

California State Polytechnic University, Pomona Human Research Protections Program



Policies and Procedures of the Institutional Review Board (IRB)



(aka Policies and Procedures for Human Research Protection)

as adopted (version 9/11/07)

(added updates and revisions: 11/14/07; 4/10/08; 8/20/08; 12/4/08; 1/7/10; 3/8/10, 5/13/11;
2/7/13; 7/24/13; 4/2/15; 12/1/16; 2/7/17, 1/18/17)

This document was modified for use by the CPP IRB from a model created by Dr. Jeffrey M. Cohen CIP, JRP Associates, Inc.. to whom acknowledgement is given. Many policies herein might not seem applicable at the time of adoption, but nevertheless have been included to offer guidance for future circumstances. As such, it is a 'living' document and may be further modified or updated as needed. The IRB expresses its appreciation to the research community associated with CPP in complying with these policies and procedures designed to assure the protection of humans. It is they who contribute to the advancement of scientific understanding and derive benefit from this document.

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1 Mission

Cal Poly Pomona (officially, the California State Polytechnic University, Pomona, referred to as Cal Poly or abbreviated as CPP) 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 Cal Poly Pomona 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, and the Federal Policy for the Protection of Human Subjects (also known as the “Common Rule”). For the purposes of this policy, all references to the Common Rule will cite the regulations in 45 CFR 46, keeping in mind that each agency and department has its own CFR section.

The actions of Cal Poly Pomona will also conform to all other applicable federal, state, and local laws and regulations regarding the conduct of research with human subjects.

To conduct this responsibility effectively, the University maintains an Institutional Review Board (IRB) to review research protocols involving human subjects and to evaluate both risk and protection against risk for those subjects. It is the function of the IRB to:

- 1) determine and certify that all projects reviewed by the IRB conform to the regulations and policies set forth in the Common Rule regarding the health, welfare, safety, rights, and privileges of human subjects; and
- 2) assist the investigator in complying with federal and state regulations.

1.1 Introduction

This manual, ***Policies and Procedures for Human Research Protection***, details the policies and regulations governing research with human subjects and the requirements for submitting research proposals for review by Cal Poly Pomona’s IRB. These policies and procedures apply to all research involving human subjects, regardless of sponsorship and performance site, where any Cal Poly Pomona faculty, staff, students, or facilities are involved.

These Policies and Procedures present the most current information for reference by potential investigators and their staff. Since the field of human research protection is constantly evolving, sections of this manual may be subject to change. The Office of the Compliance Associate at Cal Poly Pomona will keep the University’s research community apprised of all developments. For further information contact the Cal Poly Pomona Compliance Associate at (909) 869-4215.

These Policies and Procedures will be available on the IRB website (www.academic.csupomona.edu/research/irb) and hard copies will be made available upon request.

All institutional and non-institutional performance sites for this institution, domestic or foreign, will be obligated by this institution to conform to ethical principles which are at least equivalent to those of this institution, as cited in the previous paragraph or as may be determined by the US Department of Health and Human Services (DHHS) Secretary.

1.2 Ethical Principles: The Belmont Report

The Belmont Report

It is the duty of the Cal Poly Pomona IRB to review and make decisions on all protocols for research involving human subjects. The primary responsibility of the IRB is the protection of research subjects 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 subjects, indicated by free and informed consent, is assured;
- (2) that an appropriate balance exists between the potential benefits of the research to the subject or to society and the risks assumed by the subject; and
- (3) that there be fair procedures and outcomes in the selection of research subjects.

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 subjects is the assurance of voluntary informed consent. Any person who is to be a research subject, 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 Cal Poly Pomona will strive to ensure voluntary informed consent of research subjects through careful review of the recruitment and consent process, and of the consent form or information sheet to be used with subjects.

The informed consent concept is extended to those studies in which the subjects 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 subject's well-being (e.g., parents of children, guardians of the mentally disabled). 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 subject. 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 subjects. The IRB must exercise special care when considering subjects whose ability to give free and informed consent may be compromised in any way.

Beneficence: The Risk-Benefit Ratio.

The IRB is charged with deciding, for any proposed activity which falls under its jurisdiction, whether "the 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, members of the IRB must carefully assess the types and degrees of both risks and benefits for a given subject population, as well as the investigator'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 subject 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 Subjects.

Both the risks and the potential benefits of research should be spread fairly among potential individual research subjects and research subject groups. Study design and selection of subjects 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 subject 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 subject 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 subject 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 subject 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 (NIH) and the Food and Drug Administration (FDA) now require that study design include as broad a range of research subjects 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

The following are abbreviations, terms, and definitions used in this policy and procedures manual.

Human Subjects Research – For the purposes of this policy “human subject research” is defined in 45 CFR 46.102(f). In addition, student research, if it involves human subjects as defined in 45 CFR 46.102(f) is included, even if the activity does not meet the definition of research in the same section.

45 CFR 46.102(f)

Research - a systematic investigation, including 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 research plan 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 subject - a living individual about whom an investigator (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 subject or the subject's environment that are performed for research purposes.

^b Interaction includes communication or interpersonal contact between investigator and subject. This includes survey and questionnaires, even if there is no direct contact between the investigator and subject.

^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, medical records or student records). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.]

IRB - an Institutional Review Board established in accord with and for the purposes expressed in this policy.

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.

AVP – Associate Vice-President

ORSP – Office of Research and Sponsored Programs, at Cal Poly Pomona

ORGS – Office of Research and Graduate Studies, at Cal Poly Pomona (added 1/7/10: From the time these policies and procedures were produced and through summer of 2009, ORGS was the name of the department where the IRB was located. In July of 2009, Graduate Studies was split off, but the IRB was kept in the new Office of Research. The terms are essentially synonymous in usage here.)

CPP – California State Polytechnic University, Pomona

IO – Institutional Official. The IO has oversight of the University’s human research protections program, including appointment of members to the IRB, signature authority for documents provided to DHHS (Assurance Signatory Official), and resource allocations to the IRB. The IO has no voting privileges on the IRB. The IO is an ex officio member (added 11/14/07).

HRPP -- Human Research Protections Program

OHRP - Office of Human Research Protections, an agency within DHHS that has federal oversight of human subjects’ research and administering programs.

DHHS - Department of Health and Human Services within the federal government

EH&S – Environmental Health and Safety, at Cal Poly Pomona

Minimal risk - that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners for example, "minimal risk" is 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.

Certification - the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Investigator - (sometimes referred to as a “Principal Investigator” or PI) is any individual who actually conducts the research project and who, typically, submits a human subjects protocol to the IRB. In the event of an investigation conducted by a team of individuals, the investigator is the leader and person directly accountable for supervising the research at CPP. An investigator may be a CPP faculty member (including lecturers, emeriti, and FERPs), staff member, or administrator. CPP students may be investigators with the oversight of a CPP responsible investigator (RI), who sponsors and/or mentors the work of the student and assumes ultimate responsibility for the conduct of the approved protocol. Off-campus persons may be investigators using the resources of the CPP campus with a RI (responsible investigator) and must submit evidence of IRB approval from their “home” institution. All investigators must show ample evidence of training in human subjects protection and familiarity with the research discipline. The term “investigator” as defined and used by CPP may not be equivalent to the definition or use of that term by grant and contract agencies. The status of persons having a role in the conduct of research but who do not fit within any of the above definitions will have their status evaluated on a case-by-case basis by the CPP IRB.

Student - The term is inclusive of all students: undergraduate and graduate students; senior scholars; McNair scholars; Doctorate of Education students (EdD) in conjunction with other institutions. At Cal Poly Pomona, students may submit protocols. They must be supervised or mentored by a faculty member, who 1) is their advisor, 2) the "responsible faculty member," and 3) the responsible PI.

Compliance Associate - the staff position at CPP responsible for administrative support to the IRB. Duties include the receipt of protocols, communications with PIs, coordinating meetings of the IRB, assisting with the training program, and keeping records associated with the human studies research program. The compliance associate is a non-voting and ex officio member of the IRB (added 11/14/07).

President – refers to the president of Cal Poly Pomona.

Protocol – is the document completed by the PI(s) that describes the how, what, when, where, who, and why of the proposed study. It is submitted as an application of the proposed research study to the IRB for review. It includes, but is not limited to: background of the research; who will conduct it and their training; who the subjects are and how they will be recruited; how the data will be collected, for example the survey instruments; measures to provide protection against any risks; potential conflicts of interest; consent, assent, and permission forms; etc. The IRB may ask for additional material to explain and clarify the study. No work can begin on a protocol until it has been reviewed and approved by the IRB.

Full review – the process by which a study involving human subjects, either at a high level of risk or involving vulnerable subjects, must be evaluated. The IRB conducts the review “full,” meaning at a convened face-to-face meeting with quorum. What constitutes a full review is defined by federal regulation.

Expedited review - the process of reviewing a protocol by (usually) one or two members of the IRB because the study has potentially minimal risk to the human subjects. Expedited does not necessarily mean a rapid review, though it usually requires less time to complete than a full review. What constitutes expedited review is extensively defined by federal regulation.

Exempt review - the process of determining, by the IRB, that a protocol is not subject to either expedited review or full review, as defined in regulations and further in this document. Protocol applications with surveys that collect data in an anonymous fashion are often reviewed by the exempt method.

3 Institutional Authority

The President of Cal Poly Pomona has designated the Associate Vice President (AVP) from the Office of Research as the responsible institutional official (IO) for oversight of the University's human research protections program. The Office of Research is the "parent" to the Office of Research and Sponsored Programs (ORSP) in facilitating research on the CPP campus, from where grant and contract monies often come.

The IRB at Cal Poly Pomona has jurisdiction over all human subject research (as defined below) conducted under the auspices of the institution, which includes research:

- conducted at CPP,
- conducted by or under the direction of any employee or agent of CPP (including students) in connection with his or her institutional responsibilities,
- conducted by or under the direction of any employee or agent of CPP using any property or facility of CPP, or
- involving the use of this CPP's non-public information to identify or contact human subjects.

3.1 Assurance of Compliance

Cal Poly Pomona holds a Federalwide Assurance (FWA), FWA #00001280, which is granted to IRBs that register with OHRP within DHHS. As part of its FWA, Cal Poly Pomona has agreed to protect the welfare of all human subjects involved in research, whether or not the research is conducted or supported by a federal department or agency.

3.2 Cal Poly Pomona IRB Office

The Cal Poly Pomona IRB Office is managed by the Compliance Associate, who reports directly to the Cal Poly Pomona AVP. The Compliance Associate has expert knowledge in regulatory issues regarding human subjects and serves as the IRB Administrator, the initial and primary point of contact at Cal Poly Pomona for the Office of Human Research Protections (OHRP), Department of Health and Human Services.

3.3 State Law

Cal Poly Pomona and its IRB rely on the counsel of the California State University Office of General Counsel for the interpretations and applications of California State law as it applies to human subjects' research.

4 Cal Poly Pomona IRB

The Cal Poly Pomona IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under its auspices. Cal Poly Pomona has one designated IRB with the authority to review, approve, disapprove, and/or require changes in research activities involving human subjects. This IRB has been established in accordance with the requirements of current federal rules.

The IRB at Cal Poly Pomona will periodically review its activity and make a determination with recommendations as to the appropriate number of IRBs to serve CPP. It reserves the right to create sub-committees for various purposes such as to evaluate human protections on campus, to establish additional policies and procedures, and to represent the principles of human subjects protections.

4.1 Authority of the IRB

The IRB at Cal Poly Pomona reviews and has authority to approve, require modifications in, or disapprove all research activities conducted under the auspices of Cal Poly Pomona. The IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [45 CFR 46.111]. In fulfilling these responsibilities, the IRB is expected to review all research documents and activities that bear directly on the rights and welfare of the subjects of the proposed research. The protocol, the consent/assent document(s), surveys, and, for studies conducted under the Investigational New Drug (IND) regulations, the investigator's brochure are examples of documents that the IRB reviews. The IRB also reviews the methods and materials that investigators propose to use to recruit subjects.

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

- the risks to the subjects
- the anticipated benefits to the subjects and others
- the importance of the knowledge that may reasonably be expected to result
- the informed consent (or assent) process to be employed

The IRB has the authority to suspend, place restrictions upon, or terminate the 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. The IRB has the authority to observe or have a third party observe the consent process and the conduct of the research if the IRB determines it to be indicated.

4.2 Jurisdiction of the IRB

The IRB jurisdiction extends to all research (funded and not funded) involving human subjects conducted at Cal Poly Pomona as well as research conducted elsewhere by Cal Poly Pomona and/or its faculty, staff, and students.

Any IRB Chair, member, or staff person who believes that the IRB has been unduly influenced by any party shall have the opportunity to make a confidential report to either the AVP or President, depending on the circumstances. The institution will conduct a thorough investigation and corrective action will be taken to prevent additional occurrences.

Cal Poly Pomona, as part of its Federalwide Assurance, has agreed to protect the welfare of all human subjects involved in research, whether or not the research is conducted or supported by a federal department or agency. Therefore, the Cal Poly Pomona IRB has jurisdiction over all human subject research conducted at this institution, regardless of funding.

4.3 IRB Relationships

The IRB functions independently of, but in coordination with, other institutional regulatory committees such as the safety office (EH&S) and the office for grants and contracts (ORSP). The IRB, however, makes its independent determination to approve or disapprove a protocol based upon whether human subjects are adequately protected. The IRB has review-jurisdiction over all research involving human subjects conducted,

supported, or otherwise subject to regulation by any federal department or agency that has adopted the human subjects' regulations.

Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. For example, the campus is not equipped to conduct cancer studies in clinical trials and therefore an IRB-approved study may not be authorized by the administration. On the other hand, by federal regulation, a decision by the IRB to not approve a human subjects study may not be overruled and approved by the administration.

The CPP IRB meets, as necessary, with other University officials such as the provost, the IO, college deans, and academic departments.

Relationships with other institutions: Cal Poly Pomona may 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.

In the conduct of cooperative research projects, Cal Poly Pomona acknowledges that each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations. When a cooperative agreement exists, Cal Poly Pomona may enter into a joint review arrangement, rely on the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. When doing so, Cal Poly Pomona will ensure that the review arrangement is approved, in writing, by OHRP and by the appropriate officials of the institutions involved, and the particular characteristics of its local research context are considered, either (i) through knowledge of its local research context by Cal Poly Pomona IRB or (ii) through subsequent review by appropriate designated institutional officials, such as the Chair and/or other IRB members.

Cal Poly Pomona may also receive the decision of the IRB review of a protocol from another institution when a portion of the investigation involves CPP. In evaluating the submission for approval, the CPP IRB may, at its discretion: review the paperwork; mandate the creation of a consent form specific to, and meeting the policies of, CPP; mandate additional human subjects training; and/or ask for other supporting documentation and information.

When Cal Poly Pomona is the coordinating center for a multi-center protocol, the IRB will require the Cal Poly Pomona principal investigator (PI) to ensure (and demonstrate) 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 AVP, in consultation and approval with the IRB members and the Compliance Associate, appoints a Chair of the IRB. Any change in appointment, including reappointment or removal, requires written notification.

To be eligible to serve as Chair, the individual must have served for at least one year on the Cal Poly Pomona IRB. Whenever possible, the Chair will be a tenured CPP faculty member.

The Chair manages the IRB and any matters brought before it. The Chair is responsible for conducting the meetings and is a signatory for correspondence generated by the IRB. The Chair may designate other IRB members to perform duties, as appropriate, such as for review, signature authority, and other IRB functions. The Chair advises the Cal Poly Pomona AVP and the Compliance Associate about IRB member performance and competence.

The Chair is a voting member of the IRB and contributes to establishing quorum. (added 10/14/07)

The Chair is empowered to review and approve renewals of protocols in which there are no or no substantial changes to methods or subject handling. The Chair may delegate the process of pertinent information gathering to the Compliance Associate. (added 8/20/08)

The Chair is empowered to review and approve amendments to protocols in which there is no or no substantial change to risks posed to the subject. The Chair may delegate the process of pertinent information gathering to the Compliance Associate or the review to a Committee member, including the original reviewer(s). (added 8/20/08)

4.4.2 Acting Chair of the IRB

The Chair may designate an acting Chair in anticipation of his/her absence. The IO may also designate an acting Chair when the Chair is unable to do so. The acting Chair has the same authority and duties as the Chair.

4.4.3 Subcommittees of the IRB

The Chair may create a subcommittee to perform duties, as appropriate, for protocol review, signature authority, and other IRB functions. When appropriate, individuals outside of the IRB membership may be included in subcommittees.

Duties of a subcommittee may include the following:

1. Serve as designees to the IRB Chair for the **expedited review** of new or continuing protocols, and/or modifications of continuing protocols. The subcommittee must be experienced in terms of seniority on the IRB, and must be matched as closely as possible with their field of expertise to the study.
2. **Review and approve the revisions** submitted by investigators for a protocol given provisional approval, i.e., "Approval Pending Revisions" by the convened IRB.
3. **Ensure fairness and expertise of an inquiry process.** A subcommittee is appointed consisting of IRB members, and non-members if appropriate, to ensure fairness and expertise of an inquiry process (See Section 11.3 for a discussion of the inquiry process) The subcommittee is given a charge by the IRB, which can include any or all of the following:
 - a. Review of protocol(s) in question;
 - b. Review of FDA audit report of the investigator, if appropriate;
 - c. Review of any relevant documentation, including consent documents, case report forms, subject's investigational and/or medical files etc., as they relate to the investigator's execution of her/his study involving human subjects;
 - d. Interview of appropriate personnel if necessary;
 - e. Preparation of either a written or oral report of the findings, which is presented to the full IRB at its next meeting;
 - f. Recommend actions if appropriate.
4. **Conduct on-site review.** 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 an investigator who is performing particularly risky research, or for an investigator who has recently had a protocol suspended by the IRB due to regulatory concerns, an on-site review by an IRB subcommittee 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 subjects.
5. **Observe the consent process.** When appropriate, the IRB may appoint a subcommittee to observe the consent process being used in a research project.
6. **Establish policy for the campus.** As it pertains to human subjects protection, a sub-committee may be constituted to develop and recommend a policy and/or procedure to the full committee.

4.5 Resources for IRB

The ORSP at CPP provides resources to the IRB and IRB Office of the Compliance Associate, including adequate meeting and office space, staff for conducting IRB business, and funds for professional travel and training related to improvement of the IRB functions at CPP. Office equipment and supplies, including technical support, file cabinets, computers, internet access, and copy machines, will be made available to the

IRB and staff. 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 AVP, as IO and through appropriate mechanisms, will monitor and review the processes and procedures of the IRB to ensure effectiveness, efficiency, and compliance with both federal regulations and these policies and procedures.

The Cal Poly Pomona IRB Office staff will conduct investigations and audits of ongoing research when the IRB directs an audit to be conducted or a complaint or allegation of non-compliance is received.

5 IRB Membership

5.1 Composition of the IRB

1. The IRB at Cal Poly Pomona will have **at least nine members** with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. At CPP, these backgrounds might include, but are not limited to: psychology, sociology, and anthropology; kinesiology and health promotion, health, and nutritional sciences; business and public administration; education; engineering; and human performance.
2. The IRB will be sufficiently qualified through the experience and expertise of its members, and the **diversity of the members**, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
3. In addition to possessing the **professional competence necessary to review specific research activities**, the IRB will be able to ascertain the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas.
4. If the IRB regularly reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons), consideration will be given to the inclusion of one or more individuals on the IRB who are knowledgeable about and experienced in working with these subjects.
5. Every nondiscriminatory effort will be made to **ensure that the IRB does not consist entirely of men or entirely of women**, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB shall not consist entirely of members of one profession.
6. The IRB will include at least one member whose **primary concerns are in scientific areas** and at least one member whose **primary concerns are in nonscientific areas**.
7. The IRB will include at least one member who is **not otherwise affiliated with the institution** and who is not part of the immediate family of a person who is affiliated with the institution.
8. Any member may satisfy more than one membership category.

5.2 Appointment of Members to the IRB

The AVP, as IO and in consultation with the IRB chair and the Compliance Associate, shall have the authority to appoint new members to the CPP IRB. The AVP may consult, as appropriate, with department chairs and colleagues on campus to identify possible candidates and may accept nominations.

Appointments are made for an annual, renewable, term of service. Any change in appointment, including reappointment or removal, requires written notification. Members may resign by written notification to the Chair.

Alternate members. The appointment and function of alternate members is the same as that for primary (or regular) IRB members, and the alternate's expertise and perspective are comparable to those of the primary member. The IRB membership roster identifies the primary member(s) for whom each alternate member may substitute. Alternates may attend any IRB meeting and are encouraged to attend as many meetings as possible. The alternate member will not be counted as a voting member unless the primary member is absent. However, the alternate member may freely participate in the discussion. 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. The alternate in attendance at a meeting

is empowered to vote on the approval of minutes when approved electronically even when not serving as the primary member.

5.3 Use of Consultants (Outside Reviewers)

The IRB may, at its discretion or when required by federal regulation, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals do not vote with the IRB. Prior to committing to review, consultants will be informed of the Cal Poly Pomona conflict of interest policy (see http://www.csupomona.edu/~policies/Administrative/conflict_of_interest_and_financial_disclosure.html). Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor or sponsorship of the research will not be invited to provide consultation. 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 Cal Poly Pomona conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular investigator and research protocol).

5.4 Conflict of Interest – IRB Members

No IRB member will participate in the initial or 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 re-assign the protocol. See also the website:

http://www.csupomona.edu/~policies/Administrative/conflict_of_interest_and_financial_disclosure.html.

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 an Investigator (PI or RI) or other member of the research team on a research protocol submitted to the CPP IRB
2. Has a financial interest in the research whose value cannot be readily determined, whose value may be affected by the outcome of the research, or that exceeds \$10,000
3. Has received or will receive any compensation whose value may be affected by the outcome of the study
4. 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)
5. Has received payments from the sponsor that exceed \$10,000 per year
6. Is an executive or director of the agency/company sponsoring the research
7. Is the advisor or mentor, or serves on the project or thesis committee, of a protocol submitted by a student (defined above) submitted to the IRB
8. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

In accordance with Cal Poly Pomona policy, all IRB members who are Cal Poly Pomona faculty or staff will have submitted annual disclosure forms, such as conflict of interest, to the ORSP, as appropriate when obtaining funding through grants and contracts. Letters of appointment to the IRB shall include wording addressing the concerns for conflict of interest. For IRB members who are not Cal Poly Pomona faculty or staff, the IRB will maintain documentation (such as this policy manual) that all IRB members and alternates are aware of and committed to compliance with the IRB policy regarding conflicts of interest.

5.5 Duties of IRB Members

Members are expected to:

- review the materials (agenda, submission materials, protocols, proposed informed consent forms, continuing review forms and other appropriate documents including research materials) in a timely fashion
- participate fully in the review of each proposed project
- attend meetings of the IRB
- review critically protocols against the principles of human subjects protection and the policies of Cal Poly Pomona

- receive appropriate training in human subjects regulations and ethical standards (see 5.7 below)
- treat the research proposals, protocols, and supporting data confidentially, destroying hard copies and deleting electronic copies and supporting material
- participate in policy making discussions
- self-identify when there is a conflict of interest
- promote the principles of human subjects protection

5.6 Attendance Requirements

Primary members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, he/she should inform the Chair or the Compliance Associate and contact his/her appropriate alternate to serve in place. A prolonged absence (sabbatical, 'FERP' status, medical, etc.) should be discussed with the Chair or the Compliance Associate to discuss options to maintain compliance with regulations dictating committee composition.

5.7 Training/Ongoing Education of Chair and IRB Members in Regulations, Procedures, and the Like

A vital component of a comprehensive human research protection program is an education program for the institution. Cal Poly Pomona is committed to providing training and an on-going educational process for IRB members, alternates, and staff of Cal Poly Pomona IRB Office related to ethical concerns and regulatory and institutional requirements for the protection of human subjects.

Orientation

New IRB members, including alternates, have the opportunity to meet with the IRB Chair and/or Compliance Associate for an informal orientation session. At the session, the new member will be shown:

- the ORSP web site that incorporates the IRB pages
- navigation of the web site to find the protocol application, training materials, and other relevant information
- records pertinent to the IRB kept in the Compliance Associate's office
- the book Institutional Review Board Management and Function by Bankert and Amdur for reference purposes
- Federal regulations relevant to IRB.

Initial Education

Cal Poly Pomona IRB Office maintains a subscription to the web-based "**CITI Course in The Protection of Human Research Subjects**" sponsored by the Collaborative IRB Training Initiative (CITI), www.citiprogram.org. IRB members must complete the group of modules named "IRB member" which covers history, regulations, review processes, research with children, and IRB member responsibilities. All modules are available for further education.

To satisfy the initial education requirement, the IRB Chair and the IRB members must complete the required course with an overall competency level of at least 80%.

New members are required to complete the "Initial Education" requirement for IRB members before they may serve as a Primary Reviewer.

Continuing Education

To ensure that oversight of human research is ethically grounded and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB. Educational activities include, but are not limited to:

- in-service training at IRB meetings
- training workshops
- reviewing copies of "IRB: Ethics and Human Research"
- dissemination of current events articles relevant to human research protection
- unlimited access to the IRB Office resource library.

The AVP will provide support for members of the IRB to attend the annual PRIM&R/ARENA conference on human research protections.

The IRB administrator (Compliance Associate) is expected to be CIP-certified.

5.8 Liability Coverage for IRB Members

Cal Poly Pomona will indemnify and defend University faculty and staff performing within the course and scope of their employment with regard to IRB responsibilities. This coverage extends to those under the supervision of faculty and staff (i.e., students and medical residents) and volunteers (i.e., unaffiliated IRB members) for the University.

California statute (Government Code) 995. Except as otherwise provided in Sections 995.2 and 995.4, upon request of an employee or former employee, a public entity shall provide for the defense of any civil action or proceeding brought against him, in his official or individual capacity or both, on account of an act or omission in the scope of his employment as an employee of the public entity.

5.9 Review of IRB Member Performance

Service on the IRB is an important contribution to the University and its research program involving human subjects. The professional pursuits of faculty and students, federal regulations and campus policies, and the impact on subjects are all affected when a member cannot or does not serve well the IRB. The Chair and IO are obligated to evaluate the performance of the members and take appropriate action as needed on an annual basis by the Compliance Associate of the Cal Poly Pomona IRB Office.

6 IRB Records

The IRB must prepare and maintain adequate documentation of the IRB's activities including: copies of all items reviewed, including but not limited to research proposals, recruitment materials; scientific evaluations (if any) that accompany the proposals; approved consent documents; approved HIPAA Authorization document, if separate from the informed consent, any proposed amendments and the IRB action on each amendment; progress reports submitted by investigators; reports of injuries to subjects and serious and unexpected adverse events; documentation of protocol violations; and documentation of non-compliance with applicable regulations.

IRB records must also include continuing review activities; copies of all correspondence between the IRB and investigators; and statements of significant new findings provided to subjects must be maintained with the related research proposal and, when reviewed at an IRB meeting, must be documented in the minutes.

6.1 Minutes of an IRB Meeting

Proceedings of a convened meeting of the IRB are written and made available for review by the next regularly scheduled IRB meeting date. They can be approved electronically, whereby the minutes are circulated to all members (both full and alternates) via e-mail. Two-thirds (2/3) of those actually in attendance at the meeting must approve the minutes (records to be kept), allowing for minor changes (typographical errors, grammar, etc.). If less than two-thirds approve or there is a matter of significance, then the minutes are to be placed on the next agenda for further discussion. Once approved by the members, the minutes must not be altered by anyone, including a higher authority.

Per regulations, minutes of IRB meetings shall 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;
2. Attendance at the meetings including those members or alternate members who are participating through videoconference or teleconference and documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions;
3. Alternate members attending the meeting and, if voting, for whom they are substituting;
4. Actions taken by the IRB including those involving full review. The IRB must use the minutes to notify IRB members of actions taken through expedited review and those studies that have been determined to be exempt from IRB review;
5. Separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB;
6. Documentation that the research meets the four required criteria [45 CFR 46.116(d)] when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain an informed consent;
7. Documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived;
8. When approving research that involves populations covered by Subparts B, C, or D of 45 CFR 46, the minutes will document the IRB's justifications and findings regarding the determinations stated in the Subparts or the Committee's agreement with the findings and justifications as presented by the investigator on IRB forms.
9. The vote on actions, including the number of members voting for, against, and abstaining;
10. A note indicating that when an IRB member has a real or potential conflict of interest relative to the proposal under consideration, that the IRB member was not present during the deliberations or voting on the proposal (and that the quorum was maintained);
11. The basis for requiring changes in or disapproving research and documentation of resolution of these issues when resolution occurs;
12. A written summary of the discussion of controverted issues and their resolution;
13. Review of additional safeguards to protect vulnerable populations if entered as study subjects when this is not otherwise documented in IRB records;
14. The determination of the level of risk, if not recorded elsewhere in IRB records;

15. The frequency of continuing review of each proposal, as determined by the IRB, if not recorded elsewhere in IRB records;
16. Documentation, as required by 45 CFR 164(i)(2), indicating the approval of a waiver or alteration of the HIPAA Authorization.

6.2 Membership Rosters

The membership list of IRB members is maintained and kept current. It identifies members by their academic departments and disciplines. It contains information including the member's name, earned degrees, affiliated or non-affiliated status, status as a scientist (physician-scientist, other scientist, non-scientist or social behavioral scientist); regular/full/primary (voting) or alternate status, and status as Chair. This information is posted on the OFFICE OF RESEARCH/IRB web site.

The Compliance Associate reports promptly changes to the CPP IRB membership to the IRB Offices, Department of Health and Human Services.

6.3 Records Retention Requirements

The above detailed records are stored securely in the Office of the Compliance Associate at Cal Poly Pomona and are retained for at least three (3) years after the completion of the research. All records are made accessible for inspection and copying by authorized representatives of the federal OHRP and other authorized entities at reasonable times and in a reasonable manner.

Records are maintained in locked file cabinets in the Compliance Associate's office and are available only to IRB members (including the Chair), IRB office staff, the IO, and persons with justified need (because they are confidential, this is determined on a case-by-case basis).

Examples of records maintained include:

- logs of protocol applications submitted for review
- a summary of the protocol review, the type of review, and who reviewed it
- the date of protocol approval
- files of protocol applications with pertinent paperwork, marked as YY-###, meaning the two digit year and a sequential number starting at 001 each calendar year
- copies of approval memos to PIs
- agendas and minutes of meetings
- training files of members.

6.4 Written Procedures and Guidelines

This Cal Poly Pomona document ***Policies and Procedures for Human Research Protection*** details the policies and regulations governing research with human subjects and the requirements for submitting research proposals for review by the University's Institutional Review Board.

These Policies and Procedures also detail:

1. Written procedures which the IRB must follow for: conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; 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 subject.
2. Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the federal Department or Agency head of any unanticipated problems involving risks to subjects 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.

7 IRB Review Process

These procedures and guidelines apply to all research involving human subjects, regardless of sponsorship and performance site, conducted under the auspices of Cal Poly Pomona.

7.1 Human Subjects Research Determination

The responsibility for determining whether an activity constitutes human subjects research rests with the investigator. Since the University will hold them responsible for incorrect determinations, investigators are urged to request a confirmation that an activity does not constitute human subjects research from the Cal Poly Pomona IRB and Office of the Compliance Associate. If the request is verbal (by phone or in person) or by email, it is the investigator's responsibility to maintain documentation of such a decision. If the investigator 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.

7.2 Exempt Research

All research using human subjects must be approved by the institution. Certain categories of research (i.e., "exempt research") do not require convened IRB review and approval. Exempt research is subject to institutional review and must be approved by the IRB Chair, Vice Chair, or the Compliance Associate of Cal Poly Pomona.

Students may assume roles as Principal Investigators conducting exempt research as long as they have a faculty sponsor who will serve as the responsible investigator (RI) and faculty advisor on the study.

Exempt research, once approved, is **non-renewable**. The duration of study for exempt research is limited to that specified on the approved application.

Limitations on research subjects:

Vulnerable Populations:

- Children: Exemption for research involving survey or interview procedures or observations of public behavior does NOT apply, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. (See Section 10.1.1 for the definition of a child.)
- Prisoners, persons who are cognitively impaired, or persons who are economically or educationally disadvantaged: **exemptions do NOT apply**. IRB review is required.

If the answer to any of the following questions is "no," the research requires IRB review:

- Will the research use only data or specimens that are existing (i.e., archival data, data collected and "on the shelf" prior to initiating this research project for a purpose other than the proposed research)?
- Are those data or specimens publicly available?
- Will information be recorded by the investigator in such a way that it cannot in any way be linked to the subject?

7.2.1 Categories of Research Permissible for Exemption

With the above exceptions, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB convened review, but require institutional review, at Cal Poly Pomona:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - a) research on regular and special education instructional strategies, or
 - b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless

- a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2), if
 - a) the human subjects are elected or appointed public officials or candidates for public office; or
 - b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 5. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine
 - a) public benefit or service programs;
 - b) procedures for obtaining benefits or services under those programs;
 - c) possible changes in or alternatives to those programs or procedures; or
 - d) possible changes in methods or levels of payment for benefits or services under those programs.
 6. Taste and food quality evaluation and consumer acceptance studies
 - a) if wholesome foods without additives are consumed; or
 - b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA).

7.2.2 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. The IRB chair or the compliance associate making the determination of exemption may require additional protections for subjects in keeping with the guidelines of the Belmont Report.

7.3 IRB Meetings

Except when an expedited review procedure is used (See Section 7.7), the IRB must review proposed research at convened meetings (also known as **Full-Board meetings**) at which a **quorum** (see below) is present.

7.3.1 Schedule of IRB Meetings

The IRB at Cal Poly Pomona generally meets monthly during the academic year and as needed during the summer quarter. The schedule for the IRB may vary due to holidays or lack of quorum.

7.3.2 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. The IRB Chair, with the assistance of the compliance associate, will confirm that an appropriate quorum is present before calling the meeting to order.

A quorum must be maintained for each vote to occur. If a quorum is not maintained, the proposal must be deferred 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. A member who leaves a meeting for conflict of interest still counts in establishing quorum (added 11/14/07).

It is strongly recommended that members of the IRB 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 will have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions.

Alternate members will be encouraged to attend convened meetings and participate, but cannot vote unless replacing the regular, full member.

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.

7.3.3 New Protocol Applications

Applications are screened by the IRB compliance associate for completeness and regulatory compliance prior to their placement on the agenda and distribution for review.

The Protocol Application must include or address the following. Additional information may be requested for adequate review of the application:

1. Title of the study
2. Purpose of the study
3. Sponsor of the study
4. Results of previous related research
5. Subject inclusion/exclusion criteria
6. Recruitment procedures
7. Justification for use of any special/vulnerable subject populations
8. Study design (including, as needed, a discussion of the appropriateness of research methods)
9. Description of procedures to be performed
10. The possible/potential risks to the subjects
11. Provisions for minimizing risks/managing adverse reactions
12. The anticipated benefits of the research
13. An assessment of the risk/benefit ratio
14. Circumstances surrounding the consent procedure
 - a. Setting
 - b. Subject autonomy concerns
 - c. Language difficulties
 - d. Vulnerable populations
 - e. Procedures for documenting informed consent
 - f. Obtaining assent from minors
 - g. Using witnesses and/or translators
15. Document storage
16. Compensation to subjects for their participation
17. Compensation for injured research subjects
18. Costs to subjects for their participation in the study
19. Costs to third-party payers because of subject's participation
20. Provisions for protection of subject's privacy
21. Description of the resources available to protect research subjects, including supervision, number and training of staff, appropriate support services.

Primary Reviewer: The IRB Compliance Associate, in consultation with the Chair, may assign a primary reviewer from the members of the IRB for all protocols requiring full IRB review. Reviewers are typically assigned protocols based on their related expertise. When making reviewer assignments, the Compliance Associate 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. The primary reviewer receives the following documentation, as applicable:

1. Protocol application, including the description of the study
2. Proposed consent and/or parental permission/assent form(s)
3. Recruitment materials/subject information (including all surveys and questionnaires)

For sponsored research only:

1. Grant application(s)/contracts
2. Fully-executed OSPA transmittal(s) for sponsorship administered through the University
3. Budget(s)

Other IRB Members receive the following documentation:

1. Protocol application, including the description of the study
2. Recruitment materials/subject information (including all surveys and questionnaires)
3. Proposed consent and/or parental permission/assent form(s)

Primary reviewers can utilize the CPP IRB protocol "Primary Reviewer Checklist" as a guide to completing their review.

Copies of the full materials will be made available for any optional review at the request of any IRB member.

NOTE: Investigators who have other individuals write their protocols and responses to the IRB must recognize that the ultimate responsibility of any study lies with the Principal Investigator (PI). It is incumbent upon the PI to check all material that is submitted to the IRB for review.

7.3.4 Pre-Meeting Distribution of Documents

The place and time of the meeting is set forth on the agenda cover sheet distributed to all IRB members, including alternates.

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.

Before the meeting, each protocol application (including background information, project protocol, and informed consent) is carefully reviewed by the primary reviewers.

At the meeting, the Primary Reviewer presents an overview of the goals, design, study procedures, safety procedures, and qualifications of the investigators. Particular attention is paid to the risk/benefit ratio of the investigation and the adequacy of the consent form in conveying human subjects concerns. Problems identified by the Primary Reviewer or by other IRB members are discussed and suggestions for any necessary changes are agreed upon by the IRB. These issues are considered in the vote to decide IRB action. Length of discussion can vary from a few minutes to over an hour when investigators make formal presentations or information from outside experts is required.

At the discretion of the IRB, the Principal Investigator(s) may be invited to the IRB meeting to answer questions about their proposed or ongoing research.

7.3.5 Consultants

When necessary, the IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. The consultant's findings will be presented to the full board for consideration either in person or by the Cal Poly Pomona Office of the Compliance Associate. If in attendance, these individuals will provide consultation but will not participate in or observe the vote. Prior to committing to review, consultants will be informed of the IRB conflict of interest policy. 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. 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).

7.3.6 Conflicts of Interest

As noted in Section 5.4, no IRB member will participate in the initial or 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 re-assign the protocol.

Except when requested by the IRB to be present to provide information, IRB members will absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest. The Chair will allow for committee discussion once the conflicted member has recused him/herself. The absent member is not counted toward quorum and his/her absence during the discussion and vote on the protocol will be noted in the IRB meeting minutes.

7.3.7 Possible IRB Actions Taken by Vote

The CPP IRB recognizes the following options for voting on protocols:

Approval - the study is approved as submitted.

Approvable Pending Revisions - the protocol and/or consent form require minor revisions, such as wording changes, with replacement language provided. The needed revisions are agreed upon at the meeting. These revisions are presented to the Principal Investigator for incorporation by simple concurrence. The IRB Chair, a subcommittee of the IRB, or the IRB Compliance Associate 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.

The date of approval is the date the fully-convened IRB approved the protocol rather than the date that the minor changes were approved by the IRB Chair or the compliance associate.

Deferred for substantive issues regarding the protocol and/or consent form must be addressed. This action is taken if 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 must not occur until subsequent review of the material the PI submitted by the convened IRB.

If the application is deferred the following will occur:

1. The Compliance Associate informs the investigator in writing of the IRB's decision, questions and concerns.
2. The investigator's response is sent to the Compliance Associate.
3. In order to receive approval for a deferred protocol, it must be submitted for full IRB review at a subsequent, convened meeting. The Compliance Associate provides the IRB with the investigator's response, the revised protocol, and the previously submitted protocol. The item is placed on the agenda for the following meeting.
4. The protocol application is given full IRB review again.
5. The outcome of the IRB's deliberations is once again communicated to the investigator in writing.
6. 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 subjects approval is required by the sponsoring agency. The other is if the involvement of human subjects 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 Principal Investigator must submit such materials for approval at least 60 days before

recruiting human subjects into the study, or into any pilot studies or pre-tests. Approval in principle is granted to satisfy sponsoring agency requirements or to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects.

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

7.3.9 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.

The following factors will determine which studies require review more frequently than on an annual basis:

1. The probability and magnitude of anticipated risks to subjects.
2. The likely medical condition of the proposed subjects.
3. The overall qualifications of the Principal Investigator and other members of the research team.
4. The specific experience of the Principal Investigator and other members of the research team in conducting similar research.
5. The nature and frequency of adverse events observed in similar research at this and other institutions.
6. The novelty of the research making unanticipated adverse events more likely.
7. 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 subjects either studied or enrolled. If a maximum number of subjects studied or enrolled is used to define the approval period, it is understood that the approval period in no case can exceed 365 days and that the number of subjects studied or enrolled determines the approval period only when that number of subjects is studied or enrolled in less than 365 days.

7.3.10 Independent Verification Regarding Material Changes

Protecting the rights and welfare of subjects sometimes requires that the IRB verify independently, utilizing sources other than the investigator, 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 consider the following factors in determining which studies require such independent verification:

1. The probability and magnitude of anticipated risks to subjects.
2. The likely condition of the proposed subjects.
3. The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed.
4. Prior experience with the Principal Investigator and research team.
5. Any other factors that the IRB deems relevant.

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

7.3.11 Consent Monitoring

In reviewing the adequacy of informed consent procedures for proposed research, Cal Poly Pomona's IRB may on occasion determine that special monitoring of the consent process by an impartial observer (consent monitor) 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 subjects, or if subjects 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 investigator or a research project.

7.3.12 Reporting IRB Actions

All IRB actions are to be communicated [45 CFR 46.109(e), 46.113] to the Principal Investigator (PI), or designated primary contact person for the protocol, in writing within ten (10) working days by the Cal Poly Pomona Compliance Associate or the Chair of the IRB. The IRB will notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity.

For approved research, investigators are informed that:

1. **modifications to approved projects** must be reviewed and approved by the IRB before they are initiated;
2. **unexpected adverse events/reactions** must be reported to the IRB within ten working days of receipt.
3. **monitoring** may occur. The frequency of monitoring will be determined by the IRB at the time of initial or continuing review, and investigators will be so informed.

If the IRB decides to disapprove or require modifications to secure approval of a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator 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 available upon request by Cal Poly Pomona institutional officials and are stored permanently and securely in the Compliance Associate's office within the Office of Research and Sponsored Programs.

7.4 Continuing Review of Active Protocols (Renewals)

Approved research is subject to continuing IRB review at least yearly, or more frequently if specified by the IRB [45 CFR 46.109(e)], but not sooner than 30 days prior to the protocol termination (expiration) date. This review must take place **before the approval expiration date**; any lapse in approval will result in suspension of subject recruitment/enrollment and, if the research is DHHS-sponsored, notification to the funding agency. The approval date and the termination (expiration) date are clearly noted on all IRB communications sent to the PI and must be strictly adhered to. Investigators should allow sufficient time for development and review of renewal submissions.

To assist investigators the Compliance Associate will send out renewal notices to investigators in advance of the expiration date; however, it is the investigator's responsibility to ensure that the continuing review of ongoing research is approved prior to the expiration date. The PI must allow sufficient time for the review and re-approval process to be completed before the current approval expires. Retrospective approval for work done after the expiration date cannot be granted. By federal regulation, **no** extension to that date can be granted.

Research activities are subject to internal audit and verification from sources other than the investigator. This is to assure that no material changes have occurred since the last IRB review.

The Chair of the IRB may choose to either renew a protocol with no substantial changes or refer it to the committee (in whole or part) for a *de novo* review.

7.4.1 Continuing review process

In accordance with Department of Health and Human Services (DHHS) regulations at 45 CFR 46.108(b) and at 46.115(a)(2), continuing review by the convened IRB, with 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 subjects. 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 should at least receive and review a protocol summary (i.e., description of study) 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 subjects enrolled;
- number of subjects who withdrew prematurely and reason(s) for their withdrawal
- a current copy of the description of study;
- a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
- any relevant multi-center trial reports;
- any other relevant information, especially 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 HIPPA Authorization document.

At least one member of the IRB (i.e., a primary reviewer) also should receive a copy of the complete protocol including any modifications previously approved by the IRB. Furthermore, upon request, any IRB member also should have 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 should ensure the following:

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

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

7.4.2 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 "Expedited Review Categories"). 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.

7.4.3 How is the Continuing Review Date Determined?

Department of Health and Human Services (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) the 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 subjects.

At Cal Poly Pomona, 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 an investigator who is performing particularly risky research, or for an investigator 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 subjects.

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 reviews and approves a protocol without any conditions at a convened meeting on October 1, 2002. Continuing review must occur within one year of the date of the meeting, that is, by October 1, 2003.

Scenario 2: The IRB reviews a protocol at a convened meeting on October 1, 2002, and approves the protocol contingent on specific minor conditions the IRB Chair or his/her designee can verify. On October 31, 2002, the IRB Chair or designee confirms that the required minor changes were made. Continuing review must occur within one year of the date of the convened IRB meeting at which the IRB reviewed and approved the protocol, that is, by October 1, 2003.

Scenario 3: The IRB reviews a study at a convened meeting on October 1, 2002, and has serious concerns or lacks significant information that requires IRB review of the study at subsequent convened meetings on October 15 and October 29, 2002. At their October 29, 2002, meeting, the IRB completes its review and approves the study. Continuing review must occur within one year of the date of the convened meeting at which the IRB reviewed and approved the protocol, that is, by October 29, 2003.

For a study approved under expedited review, continuing review must occur within one year of the date the expedited reviewer gives final approval to the protocol.

Review of a change in a protocol ordinarily does not alter the date by which continuing review must occur. This is because continuing review is a 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 must occur on or before 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, 2003, in the above scenarios 1 and 2, and October 29, 2003, in Scenario 3, even if the continuing reviews took place up to 30 days prior to these dates.

7.4.4 What occurs if there is a Lapse in Continuing Review?

The IRB and investigators must plan ahead to meet required continuing review dates. If an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. **Enrollment of new subjects cannot occur after the expiration of IRB approval.**

The **continuation of research after expiration of IRB approval** is a violation of the regulations. If the IRB has not reviewed and approved a research study by the study's current expiration date, i.e., IRB approval has expired, research activities should stop. No new subjects may be enrolled in the study.

7.4.5 Studies that are Approved but Never Started

When the IRB approves a study, continuing review should be performed at least annually. For the purposes of continuing review, the review date is determined by the date of initial IRB approval. Written progress reports should be received from the investigator for all studies that are in approved status prior to the date of expiration of IRB approval. If subjects were never enrolled, the investigator's progress report would be brief. Such studies may receive continuing IRB review using expedited procedures. If the study is finally canceled without subject enrollment, records will be maintained for at least three years after cancellation.

7.5 Modification of an Approved Protocol

Investigators may wish to modify or amend their approved applications. **Investigators 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 subject (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. The IRB chair is authorized to evaluate how to proceed to approve the amendment. 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 human subjects approval. The amendment can be submitted as an e-mail request, including pertinent details, or on the protocol application, by checking the box to indicate it is an amendment to an existing approved protocol.

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]. 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.

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. 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 subjects' continued welfare.

7.6 Adverse Events and Unanticipated Problems

Adverse events and data safety monitoring reports made known to the IRB are to be reviewed by the Chair of the IRB. The reports which the Chair determines not to be directly related to the study and/or not reflecting an increase in the level of risk to the subjects are given an expedited review. All other reports are referred to the IRB for review at the next convened meeting.

All reports of unanticipated problems are initially reviewed by the Compliance Associate. After reviewing the report, the Compliance Associate, in consultation with the Chair and Institutional Official, will possibly contact the investigator for further information and/or discuss the matter with them. After determining the nature of the problem, one of two things is to be done: either 1) route them immediately to the IRB Chair for review and immediate response, if the problem is serious, or 2) record, file, and report to the IRB if the problem is not serious. The seriousness of the problem may result in the need to revise the consent document(s) or protocol.

7.7 Expedited Review of Research

The CPP IRB may use the expedited review procedure [45 CFR 46.110] to review either or both of the following at its discretion:

1. some or all of the research appearing on the list below and found by the reviewer(s) to involve no more than minimal risk,
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, makes no substantial alteration in (i) the level of risks to subjects; (ii) the research design or methodology; (iii) the number of subjects 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 (i.e., a subcommittee of the IRB) designated by the Chair or Compliance Associate from among members of the IRB. For IRB members to serve as designees to the IRB Chair for expedited review, they will be matched as closely as possible with their field of expertise to the study. Alternate members may be designated as expedited reviewers.

When reviewing research under an expedited 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, including the complete protocol, recruitment flyers, survey instruments, etc.

In reviewing the research, the reviewers 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 in 45 CFR 46.108.

7.7.1 Categories of Research Eligible for Expedited Review

The activities listed below should not be deemed to be of minimal risk [63 FR 60364-60367, November 9, 1998] simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

- The categories in this list apply regardless of the age of subjects, except as noted.
- The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- The expedited review procedure may not be used for classified research involving human subjects.
- The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

Research categories 1 through 7 pertain to both initial and continuing IRB review:

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. [Children are defined in the DHHS regulations as "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."][[45 CFR 46.402\(a\)](#)]
- (3) Prospective collection of biological specimens for research purposes by noninvasive means.

- Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
- (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)
- Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). **[Note:** Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. See Exempt Categories and 45 CFR 46 101(b)(4). This listing refers only to research that is not exempt.]
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. **[NOTE:** Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. See Exempt Categories and 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.]
- (8) Continuing review of research previously approved by the convened IRB as follows:
- (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; *or*
- (b) where no subjects have been enrolled and no additional risks have been identified; *or*
- (c) where the remaining research activities are limited to data analysis.
- [Of note: Category (8) identifies three situations in which research that is greater than minimal risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure. For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.]
- (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. [Under Category (9), an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves

no greater than minimal risk and no additional risks have been identified. The determination that "no additional risks have been identified" does not need to be made by the convened IRB.]

All members of the IRB will be apprised of all expedited review approvals 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.

7.8 Further Review/approval of IRB Actions by Others within the Institution

Research that has been approved by the IRB is subject to review and disapproval by institutional officials, but those officials may not approve research that has been disapproved by the IRB. [45 CFR 46.112]

7.9 Initiation of Research Projects

All research involving human subjects must be reviewed and approved by the IRB prior to initiation of the research project. Approved research is subject to continuing review by the IRB at least yearly, or more frequently if specified by the IRB [45 CFR 46.109(e)]. The date of continuing review will be based on the date of IRB approval. [see Continuing Review for further details.]

The approval date and the termination (expiration) date are to be clearly noted on all IRB certifications sent to the PI and must be strictly adhered to. Please allow sufficient time for development and review of renewal submissions. By federal regulation, no extension to that date can be granted.

Research activities are subject to internal audit and verification from sources other than the investigator. Included in that audit will be an evaluation no material changes have occurred since the last IRB review.

The IRB reserves the right to observe the consent process conducted under any research protocol and to inspect the records of investigators to ensure the protection of human research subjects.

7.10 Appeal of IRB Decisions

If a subcommittee of the IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator may appeal, in writing, for review by the convened appropriate IRB.

If the convened IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator should first discuss the matter with the Chair of the IRB or the Compliance Associate, 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 investigator may appeal the decision of the IRB, in writing to the Chair and Compliance Associate. The IRB will reconsider the appeal based upon the new information provided and will continue to re-review protocols as long as the investigator wishes to appeal.

7.11 Cancelling a review

(section added 1/7/10)

The IRB reserves the right to cancel a review effort that becomes inactive. Circumstances including lack of response by the PI(s) to Board instructions or no reply to emails asking for updates are examples of reasons to do so. The Compliance Associate will inform the PIs of the action and close the file. The process of review and approval may be restarted upon the submission of a new, current protocol application.

8 Criteria for IRB Approval of Research

In accordance with 45 CFR 46.111, in order to approve research, the IRB must determine that all of the following requirements are satisfied:

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

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. 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 subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable.

a) In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

b) The issue of coercion is especially important in educational settings. This aspect is emphasized in the review of protocols.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

8.1 Risk/Benefit Assessment

The goal of the assessment is to ensure that the risks to research subjects posed by participation in the research are justified by the anticipated benefits to the subjects or society. Toward that end, the IRB at CPP will:

1. judge whether the anticipated benefit, either of new knowledge or of improved health or welfare of the research subjects, justifies asking any person to undertake the risks;
2. disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits.

The assessment of the risks and benefits of proposed research - one of the major responsibilities of the IRB - involves a series of steps, which will:

1. **identify the risks** associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research;
2. **determine whether the risks will be minimized** to the extent possible;
3. **identify probable benefits** to be derived from the research;
4. **determine whether the risks are reasonable in relation to the benefits** to subjects, if any, and assess the importance of the knowledge to be gained;
5. **ensure that potential subjects will be provided with an accurate and fair description** of the risks or discomforts and the anticipated benefits;

The CPP IRB recognizes that risks to subjects are minimized:

1. by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and
2. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Further, the IRB recognizes that risks to subjects are reasonable in relation to anticipated benefits, if any, and to the importance of the knowledge that may reasonably be expected to result by adhering to the following:

1. In evaluating risks and benefits, it will consider only those risks and benefits that may result from the research - as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research; and
2. It 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.

8.1.1 Scientific Merit

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

- 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 CPP IRB will draw on its own knowledge and disciplinary expertise, and it may draw on the knowledge and disciplinary expertise of others, such as reviews by a funding agency, or departmental review.

The signature of a faculty member in 'charge' of a student's project (by mentoring, sponsoring, guiding, serving on a thesis committee, etc.) is required on the protocol application. This is to assure one measure of review of the project for merit and that neither the student nor the subjects are unduly exposed to risk.

8.2 Selection of subjects is equitable

The IRB will review the inclusion/exclusion criteria for the research to ensure equitable selection of subjects. In making this assessment the IRB will take into account the purpose(s) 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, students, prisoners, fetuses, pregnant women, human *in vitro* fertilization, persons who are cognitively impaired, or persons who are economically or educationally disadvantaged (see Vulnerable Populations).

8.2.1 Recruitment of Subjects

The IRB will ask for and review all recruitment procedures, materials and advertisements to ensure that they are consistent with the protocol, accurate, and non-coercive. When subjects are being paid, the 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 subjects should not be considered a benefit to participation.

8.3 Informed Consent

The IRB will ensure that informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116. 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. See Section 9 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.

8.5 Privacy and Confidentiality

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

Definitions

- Privacy - having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
- Confidentiality - methods used to ensure that information obtained by researchers about their subjects is not improperly divulged.

Regulations

46.102(f) includes the following in its definition of human subjects:

- Private information - 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).
- Identifiable information – information where the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Confidentiality

- Confidentiality and anonymity are not the same. “Anonymous” research is research conducted in such a way that it is not possible to trace any data or information gathered back to the subjects from whom it was obtained. All other research is such that the data gathered are “confidential.”
- Names are not the only identifiers. Bronco IDs and social security numbers are other possibilities on campus, but their use must be justified due to the potential loss of personal identity.
- Subjects’ participation in the research may need to be kept confidential as well as their data.
- See Section 14.1 for detailed information regarding certificates of confidentiality.

8.6 Vulnerable Populations

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

9 Informed Consent

9.1 Informed Consent Process

No investigator may involve a human being as a subject in research without obtaining the legally effective informed consent of the subject or the subject's legally authorized representative, unless a waiver of consent has been approved by the IRB in accordance with Section 9.3 of this policy. Investigators must obtain consent prior to entering a subject 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 subject 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 investigator, 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 subject or the representative must be in language understandable to the subject or the representative. Translation into another language may be required by the CPP IRB.

No informed consent, whether oral or written, may include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights.

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 investigator conducts the interview and obtains consent, the investigator 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

Informed consent must be sought from each potential subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

The basic elements of informed consent are:

1. a statement that the **study involves research**, an explanation of the **purposes** of the research and the expected duration of the subject's participation, a description of the **procedures** to be followed, and identification of any procedures which are experimental; a description of any reasonably foreseeable **risks** or discomforts to the subject;
2. a description of any **benefits** to the subject or to others which may reasonably be expected from the research;
3. a disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject;
4. a statement describing the extent, if any, to which **confidentiality** of records identifying the subject must be maintained;
5. 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;
6. an explanation of whom to **contact** for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

7. a statement that participation is **voluntary**, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

These items are to be included and described in the CPP protocol application.

Additional elements of informed consent to be applied, as appropriate, include:

1. a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. any additional costs to the subject that may result from participation in the research;
4. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation must be provided to the subject;
6. the approximate number of subjects involved in the study.

9.3 Waiver of Informed Consent

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 subjects;
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. the research could not practicably be carried out without the waiver or alteration; **and**
4. whenever appropriate, the subjects 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.

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 subject or the subject's legally authorized representative at the time of consent.
2. A copy of the consent form must be given to the person signing the form.
3. The consent form may be either of the following:
 - a. a **written consent document** (preferred by the IRB) that embodies the elements of informed consent; it may be read to the subject or the subject's legally authorized representative, but the subject or representative must be given adequate opportunity to read it before it is signed; or
 - b. a **short form written consent document** (with justification to the IRB for its use) stating that the elements of informed consent have been presented orally to the subject or the subject'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 presented to be signed by the subject or representative; 3) the witness must sign both the short form and a copy of the summary; 4) the person actually obtaining consent must sign a copy of the summary; 5) a copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

9.5 Waiver of Documentation of Informed Consent (Waiver of Signed Consent)

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

1. only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (**NOTE:** Subjects must be asked whether they want documentation linking them with the research, and their wishes must govern.), or
2. the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
3. in cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects 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 investigator. The wording on the informed consent form must contain all of the required elements and meet all other requirements as described in this section.

The IRB needs to ensure that the required language for a valid authorization to release health information is included in separate HIPAA (Health Insurance Portability and Accountability Act) Authorization form. The IRB may waive the requirement for an authorization or may alter the form or content of the authorization only in accordance with and as permitted by the HIPAA Privacy Rule (45 CFR 164.508). Such actions and the justification for them must be fully documented in the minutes of the IRB meeting where the action was taken or reported (if approved by expedited review).

9.7 Parental Permission and Assent

See Section 10.1.1 for policies on parental permission and assent in research involving children.

9.8 Surrogate Consent

The regulations generally require that the investigator obtain informed consent from subjects. Under appropriate conditions, investigators also may obtain informed consent from a *legally authorized representative* of a subject (surrogate consent).

Definition: *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research [45 CFR 46.102(c)].

This policy is designed to protect human subjects 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.

Surrogate consent may be obtained from a court appointed guardian of the person **or** a health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC). For example, a subject might have designated an individual to provide consent with regard to health care decisions through a durable power of attorney and have specified that the individual also has the power to make decisions on entry into research.

Such consent may be requested and accepted only when the prospective research participant is incompetent or has an impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note. The determination must be made in accordance with the following requirements:

1. The practitioner may determine after appropriate medical evaluation that the prospective research subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
2. Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research subject lacks decision-making capacity is based on a diagnosis of mental illness.

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

If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study.

9.9 Consent and Language Barriers

Researchers should prepare both English language and translated consent forms for proposals that include non-English-speaking subjects. An explanation of the translations and evidence of the comparability of the English and non-English consent forms may be requested by the IRB. The IRB may consult with language experts or require a "back-translation" into English. The translation should provide documentation to verify the accuracy of the translation and back-translation. As appropriate, the IRB may request additional protections in the description of methods for non-English-speaking subjects, including but not limited to, evidence that the translation took place, identification of the translator, and documentation of the translator's belief that the subject understood the study and the consent process.

10 Vulnerable Populations

10.1 Research Involving Children

Research involving children is governed by 45 CFR 45, Subpart D.

10.1.1 Definitions

Children – are individuals 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. Residents under 18 years of age are considered minors in California, unless they are "emancipated" by court order. For research with children in other jurisdictions, such as foreign countries, the investigators may be asked to clarify the age of being an adult.

Assent - a child's affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent.

Permission - the agreement of parent(s) or legal guardian to the participation of their child or ward in research.

Parent - a child's biological or adoptive parent.

Legal guardian - an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

10.1.2 Allowable Categories

Research with minor children will be reviewed and categorized by the IRB into one of the following groups. The IRB will establish the extent of risk to the child based upon his/her age, maturity, and psychological state. Consent by one or both parents (or legal guardians) and assent by the child are dependent upon numerous factors which the IRB will consider and evaluate on a protocol by protocol basis. Stipulations in federal regulations apply, but they also allow for determinations by the CPP IRB.

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, thus minimal risk. [45 CFR 46.404]
 - Only one parent or legal guardian needs to give permission
2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject. [45 CFR 46.405]
 - The risk is justified by the anticipated benefit to the subjects
 - Only one parent or legal guardian needs to give permission
 - Assent by the child is required
3. Research involving greater than minimal risk and no reasonable prospect of direct benefit to the individual subject, but likely to yield generalizable knowledge about the subject's disorder or condition. [45 CFR 46.406]
 - The risk represents a minor increase over minimal risk;
 - The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations
 - The permission of both parents, or 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)
 - Assent by the child is required

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]
 - Research in this category must be approved by the Secretary of Health and Human Services, and requires consent of either both parents, or legal guardian

10.1.3 Parental Permission and Assent

10.1.3.1 Parental Permission

In accordance with 45 CFR 46.408(b), the IRB must determine that adequate provisions have been made for soliciting the permission of each minor's parent(s) 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 meeting minutes.

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
- When 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 subject population for which parental or guardian permission is not a reasonable requirements to protect the subjects (for example, neglected or abused children)
- An appropriate mechanism for protecting the minors who will participate as subjects 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 subjects, 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

The assent process should be tailored to the age, maturity, and psychological state of the children involved and should be easy for the children to understand. The CPP IRB recommends the following to obtain assent, but may require other means such as all noted below and in certain circumstances:

- verbal script (ages 7 to 11),
- written assent document (ages 12 to 15), and
- a written assent matching the detail of an adult consent document (ages 16 to 17).

Minor subjects 12 years of age or older must sign assent after the parent or legal guardian has given consent unless [45 CFR 46.404]:

- The research holds out the prospect of direct benefit to the subject and which is available only in the context of the research (e.g., new therapy when none is available)
- The subject is incapable, mentally or emotionally, of being reasonably consulted
- The IRB specifically waives the requirement.

Except when the above exclusions are present, children between the ages of 7 and 12 must give positive assent directly to participation in the research.

At times there may be inconsistency between parental permission and child assent. A "no" from the child should be regarded as the desire of the child and seen to override a "yes" from a parent. Conversely, a child typically cannot decide to participate in the research project 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 underlying principle is that children should not be forced to be research subjects, even when their parents give permission and consent to it.

The Assent Form

Researchers must 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, in simple, age-appropriate language;
2. describe what will happen and for how long or how often;
3. say it is up to the child to participate and that it is okay to say no;
4. explain if any aspect of involvement in the research will hurt and if so for how long and how often;
5. say what the child's other choices are, including withdrawing from participation;
6. describe any good things (benefits) that might happen;
7. say whether there is any compensation for participating; and
8. encourage the asking of 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 should include more information and may use more complex language.

In determining whether children are capable of assenting, the CPP IRB will take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.

If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or 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 subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances detailed in the Waiver of Informed Consent section of this manual.

In addition, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or legal guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), it may waive the consent requirements for parents or legal guardians, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further 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 research activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

When parental or legal guardian permission is obtained, it must be documented in accordance with and to the extent described in the Informed Consent section of this manual. When a child's assent is required, the IRB will determine whether and how the assent must be documented.

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 subjects, but likely to yield generalizable knowledge about the subject'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 subjects are not wards.

If the research meets the condition(s) above, an advocate must 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 investigator(s), or the guardian organization.

10.2 Research Involving Pregnant Women, Human Fetuses and Neonates

[45 CFR 46, Subpart B; Federal Register: November 13, 2001 (Volume 66, Number 219)]

10.2.1 Definitions

Dead fetus - a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor 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 encompasses 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 if all of the following conditions are met [45 CFR 46.204]:

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, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
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, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the 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 [45 CFR 46.205]:

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 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

1. 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.
2. 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 subjects and all pertinent sections of this manual are applicable. [45 CFR 46.206]

10.2.5 Research Not Otherwise Approvable

The Secretary of the Department of Health and Human Services (DHHS) will fund research that the IRB does not believe meets the requirements of **Research Involving Pregnant Women or Fetuses** or **Research Involving Neonates** only if [45 CFR 46.207]:

1. 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
2. The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:
 - a. That the research in fact satisfies the conditions of **Research Involving Pregnant Women or Fetuses**, as applicable; or
 - b. The following:
 - 1) 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;
 - 2) The research will be conducted in accord with sound ethical principles; and
 - 3) 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

Research involving prisoners is governed by 45 CFR 46, Subpart C.

10.3.1 Applicability

This policy applies to all biomedical and behavioral research conducted under the auspices of Cal Poly Pomona involving prisoners as subjects. Even though a University IRB may approve a research protocol involving prisoners as subjects according to this policy, investigators are still subject to the administrative regulations of the California State Department of Corrections and Rehabilitation and any other applicable state or local law. [45 CFR 46.301]

10.3.2 Purpose

Whereas 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 subjects 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

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

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

In addition to all other responsibilities prescribed for the review process sections of this set of *Policies & Procedures*, the CPP IRB will review research involving prisoners and approve such research only if it finds that [45 CFR 46.305]:

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 subjects;
 - 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 subjects;
 - 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);
 - d. research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
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 subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects 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 subject population;
6. adequate assurance exists that parole Board 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 subjects 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 subjects of this fact.

10.3.6 Waiver for Epidemiology Research

The Secretary of DHHS has waived the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

- (1) In which the sole purposes are

- (i) To describe the prevalence or incidence of a disease by identifying all cases, or
 - (ii) To study potential risk factor associations for a disease, and
- (2) Where IRB has approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that
- (i) The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and
 - (ii) Prisoners are not a particular focus of the research.

The specific type of epidemiological research subject to the waiver involves no more than minimal risk and no more than inconvenience to the human subject participants. The waiver would allow the conduct of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a)(2).

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

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 subjects and to maintain the confidentiality of the data.

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

Research involving subjects who are mentally ill or subjects 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 subject; 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.

10.4.1 IRB composition

The IRB membership must include at least one member who is an expert in this area of 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.

The IRB may and will utilize *ad hoc* members as necessary to ensure appropriate expertise.

10.4.2 Approval Criteria

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

1. Only incompetent persons or persons with impaired decision making capacity are suitable as research subjects. Competent persons are not suitable for the proposed research. The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects. Incompetent persons or persons with impaired decision-making capacity must not be subjects 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 subjects of research that imposes a risk of injury, unless that research is intended to benefit that subject and the probability of benefit is greater than the probability of harm.
3. Procedures have been devised to ensure that participant's representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision making capacity. Health care agents [appointed under Durable Power of Attorney for Health Care (DPAHC)] and next-of-kin, or guardians, 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 subject would do if competent, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.

10.4.3 Additional Concerns

Both investigators and IRB members must be aware that for some subjects, their decision-making capacity may fluctuate. For subjects 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 investigators to monitor the decision-making capacity of subjects enrolled in research studies and to determine if surrogate consent must be re-obtained.**

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

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

11 Complaints, Non-compliance, and Suspension or Termination of IRB Approval of Research

11.1 Complaints

The Chair of the IRB and the Compliance Associate at Cal Poly Pomona will promptly handle (or delegate staff to handle), and, if necessary, investigate all complaints, concerns, and appeals received by the IRB. This includes complaints, concerns, and appeals from investigators, research participants, and others.

11.2 Non-compliance

All members of the CPP community involved in human subject 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 subjects.

- “Non-compliance” is defined as failure to comply with any of the regulations and policies described in these Policies and Procedures.. Non-compliance may be minor or sporadic or it may be serious or continuing.
- “Minor or sporadic non-compliance” is defined as failure to comply with IRB policies, which in the opinion of the IRB Chair and Compliance Associate are administrative in nature. Examples of minor or sporadic non-compliance could include turning in a report of an unanticipated problem a day late or failure to date a consent form.
- “Serious non-compliance” is defined as failure to follow any of the regulations and policies described in this document 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 by any investigator (student, responsible investigator, etc.) without prior IRB approval is considered serious noncompliance.
- “Continuing non-compliance” is defined as 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.

If, in the judgment of the IRB Chair and Compliance Associate, the reported non-compliance is not serious, not continuing, and the proposed corrective action plan seems adequate, no further action is required.

If, in the judgment of the IRB Chair and Compliance Associate, the non-compliance is serious or continuing, a formal inquiry (described below) will be held.

If, in the judgment of the IRB Chair and Compliance Associate, any report or allegation of non-compliance warrants suspension or termination of the research before completion of any review or investigation to ensure protection of the rights and welfare of participants, the IRB Chair may terminate or suspend the research as described in below with subsequent review by the IRB.

11.3 Inquiry Procedures

In the event of a reported instance of non-compliance by an Investigator with any of the regulations, policies, or procedures described in these *Policies and Procedures*, the CPP IRB will make a good-faith effort to work with the Investigator to gather relevant information and to clarify any misunderstandings that may have resulted in a concern over non-compliance.

If, after seeking information from the Investigator, the IRB determines that there may be grounds for a report of non-compliance, the IRB will conduct a thorough inquiry. A determination may be made that an inquiry is necessary by the IRB based on several issues that may include but are not limited to:

1. Subjects' complaint(s) that rights were violated;
2. Report(s) that the investigator is not following the protocol as approved by the IRB;
3. Evidence of failure to submit to the CPP IRB for review research being conducted with human subjects at CPP or by an Investigator, as defined by these *Policies and Procedures*.

4. Unusual and/or unexplained adverse events in a study;
5. An external (e.g., sponsor) audit;
6. Repeated failure of investigator to report required information to the IRB.

A subcommittee is to be appointed consisting of IRB members, and non-members if appropriate, to ensure fairness and expertise. The subcommittee is given a charge by the IRB, which can include any or all of the following:

1. Review of the protocol(s) in question;
2. Review of FDA audit report of the investigator, if appropriate;
3. Review of any relevant documentation, including consent documents, case report forms, subject's investigational and/or medical files etc., as they relate to the investigator's execution of her/his study involving human subjects;
4. Interview of appropriate personnel if necessary;
5. Preparation of either a written or oral report of the findings, which is presented to the full IRB at its next meeting;
6. Recommend actions if appropriate.

The IRB determines the appropriate action based on its own knowledge and the facts gathered by the appointed subcommittee's investigation.

The investigator is to be informed about the IRB subcommittee's determination in writing.

11.4 Unreviewed Research

In the event that the IRB determines that research with human subjects is or has been conducted at CPP or by an Investigator as defined in these *Policies and Procedures* but which has not been submitted for review and approval by the CPP IRB, the IRB will immediately inform the Institutional Official of the non-compliance. The Institutional Official will then report such non-compliance to those who, in the judgment of the IO, need to be informed, who would include, but are not limited to: the Investigator, the appropriate Faculty Advisor or Mentor, the Department Chair, College Dean, and/or School Director.

11.5 Suspension or Termination

In the event of non-compliance, and pursuant to the procedures specified in section 11 of these *Policies and Procedures*, the Cal Poly Pomona 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 subjects. Any suspension or termination of approval must include a statement of the reasons for the IRB's action in writing and must be reported promptly to the investigator and, if appropriate, the sponsor, appropriate institutional officials, and the Department of Health and Human Services or Agency head.

When study approval is terminated by the IRB, in addition to stopping all research activities, any subjects currently participating will be notified that the study has been terminated. Procedures for withdrawal of enrolled subjects should consider the rights and welfare of subjects. If follow-up of subjects for safety reasons is permitted and/or required by the IRB, the subjects will be so informed and any adverse events/outcomes will be reported to the IRB and the sponsor.

Failure to abide by these Cal Poly Pomona ***Policies and Procedures for the Protection of Human Subjects*** and federal regulations may result in the following sanctions, among others:

1. Suspension or termination of IRB approval of specific research protocols or of all research involving human subjects in which the investigator participates. Repeated circumstances could result in the loss of privilege to conduct human subject research within the department or college.
2. Sponsor actions. In making decisions about supporting or approving applications or proposals covered by this policy the Department of Health and Human Services 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 or persons who would direct or has/have directed the scientific and technical

aspects of an activity has/have, in the judgment of the Department of Health and Human Services or Agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects. (For research involving FDA-regulated products, these reports are to be sent to the FDA.)

3. Institutional or individual action by the federal OHRP and/or the FDA. The federal OHRP and/or the FDA may
 - withhold approval of all new Cal Poly Pomona studies by the IRB;
 - direct that no new subjects be added to any ongoing studies;
 - terminate all ongoing studies, except when doing so would endanger the subjects; and/or
 - notify relevant state, federal and other interested parties of the violations.
4. In the event of non-compliance, the IRB will notify all relevant officials, administrators, or faculty of the event, as appropriate. The IRB will refer for **disciplinary action** the investigator or other personnel involved in a study pursuant to Cal Poly Pomona policies and procedures, up to and including revoking confirmation of a degree, retraction of a published paper, and dismissal.

Failure to secure necessary Cal Poly Pomona IRB approval before commencing human subject research must be reported to the Institutional Official responsible for the IRB and to the appropriate dean and Provost for possible disciplinary action.

Investigators should also be aware that, in general, Cal Poly Pomona **indemnifies** them from liability for adverse events that may occur in CPP studies that are approved by the CPP IRB. Failure to follow approved procedures may compromise this indemnification and make the investigator **personally liable** in such cases.

11.6 Reporting

Unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with regulations or the requirements or determinations of the IRB, and suspensions or terminations of IRB approval must be promptly reported by the IRB and the CPP Compliance Associate to the:

1. Institutional Official
2. Investigator's department chair and dean as appropriate, and
3. The federal Office for Human Research Protections and any sponsoring department or agency head.

If the determination includes suspension of an investigator, the federal OHRP, Division of Oversight Compliance must be notified by the Compliance Associate.

All appropriate institutional officials must be informed of the IRB's decision.

12 Investigator Responsibilities

Principal investigators (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. This policy applies to faculty members and their students.

In order to satisfy the requirements of this policy, PIs who conduct research involving human subjects 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 subjects
- have sufficient resources necessary to protect human subjects, including: supervision, a sufficient number of appropriately trained staff, and appropriate support services
- protect the rights and welfare of prospective subjects
- have plans to monitor the data collected for the safety of research subjects
- have a procedure to receive complaints or requests for additional information from subjects and respond appropriately
- ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating faculty and research staff
- obtain and document informed consent as required by the IRB and ensuring that no human subject is involved in the research prior to obtaining their consent
- ensure that all research involving human subjects receives IRB review and approval in writing before commencement of the research
- comply with all IRB decisions, conditions, and requirements
- ensure that protocols receive timely continuing IRB review and approval
- report unexpected or serious adverse events to the IRB
- 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.

12.1 Investigators

(section revised 7/24/13)

Principal Investigators

At Cal Poly Pomona **faculty or staff members with University-paid appointments** may serve as the Principal Investigator or as the faculty sponsor on a research project involving human subjects.

Adjunct faculty of the University and any investigator whose status is considered to be “in training” (e.g., medical residents) may not serve as the PI but may serve as a co-investigator (co-PI).

The IRB recognizes one responsible PI (RI) for each study, who has ultimate responsibility for the research activities. Protocols that require skills beyond those held by the PI must be modified to meet the investigator's skills or have one or more additional qualified faculty as co-investigator(s). In the case of a student submitting a protocol as a PI, there must be a responsible PI listed as the co-PI.

Student Investigators

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

Research Team

The PI and other individuals, also known as co-investigators, 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, constitute the “research team.”

12.2 Protocol Development

Using the IRB protocol application, the investigator must carefully develop the description of the research project and thereby complete the protocol application and consent/assent form(s), making sure that consent information is in agreement with the research plan.

The protocol application must include or address:

1. Title of the study
2. Purpose of the study
3. Sponsor of the study
4. Results of previous related research
5. Subject inclusion/exclusion criteria
6. Recruitment procedures
7. Justification for use of any special/vulnerable subject populations
8. Study design (including, as needed, a discussion of the appropriateness of research methods)
9. Description of procedures to be performed
10. The possible/potential risks to the subjects
11. Provisions for minimizing risks/managing adverse reactions
12. The anticipated benefits of the research
13. An assessment of the risk/benefit ratio
14. Circumstances surrounding the consent procedure
 - Setting
 - Subject autonomy concerns
 - Language difficulties
 - Vulnerable populations
 - Procedures for documenting informed consent
 - Obtaining assent from minors
 - Using witnesses and/or translators
15. Document and data storage
16. Compensation to subjects for their participation
17. Compensation for injured research subjects
18. Costs to subjects for their participation in the study
19. Costs to third-party payers because of subject's participation
20. Provisions for protection of subject's privacy
21. Description of the resources available to protect research subjects, including: supervision, number and training of staff, appropriate support services
22. Training and experience with human subjects and conduct of research with human subjects.

Proposed consent/assent form (as applicable) must include or address:

1. The general principles and basic elements of informed consent
2. Translated consent documents, as necessary, considering likely subject population(s)
3. Approved formats for consent or waiver of consent conditions.

The investigator must submit the IRB protocol application form and all attachments to all other appropriate institutional regulatory offices (e.g., CPP's Environmental Health and Safety) for appropriate review and sign-off.

If the research is DHHS-sponsored, materials delivered to the IRB must include the entire sponsoring application. If there is a significant variation between the DHHS application and the IRB protocol, the investigator must identify and justify the discordance. Members of the ORSP may review IRB applications against funding and contract requirements, guidelines, and approved documents.

12.3 Changes to Approved Research

Investigators 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 subject (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 Compliance Associate. 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 the Compliance Associate. The IRB Chair or Compliance Associate must sign and return a letter to indicate approval. **NOTE:** IRB approved amendments to ongoing research do NOT extend the original approval expiration date.

12.4 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 subjects warrants more frequent review. **This renewal must take place prior to the approval expiration date noted on the approved protocol;** otherwise, subject recruitment/enrollment must be suspended and, if the research is DHHS-sponsored, the Agency must be notified.

It is the responsibility of the investigators to submit a timely continuing review application. As a courtesy, Cal Poly Pomona IRB Office will send a reminder notification approximately six weeks prior to the expiration of each approved protocol. The investigator 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): progress of the research, including the following information from the past year (cumulative data must also be included after the first renewal):

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

12.5 Required Reports to the IRB

Prompt reporting, within 10 working days, to the IRB Chairperson through the Compliance Associate is required when any unanticipated problem involving risks to subjects or others occurs.

1. Investigators must promptly report to any unexpected or serious adverse event. This includes study-related injuries or events, including those which are previously unknown reactions that are more severe than mild, as well as expected or well-described reactions that are either life-threatening or fatal.
2. Investigators 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.
3. When an approved research project is completed, the investigator must promptly notify the IRB and file with the IRB 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 the University, the PI is not required to submit any further reports of the research to the IRB.

12.6 Investigator-Required Record Keeping

Investigators must retain copies of approved IRB documents. Though the IRB and Compliance Associate will send our reminders, they must implement a system to comply with approval expiration dates.

In addition to providing a copy of the signed and dated consent form to each subject, a copy must be stored securely by the PI and placed in the subject's medical record (if the subject 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 three years after completion of the research.

12.7 Conflict of Interest – Investigators

All investigators must follow the Cal Poly Pomona Conflict of Interest Policy (see http://www.csupomona.edu/~policies/Administrative/conflict_of_interest_and_financial_disclosure.html). Investigators must identify for resolution under that policy's specific procedure any conflict of interest associated with a study, including but not limited to their personal investment in or other financial relationship with a company that might profit from the study. If the Investigator is permitted to proceed with the study following review under that policy, the research consent form provided to subjects should include an appropriate description of any relationship that might be received as a potential conflict of interest. **This information must be reflected in the consent form.**

As part of the application process for IRB approval, all investigators must disclose any potential or real financial conflict of interest they may have as a result of the sponsorship for that study.

If the Conflict of Interest status of an investigator changes during the course of a study, the individual is required to declare this to the Compliance Associate and the ORSP.

12.8 Training/Ongoing Education of Principal Investigator and Research Team

As stated elsewhere in these *Policies & Procedures*, one component of a comprehensive human research protection program is an education program for all individuals involved with research subjects.

Investigators, including responsible investigators (RI), must review core training documentation including Cal Poly Pomona *Policies and Procedures for Human Research Protection* and the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Cal Poly Pomona and the IRB maintain a subscription to the web-based “**CITI Course in the Protection of Human Research Subjects**” sponsored by the Collaborative Institutional Training Initiative (CITI) and the University of Miami. To satisfy the initial education requirement, investigators must complete the required modules with an overall competency level as established by the committee at 80%.

New research protocols and applications for continuing review will not be approved from investigators (and applicable members of their team) who have not completed their required training.

Waiver of Initial Education - If investigators or members of their research team can verify that they have successfully completed human subjects research training equivalent to that required by CPP IRB, they may request a waiver of the requirement. For example, certification of attendance at one of PRIM&R's **IRB 101 On the Road** workshops or completion of the Department of Veterans Affairs training, **Overview of Good Clinical Practice and Human Subjects Protection**, could qualify as equivalent training and could satisfy the requirement. The IRB reserves the right to review the training and experience of those conducting the research project.

Continuing Education and Recertification - There is no requirement to recertify with CITI as of the time this set of *Policies and Procedures* was approved by the IRB. However, as with many professional certifications, investigators and/or members of their research team will be asked to obtain additional training in human subjects as warranted by changes in regulations, campus policies, changes in research objectives, non-compliance, etc.

Investigators who are also IRB Chair, IRB members, or part of the IRB staff will need to satisfy specific training requirements.

Additional Resources

1. Human research protection information will be made available on the OFFICE OF RESEARCH/IRB web page on an ongoing basis to ensure that the University research community is apprised of current regulatory and policy requirements and training opportunities.
2. The website for the federal Office of Human Research Protections is <http://www.hhs.gov/ohrp/>.

12.9 Subject Recruitment

Investigators are responsible for recruiting research subjects in a manner that is fair, ethical and equitable. IRB approval is required for all recruitment procedures and materials. Recruitment materials must be consistent with the approved IRB protocol, accurate, and not coercive. The IRB may request to see and review them.

Recruitment of subjects from other institutions (places of work, schools, public venues, etc.) may require a form of authorization or permission to recruit there, which is the obligation of the investigator. The IRB may request evidence of that.

12.10 Payment to Subjects

The CPP 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.

Payment to research subjects may be an incentive for participation or a way to reimburse a subject 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, investigators must take care to avoid coercion of subjects. 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 consent form must describe the terms of payment and the conditions under which subjects would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed).

Payment or compensation is the responsibility of the investigator, not the IRB. Concerns of identifying information to issue checks, cash, or gift certificates to payees, use of social security number, verification of U.S. citizenship or permanent resident status, etc. to receive payment are all the responsibility of the investigator.

12.11 Investigator Concerns

Investigators who have concerns or suggestions regarding Cal Poly Pomona's human research protection program should convey them to the IRB chair, Compliance Associate, or institutional official (IO), as appropriate. The appropriate entity will research the issue, and when deemed necessary, convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted.

13 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.

13.1 Historical Background

The Health Insurance Portability and Accountability Act of 1996 is an expansive federal law and 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. Department of Health and Human Services (DHHS) must develop privacy regulations. DHHS proposed regulation in November 1999, and following a public comment period in which it received more than 52,000 comments, published a final rule at the end of December 2000.

In January 2001, the Bush Administration put the Privacy Rule on hold and, in February, reopened it for public comment. President Bush then lifted the hold, indicating that changes would follow in response to the comments, but confirming the rule's effective date of April 14, 2001. The rule requires compliance by April 14, 2003 - two years after the effective date.

Notably, DHHS proposed many changes to the rule in March 2002, and after further public comment, published a final version on August 14, 2002. Despite the recent changes, the compliance deadline still remains - April 14, 2003.

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.

13.2 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. Some of these research-related changes require further interpretation. Additional guidance from the Department of Health and Human Services may be provided. The following information reflects the current interpretation of the Rule.

Effective April 14, 2003, the Health Information Portability and Accountability Act (HIPAA) becomes law. Any research that is derived from a "covered entity" within Cal Poly Pomona must comply with this law. Presently, the covered entities for Cal Poly Pomona are designated as the following:

[Please be advised that changes may be necessary in response to new federal guidance or University policy. When changes are made this site must be revised and announcements regarding those changes will be posted on the OHRP website in this section.]

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 so-called "Common Rule", separate federal legislation designed to protect human subjects involved in research. HIPAA describes privacy standards for protecting PHI (protected health information), and so only applies to research that involves humans' (not animals') health information. (see [NIH - HIPAA Privacy Rule, Information for Researchers](#) for further information)

HIPAA and New Documentation Requirements

New research documents include a HIPAA authorization form, a waiver of authorization form, and a de-identification form.

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 (protected health information), 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.

HIPAA and Existing Studies

Studies that enroll human subjects prior to April 14, 2003 may proceed according to the protocol documents that were approved by the IRB. After April 14, 2003, researchers may continue to collect and use data gathered from these subjects, and no new documentation is required. However, any research subject enrolled AFTER April 14, 2003 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 Special Topics

14.1 Certificate of Confidentiality

Statutory Basis for Protection

Protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research is provided by the Public Health Service Act §301(d), 42 U.S.C. §241(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 proceedings to identify such individuals."

Certificates of Confidentiality constitute an important tool to protect the privacy of research study subjects. Certificates are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research subjects 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 subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to subjects. For more information, the OHRP can be consulted.

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 subjects).

Any investigator engaged in research in which sensitive information is gathered from human subjects (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 subject's medical record that could lead to social stigmatization or discrimination; or
- information about a subject'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 Compliance Associate within the OFFICE OF RESEARCH for help in applying for a certificate.

The IRB may require investigators to apply for a Certificate of Confidentiality.

Limitations

The protection offered by a Certificate of Confidentiality is not absolute. A Certificate protects research subjects 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 such matters as child abuse, a subject'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 subjects 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 subject if

- the subject (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 Department of Health and Human Services (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.

14.2 Mandatory Reporting

While preparing a research protocol, investigators must keep in mind that the State of California mandates reporting to designated officials and/or agencies for the following.

- Child Abuse - California Child Abuse and Neglect Reporting Act (CANRA) - California Penal Code Section 11164-11174.3
- Elder Abuse - California Penal Code section 368
- Communicable Disease - There are requirements that public health professionals must report about 85 communicable diseases to local health departments. See Title 17 CCR section 2500 et seq; Title 16 CCR section 1364.10 (failure to report communicable disease is a misdemeanor). See also www.lapublichealth.org/ACD/cdrs3.htm or inquire at the CPP Student Health Center.

Investigators should consult these sources to determine if potential subjects should be advised of mandatory reporting requirements during the informed consent process. California statutes are accessible at www.leginfo.ca.gov/calaw.html.

14.3 Cal Poly Pomona Students and Employees as Subjects

As it is part of the culture at CPP to encourage learning-by-doing and to be involved in community-based projects, activities that involve research with human volunteers are likely to occur. Members of the CPP community themselves might then be the subjects of a research project. Moreover, it is important to distinguish whether the project constitutes research as defined in federal regulation and review of the project would be necessary by the IRB.

When Cal Poly Pomona students and/or employees are being recruited as potential subjects, researchers must ensure that there are additional safeguards for these subjects. The voluntary nature of their participation must be of primary concern and without undue influence on their decision. Researchers must emphasize to subjects that neither their academic status or grades, or their employment, will be affected by their participation decision.

To minimize coercion, investigators should avoid, whenever possible, the use of their students and employees in their research. This statement is not made to preclude their use. Investigators should solicit subjects through means such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes other than their own. However, when a faculty member's own students are the subjects of the research, such as in evaluating a teaching method, then, as the PI, the above concerns must be addressed in the protocol application submitted to the IRB.

14.4 Psychology Department Subject Pool

The Psychology Department of Cal Poly Pomona employs the use of a "subject pool" for student-subjects.

The Department of Psychology subject pool consists of all students enrolled in Psy 101 and Psy 103. As part of the course requirement, students are expected to earn 6 Psychology Experience Credits (PECs), unless otherwise arranged between the department chair and the instructor. Like other course requirements, PECs are factored into final course grades, normally accounting for 5% to 10% of the grade. PECs may be

earned by any of three methods. Depending on the needs of the department the following are those that may be offered: (1) participating in IRB-approved research studies conducted under the supervision of psychology faculty, (2) writing summaries of published research using library resources, and/or (3) participating as a client in one or more simulated psychology sessions for the purpose of training advanced undergraduate and graduate students in psychology. Students may earn all 6 PECs by any one method, or they may earn some PECs by each method.

Any investigator (e.g., faculty, graduate student) using the department subject pool must have successfully completed an appropriate group of modules within the “**CITI Course in the Protection of Human Research Subjects.**” Department policies governing the use and operation of the subject pool are reviewed and revisions pertaining to research activities are submitted to IRB for approval.

14.5 Student Research

At Cal Poly Pomona, students may submit protocols, but they must be supervised by a faculty member, who serves in several capacities as their advisor, the "responsible faculty member," and the responsible investigator (RI). See also section 2 for definitions.

Students who are learning scientific methods in the classroom by conducting projects for pedagogical reasons and who do not intend to publish or otherwise disseminate their results do not meet the federal definition of research and thus these projects do not need to be reviewed by the IRB. Because such activities occur within the context of a course, they are *de facto* educational and, thus, do not need to be deemed educational by any additional review.

The concept of ethical review of research is an important aspect of education in research methods. Use of the CITI training program and its incorporation into classroom work is highly recommended.

One objective of an overall human subjects protection program is to ensure that class assignments include appropriate precautions. The CPP IRB is available to advise on the scope and nature of assignments, as they pertain to the regulations, to ensure minimization of risk.

14.6 Class projects

Class projects could fall into several categories:

1. Classes where all students conduct the same project. The faculty instructor will complete an IRB application for the course being taught, including the course syllabus as an attachment, and submit it for approval.
2. Classes where students select projects from a list of topics. The review process for these classes is the same as above, except that the instructor must address all of the relevant human subjects protections issues for each topic.
3. Classes where students (individually or in groups) develop their own projects. The review process for these classes is the same as above, except that each student (or group) must submit a brief form (included with the instructor's umbrella application) which addresses all of the relevant human subjects protections issues for their project.

Class projects are expected to fall within the exempt or expedited categories of minimal risk research. This will enhance the likelihood that the review can be completed in time for the students to complete their projects. In situations where students conduct more than minimal risk research as part of a class project, requiring full IRB review, approval in sufficient time can not be guaranteed.

For class projects approved under these procedures, the instructor assumes responsibility for the conduct of the student research and is responsible for ensuring that projects are conducted in accordance with the IRB's requirements. Instructors must educate students on the ethical conduct of research and help them prepare applications for IRB approval. Use of the CITI training program is recommended for this purpose.

14.7 Independent Study, Theses and Dissertations, McNair and Senior Scholars

These research activities are considered to meet the federal definition of human subjects research and must be independently submitted to the IRB by the student-researcher, who is deemed the investigator. However, when students conduct research as part of a course of study, *a faculty member ultimately is responsible for*

the protection of the subjects, becoming the responsible investigator (RI), even if the student is the primary researcher and actually directs the project. These provisions apply when students are not formally enrolled in independent study for credit, but are engaged in research to gain experience as preparation for application to graduate study. They apply to former students and volunteers who are not currently enrolled as students, working under the supervision of a faculty member.

Advisors assume the responsibility for students engaged in independent research. Instructors are responsible for research that is conducted as part of a course.

Training in the concepts of human subjects protections is a requirement of those involved in these activities.

14.8 Oral History Research

The CPP IRB recognizes that this discipline of research, where there is significant interaction with human subjects in the conduct of recording their oral history, has unique methodologies, is practiced guided by its code of ethics (1), and is built on a relationship of trust between the interviewer/investigator and narrator/subject. As once described, “oral history involves interviews for the record, explicitly for preservation as a historical document.”

The IRB acknowledges the statements of the American Historical Association and the Oral History Association (2) as they have worked with OHRP to obtain exclusion of oral history projects from IRB review. Federal regulations define research as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” The OHRP has explained that *some* forms of oral history data collection may not constitute “research” under these regulations. But it has also explained that some forms of oral history data collection *may be* research. (3) The CPP IRB believes that the principles behind human subjects protection must be addressed in oral history, and other forms of qualitative research methodologies. This decision is in keeping with regulation CFR 46.103 (b)(1) which explicitly declares that institutions do have “responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution.” In order to fulfill this responsibility, the CPP IRB has determined that all instances of oral history data collection using open-ended, qualitative interviews of a nonrandom sample of individuals should receive at least an initial review by the IRB.

In determining whether the proposed data collection constitutes “research” under the federal guidelines, the IRB will be guided by these principles:

- A. Oral history activities *the sole purpose of which* is to document a specific historical event or the experiences of individuals without an intent to draw conclusions or generalize findings would generally not constitute “research” as defined in federal regulations. Examples might be oral histories taken exclusively for the intent to archive the experiences documented with a local historical society or museum.
- B. Oral history activities undertaken for the purpose of archiving data to be used in the preparation of work to be published or presented in a scholarly forum, or for the purpose of developing or contributing to generalizable knowledge would constitute research. Examples might be oral history data collection for the purpose of informing public policy debate with generalized findings, or for the purpose of providing a repository of information for other investigators to conduct research as defined by 45 CFR 46.

Thus, the CPP IRB, in consultation with the IO, has established the following regarding oral history projects. A protocol describing the study must be submitted to the IRB for review. Protocols that, in the judgment of the IRB, constitute “research” under the federal regulations and which satisfy the criteria given below will be granted approval under “exempt” status by the IRB administrator with the chair’s oversight. Any aspect of the protocol falling outside of these specific criteria will be referred to the chair for a more detailed review.

- evidence of appropriate training, specifically the CITI human subjects program
- a statement of the topic of the interview
- a broad description of the questions that could potentially be asked, acknowledging that an oral history interview is by definition open-ended
- a written evaluation of the risks
- a completed informed consent form on Cal Poly letterhead indicating the topic of the interview, the estimated duration of the person’s participation, and the question or questions that might be used to begin the interview. The consent form should also contain a statement that participation is voluntary,

that it is possible the subject matter might be difficult in some way for the person to speak about and that, therefore, the participant can stop at any time.

- the researcher's name and contact information on it.
- assurance that minors will not be involved.

Citations:

1) the Oral History Association, <http://omega.dickinson.edu/organizations/oha/>, *Principles and Standards and Evaluation Guidelines*

2) www.historians.org/Perspectives/Issues/2004/0403/0403new1.cfm

3) The statement by the Office for Research Protections, entitled "Application of the Department of Health Services Regulations for the Protection of Human Subjects at 45 CFR 46, Subpart A to Oral History Interviewing," is available at http://omega.Dickenson.edu/organizartions/oha_irb.html.

14.9 Research Involving Coded Private Information

Cal Poly Pomona policy is based on the OHRP guidance document entitled, "**Guidance on Research Involving Coded Private Information or Biological Specimens**" (August 10, 2004 <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>). This document:

- Provides guidance as to when research involving coded private information is or is not research involving human subjects, as defined under HHS regulations for the protection of human research subjects (45 CFR part 46).
- Reaffirms OHRP policy that, under certain limited conditions, research involving **only** coded private information is not human subjects research.
- Provides guidance on who should determine whether human subjects 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 investigator to readily ascertain the identity of the individual to whom the private information 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.

Under the definition of human subject in Section 2 of this policy, *obtaining* identifiable private information for research purposes constitutes human subjects research. *Obtaining* means receiving or accessing identifiable private information for research purposes. This includes an investigator's use, study, or analysis for research purposes of identifiable private information already in the possession of the investigator.

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

Research involving **only** coded private information do **not** involve human subjects if the following conditions are both met:

- (1) the private information was not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
- (2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information pertain because, for example:
 - (a) the key to decipher the code is destroyed before the research begins;
 - (b) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS 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 investigators under any circumstances, until the individuals are deceased; or
 - (d) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

In some cases an investigator who obtains coded private information 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 investigator knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private information pertain, then the research activity now would involve human subjects. Unless this human subjects research is determined to be exempt (See Section 7.2), IRB review of the research would be required. Informed consent of the subjects also would be required unless the IRB approved a waiver of informed consent (See Section 9.3).

Who Should Determine Whether Coded Private Information Constitutes Human Subjects Research

The investigator in consultation with the IRB Chair or the Compliance Associate will determine if the research involving coded information requires IRB review. If the request is verbal (by phone or in person) or by email, it is the investigator's responsibility to maintain documentation of such a decision. If the investigator 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.

14.10 Research with minors in an educational setting

(section revised 12/1/16)

The CPP IRB has established policies regarding research activities dealing with minors in an educational setting because of its prominence at Cal Poly Pomona. CPP is acknowledged to have considerable investment in training teachers and conducting pedagogical research. By IRB policy and federal regulation, the participation of any students, staff, or faculty in a research project either as investigators or as subjects must involve the IRB to evaluate the potential risks to the persons enrolled in such projects. To wit, "the provisions of the Common Rule apply to all subjects, regardless of age or circumstance, including public school students. There are three direct references to children in the Common Rule, all of which identify children as vulnerable subjects. Although teachers, principals, school board staff, and the communities they serve are all concerned with the welfare of the children in their care, researchers and IRB members must be aware that there are vulnerabilities unique to school-based research." (p. 341, Institutional Review Board Management and Function, Bankert and Amdur, 2006)

The following summarize the procedures applying to the conduct of research with minors in education.

- The submission must include the advertising mechanism (paper flyers, e-mail communication, etc.) so that the IRB can review the text.
- The submission must describe the means of obtaining informed consent as it typically applies to adults (permitting the child's involvement) and/or assent as it typically applies to minors.
 - Waivers of parental (guardian) permission for minors to participate must be justified against regulations and any internal or institutional requirements.
 - Consents need to be written at appropriate comprehension levels and translated into other languages as appropriate.
- Evidence from the school administration authorizing the study must be included in the protocol.
- Investigators conducting the research project must show evidence of training in the protection of human subjects.
 - CITI, www.citiprogram.org, is the default training mechanism at Cal Poly.
 - The training must include modules pertaining to "minors as vulnerable subjects."
 - Investigators may be asked by the IRB to take additional training prior to receiving protocol approval.
- Coercion is a very real possibility in educational circumstances. A teacher studying her/his own students can exert undue influence without even being aware of it.
 - The teacher as the research investigator must address this risk and how it will be minimized in the protocol.
 - Whether extra credit is to be granted for participation (i.e., compensation) in the project must be explained.
 - Parents need to be assured that their children will not be harmed (physically, emotionally, or intellectually) by participating (or not). If the potential exists, the justification must be clearly described.
 - These same factors need to be addressed in the informed consent forms.

- While typically an educational study has minimal risk associated with it, there is still the possibility that during its conduct child abuse and/or neglect could be revealed. Policies regarding “mandatory reporting” would then need to be considered.
- Provisions of FERPA (The Family Educational Rights and Privacy Act) allow researchers to access educational records belonging to students that contain names, addresses, phone numbers, etc., but not data like attendance, ethnicity, test scores, etc. without consent. The school must have told parents that such ‘directory’ type information can be released, and that the parents can choose not to disclose it. During review of the application, confirmation of this may be requested.
- Provisions of PPRA (The Protection of Pupil Rights Amendment) as amended by the “No Child Left Behind Act” of 2001 include the right of parents/guardians to inspect surveys and questionnaires used in a school and require their permission when the surveys collect sensitive information.
- Circumstances of review, as adopted by the IRB (these are typical and the IRB may apply a different review):
 - exempt review
 - is defined by federal regulation (45 CFR 46.101(b)) as, “research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies or (2) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.” This does not mean that it is exempt from review; rather, an application must still be submitted for the IRB to determine that the research plan is exempt;
 - observations of children in public settings when the researchers do not interact with the subjects;
 - studies using existing data about children, (a) if it is publicly available, or (b) if it is recorded in such a way by the investigator that the identity of the children cannot be determined either directly or indirectly;
 - studies of educational programs related to evaluation and assessment (see section 14.15)
 - studies conducted by federal departments or agencies about government programs, such as welfare programs.
 - expedited review
 - educational research conducted in other countries;
 - research involving interviews, surveys, or observation in which the researcher (or a designee) participates in the activities observed;
 - studies involving audio- or videotaping;
 - taste and food quality evaluations and consumer acceptance studies conducted at a school.
 - full review
 - studies involving a medical procedure conducted in a school setting
 - studies of behavior considered to be sensitive conducted in a school setting
- While educational research in private schools is not subject to the same federal regulations as in public schools, unless conducted under an applicable program of the US Dept. of Education, the CPP IRB will still generally apply these policies and procedures in its review.
- The CPP IRB will not consider protocols from unaffiliated investigators (see section 14.14) which involve minors in education.
- The use of students’ classwork and assignments for research purposes must be requested by the PI through a consenting process.

14.11 Internet Research

Conducting research using information available on the Internet poses a number of questions for an IRB, including the CPP IRB, in terms of the IRB principles: respect for persons, beneficence, and justice. For example, persons participate in chat rooms not expecting that they are being studied. On the other hand, posting to the Internet is an open public forum and the loss of privacy is implied. Thus, the CPP IRB will review applications on a case-by-case basis and establish policy and procedures progressively.

- YouTube: Research with this web site has been determined to be exempt from review by the IRB based upon their stated policy and consultation with other IRBs.
 - The YouTube Privacy Policy states: *Any personal information or video content that you voluntarily disclose online (on discussion boards, in messages and chat areas, within your playback or profile pages, etc.) becomes publicly available and can be collected and used by others.... Any videos*

that you submit to the YouTube Sites may be redistributed through the internet and other media channels, and may be viewed by the general public (<http://www.youtube.com/t/privacy>).

14.12 Education Improvement Protocols

(section added 4/10/08, revised 12/1/16)

Because Cal Poly Pomona is extensively involved in educational research and investigation where improvement of the learning process is primary among the objectives, the IRB has established PEIP for the policy on education improvement protocols submitted for review. Reference is made to other subparts of this section 14, particularly 14.10, of these policies and procedures for their applicability.

Examples of application of PEIP include:

- The Teaching Academy (formerly called Investigating Teaching and Learning or ITaL) program. These are faculty projects designed to improve teaching in various disciplines.
- The educational multi-media (EMM) teaching program. Typically, these protocols are from master's students who create websites, on-line programs, and e-books in order to improve the learning process.

Procedural steps:

- The IRB delegates the review of such protocols to the Compliance Associate.
- The Compliance Associate assures that all components (consent form, methods, survey instrument, etc.) are included in the protocol.
- The Compliance Associate assures that the protocol satisfies the conditions of exempt review for "research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods" as defined in the DHHS CFR pertaining to human subjects research.
- Should the Compliance Associate determine that any condition is not met in the protocol as described here, then the protocol will be deferred to the committee for member review as either expedited or full.
- The chair will sign the approval memo as exempt review.
- The committee may audit any protocol approved under this procedure.

14.13 Research in International Settings

(section added 12/4/08)

The CPP IRB reviews studies involving human subjects conducted abroad by CPP investigators and in conjunction with international colleagues. Additionally, the US Code of Federal Regulations (CFR) Basic HHS Policy for Protection of Human Research Subjects addresses international research as follows: 46.101 (g) "[U.S.] policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research" and (h) "When research ... takes place in foreign countries, procedures normally followed in the foreign countries to protect may differ from those set forth in the CFR."

There are cultural norms to consider and differences in local legislation abroad and responsibilities of investigators. When there are international IRBs involved we will be aware of *cultural imperialism* and try to accommodate local rulings, particularly around areas of informed consent/parental permission/assent of minors, documentation, and determining when subjects are children as defined by the regulations.

The IRB requires, however, that all studies comply with U.S. standards *to the extent possible* when conducting research abroad. It is the responsibility of the researcher to (a) comply with IRB regulations, (b) inform the IRB of the need to vary IRB regulations due to the international context, and (c) indicate to the IRB how adjustments to your protocol will comply with the regulations or, at a minimum, preserve the spirit of the regulations. Consequently, investigators should consider the following:

- Describe the training that international colleagues will receive in human subjects protections (e.g., will the CPP principle investigator (PI) be the mentor and have oversight? Is training with the CITI program practicable?).
- Determine the Principal Investigator: CPP investigators or colleagues abroad? If the PI is abroad, pre-eminence may be extended to the colleague and its IRB (or equivalent).
- Assess U.S. regulations (CFR) and their impact. Would they be directive, with a sense of obligation to comply?
- Determine what an American journal, where the PI intends to publish, expects in terms of IRB review and approval for such research.
- Determine whether the local population used as human subjects might be construed as vulnerable under U.S. standards. Provide clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.
- Evaluate the liabilities that could affect the University and the participants, *especially when the study originates at CPP*.

Resources exist to help the PI answer these questions:

- The Harvard Public Health Rules web site (<http://www.hsph.harvard.edu/now/20070914/>) provides information including IRB (aka ethics committee or ethical review committee) officer contacts.
- Harvard School of Public Health (<http://www.hsph.harvard.edu/>)
- The Global Research Ethics Map (https://webapps.sph.harvard.edu/live/gremap/index_main.cfm?CFID=3027999&CFTOKEN=46703750).

14.14 Research at Cal Poly Pomona by Unaffiliated Investigators

(section added 3/8/10, revised 5/13/11; revised 2/2/17)

The CPP IRB is supportive of research by others who want to collect data from human subjects at Cal Poly Pomona, while at the same time being mindful of the impact on resources and implications for the campus. Individuals may of course collaborate with members of the CPP faculty and staff to conduct investigations of mutual interest; this section is not meant to address or restrict such collaborations. However, there may be persons without direct or formal association to Cal Poly Pomona who request authorization to use CPP facilities or the campus population in order to conduct a study involving human participants. Here, this would be regarded as research – by the OHRP definition - conducted by an “unaffiliated investigator.”

An “unaffiliated investigator,” as used in this policy and procedures document, is any researcher who is not either (1) a student, (2) a faculty member, or (3) a staff member at Cal Poly Pomona. The unaffiliated investigator must be affiliated with another *bona fide* research organization, termed here as the “home institution.” It may be the academic institution or a research agency (contract, governmental, or not-for-profit) with which the investigator is currently affiliated or the degree-granting institution in which the investigator is enrolled as a student.

Conduct of research. An unaffiliated investigator may conduct research at CPP only with the prior approval of the CPP IRB. Responsibility for the actual conduct of the research remains solely with the unaffiliated investigator. It is understood that approval to conduct human subjects research at Cal Poly Pomona in no way implies that either the CPP IRB, the Office of Research, or any official of Cal Poly Pomona assumes responsibility for the conduct of research on campus by unaffiliated investigators. The unaffiliated investigator may independently want to enlist the aid of someone on the CPP campus (a “facilitator”) to assist with logistical matters, such as providing access to records, making available research facilities or space, obtaining contact information for faculty, staff, or students of Cal Poly Pomona, or distributing materials with which to recruit participants. Alternatively, the CPP IRB can require a facilitator as a condition of approval. Depending upon the extent of the involvement (e.g., actual data collection), the IRB may place obligations on the facilitator (e.g., requiring training in human subjects research).

The unaffiliated investigator must understand that neither the IRB nor its staff can become involved in the actual conduct of the research. Such involvement would include, for example, recruiting participants, obtaining consent, and distributing surveys.

The unaffiliated investigator must give a rationale for wanting to use – specifically - the Cal Poly Pomona campus population. This should be in the hypothesis or subject description sections of the protocol from the home institution and in the request of the IRB to be authorized to conduct research at Cal Poly Pomona.

Requirement to comply with all CPP IRB policies and procedures. As described in Sections 1 (“Mission”) and 3 (“Institutional Authority”) of these policies (<http://www.cpp.edu/~research/irb/policy-and-procedures/index.shtml>), the CPP IRB retains oversight of human research conducted on campus by unaffiliated investigators and such investigators will be expected to comply with all CPP IRB policies. The CPP IRB reserves the right to ask for and obtain other evidence from the unaffiliated investigator to authenticate the proposed research to be conducted at Cal Poly Pomona. This could include, in addition to training records, authorizations for the use of survey instruments and data collecting equipment and financial information for when participants are to be monetarily compensated.

Training in human subjects research. Unaffiliated investigators must demonstrate their training in human subjects research equivalent to what the CPP IRB would demand of a CPP investigator to possess in a similar research study. The CPP IRB expects at minimum the training equivalent to the group of modules labeled “CPP introduction to human subjects 101” obtained through CITI (www.citiprogram.org).

IRB protocol reviews. Prior to seeking approval at CPP, the unaffiliated investigator is obligated to obtain approval from the human subjects protections committee at the unaffiliated investigator’s home institution. The unaffiliated investigator must provide to the CPP IRB the final protocol (including surveys, consents, etc.) with the approval memo from the home institution. In most circumstances, the chair of the CPP IRB will review and accept it (or not) as presented. The unaffiliated investigator is responsible for ensuring that all matters of concern to CPP (contained in CPP’s protocol application) during this review are addressed in the protocol of the home institution as well. Therefore, the CPP IRB recommends that unaffiliated investigators seek all approvals in a simultaneous manner with CPP, enabling any issues or contradictions between institutions to be addressed together and more expeditiously.

The CPP IRB may request the unaffiliated investigator to make modifications or amendments to the protocol from the home institution. The unaffiliated investigator is obligated to inform -- in a timely manner -- CPP of modifications, adverse events, renewal, and/or closure associated with the protocol at the home institution.

IRB protocols are processed through an electronic system (Cayuse IRB) which requires a CPP affiliation (“Bronco” identification). Unaffiliated investigators won’t have access to it, so the IRB staff must create the protocol in a submission folder and receive all protocol materials on their behalf, which necessitates extra time for review and approval.

The use of an IAA – Institutional Review Board (IRB) Authorization Agreement – or equivalent may be needed to satisfy fulfillment of some items indicated in this section. The IAA is expected to come from the IRB at unaffiliated investigator’s institution. Reference is made to the OHRP example at <http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwaf/forms/irb-authorization-agreement/index.html>

Indicating institutional affiliations in documents. Documents such as recruitment flyers and emails, consent forms, surveys, etc., must include the investigators’ names, home institution affiliation, and contact information for the unaffiliated investigator(s). Further, they must indicate that IRB approval has been obtained from the home institution and accepted by CPP. For example, this sentence could be used in the documents:

- This research study was originally approved by the IRB at ‘XYZ University’ under protocol number ‘12345’. It was subsequently approved for conduct at Cal Poly Pomona by its IRB under protocol YY-### (as assigned by CPP, where YY is code for the year and ### for the sequence, so it might look like 17-123).

Additionally, documents must be clear and unambiguous in respect to the various phone numbers, institutional affiliations, research offices, committees, psychological services, medical centers, etc. The subjects must be able to discern the appropriate institutions.

14.15 The IRB and Studies of Assessment and Evaluation (SAE)

(section added 2/7/13)

Many human studies at Cal Poly Pomona are engagements or investigations in which individuals (human subjects) are asked to assess and/or evaluate something. They provide input about products, programs, services, and/or policies using a variety of constructs, for example, attitudes, opinions, values, needs, expectations, preferences, and/or satisfaction. The CPP IRB has labeled such studies as SAE. Typically, they are low risk and do require IRB oversight because they fulfill the criteria to be considered research: 1) a systematic investigation of 2) human subjects that will 3) contribute to generalizable knowledge (DHHS 45.CFR 46.102 (d)).

Within the context of this guideline, the term evaluation is defined as: “the systematic determination of the quality or value of something”. See note #1.

Examples of SAE protocols include, but are not limited to:

- a College of Business Administration (CBA) assessment of persons' shopping habits to establish a business;
- a CBA evaluation of a product by asking the opinions of people using the item;
- a survey of patrons at a park by landscape architecture faculty or students regarding their satisfaction with the park;
- an evaluation of a process or activity at a work-site where opinions of employees or clients are collected for a Masters in Public Administration degree;
- an investigation by a student of social behavior of the means and effectiveness of specific advertising, and,
- generally, any evaluation of consumer satisfaction with a program, product or policy to determine its merit, worth, and/or value.

Note: Guidance for IRB protocols that involve assessment or evaluation in classroom activities, demonstrations, and assignments appears in Section 14.5 (Student Research), Section 14.6 (Class Projects) of the *Cal Poly Pomona Policies and Procedures of the IRB*. Guidance for Education Improvement Protocols (PEIP) appears in Section 14.12 of this document. It may be more appropriate to consult these sections for IRB protocols of this nature.

Typical SAE Research Methodology. SAE protocols may utilize various data collection methods, such as questionnaires (both paper and electronic surveys), interviews (face-to-face and by phone), focus groups, and observation. Besides the attitudes, opinions, and other constructs (as listed above) of individuals, personal data such as gender, age, race/ethnicity (see #2), zip code of residency, income, etc. are also often obtained from the subjects, some of which could be used to identify individual respondents even though personal identifying information such as names, telephone numbers, and email addresses are not obtained. These data are recognized as important in such research and IRB policy does not preclude or prohibit the collection of such information. However, the concerns for the IRB are: the level of risk for participants, that the data collected from them are stored securely and protected, and whether the participants/data are anonymous or confidential. While typically there is little risk (“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”) associated with SAE protocols, research has shown that as few as three variables can readily re-identify persons in anonymous data sets (see #3). Thus, the IRB must be assured that the researcher has procedures in place to protect against the release of the data (inadvertent or otherwise) and, in the event of an inadvertent or accidental release of data, that participants cannot be readily identified from the records; this is accomplished through review of the protocol when it is submitted to the CPP IRB.

The CPP IRB has determined that if a SAE protocol is anonymous, then the review may be delegated to the Compliance Associate. If not (that is, confidential data collection), the Compliance Associate will refer the review to an IRB member(s). **Note:** To elaborate for the purpose of SAE protocols, this distinction is made. Confidential means that the researcher knows who the respondent is, but is keeping such information concealed. Anonymity can involve interviewing without ever collecting identifying information. Thus, face-to-

face interviews cannot be anonymous, but asking random people “off the street” questions about something (like a park or a piece of art) - without collecting their names - is a kind of anonymity as long as subjects are not recorded in any way.

These are the criteria by which the Compliance Associate will conduct an initial review:

- Verifies that all required components (e.g., means of recruitment, consent form, methods, survey instrument, appropriate training, etc.) are included in the protocol.
- Assures that the protocol satisfies the conditions of category 2 of exempt review as defined in the DHHS CFR (following) pertaining to human subjects research.
Research involving the use of ... survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- Assesses further the appropriate understanding and usage of the terms anonymity and confidentiality in the protocol, the informed consent form, and the survey instruments.
- Examines surveys to be used, evaluating the level of risk and the logistics of e-surveys (implied consent, skipping vs. required questions, etc.).

Additionally, whether by IRB member(s) or the Compliance Associate, the IRB will consider the following during the review and approval process for SAE protocols:

- Location of the Research and the Potential for Coercion. Does the PI work at the proposed location? Is the PI in a position of some power or authority over others who may be recruited to participate? Could the survey or study be seen as coercive if an employee doesn't want to participate? And, if so, what are the ways in which the PI plans to ameliorate these concerns?
- Adequate Descriptions of Anonymity and Confidentiality. Either circumstance can apply in SAE protocols. The protocol must clearly distinguish between confidential and anonymous data collection and use. Confidential data may be rendered anonymous through either the aggregation of individual responses during the data analysis and reporting processes or by some other means of de-identification. The PI should explain how anonymity is ensured in the reporting of results. In the case where the SAE protocol is determined to be confidential, the review will be done by an IRB member.
- The Need for Permissions or Authorizations. As applicable, PIs must document that they have permission and/or authorization to use a site for research purposes (e.g., to conduct a survey at a commercial establishment like a restaurant) and/or recruit/engage individuals at a site for the research (e.g., to allow employees to use their time at work for the research study). In other words, are decision-makers and administrators within the company or institution aware that their employees or other resources are being used as 'subjects' for research purposes? The potential for liability does exist and the IRB requires securing these permissions as necessary.
- The Sampling Plan and Inclusion of Under-represented Groups. Are under-represented groups adequately included? This fulfills the IRB principle of justice. Is the sample representative of a specific population or one of convenience? Is the stated number of subjects meant to be those recruited or actually sampled, in other words what is the anticipated return or response rate? Is oversampling under consideration (collecting data from more than the estimated sample size in order to account for low response rates)?
- Data Security. Once the data are collected, how will the security of the material be ensured, that is protected against inadvertent release? Who will have access to the data? How long will the PI retain the data and the completed data collection tools (e.g., completed surveys, interview transcripts, audio or video records).
- Participant Benefit/Risk Analysis. What statements has the PI made in the protocol and the informed consent form to justify the “use” of human participants in this research?

If the Compliance Associate has any concerns about the conditions above or determines that any have not been adequately addressed or met, then the application will be referred to an IRB member(s) for review. Otherwise, on the approval and recommendation of the Compliance Associate, the IRB Chair will sign the approval memo as an exempt review. The committee may audit any protocol reviewed and approved under the SAE procedure.

Guidance and Advisory Notes

- 1) Scriven, M. (1991). Evaluation thesaurus. 4th ed. Newbury Park, CA: Sage Publications.
- 2) In 2008, the US Census Bureau adopted the following changes in its procedures for asking race/ethnicity demographic questions. (Refinement of race/ethnic classifications continues at the federal level; see for example http://arksped.k12.ar.us/documents/data_n_research/DDS_FAQ_NEW_FEDERAL_RACE_n_ETHNICITY.pdf). It is recommended that PIs use the following conventions in consumer survey type protocols.
 - It is more appropriate to use the term “Latino/a” rather than “Hispanic.” There are some Latinos who are not Hispanic, e.g., Portuguese and Brazilians.
 - Asian/Pacific Islander is often split as separate categories: (1) Asians and (2) Pacific Islanders. Asians normally refer to East Asians (e.g., Japanese, Koreans, Chinese), while Pacific Islanders include Australasians, etc.
 - Use “Caucasian” or “Anglo-American,” not “Caucasian American.”
 - Bi-racial or multi-racial -- rather than multicultural – may be the more appropriate term. Someone could be of Asian descent but identify with Chinese and American cultures, and consider him/herself to be multicultural.
- 3) L. Sweeney. Weaving Technology and Policy Together to Maintain Confidentiality. Journal of Law, Medicine & Ethics, 25, nos. 2&3 (1997): 98-110 [<http://dataprivacylab.org/dataprivacy/projects/law/jlme.pdf>].

14.16 Circumstances under which the IRB office staff can approve protocol amendments

(section added 02/04/2015)

Introduction: Protocols and their amendments in the IRB office are reviewed by staff – applying administrative checks -- before sending them on to designated reviewers, a full IRB at a convened meeting, or to the chair. In all cases, the chair “signs off” to indicate approval of the process such that the study can be conducted. With low impact amendments, meaning no or negligible change in risk, the process does not need to involve an IRB member to perform an ethics review.

Scope: This procedure addresses and identifies the circumstances whereby IRB staff can both review and approve amendments for sign-off by the chair, on behalf of the Board.

Amendments to protocols generally include the following:

- A change of study design, methodology, or recruitment methods
- Changes to any data collection documents, including surveys and questionnaires
- Changes to consent documents
- Changes to the population proposed in the approved protocol
- Changes in funding
- Addition/Deletion of investigators
- Change of protocol title
- Addition/Deletion of research performance sites

Why: Protocol amendments (with minor changes) can be reviewed and approved by IRB office staff in order to speed the process compared to soliciting IRB member reviewers. For example, when a PI wishes to amend a protocol to add similar questions to a survey, the staff could potentially respond within an hour, instead of notifying and receiving a response from the member.

Examples of protocol amendments that can be reviewed by the IRB office staff include, but are not limited to:

- Addition of similar questions to surveys
- Addition of co-PIs with all criteria (training, signature, etc.) satisfied
- Addition of research assistants
- Addition of sites to conduct research (with appropriate authorizations from site personnel)
- Renewal of a protocol which has changes within the allowed circumstances outlined in this section
- Correction of typos, grammar, spelling, etc.
- Removal of personnel, such as students who graduate
- Change of study duration and start/end periods

Amendments which include the following **cannot** be approved by the staff and will instead be referred to an IRB member. The review of the amendment would typically go to the original protocol reviewer. In case of his/her absence, it would defer to other members with chair consultation.

- Change of the PI
- Changes that increase the risk or potential for harm or risk
- Any other circumstance where the IRB office does not feel comfortable or consider it within the purview of the office to approve an amendment after reviewing it

References:

1) Bankert, E. A., & Amdur, R. J. (2006). *Institutional review board: Management and function*. Sudbury, MA: Jones and Bartlett.

14.17 Clarification of investigator roles and level of engagement

(section added 04/01/2015)

Studies with human subjects (participants) at Cal Poly Pomona are initiated and conducted by a variety of persons including students, staff, faculty, administrators, and collaborators from outside of the university, all of whom are involved with the research in some way but not all are necessarily investigators. The term investigator itself connotes different meanings in various circumstances and research disciplines. This section is meant to provide guidance on which roles would obligate a person involved in a research study with human subjects to be named as an investigator, to obtain training, and/or to sign the "Declaration by all Investigators" as stated in the IRB protocol. Further, it defines and provides examples of being engaged in the research study.

The CPP IRB has utilized OHRP's definition (reference below) for the term "Investigator" to refer to "an individual involved in performing various tasks related to the conduct of human subjects research activities." Therefore, to be involved is the equivalent of being engaged. Such involvement or **engagement** includes, per OHRP, the following four items:

- 1) Obtaining information about living individuals by intervening or interacting with them for research purposes;
- 2) Obtaining identifiable private information about living individuals for research purposes;
- 3) Obtaining the voluntary informed consent of individuals to be subjects in research; and
- 4) Studying, interpreting, or analyzing identifiable private information or data for research purposes.

The CPP IRB designation of a "Primary Investigator" or PI is the person designated to have overall responsibility of the research study. OHRP uses the term "principal investigator." PIs include, but are not limited to:

- Faculty with University-paid appointments
- Staff members, whether conducting a study on behalf of their job or enrolled in an educational program for a degree
- Students, whether undergraduate or graduate. Students must have a faculty advisor (also known as mentor or committee chair) who is listed in the "Other Investigators" category of the protocol application. A student cannot fulfill the PI role without a faculty advisor listed in the Other Investigators section.
- Medical personnel

The CPP IRB term "Other Investigators" refers to any additional individuals involved in the research study through any roles such as (but are not limited to):

- Any of the categories listed above under "Primary Investigator"
- Co-Primary Investigators or co-PIs, faculty advisors, adjunct faculty of the University, or any other investigator whose status is considered to be "in training"
- Collaborators, for example investigators from other research institutions who are contributing to and engaged in the research

- Facilitators, who for example enable an investigator not affiliated with CPP to conduct research at CPP (see section 14.14)

The term “Research Associate” or RA is used for individuals not engaged with the research study as defined here, but still has a connection. For example, the RA includes, but is not limited to, those who do the following and adhere to a code of confidentiality:

- process data sets, which have had identifiers removed, with statistical tools
- analyze biological samples, which may have had identifiers removed
- write transcripts from interviews
- sponsor the study by providing funds

Being not engaged, the RA:

- does not recruit or obtain consent from subjects
- is not required to sign the “Declaration by all Investigators”
- should receive training about human subjects and the responsible conduct of research
- can be included in the IRB protocol, but not within the sections designated for investigators

A RA could in the course of the research become engaged and thereby fulfill the criteria of investigator.

The RA must then be amended to the protocol as an investigator. The evaluation steps and final determination of fulfilling the role of RA remain with the IRB during review of the protocol.

Reference:

- 1) "Frequently Asked Questions," *Who are "investigators"?* U.S. Department of Health & Human Services, n.d. Web. accessed 13 Nov. 2014; <http://www.hhs.gov/ohrp/policy/faq/investigator-responsibilities/who-are-investigators.html>

14.18 Service as a Member of the IRB

(section added 01/11/2018)

The mission of the CPP IRB is to support human subject research (HSR) through representation by faculty members of the various disciplines of research conducted on the campus. Serving on the IRB -- conducting protocol reviews, creating guidelines to ensure the ethics of the research program, etc. - is an important task for other HSR investigators (including faculty, students, and administrators) in the CPP research community. As a volunteer on the IRB, it can be time-consuming, but the rewards include learning the IRB process, knowing the kinds of research occurring at CPP, obtaining service credit, assuring regulatory compliance when ethical research with human subjects is conducted, and deriving satisfaction from other IRB-associated aspects.

Reference is made to section 5 of this Policies and Procedures manual, especially 5.2 “Appointment of Members to the IRB” and 5.9 “Review of IRB Performance.”

Recruitment and Appointment

The composition of an IRB is defined by federal regulation at 45 CFR 46.107: “Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.” Because CPP is a polytechnic university, many disciplines are necessarily represented on the IRB and consequently the size exceeds the minimum.

The President has delegated, according to regulatory requirements, the authority to officially appoint the members of the IRB to the Institutional Official (IO). Recruitment of members may be from any source. The IO will consult with the Chair (who has consulted with existing Board members) and may consult with college deans and/or department chairs for recommendations on appointments. Persons may nominate themselves or be nominated. Recruitment from unit 3 employees (faculty and lecturers) via a call for service opportunity from the Academic Senate, and will be initiated by the IO. Staff may serve as members.

The Board must be constituted as per federal regulations, which include having at least one non-scientific person and having others who possess specific characteristics in terms of cultural and professional experience. The members include the chair, the vice-chair, regular members and their discipline-aligned alternate, and an unaffiliated (outside) member who represents the community and public interests.

Recruitment of the unaffiliated position shall be independent of the senate process, since federal regulations require the unaffiliated person to be independent of the institution. Recommendations for the unaffiliated position may be solicited from IRB members and after a Board quorum vote, the chair will make a recommendation to the IO for appointment.

The term of membership for members is set at four (4) years, which is consistent with other CSU campuses. Some terms may be set shorter in order to maintain a staggered/overlapping balance of approximately one-fourth of the members being appointed each year. A member may be reappointed, or ask to be considered for reappointment. Consideration for reappointment will be by joint agreement of both the IO and Chair (who has consulted with existing Board members). While not required, it is anticipated that the alternate would assume the regular member's position. A regular member may assume an alternate position, too.

The selection of chair and vice-chair is made by the Board members with confirmation by the IO. The term for chair and vice-chair is set at two (2) years. A chair may be reappointed. While not required, it is anticipated that the vice-chair would assume the chair's position when vacated.

A member who leaves the Board in good standing may serve as a consultant. Consultants contribute information and experience but cannot vote per federal regulations. Consultants are not considered part of the Senate's definition of university committee; thus, they serve unofficially and do not require a call for service opportunity.

Compensation

Whitney (*Balanced Ethic Review – A Guide for Institutional Review Board Members*, Springer, 2016) wrote that "IRBs have long meetings with substantial additional time spent in preparation. Joining the IRB is a significant commitment.", "Many IRBs require far more work than any other institutional committee.", and "Some institutions do not (pay IRB members) on the ground that everyone has an obligation to participate in the institution's governance."

While there is no financial compensation, the chair and IO will recognize service in several ways, such as thank-you notes, letters regarding participation, and contributions to RTP (retention, tenure, and promotion) packages. Additionally, food is provided during most Board meetings.

Unaffiliated members may be compensated for their mileage and similar expenses.

Expectations

Members are obliged to:

- Attend greater than fifty percent of the meetings of the IRB, typically held monthly during the academic year, and other times as necessary. Extended absences and sabbaticals should be discussed with the chair and IRB office. Alternates are obligated to attend meetings when a member cannot, however, are welcome to attend all meetings.
- Respond to Board communications (emails, protocol notifications, etc.)
- Contribute to the workload which includes review of protocols and help in the development of guidelines for Board business. Every year, the chair in collaboration with the IO, will set expectations for satisfactory member participation, which initially are set at completing five or more protocols and contributing substantially to two or more guidelines.
- Complete tasks within a reasonable time frame, and to inform the IRB office if delays are expected.
- Review and vote on minutes of Board meetings. Two-thirds of those present at the meeting, including alternates by previous Board decision, may vote electronically to approve minutes; otherwise, the vote is a simple majority of regular members at the following Board meeting.
- Learn the processes and procedures of the HSR program, including the use of the electronic protocol system.
- Be ambassadors of the IRB and HSR regulations within their academic units. That is, serve as an information resource to the CPP community engaged in HSR.
- Declare conflicts of interest when reviewing protocols and maintain confidentiality for matters brought to the board.
- Evaluate the potential risk and harm of proposed human activity primarily – human subject protections - while secondarily applying one's research background. In other words, ethics comes before

methodologies, but it is recognized that they are tied together. Provide review comments that address the ethical principles of human subject's protection (respect, beneficence, and justice).

- Complete the CITI group of modules designated for CPP IRB members for IRB training soon after appointment in order to be compliant with federal regulations. Further, members need to maintain their IRB knowledge familiarity with HSR regulations through continuing education.

Dismissal and Inability to Serve

Members of the IRB must be in good standing at the university. If a member has been deemed unacceptable for employment within the university, or can no longer serve as below, the member can be immediately dismissed from the Board. Confirmation of poor standing may be received from Faculty Affairs or a comparable authorizing campus organization. Members may submit a letter of resignation to the IO, copying the chair.

Members, including unaffiliated members, may be removed from the IRB for not fulfilling expectations, by mutual agreement of the chair or vice chair, and IO, for reasons that include, but are not limited, as follows.

- Unable to attend IRB meetings.
- Unable to assist in implementing CPP policy.
- Unable to participate in protocol review.
- Failing to declare a conflict of interest.
- Breaching confidentiality.
- Being non-collegial or disruptive to governance of the Board.
- Being out-of-date with training or refusing to obtain continuing education pertinent to IRB matters.
- Participation in the Faculty Early Retirement Program (FERP). Faculty who "FERP" may serve only as consultants to the Board – not as a member. This is because of the logistical complications of serving during non-contracted academic periods.

IRB Office

The IRB office (aka research compliance office) will assist the IO:

- with preparing an appointment letter
- with preparing a dismissal letter
- with informing regulatory authorities (e.g., OHRP) about appointments and any related changes regarding the IRB.