Ethical Foundation of Human Research Protections

The *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* was written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to identify the basic ethical principles underlying the conduct of research involving human subjects.

More commonly known as the “Belmont Report”, this report identified the following three fundamental ethical principles that must be carefully considered to ensure the ethical practice of research involving human participants:

1. **Respect for Persons**
2. **Beneficence**
3. **Justice**

Each IRB member should be familiar with the Belmont Report and apply its ethical principles when conducting protocol review. The CITI Training Modules you will complete will cover the Belmont Report, but the following material is provided for reinforcement of the principles and for your future reference, if needed. A copy of the Belmont Report can be found in Appendix A of this manual.

**Respect for Persons**

The principle of respect for persons requires the consideration of three ethical standards. First, prospective research participants should be treated as autonomous agents capable of making an independent decision to enter into a research study. To assist participants in being prepared to make such a decision, the researcher must provide accurate information about the study as a part of the informed consent process. No pressure to participate should be applied by any involved parties, and the prospective participants or their legally authorized representative must be given the time needed to consider the information provided and decide whether to participate.

Second, additional provisions must be taken to protect prospective participants that have a diminished capacity to act as an autonomous agent. Independent cases arise when a prospective subject lacks the capacity to make an informed decision. In other cases, prospective subjects represent a class of participants that is considered to have a diminished capacity (for example, children). In both cases, additional safeguards must be in place to ensure that prospective participants or their legally authorized representative still have the opportunity to decide whether to participate.

Lastly, respect for persons dictates that the researcher should design procedures and safeguards that minimize the risk of invasion of privacy and assure confidentiality of data.

**Beneficence**

Beneficence refers to the responsibility of the researcher to maximize possible benefits and minimize possible risks. The researcher and the IRB must be able to differentiate between the possible benefits and risk of harms for the prospective participants and those for society as a whole. During the IRB review of research protocols, the risk to benefit ratio is assessed and a determination is made whether this ratio is acceptable.

St. Joseph Health (SJH) IRB classifies each study into one of two approvable risk categories:

1. **Minimal Risk**: The magnitude of harm or discomfort anticipated in the research is no greater than that encountered in daily life or during the performance of routine physical or psychological examinations or tests.
2. **Greater than Minimal Risk:** The research involves greater than minimal risk to potential research subjects. For research with minors, the following additional categories are used to classify greater than minimal risk:
   
a. **Greater than Minimal Risk WITHOUT Prospect of Benefit:** The research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject’s disorder or condition.
   
b. **Greater than Minimal Risk WITH Prospect of Benefit:** This research involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects.

**Justice**
No individual or group of participants should unduly bear the risks of research nor unfairly receive its benefits. By fairly distributing the risks and benefits of research, the researcher is able to adhere to the practice of this principle. Likewise, equitable selection of subjects is of importance. The IRB has the responsibility of reviewing any requests by researchers to exclude selected subject populations (e.g. pregnant woman).

**Regulatory Foundation of Human Research Protections**
There are several regulations and policies that govern research involving human subjects. An IRB member must apply these regulations and policies in order to determine whether proposed research plans are in compliance. The Human Research Protection Program (HRPP) Office will assist in providing relevant information to IRB members when specific regulations or guidance are implicated. Reviewing research with human subjects requires a working knowledge of the following regulations and policies:

**Office for Human Research Protections (OHRP) Common Rule**
All research involving human subjects must adhere to OHRP regulation 45 CFR 46 also known as the Common Rule. The OHRP website includes agency guidance on a variety of topics such as biological tissue banks, financial conflicts of interest, continuing review, and review of research involving prisoners or children. In addition to establishing guidelines for human subjects research, the Common Rule also addresses the conduct of research with the vulnerable populations of fetuses and pregnant women, prisoners, and children. Particular attention must be given in determining the risk to benefit ratio for these subject populations and to applying additional safeguards, which are listed in the regulations. Relevant sections of the regulations include the following areas: Pregnant Women, Human Fetuses, and Neonate (Subpart B); Prisoners (Subpart C); and Children (Subpart D).

**Food and Drug Administration (FDA)**
Clinical investigations that involve the use of a test article (e.g. drug, device, or biologic) and one or more human subjects fall under the Food and Drug Administration Human Subjects Protection regulations. Two pertinent sections of FDA regulations are 21 CFR 50 (IRB) and 21 CFR 56 (Protection of Human Subjects). Additional FDA regulations may apply, such as 21 CFR 312 (Investigational New Drugs), 21 CFR 812, 814 (Investigational New Devices), and 21 CFR 54 (Financial Disclosure by Clinical Investigators).

**HIPAA**
The Health Insurance Portability & Accountability Act, commonly known as HIPAA, is another piece of legislation that impacts the conduct of human subjects research. The HIPAA Privacy Rule regulation establishes national standards for the protection of private health information known as Protected Health Information (PHI) under this Act.
An IRB, or privacy board, is responsible for reviewing proposed HIPAA Authorization forms and requests to waive, partially waive, or alter the authorization process for research projects.

State Regulations
There are numerous California State Statutes that address the conduct of research with human subjects. These include the following sections of the California Health and Safety Code (HSC): Human Experimentation (HSC 24170-24179.5); Minimum Statutory Protection for the Citizens (HSC 24170); Human Cloning (HSC 24185-24187); Experimental Use of Drugs (HSC 111515-111545); AIDS Research Confidentiality Act (HSC 121075-121125) and Hereditary Disorders Act (HSC 124980). Additional regulations that apply to research can be found in the California Penal Code: Biomedical and Behavioral Research (Penal Code 3500) and Prisoners Rights as Research Subjects (Penal Code 3521-3523). A section in the California Civil Code requires that the HIPAA Authorization be provided in a typeface of at least 14 point (Civil Code 56.11(a)).

Ethical and Religious Directives for Catholic Health Care Services
SJH follows the Ethical and Religious Directives for Catholic Health Care Services (ERDs); therefore, the consent form must use language that allows for abstinence as a method of birth control in order to be in conformity with the Catholic Directives. The consent does not have to list abstinence as a possible method of birth control, but it cannot exclude it. In some instances, the sponsor requires language that will not allow abstinence as a method of birth control. Therefore, those studies cannot be conducted under SJH.

Sponsors
Many research projects are funded by federal, state or industry sponsors that have issued additional human research requirements. Examples of sponsors who have issued additional human research protection requirements include Department of Defense, U.S. Department of Education, National Science Foundation, Centers for Disease Control, U.S. Department of Justice, Bureau of Prisons, the National Institutes of Health, and selected NIH funded programs such as the General Clinical Research Center.

SJH Policies and Procedures
SJH has established policies and Standard Operating Procedures (SOPs) that govern human subjects research conducted by its researchers. The SOPs can be found on the SJH website at www.stjoe.org/researchSOPs.

IRB Basics
What is the role of the IRB?
The primary role of an IRB is to protect the rights and welfare of human participants. To carry out this role, the IRB is given authority to perform the following tasks:

• Approve, modify, or disapprove research protocols
• Conduct continuing reviews of already approved research protocols including but not limited to annual review, review of unanticipated problems, and serious or continuing noncompliance
• Observe and verify changes in research procedures
• Suspend or terminate approval of research protocols

Who is on an IRB?
IRB committees must be composed of at least five members and preferably have members of both genders. IRB committees are expected to have members with appropriate expertise based upon the types of research reviewed and at least one member whose primary concerns are in nonscientific areas. The nonscientific member must be present at each IRB meeting in order to comprise a quorum. At least one member must be someone whose primary concerns are in
scientific areas and at least one member must be someone who is not otherwise affiliated with a SJH hospital. If FDA clinical investigations are reviewed, IRB membership must include a physician.

Federal policy also allows IRBs to have alternate members. Alternate IRB members may be appointed as back up for more than one of the voting IRB members. These members have the same authority and responsibilities as the voting IRB members. If the voting and alternate members attend the same meeting only one individual may vote.

When does the IRB Meet?
There are two registered IRBs in the SJH Organization. Each IRB committee meets once per month according to the annually distributed schedule with each meeting lasting anywhere from 30 minutes to 3 hours depending on the number of agenda items and length of discussions.

IRB members will be provided with meeting materials approximately 1 week in advance of the IRB meeting.

What is the expected agenda volume?
An assessment is made on a case by case basis for limiting items reviewed on the agenda. Dependent on the number of items assigned on the agenda, new study submissions will generally be limited at 5 new study submissions per meeting, if feasible.

In between IRB meetings, HRPP staff facilitates expedited reviews. The fully convened IRB will be notified of these reviews in the IRB agenda.

Basic IRB Member Responsibilities
IRB members have specific responsibilities that, when met, assist the IRB as a whole in achieving its role and carrying out its authority.

1. Conducting Protocol Review

How does an IRB make a decision?
Serving on the IRB requires a commitment to actively participate in the review of research protocols. There are many issues that must be addressed before an initial or continuing research protocol can be approved. The guiding ethical principles of the Belmont report must be considered in conducting each review. The IRB must also determine that all of the eight federal criteria are met prior to approving each research protocol.

What criteria must be met for research to be approved?
The regulations dictate the criteria that must be met before the IRB can approve a research protocol.

The criteria for approval of research are set forth in the federal regulations. To approve research, the IRB should determine that all of the following criteria are met prior to issuing an IRB approval:

a. 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.

b. 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.

c. Selection of subjects is equitable. 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.

d. 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 federal regulations.

e. Informed consent will be appropriately documented, in accordance with, and to the extent required by federal regulations.

f. When the study is greater than minimal risk, clinical research, or an NIH funded/FDA regulated clinical trial, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

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

h. Where any of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect subjects.

Additional safeguards must be applied when reviewing research involving the following:
- Pregnant women, human fetuses, or neonates
- Prisoners
- Children/minors
- Decisionally challenged
- Employees or students of the researchers

What else should the IRB members consider when reviewing a protocol?
In addition to meeting federal and other institutional criteria, research proposals are reviewed for other issues that arise, such as the use of recruitment advertisements and incentives given to subjects for participation. These issues are reviewed to ensure that research subjects are not being unduly coerced or misled into participation in the research study.

SJH IRB reviews research proposals for multisite studies including sites in California and Texas. IRB review must account for local context issues in considering approval of research. SJH IRB can account for local context issues using the following mechanisms:
  a. Having members and alternates of the SJH IRB committees who are representatives of local attitudes regarding research.
  b. Using consultants as necessary in the review of research.

It is important that during the IRB review of a new project, the members separate concerns about the protocol itself and the local operational issues, which are separate from the protocol.
What determinations must the IRB make when conducting initial protocol reviews?

For information on IRB Determinations, please refer to the General IRB Process for All Submissions

Conducting Risk/Benefit Assessment

The IRB must always make a determination for all research protocols to whether a study is considered minimal risk, or greater than minimal risk.

Risk is defined as the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

- **Minimal Risk** means the probability and magnitude of harm or discomfort anticipated in the proposed research is not greater than those ordinarily encountered in daily life of the general population or during the performance of routine physical or psychological examinations or tests. Examples of procedures that typically are considered minimal risk include collection of blood, moderate exercise, medical record chart reviews, and quality of life questionnaires and surveys.

- **Greater Than Minimal Risk** is defined as research procedures that may include risk beyond that which is ordinarily encountered. Examples of procedures that are considered greater than minimal risk include maximal exercise testing, experimental drugs, biologic or medical devices, stressful psychological testing, and use of special populations.

The IRB is responsible for the following:
- Identify the risks associated with the research as distinguished from the risks of therapies the subjects would receive even if not participating in research
- Determine that the risks will be minimized to the extent possible;
- Identify the probable benefits to be derived from the research;
- Determine that the risks are reasonable in relation to the benefits to subjects, if any, and the importance of the knowledge to be gained; and
- Assure that potential subjects will be provided with an accurate and fair description (during consent) of the risks or discomforts and the anticipated benefits.

The IRB should take the following steps in making a Risk/Benefit Assessment:

**Step 1** - Identify and distinguish risks associated with:
- Procedures performed solely for research
- Procedures or therapies subjects would receive even if not in research
- Procedures that are experimental or investigational

**Step 2** - Identify the context in which research procedures are performed
- Are research procedures added to a conventional (Standard of care) treatment?
- Examples: extra blood draw at routine draw; additional time in CT scanner for research imaging; additional biopsies; longer anesthesia time to measure O2 saturation levels

**Step 3** - Consider the subject population
- Age, health status
- Are they more sensitive or vulnerable to the risks posed by the research?
- How are they identified and recruited?
- Should additional protection be in place to minimize risks and maximize benefits?
Step 4 - Minimal risk or greater than minimal Risk?

- Do the risks of the research procedures meet the federal definition of “minimal risk”? If yes, can continuing review be conducted through the expedited review procedure?

The IRB is ultimately responsible for protecting the safety, rights and welfare of human research subjects. During the review of research protocols, the IRB is responsible for ensuring that (i) risks to participants are minimized by using procedures consistent with sound research design and that do not unnecessarily expose participants to risk; and (ii) risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

In order to fulfill these two criteria, a level of scientific or scholarly review is required before the IRB can approve a research protocol. The IRB may draw on its own knowledge and expertise, or the knowledge and expertise of others, to provide this review.

Significant and Nonsignificant Risk Device Assessments

In addition to determining whether a protocol presents minimal risk or greater than minimal risk, the IRB must make a determination for all device studies where safety or effectiveness is being evaluated as to whether the device is considered Significant Risk or Nonsignificant Risk (SR/NSR).

- **Significant Risk Device:** An Investigational Device that:
  1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
  2) Is purported or represented to be for a use in supporting or sustaining human life and present a potential for serious risk to the health, safety, or welfare of a subject;
  3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
  4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject

- **Nonsignificant Risk Device:** An Investigational Device that does not meet the definition for a Significant Risk Device (21CFR 812.2(b)).

Unless the FDA has already made a risk determination for the device study, the IRB must review the sponsor’s SR or NSR determination for every investigational medical device study it reviews and modify the determination if the IRB disagrees with the sponsor. If the FDA has already made the SR or NSR determination for the device study, the agency’s determination is final. If the device already has an approved IDE, the IRB will required documentation from the sponsor that the IDE number applies to the device to be used for the study under review.

If the IRB determines the device is NSR, the IRB may approve the study using the criteria at 21 CFR 56.111. In that case the study may then begin without submission of an IDE application to FDA.

If the IRB disagrees with the sponsor’s NSR assessment and decides the device study is a SR study, the IRB will tell the clinical investigator, and where appropriate, the sponsor. The IRB may conditionally approve the study as an SR device study, but the study may not begin until FDA approves the sponsor’s IDE application, or provides a determination that the device as proposed for use in the investigation is Nonsignificant Risk.
The IRB considers the following in determining whether a device study poses a SR or NSR:

- Whether the proposed NSR device study meets the definition of “significant risk”
- The proposed use of the device as well as any protocol related procedures and tests, not just the device alone.
- The nature of the harm that could potentially result from use of the device in the intended population
- Additional information from the sponsor, if needed

IRB members should not confuse their responsibility to make an SR/NSR determination for a device study with the concept of “minimal risk”. The term “Minimal Risk” is used in the regulations in part to identify certain studies that the IRB may approve through an expedited review procedure. SR/NSR determinations are separate and distinct from Minimal Risk / Greater than Minimal Risk determinations. Some NSR studies may qualify as minimal risk and the IRB may choose to review those studies under expedited review procedures.

Humanitarian Use Device (HUD)
A Humanitarian Use Device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year.

A HUD can be approved for marketing through a humanitarian device exemption (HDE). Humanitarian Device Exemption (HDE) is a special approval given by the FDA that allows marketing a device. An HDE is given even though the efficacy of the device has not been tested or proven because it is not financially feasible to do the usual clinical testing when so few individuals are affected. Although use of a HUD is not considered “research” or “investigational” when used as approved by the FDA. The FDA requires that all such uses be approved by local Institutional Review Boards prior to use.

The IRB must conduct initial (full board) as well as continuing review (full board or expedited) of the HUD. It is the responsibility of the IRB to ensure that health care providers are qualified through training and expertise to use the device as required in the HDE Approval Order, and to ensure that patients receive the labeling information prepared by the HDE holder or, when safety and effectiveness data is being collected for a PMA, informed consent is obtained.

SR/NSR determinations do not apply to HUDs. Use of a HUD at a facility to treat or diagnose patients is not considered a clinical investigation. The HUD as such is legally marketed for use within its HDE-approved indications.

2. Conducting Continuing Review
The criteria for IRB approval are the same during continuing review as they are in initial review. The IRB will determine if the study should be terminated, amended, or approved to continue.

In conducting continuing review, the IRB should review, at a minimum: the current IRB approved protocol; a status report on the progress of the research, including the number of subjects accrued, brief summary of amendments since the last review, description of any unanticipated problems involving risks to subjects, withdrawal of subjects from the research, or complaints about the research; summary of any recent literature, findings, or other relevant information, especially about risks associated with the research; copy of the current informed consent document; and/or any proposed modifications to the informed consent or protocol.
The IRB will consider the following during continuing review:

- Any unanticipated problems involving risks to research participants
- Any new information regarding the risks and benefits to the research participants
- Research progress
- Informed consent process and use of correct approved consent
- Changes in the risk/benefit ratio
- Investigator and institutional issues
- Whether the information contained in the consent document is accurate and complete

The IRB may approve renewal of research for a defined time period no greater than one year. If additional risks to participants are identified, then the IRB may approve the renewal with additional restrictions (e.g., limiting number of research participants enrolled or requiring more frequent reporting to the IRB).

Lapse of IRB approval

A lapse in IRB approval of research occurs whenever continuing review information has not been provided to the IRB and, therefore, the IRB has not conducted continuing review and reapproval of the research by the expiration date.

In such circumstances, all research activities including intervening or interacting with subjects and obtaining or analyzing identifiable private information about human subjects must stop after IRB approval expired unless it is determined to be in the best interests of already enrolled subjects to continue participating in the research. Continuing participation of already enrolled subjects in a research project during the period when IRB approval has lapsed may be appropriate, for example, when the research interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects. Enrollment of new subjects cannot occur after the expiration of IRB approval.

The determination regarding whether it is in the best interest of already enrolled subjects to continue to participate in research after IRB approval has expired may be made initially by the investigator, BUT the investigator should submit a request for confirmation that the IRB agrees with this determination. The determination may be made by the IRB Chair or by another IRB member designated by the IRB Chair, or at a convened meeting. If the IRB determined that it is not in the best interest of already enrolled subjects to continue to participate, investigators must stop all human subjects research activities.

When continuing review of a research project does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. Lapse of IRB approval is not considered to be a suspension or termination of IRB approval. Therefore, such expirations of IRB approval do not need to be reported to OHRP as suspensions or terminations of IRB approval. However, if the IRB notes a pattern of non-compliance with the requirements for continuing review (e.g. an Investigator repeatedly or deliberately neglects to submit materials for continuing review in a timely fashion), then the IRB should determine whether such a pattern represents serious or continuing noncompliance that needs to be reported to appropriate Institutional Officials and regulatory agencies.

When IRB approval of an ongoing research project lapses and the investigator wants to continue the project, the IRB should complete continuing review for the project as soon as possible. Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred.
3. Applying Discipline and Regulatory Knowledge

**What type of expertise do IRB members need to be effective?**

IRB members must exhibit expertise and be willing to apply that knowledge in the review of research protocols. There are three primary areas of expertise that an IRB member should practice. These are as follows:

- **Specialized experience:** Many IRB members have scientific, medical, or other professional or non-professional backgrounds and are expected to apply this knowledge in the review of research. This often proves useful to the IRB in its review of research that involves vulnerable subject populations such as children, prisoners, pregnant women, or decisionally challenged persons. Other members of the IRB are members of the community and not affiliated with SJH. These members serve as a rich resource to the IRB by reflecting the interests of the community including the interests of many prospective and current research participants. In order to document the expertise of each member, IRB members must submit an updated CV, Financial Interest Disclosure and Confidentiality agreement at the time of appointment.

- **SJH policies and procedures:** The IRB member must exhibit knowledge and application of SJH policies and procedures.

- **Federal regulations:** There are several sets of federal regulations that apply to the review of research involving human subjects. It is the responsibility of the IRB member to be familiar with these regulations and understand when each set applies to protocols based upon the nature of the research. These regulations are covered in the Collaborative Institutional Training Initiative (CITI) training each IRB member completes.

4. Attending Full Review Meetings

**How important is IRB meeting attendance?**

In order for an IRB meeting to be officially convened for full review, a quorum of the majority of the IRB member roster must be present. If a quorum is not established, no final actions can be taken upon the research protocols to be reviewed at that meeting and vital research may be greatly delayed. Also, Continuing Review approvals may lapse if a quorum is unavailable.

Each IRB member brings expertise to the review of research protocols and has an important and unique contribution to make in the overall conduct of full reviews. Even if a quorum is obtained, the full review cannot be conducted without a nonscientific member, scientific members and, for FDA regulated studies, a physician.

When an IRB member is unable to attend a scheduled IRB meeting, he/she is expected to notify the HRPP Office and to contact their alternate representative so that they can attend the meeting if possible. It is important that the HRPP Office be notified early so that the alternate member has ample opportunity to review the agenda materials.

5. Avoiding IRB Member Conflict of Interest

No IRB member may participate in the review of research for which the member has a conflicting interest, except to provide information requested by the IRB.

**What constitutes IRB member conflict of interest and how is it managed?**

A conflict of interest involves any situation where an IRB member has significant personal or financial interest which has the potential to bias the design, conduct, reporting, or reviewing of the research. Examples of a conflicting interest would be if the IRB member is:

- Principal Investigator (PI);
- Co-Investigator;
• Receiving funding from the study, as listed in the study budget;
• In a supervisory role over the PI of the study (e.g. faculty advisor);
• Family member of the PI; or
• Responsible for business development at the organization (e.g. director of grants and contracting, the vice president for research, or any other person responsible for raising funds or garnering support for research).

A financial conflict of interest is defined as anything of monetary value, including, but not limited to:
• Salary or other payments for services (e.g., consulting fees or honoraria);
• Equity interests (e.g., stocks, stock options or other ownership interests, excluding any interest arising solely by reason of investment in a business by a mutual, pension, or other institutional investment fund over which the IRB member or his/her immediate family does not exercise control);
• Intellectual property rights (e.g., patents, copyrights and royalties from such rights).

IRB members should recuse themselves from participating in IRB review of a project for which the member has a conflicting interest except to provide information as requested. IRB members who have conflicting interest regarding a project, which is scheduled to undergo IRB full review, should disclose the conflicting interest to the IRB and the HRPP Office. The IRB member should recuse during the IRB vote. The conflicted member is not counted as part of the quorum.

Individuals responsible for business development, or whose role or interests might compromise the integrity of the review process, should not serve as a member of the IRB.

6. Mandatory Education Requirements

What are the IRB members’ mandatory education requirements?
SJH’s requirement for education in human subjects protection was initially implemented in response to the National Institute of Health (NIH) requirements of training. All investigators/key personnel conducting research involving human subjects, or data or biological specimens derived from them, are required to be trained in the protection of human subjects. Likewise, each IRB member is required to complete this education requirement and recertify every two years.

The requirement is met by successful completion of the CITI web-based human subjects’ protection training program. The SJH policy regarding CITI training and instructions for completing the course are found in Appendix C of this manual.

7. Handling Allegations or Reports of Noncompliance and Unanticipated Problems Involving Risks to Subjects or Others

What is the IRB member role in handling alleged or reported cases of noncompliance or unanticipated problems?
Unanticipated problems and incidents of alleged noncompliance with federal or IRB policy and procedures are periodically reported to the IRB by subjects, family members, research staff, colleagues, HRPP staff or other individuals within a SJH site or within the community. The IRB Chair, IRB Manager, and IRB members may be involved in serving on investigation committees, collecting information, interviewing respondents or complainants, and reviewing and/or inspecting research records. The IRB makes a final determination regarding whether an event is an unanticipated problem or if noncompliance occurred, and if so, what sanctions or protocol/informed consent revisions are needed.
The HRPP Office will report the incident to any oversight agencies, if applicable, and the appropriate institutional official.

8. Maintaining Confidentiality

What are IRB members’ responsibilities for maintaining confidentiality?
IRB members must maintain the confidentiality of any subject data that is presented to them in the review of research protocols. In addition, IRB members should maintain the confidentiality of all information collected from the researchers during the review. The IRB committee also handles sensitive information regarding noncompliance issues, and members are asked not to discuss these topics in their department, family, or any other outside settings. Each IRB member is asked to sign a confidentiality agreement at the time of appointment documenting the commitment to maintaining confidentiality.

9. Determining When Federally Mandated Reports are Required

When must the IRB submit reports to federal regulatory agencies?
The IRB is subject to federal requirements to report certain issues that arise in the conduct of research. The HRPP Office provides support to the IRB committee in the preparation and actual submission of such reports. Per federal regulation, the Food and Drug Administration (FDA) and/or the Office for Human Research Protections (OHRP) should be notified when any of the following are directly related to the conduct of federally funded or FDA regulated research protocol:

- Any unanticipated problem involving risks to subjects or others
- Any serious or continuing noncompliance with the regulations or requirements of the IRB
- Any suspension or termination of IRB approval for research due to noncompliance

The IRB is responsible for making a determination whether an incident meets these federal criteria for reporting to FDA or OHRP.

Member Evaluations
IRB members are evaluated on an ongoing basis by the SJH Institutional Official for Research, HRPP Staff, and IRB Chairs (when applicable). However, formal evaluations will occur annually. The goal of these evaluations is to promptly identify areas for improvement of the board members and committee composition.

The following will be assessed during the evaluations:

- Attendance (voting members are expected to attend the majority of annually scheduled IRB meetings)
- Familiarity with State, Federal, and Institutional Regulations and/or Policies
- Meeting Preparation and Participation
- Expedited Review Involvement, if applicable
- Confidentiality Agreement on file
- CV on file
- CITI Training Continuance
- Annual Conflict of Interest Disclosure on file
- Subcommittee Service, if applicable
IRB Chairs and Vice Chairs will be evaluated on the following additional responsibilities:

- Effective leadership
- Meeting management
- Reviews and assessments conducted outside of Convened meetings.

Feedback from the IRB Member Evaluations will be provided to the members via email.

**References**

**Regulations:**

45 CFR 46 (OHRP Protection of Human Subjects)
45 CFR 164 (HIPAA--Sections 154.512(i) "Standard: Uses and disclosures for research purposes" and section 154.514 all)
21 CFR 50 (FDA Protection of Human Subjects)
21 CFR 56 (Institutional Review Boards)
21 CFR 312 (Drugs)
21 CFR 600 (Biologics)
21 CFR 812 (Devices)

**Guidance:**

[FDA Guidance and Information Sheets](#)
[OHRP Policy and Guidance](#)