representative to submit a UCR HRRB Protocol to the UCR IRB staff, detailing the procedures to which this pool will adhere. The IRB will review and process this protocol as described in Section 7: IRB Review Process.

As part of the course requirement, students may earn class credit by participating as participants in studies being conducted by a UCR PI. However, students cannot be required to serve as a human participant; an alternative assignment involving the same amount of time and for the same amount of
extra credit from the instructor must be offered. Examples of alternative assignments are: (1) writing summaries of published research using library resources or (2) participating as a client in one or more simulated sessions for the purpose of training advanced undergraduate and graduate students.

Department subject pools must be constituted and maintained in accordance with the ethical guidelines set forth by the Common Rule, applicable professional organization guidelines, and as appropriate, with the approval of the UCR IRBs. Any researcher (e.g., faculty, graduate student) using the department subject pool must have successfully completed a training course in the protection of human research participants. Department policies governing the use and operation of the subject pool will be reviewed, and revisions pertaining to research activities must be submitted to IRB for approval.

15.3 UCR Students and Employees as Participants

When UCR students and/or employees are being recruited as potential participants, researchers must ensure that there are additional safeguards for these participants. The voluntary nature of their participation must be primary and without undue influence on their decision. Researchers must emphasize to participants that their academic status, grades, or their employment will not be affected by their participation decision.

To minimize coercion, PIs should avoid, whenever possible, the use of their students and employees in procedures which are neither therapeutic nor diagnostic. In these latter situations, PIs should solicit participants through means such as bulletin board notices, flyers, newspaper advertisements, and announcements in classes other than their own. When entering a classroom to recruit students and conduct research (e.g., administer a survey) PIs must do so at the end of the class period to allow non-participating students the option of leaving the classroom, thereby alleviating pressure to participate.

15.4 Deception

The UCR IRB distinguishes between two types of deception: deception by commission and deception by omission. Deception by commission occurs when participants are misled about the true purpose of the research. Deception by omission occurs when an important aspect of the research is withheld from participants.

The IRB recognizes that the use of deception in research is a valuable research technique, although it also presents special challenges to researchers to ensure that research is conducted ethically. PIs who use deception in research will be asked to complete Appendix E: Research Involving Deception. This form helps the HRRB determine whether the use of deception increases risks to participants, and thus increases the level of IRB review. If such determinations are made, the HRRB will communicate this via email to the PI.

15.5 Oral History

The following is based on guidance received from OHRP:

A decision whether oral history or other activities solely consisting of open ended qualitative type interviews are subject to the policies and regulations outlined in an institution’s FWA and DHHS regulations for the protection of human research participants [45 CFR 46] is based on the prospective intent of the PI and the definition of “research” under DHHS regulations at 45 CFR 46.102(d): “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”

Specifically, for the purposes of this policy, the evaluation of such activities hinges upon whether the person is engaged in the creation of “generalizable knowledge,” that is, whether the activity
represents a systematic investigation in which the person engaged in such activities intends to develop or contribute to generalizable knowledge. See Section 2: Definitions for a definition of generalizable knowledge.

General principles for evaluating Oral History type activities

1) Oral history activities, such as open ended interviews, that ONLY document a specific historical event or the experiences of individuals without intent to draw conclusions or generalize findings would NOT constitute “research” as defined by DHHS regulations.

Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the video tape does NOT intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.

2) Systematic investigations involving open-ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) WOULD constitute “research” as defined by DHHS regulations.

Example: An open ended interview of surviving Gulf War veterans to document their experiences and to draw conclusions about their experiences, inform policy, or generalize findings.

3) Oral historians and qualitative PIs may want to create archives for the purpose of providing a resource for others to do research. Since the intent of the archive is to create a repository of information for other PIs to conduct research, the creation of such an archive WOULD constitute research as defined by DHHS regulations.

Example: Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research since the intent is to collect data for future research.

PIs are advised to consult with the IRB Office regarding whether their oral history project requires IRB review.

15.6 Multiple Site Studies

When there are plans to conduct research at external sites the UCR PI must supply UCR’s IRB with

1) contact information for the external site,

2) whether that site has granted permission for the research to be conducted, and

3) whether that site has an IRB and if so, whether that IRB has approved the research or will rely upon UCR’s IRB.

When the UCR PI plans to conduct research at external sites that are engaged in the research and that site’s IRB plans to rely upon UCR’s IRB, there will be a clear statement signed by both IRBs that the UCR IRB will be the IRB of record.

When the UCR PI is the lead PI of a multi-site study, applications will include information about the management of information that is relevant to the protection of participants, such as unanticipated problems involving risks to participants or others, interim results and protocol modifications. The UCR IRB will evaluate whether the management of information that is relevant to the protection of participants is adequate.
15.7 Certificate of Confidentiality

15.7.1 Statutory Basis for Protection

Protection against compelled disclosure of identifying information about participants of biomedical, behavioral, clinical, and other research is provided by the Public Health Service Act §301(d):

“The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify such individuals.”

Certificates of Confidentiality constitute an important tool to protect the privacy of research study participants. Certificates are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the PI and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

Certificates of Confidentiality may be granted for studies collecting information that if disclosed could have adverse consequences for participants or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants. For more information, see the NIH Certificates of Confidentiality Kiosk.

Certificates are granted sparingly. The study’s funding source, if any, is not relevant to the decision.

The certificate goes beyond the consent form in ensuring confidentiality and anonymity. Without the certificate, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the participants).

Any PI engaged in research in which sensitive information is gathered from human participants (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality. Research can be considered “sensitive” if it involves the collection of:

- information about sexual attitudes, preferences, practices;
- information about personal use of alcohol, drugs, or other addictive products;
- information about illegal conduct;
- information that could damage an individual’s financial standing, employability, or reputation within the community;
- information in a participant’s medical record that could lead to social stigmatization or discrimination; or
- information about a participant’s psychological well-being or mental health.

This list is not exhaustive. Researchers contemplating research on a topic that might qualify as sensitive should contact the IRB Office for help in applying for a certificate.
The IRB may require PIs to apply for a Certificate of Confidentiality.

15.7.2 Limitations

The protection offered by a Certificate of Confidentiality is not absolute. A Certificate protects research participants only from legally compelled disclosure of their identity. It does not restrict voluntary disclosures.

For example, a Certificate does not prevent researchers from voluntarily disclosing to appropriate authorities matters such as child abuse, a participant’s threatened violence to self or others, or from reporting a communicable disease. However, if researchers intend to make such disclosures, this should be clearly stated in the informed consent form which research participants are asked to sign.

In addition, a Certificate of Confidentiality does not authorize the person to whom it is issued to refuse to reveal the name or other identifying characteristics of a research participant if

- the participant (or, if he or she is legally incompetent, his or her legal guardian) consents, in writing, to the disclosure of such information;
- authorized personnel of the DHHS request such information for audit or program evaluation, or for investigation of DHHS grantees or contractors and their employees; or
- release of such information is required by the Federal Food, Drug, and Cosmetic Act or regulations implementing that Act.

15.8 Mandatory Reporting

While preparing a research protocol, PIs must keep in mind that the State of California mandates reporting to designated officials and/or agencies according to the California Penal Code Sections 11164-11174.3.

PIs should consult these sources to determine if potential participants should be advised of mandatory reporting requirements during the informed consent process.

15.9 Genetic Studies

Genetic research studies may create special risks to human participants and their relatives. These involve medical, psychosocial, and economic risks, such as the possible loss of privacy, insurability, and employability, change in immigration status and limits on education options, and may create a social stigma.

In studies involving genetic testing, several questions need to be addressed, including:

1) Will test results be given?
2) Will disease risk be quantified, including the limits on the certainty of the testing?
3) Will a change in a family relationship be disclosed, such as mistaken paternity?
4) Does the participant or family member have the option not to know the results? How will this decision be recorded?
5) Could other clinically relevant information be uncovered by the study? How will disclosure of this added information occur?
6) Do any practical limitations exist on the participant’s right to withdraw from the research, withdraw data, and/or withdraw DNA?
7) Is the participant permitted to participate in the study while refusing to have genetic testing (such as in a treatment study with a genetic testing component)?
For DNA banking studies, several questions need to be addressed, including:

1) Will DNA be stored or shared? If shared, will the participant’s identity be known by the new recipient PI?

2) Will the participant be contacted in the future by the PI to obtain updated clinical information?

3) How can the participant opt out of any distribution or subsequent use of his/her genetic material?

15.10 Research Involving Coded Private Information or Biological Specimens

This UCR policy is based on the OHRP guidance document entitled, “Guidance on Research Involving Coded Private Information or Biological Specimens” (August 10, 2004). This document:

- Provides guidance as to when research involving coded private information or specimens is or is not research involving human participants, as defined under DHHS regulations for the protection of human research participants [45 CFR 46].

- Reaffirms OHRP policy that, under certain limited conditions, research involving only coded private information or specimens is not human participants research.

- Provides guidance on who should determine whether human participants are involved in research.

For purposes of this policy, coded means that: (1) identifying information (such as name or social security number) that would enable the PI to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Under the definition of human participant in Section 2: Definitions of this policy, obtaining identifiable private information or identifiable specimens for research purposes constitutes human participants research. Obtaining means receiving or accessing identifiable private information or identifiable specimens for research purposes. This includes a PI's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the PI.

In general, private information or specimens are considered to be individually identifiable when they can be linked to specific individuals by the PI(s) either directly or indirectly through coding systems. Private information or specimens are not considered to be individually identifiable when they cannot be linked to specific individuals by the PI(s) either directly or indirectly through coding systems.

Research involving only coded private information or specimens do not involve human participants if the following conditions are both met:

1) the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

2) the PI(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:

   a) the key to decipher the code is destroyed before the research begins;

   b) the PI(s) and the holder of the key enter into an agreement prohibiting the release of the key to the PI(s) under any circumstances, until the individuals are deceased (note that the DHHS regulations do not require the IRB to review and approve this agreement);

   c) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the PI(s) under any circumstances, until the individuals are deceased; or
d) there are other legal requirements prohibiting the release of the key to the PIs, until the individuals are deceased.

In some cases a PI who obtains coded private information or specimens about living individuals under one of the conditions cited in 2(a)-(d) above may (1) unexpectedly learn the identity of one or more living individuals, or (2) for previously unforeseen reasons now believe that it is important to identify the individual(s). If, as a result, the PI knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private information or specimens pertain, then the research activity now would involve human participants. Unless this research is determined to be exempt (See Section 7.2: Exempt Research), IRB review will be required. Informed consent from participants also would be required unless the IRB approved a waiver of informed consent (See Section 9.3: Waiver of Informed Consent).

15.10.1 Who Should Determine Whether Coded Private Information or Specimens Constitutes Human Participants Research

The PI in consultation with the IRB Chair or Director will determine if the research involving coded information or specimens requires IRB review. If the request is verbal (by phone or in person) or by email, it is the PI’s responsibility to maintain documentation of such a decision. If the PI submits a formal submission, the request must include sufficient documentation of the activity to support the determination. Formal submissions will be responded to in writing and a copy of the submitted materials and determination letter/email will be kept on file.

16 Agency Specific Regulations

Research funded by the some agencies must also comply with that agency’s regulations in addition to the regulations set forth in the Common Rule.

16.1 Department of Education

The U.S. Department of Education (ED) has additional regulations governing human participants research that must be followed by the IRB, PIs, and research staff.

For example, ED funded research must indicate that access to instructional material used in the research or experimentation program\(^1\) will be available for inspection by the parents or guardians of the children\(^2\) engaged in such research. This includes teachers’ manuals, films, tapes, or other supplementary instructional material.

\(^1\)ED defines research or experimentation programs or projects as any programs or projects in any research that is designed to explore or develop new or unproven teaching methods or techniques.

\(^2\)Children are defined by the ED as persons not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

Additionally, for ED research that purposefully includes of children with disabilities or individuals with mental disabilities as research participants and is specifically funded by the National Institute on Disability and Rehabilitation Research, the IRB is required to include at least one person primarily concerned with the welfare of these research participants during the review process.

Other general requirements are described in the Family Educational Rights and Privacy Act (FERPA), a Federal law that protects the privacy of student education records, and the Protection of Pupil Rights Amendment (PPRA).
16.1.1 **Family Educational Rights and Privacy Act**

Under the Family Educational Rights and Privacy Act (FERPA), parents and students must provide permission/assent to release a student’s education records, unless the records are released to organizations conducting studies for, or on behalf of, educational agencies or institutions to:

- Develop, validate, or administer predictive tests;
- Administer student aid programs; and/or
- Improve instruction.

If the purpose of the research is as described above, PIs must receive IRB approval to waive parent/student permission/assent and submit the original written agreement with the school or school district that specifies:

- The determination of the exception;
- The purpose, scope, and duration of the study;
- The information to be disclosed;
- That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information;
- That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization with legitimate interests;
- That the organization is required to destroy or return all personally identifiable information when it is no longer needed for the purposes of the study; and
- The time period during which the organization must either destroy or return the information.

PIs who are not developing, validating, or administer predictive tests; administering student aid programs; and/or improving instruction may obtain education records without parent/student permission/assent under FERPA if all personally identifiable information has been removed including:

- Student’s name and other direct personal identifiers, such as the student’s social security number or student number.
- Indirect identifiers, such as the name of the student’s parent or other family members; the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable; date and place of birth and mother’s maiden name.
- Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
- Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

The process to grant exceptions to parental/student permission/assent consent to release student records for research will be delegated to the IRB or another individual or component of the organization (e.g., a FERPA committee).
16.1.2 Protection of Pupil Rights Amendment

All research involving children at school, regardless of their funding source, must comply with the Protection of Pupil Rights Amendment (PPRA) in that:

- Parents of students have, upon the request of the parent, the right to inspect or obtain more information about
  - any instrument used in the collection of personal information, including research surveys;
  - any instructional material used as part of the educational curriculum for the student;
  - the administration of physical examinations or screenings that the school or agency may administer to a student; and
  - the collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.

- Such requests by a parent for reasonable access to such information and/or materials must be granted within a reasonable period of time after the request is received.

In addition, parents must be informed of how student responses to the following questions will be kept confidential:

- Political affiliations or beliefs of the student or the student’s parent.
- Mental or psychological problems of the student or the student’s family.
- Sex behavior or attitudes.
- Illegal, anti-social, self-incriminating, or demeaning behavior.
- Critical appraisals of other individuals with whom respondents have close family relationships.
- Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
- Religious practices, affiliations, or beliefs of the student or the student’s parent.
- Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

If the research is funded by ED, prior consent must be obtained from the student (if the student is an adult or emancipated minor), or the parent or guardian (if the student is an un-emancipated minor), before the student may participate in an ED-funded survey, analysis, evaluation, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal one or more of the items above.

16.2 Department of Justice

Research funded by the U.S. Department of Justice (DoJ) must comply with DoJ regulations in addition to the regulations set forth in the Common Rule.

For example, all DoJ-funded research must have a privacy certificate approved by the NIJ Human Subjects Protection Officer. This certificate is signed assurance that any identifiable data obtained through the research will only be used for research or statistical purposes and that compliance with
the request for information is not mandatory. The privacy certificate therefore supersedes all mandatory reporting laws (see Section 15:8: Mandatory Reporting). For example, under a privacy certificate, the investigator and his/her research staff do not have to report child abuse unless the participant signed another consent form to allow child abuse reporting. However, if a participant reports immediate harm to him/herself or others, the investigator will break his/her confidentiality agreement with the participant. The participant must be informed of this caveat during the informed consent process.

The privacy certificate also includes the PI’s assurance that participation in a project may be terminated at any time, and that participants will be informed if findings in a project cannot, by virtue of sample size or the uniqueness of the participant, be expected to totally conceal the identity of an individual.

In addition to the privacy certificate, all researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.

A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

16.2.1 Bureau of Prisons

DoJ has additional regulations for research conducted within the Bureau of Prisons (hereafter, “Bureau”).

Study Design

Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research. PIs must still notify the UCR IRB of their involvement in these projects.

Research conducted within the Bureau must meet the requirements of 28 CFR 512, such as:

- The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- The research design must be compatible with both the operation of prison facilities and protection of human subjects. The researcher must observe the rules of the institution or office in which the research is conducted.
- Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.
- All research proposals will be reviewed by the Bureau Research Review Board.

The project must have an adequate research design and contribute to the advancement of knowledge about corrections.

PIs conducting research within the Bureau must have academic preparation or experience in the area of study of the proposed research. Research proposals must be submitted on the general UCR HRRB Protocol (which includes the general descriptors required under 28 CFR 512.12) with the basic IRB requirements for a protocol submission (including consent documents and measures) and a comprehensive statement as required by the Bureau that includes:

- A review of related literature;
- Specific resources required from the Bureau of Prisons;
• A description of any anticipated effects of the research study on organizational programs and operations;
• The significance of anticipated results and their contribution to the advancement of knowledge;
• Relevant research materials such as vitae, endorsements, and interview schedules; and
• A statement regarding assurances and certification required by 28 CFR 46, if applicable.

Selection of Participants
The selection of participants within any one organization must be equitable. Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are participating in authorized research being conducted by Bureau employees or contractors, and are no longer in Bureau of Prisons custody.

Confidentiality
Regarding the confidentiality of data acquired from research conducted within the Bureau, non-employees of the Bureau may receive unidentifiable data if advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.

PIs must not provide research information that identifies a participant to any person without that participant’s prior written consent to release the information. For example, data that identifies a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.

Records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system, unless this data is maintained at an official Department of Justice site.

If the PI is conducting a study of special interest to the National Institute of Justice (NIJ) Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the PI may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

Consent
In addition to the items listed in Section 9.2: Basic Elements of Informed Consent [45 CFR 46.116], consent documents to be used for research conducted within the Bureau must include the following elements of disclosure:

• Identification of the researchers.
• Anticipated uses of the results of the research.
• A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable);
• A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the participant indicates intent to commit future
criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.

- A statement that participation in the research project will have no effect on the inmate participant’s release date or parole eligibility.

**Reporting Requirements**

At least once a year, the researcher conducting research within the Bureau of Prisons shall provide the ORE Chief a report on the progress of the research.

At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. This report must include an abstract of the findings.

Prior to submitting for publication the results, the researcher shall provide two copies of the material, for informational purposes only, to the ORE Chief.

Any publication of results shall acknowledge the Bureau's participation in the research project and expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.

**16.3 Department of Defense**

Regulations specific to the U.S. Department of Defense (DoD) may be found at 32 CFR 219.

**16.3.1 DoD Training Requirements**

The ORI will notify the IRB and the research community of new regulations, guidance, and educational/training requirements from DoD. However, it is ultimately the responsibility of the researcher to ensure that he/she and his/her research staff meet all of DoD and the applicable component’s (e.g., Department of the Navy, Department of the Army, etc.) current educational requirements before the commencement of the research.

**16.3.2 Participant Recruitment**

DoD defines “research involving a human being as an experimental participant” as an activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (DoD Directive 3216.02 E2.1.3). Examples of interventions or interactions include, but are not limited to, a physical procedure, a drug, a manipulation of the participant or participant’s environment, and/or the withholding of an intervention that would have been undertaken if not for the research purpose.

If a participant of DoD funded research meets the definition above, a waiver of the consent process may only be obtained through the Secretary of Defense. If a participant does not meet this definition, the IRB may waive the consent process.

For research involving U.S. military personnel policies and procedures, the DoD requires additional protections for military research participants to minimize undue influence:

- Officers are not permitted to influence the decision of their subordinates.
- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.
• When recruitment involves a percentage of a unit, an independent ombudsman is present.

U.S. military personnel may not receive dual compensation for their participation in research. Specifically, an individual may not receive pay or compensation for participation in research during duty hours. Compensation may only be received when the individual's participation in research takes place when he/she is not on duty.

Research involving prisoners of war is prohibited. The IRB and PI must review the definition of "prisoner of war" for the DoD component granting the addendum to ensure that no prisoners of war are included in the research.

16.3.3 Research Monitoring

The IRB will appoint a research monitor for a DoD-funded research if the study involves greater than minimal risk. The IRB may also require a research monitor for studies involving no more than minimal risk, if appropriate.

The independent research monitor will be appointed by name by the IRB, and will be given the authority to stop a research study in progress, remove individuals from study, and take any steps to protect the safety and well-being of participants until the IRB assesses the situation.

16.3.4 Other DoD Requirements

• If DoD-funded research is conducted outside of the United States, the PI must follow all of that country or region’s local laws, regulations, customs, and practices. In addition, the PI must obtain permission to conduct research in that country by certification or local ethics review. This certification must be submitted to the IRB office for documentation in the PI’s file(s) before the PI and his/her research staff may begin collecting data.

• Surveys to be administered to DoD personnel must be submitted, reviewed, and approved first by the IRB, and then by the Department of Defense before they may be used.

• Consent documents must describe the provisions for research-related injury that follow the requirements of the DoD component. PIs should contact their DoD Funding unit’s liaison to determine specific disclosure requirements.

• For multi-site research receiving funding from DoD, a formal agreement between the organizations that specifies the roles and responsibilities of each party must be submitted to the IRB.

• Serious or continuing non-compliance related to DoD-funded research will be reported to the DoD Director, as described in Section 12: Reporting to Regulatory Agencies and Institutional Officials.

• DoD may require submission of records to DoD for archiving.