Chapter 13:

Investigator's Role and Responsibilities

Chapter Contents

Chapter 13
Investigator's Role and Responsibilities

This chapter defines the role of Principal Investigator, co-investigator, and student investigator. It identifies the specific responsibilities, qualifications, and interactions an investigator has when conducting human subjects research.

13.1 Definition and Role of Principal Investigator (PI)

The term Principal Investigator (PI) implies specific responsibilities and interactions for conducting research. Investigators have a responsibility to protect the rights and welfare of participants. In addition to following applicable federal, state, and local regulations, investigators are expected to follow ethical principles and standards appropriate for their discipline and research. Investigators must also follow Good Clinical Practice (GCP) guidelines in designing and conducting clinical trials. USC policies, procedures, and education programs are provided to help investigators carry out research studies ethically. Refer to Section 13.3 - Good Clinical Practice (GCP) Course for training requirements. The PI bears ultimate responsibility for the scientific, technical, and administrative aspects of the research project, even when certain tasks have been delegated to or co-investigators, sub-investigators, staff, or students.

Who may be a Principal Investigator on an IRB application

At USC, the following may be listed as Principal Investigator in iStar:

- USC faculty and staff (excluding temporary personnel)
- Students including undergraduates, master and doctoral students, medical students, residents/interns, clinical, research and postdoctoral fellows. Student investigators must designate a Faculty Advisor on the IRB application. Faculty Advisors are responsible for the scientific and ethical quality of student research projects. For more information, see Section 13.7 – Faculty Advisor's Assurance for Student Investigators

- For research conducted by PIs who are not USC faculty, PI requirement should be consistent with local policy (such as faculty from Cedars-Sinai Medical Center)

In contrast, for grants management principal investigators can only include:

All tenured, tenure track, and non-tenure track faculty, and research scientists (with the exception of lecturers, adjunct, and part-time clinical faculty) may act as Principal Investigators. Postdoctoral, Research Associates and Postdoctoral Teaching Associates, as defined by USC's Postdoctoral Scholars Policy, may act as co-principal investigators on sponsored projects, but may not be principal investigators unless a specific waiver and approval is granted upon recommendation by the Department and approval of the appropriate Dean. The signature of the Dean/Department designee on a Proposal Approval Record (PAR) is equivalent to departmental authorization that the person may act as a principal investigator.

For additional information refer to the Guide to Research at USC and the Postdoctoral Scholars Policy.

IRB Review of Investigator Qualifications

One of the responsibilities of the IRB is to determine that the investigator is appropriately qualified to conduct and supervise the proposed research. In many cases, previous experience with an investigator allows the IRB to readily determine an investigator's qualification. However, if the IRB has no knowledge about an investigator, the IRB may request additional documentation to evaluate an investigator's qualifications (such as curriculum vitae, medical licensure or relevant publication). The IRB may also need to assess an investigator's training specific to the proposed study, particularly if the research involves higher risk, vulnerable subjects or novel technologies.

Principal Investigator Responsibilities

The PI initiates the research proposal, defines the scope of the work, controls the conduct of research, and directly supervises any others (faculty, staff, or students) involved in the research. The PI specifies and participates in the selection of supplies, equipment, and subcontractors (if applicable). The PI certifies the percentage of effort for other faculty and staff working on the project, certifies the accuracy of charges, notifies and communicates with sponsor personnel and collaborating organizations as needed, and manages the orderly execution and close out of the project.

Investigator Responsibilities to IRB

PIs are responsible for ensuring that research is conducted according to valid research design and methods. PIs must adhere to an IRB approved study plan (protocol) and terms of the grant, contract and/or signed funding agreements as well as applicable laws, regulations, and institutional policies.

Initial Study Responsibilities

Prior to commencing research PIs must:

- Obtain approval from the appropriate department, institute and Dean or designee of the school for any proposal to be submitted to the Health Sciences IRB (HSIRB). Some schools (such as the Keck School of Medicine) require additional approvals, for example, from a Division Chief.
- Ensure appropriate research compliance committee (Institutional Animal Care and Use Committee review and approval of a sponsored project's protocol in accordance with those committees' policies and procedures. Studies submitted to the University Park (UPIRB) may require school or department approvals as determined by the particular school or department, or other committees as deemed necessary.
- Submit an application for IRB review and approval. All IRB applications must be submitted through the iStar system.

Note: If research initiated at another Institution will be continued at that Institution and/or transferred to USC, the investigator must contact the USC IRB for information and submission requirements. Refer to Appendix J – IRB Requirements for Research with Other Sites for guidance.

Ongoing Study Responsibilities

PIs must keep the IRB informed about their study and are required to:

- Submit annual progress reports to the IRB for expedited and Full Board review studies unless the study is expedited and has a 2-year approval (see Section 9.2 – Continuing Review)

- Submit an amendment to the IRB if a change to an IRB-approved study is necessary. The IRB must review and approve the changes before these are implemented unless the change to the study is initiated to prevent an immediate hazard to subjects (see Section 9.1 – Amendments – Changes to Research after Approval)

- Submit reportable events and reports to the IRB as applicable. Reportable events and reports include adverse events, unanticipated problems involving risks to subjects, protocol deviations, data safety monitoring reports, and protocol changes initiated to eliminate immediate hazard to subjects (see Section 7.15 – Reportable Events and Section 7.16 - Reports)

Close Out Study Responsibilities

PIs must submit a final progress report to close out a study when a study is completed or terminated (see Section 9.3 - Project Closure). PIs who plan to leave USC and have active studies are required to:

- Close the study/ies: investigators must submit a final progress report (Continuing Review in iStar) or complete the "Close Study" activity in iStar

- Transfer the study to another USC investigator: submit an amendment to change the Principal Investigator

- Transfer the study to another Institution: investigators must close the study at USC by submitting a final progress report (Continuing Review in iStar) or complete the "Close Study" activity in iStar

- Continue study at USC and at another site: investigator should contact the USC IRB for more information and guidance.

13.2 Investigator-Initiated Research and Sponsor-Investigators

Investigator-Initiated research has many different meanings. The National Institute of Health (NIH) uses the term "investigator-initiated research" to describe an investigator submitting an application to the NIH on a topic of his or her choice. Investigator-initiated research differs from targeted research in which investigators respond to an institute's call

for applications in research topics specified in requests for applications (RFA) or requests for proposals (RFP).

Investigator-initiated research, in the context of clinical trials with an IND or IDE, is when an investigator is also considered the sponsor (sponsor-investigator) and must fulfill all regulatory requirements, FDA expectations, and monitoring expectations of a sponsor. This differs from studies initiated and funded by a sponsor in which the sponsor provides the protocol. In addition to FDA regulations, sponsor-investigators must comply with California laws that affect research sponsors, such as manufacturing regulations for experimental drugs and devices. For additional information, refer to the California Health and Safety Code Sections 111515-111545 and 111550-111610.

The iStar application requires investigators to indicate when the IND/IDE is held by USC faculty or investigator. Sponsor-investigators must also complete the Sponsor-Investigator attestation in iStar when submitting their study to the IRB. Investigators who plan to conduct sponsor-investigator research should contact the HSIRB Chair for assistance. For more information refer to Section 18.4 – Sponsor-Investigators.

13.3 Educational Requirements

Human Subjects Protections Course

For an application to be approved by the USC IRBs, all study personnel must complete human subjects training. The online course used is provided by the Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org, providing a certificate of completion valid for three years.

Prior to a certificate expiring, a notification is sent from iStar to the researcher. Study personnel who have completed the human subjects basic course must renew their certification every three years. A refresher course is provided on www.citiprogram.org.

Human subjects training is not required for studies that are considered Not Human Subjects Research (NHSR).

Proof of human subjects training from outside Institutions are accepted in lieu of CITI certification. For CITI educational requirements, refer to the OPRS website at: http://oprs.usc.edu/citi.

Good Clinical Practice (GCP) Course

GCP training has been required for all PIs and staff on studies meeting the NIH definition* of clinical trials since 2015.

2016 regulations mandate a GCP "refresher course" be completed every three years after completion of the initial training.

Although GCP training is primarily intended for study staff who collect data through intervention or interaction with a subject, or have access to private identifiable information anyone on the study team may be asked to take it at the request of the IRB.

USC offers a GCP online training program that includes refresher courses through CITI. For more information, contact the OPRS at (213) 821-1154 or visit the OPRS website: http://oprs.usc.edu/citi.

*A clinical trial is a "*research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes*".

HIPAA Course

The "Privacy Rule" also known as the Health Insurance Portability and Accountability Act establishes minimum Federal standards for safeguarding the privacy of individual's identifiable health information. For more information, refer to Section 11.5 – Health Insurance and Portability Accountability Act (HIPAA).

USC researchers who use/access protected health information are required to complete USC's HIPAA online educational program. For detailed information regarding HIPAA policies, forms, procedures, and to access the online educational program, visit the Office of Compliance's website: http://ooc.usc.edu/hipaa-privacy-regulations.

13.4 Professional Qualifications of PIs

No person is allowed to perform medical procedures at USC without being properly credentialed /licensed and have the required hospital privileges. Persons with a foreign medical degree/license are not credentialed /licensed to perform medical procedures in California.

Credentialing for licensure is the responsibility of the Office of Compliance.

The HSIRBs may require new PIs (first time submitters) to provide a copy of their curriculum vitae and medical license, and if necessary, additional supporting information to document that the investigator is qualified to conduct the research activity.

13.5 USC Investigators Conducting Multi-Site Research

Procedures for USC Investigators conducting multi-site, research at non-USC sites or acting as the designated coordinating center are described below. This only applies to full board and expedited studies.

For additional information, refer to Section 4.3 – Responsibilities Defined under the FWA.

The following procedures are for review and oversight of multi-site, non-exempt research.

IRB Review of Resource Adequacy

Once an investigator submits a new IRB application, it undergoes an administrative review by an IRB staff reviewer to ensure the application is complete. Upon initial review of the application, the staff reviewer ensures that the PI has listed any organizational units/departments/committees that are involved in the conduct of the research and that the investigator has secured approval from each department. If there are any organizational units that have not been listed, or the PI has not secured appropriate approval, the staff reviewer will send correspondence via iStar to the PI informing them that approval from the organizational units/departments/committee must be obtained prior to IRB approval.

Once a new study is submitted to the Full Board for review, it is the IRB committee's responsibility to ensure that the Investigator has listed the organizational units/departments/committees that are involved in the conduct of the research in the IRB application and that the investigator has secured approval from each organizational unit/department/committee. If during the IRB's consideration of the study the investigator has not obtained approval, the IRB must stipulate that such approval be obtained prior to IRB approval. Additionally, the IRB considers whether resources are adequate to conduct proposed research. For example, if the research involves specialized medical equipment or staff, the IRB may ask the investigator to confirm that such resources are available to conduct the research.

Non-USC / Non-Engaged Research Sites in Multi-Site Research

USC investigators who conduct non-exempt research at non-USC sites are required to obtain permission to conduct the study when the site itself is not "engaged" (refer to Section 4.5 – Engagement in Research).

A permission letter is necessary to ensure that relevant information regarding the proposed research has been shared with, and agreed to, by the appropriate agency/institutional authority. The institutional authority is someone who has signatory authority (such as a Principal, clinic Director, school board Chair, or superintendent) for the organization. The site contact information in addition to the permission letter must be uploaded to the USC IRB application. A template letter is available on the IRB website: Research Site Permission Template.

Waivers may be granted for minimal risk research and certain social behavioral studies.

Common Reasons for Waiving the Site Permission Requirement:

- Obtaining site permission is not practicable
- The research is being conducted at a large number of sites
- The data being collected is anonymous
- The behavior studied is not related to site/place
- The study involves less than minimal risk

Common Reasons for NOT Waiving the Site Permission Requirement:

- Research involves greater than minimal risk
- Safety concerns for participants or researchers
- Permission is required by the site (such as LAUSD, health clinics, hospitals)
- Amount of time and effort required to obtain permission is minimal, and a courtesy
- Subjects are vulnerable and permission letters are usually required (children, cognitively impaired populations) (See Chapter 14 – Vulnerable Subject Populations)

Multicenter Clinical Trials and Centralized IRB Review Process

A centralized IRB review process involves an agreement under which multiple study sites in a multicenter trial rely in whole or in part on the review of an IRB other than the IRB affiliated with the research site.

Section 56.114 (21 CFR 56.114, Cooperative Research) provides that, "institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort."

NIH Single IRB (sIRB) for Multi-Site Research

The National Institutes of Health (NIH) has mandated the use of a single IRB for multi-site research. The policy will go into effect September 2017 for future research funded by NIH with the purpose of streamlining the IRB process and easing administrative burden. (See Appendix N - Requisites for Single IRB). NIH Policy on the Use of a Single IRB (sIRB)

USC as Coordinating Center for Multi-Site Research

The term "study coordinating center" may refer to studies ranging from a data center focused on the aggregation, management, and analysis of data from multiple sites to a

phase III, greater than minimal risk study conducted at a large number of institutions internationally. Likewise, the responsibility of an investigator and coordinating center will vary. The nature of the study and the coordinating center's role in the project, will determine the reporting and monitoring considerations required by the Food and Drug Administration (FDA). For additional information regarding the responsibilities of coordinating centers, please refer to the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines.

If a USC PI is the lead investigator for a multi-site study and USC is the coordinating center, an adequate plan for the management of information from all sites relevant to the protection of participants is required. This plan should include:

- A description of the types of events to be reported (such as unanticipated problems involving risks to subjects or others, adverse events, noncompliance, significant new information or findings, required protocol modifications)
    - When the reports must be made and sent to the coordinating center
    - How to make the reports to the coordinating center (specific forms, IRB forms)
    - To whom the reports should be made (such as lead investigator, other)
    - The process for disseminating these reports to the non-USC sites
- A description of how the coordinating center will ensure that each participating non-USC site has obtained IRB approval before initiating research activities

It is the Lead PI's responsibility to submit an adequate management and communication plan in iStar for research being conducted at multiple sites.

Data Coordinating or Stastical Center Responsibilities

This type of application places emphasis on how the Lead PI will assume responsibility for collection, storage, management and statistical analysis of data collected.

- Designing data forms
- Providing instruction on use of the forms
- Managing data and statistical analysis
- Overseeing secure data transmission and storage
- Protecting confidentiality of data and ensuring its integrity

Helpful inks

- OHRP: "Guidance on Engagement of Institutions in Human Subjects Research" http://www.hhs.gov/ohrp/policy/engage08.html

- Individual Investigator Agreement – Sample http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/individual-investigator-agreement/index.html#

- Using a Centralized IRB Review Process in Multicenter Trials http://www.fda.gov/RegulatoryInformation/Guidances/ucm127004.htm

13.6 Investigator Conflict of Interest

The term "conflict of interest" in this policy refers to situations in which financial, or other personal considerations compromise, or have the appearance of compromising, an individual's professional judgments in proposing, conducting, supervising or reporting research. Conflicts of interest include non-financial as well as financial.

(See "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought")

Conflicts of Interest may include but are not limited to the following:

- Equity (stocks or options, do not include mutual funds)
- Recruitment incentives, bonus payments, (these are prohibited)
- Consulting Fees
- Speaking Fees
- Travel Reimbursement
- Gifts
- Corporate Officer or Board of Directors

- Other Employment Relationship
- Trademarks/Copyrights
- Licensing Agreements
- Royalty Payments
- Patent Holdings

Conflicts of interest must be declared in the IRB application when the study investigators, research personnel, or their immediate family/domestic partner have a financial interest, and/or intellectual property interest in the sponsor or products used with the project, **equal to or exceeding $5,000 per year**. Investigators must also inform the IRB of relationships with the sponsor or party with economic interests in the research such as consultation agreements, speaker services or management roles. When these relationships exist, the potential conflict of interest is reviewed by the Office of Compliance.

Researchers who are proposing or have received HHS (including NIH, CDC, HRSA, and AHRQ) support must also make an annual disclosure of all financial interests related to their institutional responsibilities to USC, regardless of whether any of these interests give rise to a conflict of interest related to their research. The annual disclosure must be completed before a proposal can be submitted to HHS, and any identified conflicts must be managed before an account can be established. In addition, all HHS-funded investigators must complete training on conflicts of interest once every four years.

All potential or actual conflicts of interest must be disclosed online using the diSClose system.

The Conflict of Interest in Research Committee (CIRC) evaluates disclosed (or knowingly withheld) conflicts of interest.

For additional information regarding Conflict of Interest, refer to:

- USC Office of Compliance website: http://ooc.usc.edu/
- USC Conflict of Interest in Research Policy: http://policies.usc.edu/p4acad_stud/conflic_interest_research.html

- USC Institutional Conflict of Interest Policy: http://ooc.usc.edu/sites/ooc.usc.edu/files/pdfs/Institutional-Conflict-of-Interest-in-Research-Policy.pdf
- USC Conflict of Interest in Professional and Business Practices: http://ooc.usc.edu/conflict-interest-professional-and-business-practices
- USC Relationships with Industry Policy: http://ooc.usc.edu/relationships-industry
- diSClose website: https://disclose.usc.edu/
- diSClose Training Videos: http://ooc.usc.edu/diSClose-training-videos

13.7 Faculty Advisor's Assurance for Student Investigators

When a student investigator is listed as the PI on the IRB application, a faculty member must also be listed as the faculty advisor. The faculty advisor electronically approves/ signs-off on the IRB application to indicate they have reviewed the submission, it is ready for IRB review, and the faculty advisor assumes responsibility for oversight of the student's research.

The faculty advisor certifies that the student investigator is knowledgeable about IRB policies, and applicable federal regulations governing research with human subjects, and has sufficient training and experience to conduct the study in accordance with the approved protocol.

The Human Subjects Protection Program (HSPP) has implemented a mandatory human subjects education program (CITI) for all investigators, including students. Faculty advisors are considered key personnel and are required to complete CITI (see the IRB/OPRS websites for more information). Faculty advisors must ensure that student investigators and all other key personnel have completed the Human Subjects and the Health Insurance Portability and Accountability Act (HIPAA) Programs when required.

The faculty member is also responsible for the scientific quality of the student research project submitted to the IRB.

13.8 Student Investigator's Assurance

A student investigator must electronically sign the IRB application. This means they agree to meet with their faculty sponsor on a regular basis to monitor study progress. If the faculty advisor is away, the student investigator will meet with the arranged alternate faculty advisor who will assume responsibilities.

The student investigator is expected to be familiar with the policies contained in USC's Federalwide Assurance(s). Prior to initiating research activities, student investigators must complete the Human Subjects Education Program (CITI).

13.9 Failure to Submit a Project for IRB Review

There are significant implications to engaging in human subjects research activities subject to IRB review, without first obtaining IRB review and approval. USC policy requires investigators to have obtained IRB approval prior to the initiation of any research activities. If an investigator begins a project not intending to contribute to generalizable knowledge but later finds that the study results could be published or presented, IRB approval must be obtained before publishing or presenting the data. Undergraduate honors papers, Masters theses, and dissertations that are human subjects research require IRB review.

The IRB may not approve applications where an investigator circumvents IRB policies and procedures by collecting data as a "non-research" activity, and then subsequently applying for IRB approval to analyze the data as existing data. It is in the investigator's best interest to carefully consider the likelihood of the data being used for future research purposes, and err on the side of caution in seeking IRB approval prior to commencing the work.

13.10 Scientific / Research Misconduct

The University of Southern California is committed to maintaining an environment that promotes high ethical standards in the conduct of research. The University does not tolerate misconduct in any aspect of research and will deal with misconduct associated with research forthrightly in accordance with academic due process, and with respect for practices commonly accepted within the scientific community.

At USC, allegations of research misconduct, involving human subjects, are reported by the IRB to the Vice President of Research, the Executive Director of the Office for the Protection of Research Subjects (OPRS), and the Senior Associate Vice President of the Office of Compliance, and General Counsel Office for further action (scientific misconduct is not necessarily under the sole purview of the IRB).

If a USC investigator does not conduct research responsibly, according to federal regulations or University policy, the investigator is subject to both federal and USC consequences. USC is committed to fairly and uniformly investigating and reporting all instances of alleged or apparent misconduct involving research by members of the University community, regardless of the funding source. For information on how these issues are handled by the University, refer to the USC "Policy on Scientific Misconduct."

The *Responsible Conduct of Research* section of the HSPP websites contains links to information on the responsible conduct of research and tutorials on how to conduct research responsibly and ethically [http://oprs.usc.edu/education/rcr/].

Scientific misconduct is defined by the federal government for all research and all federal agencies is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Human subjects review does not include evaluation of possible scientific misconduct. Other university committees make these determinations. If there is reason to believe scientific misconduct has occurred in a human subject research project, the IRB will report it to the appropriate official.

Helpful Links:

- ORI Federal Research Misconduct Policy
  http://ori.dhhs.gov/policies/fed_research_misconduct.shtml

- NSF Research Misconduct Policy
  http://www.nsf.gov/pubs/2002/nsf02151/gpm9.jsp#930

- NIH Research Misconduct Policy
  http://grants.nih.gov/grants/research_integrity/research_misconduct.htm

- DHHS Public Health Service Policies on Research Misconduct
  http://edocket.access.gpo.gov/2005/pdf/05-9643.pdf

13.11 Resource Allocation and Ancillary Approvals

The investigator is required to document that adequate resources have been allocated for the research. In addition the department head must indicate that the submission has been reviewed to assure that the investigator has the necessary knowledge and privileges to perform the study, and that sufficient resources and adequate funds are available to perform the study as described in the submission. The IRB may not grant approval of the research until this documentation is complete.

It is the investigator's responsibility to identify all departments and organizational units that will be involved in the conduct of the research. Ancillary approvals are authorizations from units/departments/committees whose services are critical to implementation of the research. For ancillary approvals that are not coordinated through the iStar system; investigators must obtain written approval and attach it to the iStar application.

13.12 Intent to Publish Expectations

All investigators who intend to publish in an International Committee of Medical Journal Editors (ICMJE) journal must register their study in clinicaltrials.gov. The registration requirement applies to "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."

Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events."

The FDA / NIH and CMS require study registration for all "applicable clinical trials".

You must register in clinicaltrials.gov before study begins. All researchers doing health outcome studies must register in clinicaltrials.gov. For additional information about study registration for clinical trials, refer to Section 18.11 – Registration of Clinical Trials and Other Types of Research.

Helpful Links:

- Memorandum from USC Vice President of Research "ICMJE Journals Require Advanced Registration of Human Studies" https://oprs.usc.edu/files/2014/04/Registration-of-Human-Studies_4-7-14.pdf
- List of Journals Following the ICMJE Recommendations http://www.icmje.org/journals-following-the-icmje-recommendations/
- OPRS webpage "Intend to Publish your Human Subjects Research Findings?" http://oprs.usc.edu/review/publication/

13.13 Mandatory Reporting

Mandated reporters are individuals who are obligated by law to report suspected cases of child and/or elder abuse and neglect. In general, any person who has contact with children or the elderly in a professional capacity is a mandated reporter, although laws vary from state to state, as does the legal entity to which reports must be made. For the California Penal Code definition of mandated reporter see Elder Abuse and Dependent Adult Civil Protection Act Section 15630 (a) and Child Abuse and Neglect Reporting Act Section 11165.7.

Only "mandated reporters" are required to make mandatory reports of child and elder abuse. If one is not a mandated reporter, he or she need not make a mandated report.

Abuse Disclosure Notification in Consent Documents

Disclosing the obligation to report certain types of neglect and abuse in the informed consent process is only required for research projects involving mandated reporters. However, even though the requirement to report only applies to mandated reporters, Section 11166.05 broadens the scope of possible reporting beyond the mandated areas by allowing (not requiring) mandated reporters to make reports regarding children suffering from "serious emotional damage or... at a substantial risk of suffering serious emotional damage, evidenced by states of being or behavior, including, but not limited to, severe anxiety, depression, withdrawal, or untoward aggressive behavior toward self or others". This should be addressed in the informed consent process.

Elder Abuse and Dependent Adult Civil Protection Act

If a physician researcher, while conducting human subjects research, discovers or reasonably suspects that a study subject: (1) Has been the victim of a wound or other physical injury caused by a firearm (either self-inflicted or inflicted by another); or (2) Is suffering from any wound or other physical injury inflicted upon the study subject where the injury is the result of assaultive or abusive conduct, has a legal obligation to make two reports to the local law enforcement agency.

The first report must be made immediately by telephone or as soon as practically possible. The second report must be made in writing within two working days on a "Suspicious Injury Report" Form published by California's Office of Emergency Services (Form OES-920). Both the oral and written report must include the name of the injured person, if known; the injured person's whereabouts; the character and extent of the person's injuries; and the identity of any person the injured person alleges inflicted the assaultive or abusive conduct.

In the event a physician researcher becomes aware of or reasonably suspects that a study subject has been the victim of any of the injuries set forth in this policy, the physician researcher should immediately notify the IRB, the Office of General Counsel, or the Office of Compliance to ensure that the proper reports are made (California Welfare and Institutions Code 15601).

Reporting of Positive Results of Communicable Disease Testing

It shall be the duty of every health care provider, knowing of, or in attendance on, a case, or suspected case, of any of the diseases or conditions listed (click the link to Title 17, Section 2500 above) to report to the local health officer for the jurisdiction where the patient resides. Where no health care provider is in attendance, any individual having knowledge of a person who is suspected to be suffering from one of the diseases or conditions (click the link to Title 17, Section 2500 above) may make such a report to the local health officer for the jurisdiction where the patient resides.

The administrator of each health facility, clinic or other setting where more than one health care provider may know of – a case, a suspected case, or an outbreak of, disease within the facility – shall establish and be responsible for administrative procedures to assure that reports are made to the local health officer.

"Health care provider" means a physician and surgeon, a veterinarian, a podiatrist, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, a school nurse, an infection control practitioner, a medical examiner, a coroner, or a dentist.

The manner and timing of reporting obligations varies depending on the communicable disease to be reported. In the event a report may be necessary; the investigator must immediately contact the IRB or the Office of Compliance for further guidance.

Reporting Observed/Suspected Injuries in Research

This link provides information on reporting observed/suspected injuries in research: California Penal Code 11160

Child Abuse and Neglect Reporting Act

This link provides information on the child abuse and neglect reporting act: California Penal Code 11165

13.14 Investigator and Staff Safety

Investigators are ultimately responsible for the conduct and safety of their research staff (including themselves). Faculty members are also responsible for safety of student researchers. Therefore, guidance for what constitutes appropriate and professional behavior must be provided before research begins. To reduce the likelihood of risks to their research team, investigators should provide training and a written management plan for research in high risk situations or where subjects may be unpredictable (HIV/AIDs research, gang violence research, former prisoner research). A good safety plan will include rules for behavior, safety and emergency situations.

Investigators are required by regulation to report "unanticipated problems involving risks to subjects or others" to the IRB (see Section 20.2 – Unanticipated Problems Involving Risks to Subjects or Others). "Others" is widely interpreted to include members of the research team, thus IRBs must evaluate risks to study staff as well as to subjects when approving a study.

The IRB may also require safety plans/guidelines be submitted and will review the adequacy of such plans before approving the research.