Texas A&M University

IRB Member: AAHRPP Site Visit Guide

Human Research Protection Program

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What am I being asked to do?

This is a general IRB member guidance document that will also help prepare you for the Association for Accreditation of Human Research Protections Program (AAHRPP) site visit. This guidance will help prepare you for an interview and contains common information that IRB members should know. If you would like additional assistance preparing for your interview, please contact Aliese Seawright (a.seawright@tamu.edu) or Denise Puga (denisepuga@tamu.edu).

What is AAHRPP accreditation?

AAHRPP uses a voluntary, peer-driven and educational model to ensure that a Human Research Protections Program (HRPP) meets rigorous standards for quality and protection. The goals of accreditation are to improve the systems that protect the rights and welfare of individuals who participate in research, and to communicate to the public the strength of an organizations commitment to the protection of human research participants.

What rules or guidelines do you follow?

The IRB follows several sets of guidelines and regulations including:

The Belmont Report: The three ethical principles that TAMU applies to all research. These principles are: 1) Respect for persons; 2) Beneficence; 3) Justice. For the full report, go to the HHS website: The Belmont Report | HHS.gov

- TAMU commits to apply the ethical standards outlined in the Belmont Report to all human subjects research regardless of funding.

- **Common Rule:** The federal regulatory framework that governs federally funded research with human subjects and codifies the ethical principles of the Belmont Report.

  - **Pre-2018 Requirement**s: The Federal Policy for the Protection of Human Subjects or the "Common Rule" was published in 1991 and includes four subparts: subpart A, also known as the Federal Policy or the "Common Rule"; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and subpart D, additional protections for children. The Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance. TAMU studies approved prior to January 2019 are subject to the pre-2018 Common Rule.
  - **Revised Common Rule:** The Common Rule was revised in January 2019 to strengthen protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research by no longer requiring continuing review for non-exempt minimal risk research. Furthermore, the consent document was amended to include a concise introductory explanation of **key information** that would be most important to individuals contemplating participation in a study. Revisions to the Common Rule took effect on January 21, 2019, and all research approved after this date are subject to the Revised Common Rule.

Office for Human Research Protections: The Office for Human Research Protections (OHRP) oversees operation of the IRB and provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP is the office to which any serious/continuing noncompliance or unanticipated problems are reported.

FDA (Food and Drug Administration): When submissions include FDA regulated drugs, devices or biologics, TAMU follows the FDA regulations for research, 21 CFR 56.

TAMU Policies and Procedures: These include TAMU specific policies as well as federal regulations. Standard Operating Procedures for the Human Research Protection Program are available here: University Rules and SAPs - Texas A&M University

Human Research Protection Program: The Human Research Protection Program (HRPP) is composed of institutional leaders, research review committees, and agents of Texas A&M University that are responsible for protecting the rights and welfare of participants in research conducted or reviewed by Texas A&M University, including Texas A&M Health and all of its locations, the School of Law, and branch campuses in Galveston and Qatar:

- HRP-101 HUMAN RESEARCH PROTECTION PROGRAM PLAN
- Toolkit – Division of Research

Does the HRPP and IRB work alone?

The HRPP consists of integrated components tasked with protecting the rights and welfare of research participants. The IRB is only one component of the HRPP but has the biggest responsibility in helping protect participants in research. Both the HRPP and the IRB communicate with, and rely on, other components of this integrated program to ensure the rights of research participants are upheld; additional components at TAMU include: the Biosafety (IBC), Animal Welfare (IACUC) and Radiation Safety programs; Export Control, Conflict of Interest (COI), and Registrar offices; Privacy and Chief Information Security officers; Sponsored Research Services and Environmental Health and Safety.

What does the IRB do? Who do IRBs protect? What is your role?

The IRB's primary objective is to protect the rights, safety, and welfare of human subjects in research. TAMU has two IRBs: Texas A&M University IRB and Texas A&M University College of Dentistry IRB. These IRBs review and approve human subjects research in accordance with the applicable guidelines and regulations listed here.

As an IRB member your duties include:

1. Attending the convened IRB meetings.
2. Reviewing the materials for all submissions on each meeting agenda, including initial submissions, amendments, continuing reviews, adverse events, noncompliance reports, and protocol deviations.
3. Reviewing all documents (the research protocol, IRB application, informed consent form, grant application, questionnaires, advertisements, and any other applicable documents for all research

proposals) and providing written recommendations and stipulations to ensure that research protocols comply with the regulations.
4. Reviewing expedited initial submissions, amendments, and continuing reviews (when assigned).

Additional information regarding the expectations of IRB members in advance of a meeting or when serving as a designated reviewer can be found here: HRP 045 SOP Member Review Expectations

What are the requirements for IRB membership?

The IRB consists of a diverse group of members with varying backgrounds to promote complete and adequate review of research activities. Federal regulations state that IRBs must be diverse, be composed of at least five members, and must include three kinds of members: scientists, nonscientists, and people not affiliated with the institution.

- **Non-Scientific Members:** The IRB must have nonscientist member present when reviewing proposed research at a meeting to ensure there is appropriate representation for those who do not have specialized knowledge in the subject matter. The member's training, background and occupation should be primarily nonscientific. Non-scientific members are expected to provide input on matters germane to their individual knowledge, expertise and experience, professional and otherwise. Nonscientific members advise the IRB if additional expertise in a nonscientific area is required to assess if research project adequately protects the rights and welfare of subjects.
- **Scientific Members:** Scientific members are expected to review assigned applications, as well as contribute to the evaluation of a research project on its scientific merits and standards of practice. These members are able to advise the IRB if additional expertise in a scientific area is required to assess if a research project adequately protects the rights and welfare of subjects.
- **Non-Affiliated (Community) Members:** Non-affiliated members are expected to provide input regarding their individual knowledge about the local community and be willing to discuss issues and research from that perspective. A non-affiliated member is also a scientific or nonscientific member and would be expected to provide input on areas germane to his/her knowledge, expertise and experience, professional and otherwise.

What is the authority of the IRB?

The IRB has the authorities to approve and disapprove research, require modifications to secure approval, to suspend or terminate IRB approval of research, and to observe, or have a third party observe, the consent process or the research.

Please be aware that no single IRB member may disapprove a study. Only the convened IRB may disapprove research.

What is ethical research?

Research must meet approval criteria as defined by federal regulations (45 CFR 46.111). This includes minimizing risk to subjects, designing sound research that does not unnecessarily expose subjects to risk. Research should advance scientific understanding and promote human welfare. Subjects should not be asked to participate in a flawed study exposing them to risk or even inconvenience.

What is the full board/convened meeting process?

All review submissions (including initial review applications, continuing review and amendment submissions, reportable new information, or study closures) are screened by HRPP staff prior to assignment to a board meeting and designated reviewers. All submitted study materials are distributed to reviewers and attending IRB members in sufficient time prior to the meeting to allow for adequate review, at least one week before the meeting. This includes the preliminary meeting agenda, a report of all approvals by non-committee (expedited) procedures since the last agenda, the previous month's minutes, any educational items, and all submitted materials including but not limited to the study proposal, consent document(s), recruitment materials, data collection instruments/measures, and investigator's brochure/drug labeling. To learn more about the process of preparing a convened IRB meeting, please visit: HRP 040 SOP IRB Meeting

The TAMU IRB uses a primary/secondary reviewer system, both of whom are responsible for leading the discussion of the study during the meeting and for completing the required checklists. All members are responsible for familiarizing themselves with the research protocol and consent document prior to voting.

Barring holidays and other conflicts, meetings are typically held on the 1st and 3rd Wednesday of each month for The Texas A&M IRB and on the 4th Thursday of each month for The Texas A&M College of Dentistry IRB.

- HRP 314 Worksheet Criteria for Approval

What motions can you make at a convened meeting?

The IRB can make a motion to approve, require modifications to secure approval, defer, suspend, disapprove, or terminate research at a convened meeting. If the IRB takes an action to require modifications in the proposed research to secure approval, or disapproves the proposed research, the meeting minutes must be in sufficient detail to show the action taken by the IRB, and the basis for requiring changes in, or for disapproving the proposed research. Additionally, any suspension or termination of approval must include a statement of the reasons for the IRB's action. Additional information pertaining to IRB motions can be found here: HRP 041 SOP IRB Meeting Conduct - Committee Review

Do you have written checklists that you can use during your review?

The HRPP has prepared written checklists for protocol review that are available to all IRB members at the HRPP Website. These checklists are based on current regulations (federal, state and institutional) and should be used when reviewing research involving: vulnerable populations (e.g., pregnant women, prisoners, children, and cognitively impaired adults); limited IRB review (a process that is required only for certain exempt research); non-significant risk devices; waiver or alteration of consent; waiver of documentation of consent; and HIPAA Waiver of Authorization.

- HRP 405 Checklist Limited IRB Review
- HRP 410 Checklist Waiver or Alteration of Consent Process
- HRP 411 Checklist Waiver of Written Documentation of Consent
- HRP 412 Checklist Pregnant Women
- HRP 415 Checklist Prisoners
- HRP 416 Checklist Children

- HRP 417 Checklist Cognitively Impaired Adults
- HRP 418 Checklist Non-Significant Risk Device
- HRP 441 Checklist HIPAA Waiver of Authorization

What is minimal risk and how is it evaluated?

According to the federal regulations [45CFR46.102 (i)], "minimal risk means 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." Risk includes not only physical risk, but also psychological, emotional, legal, social, and financial.

The IRB evaluates the study procedures to determine the risk of a study. The IRB also looks at what may be in place for a study that helps to mitigate risk, such as experience of research personnel in conducting procedures, medical care available in the event of a problem, confidentiality procedures, etc.

Minimal risk research that fits into one or more exempt categories are administratively processed by the HRPP staff. Minimal risk research that falls into an expedited category, and exempt studies requiring limited review, are designated to an IRB member for review and approval. Studies that are greater than minimal risk must be reviewed by the full board.

- HRP 314 Worksheet Criteria for Approval

What are the kinds and levels of risk?

A risk is a potential harm or injury associated with the research that a reasonable person in the subject's position would likely consider injurious. Risks can be categorized as physical, psychological, sociological, economic, and legal. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects; and to the importance of knowledge that may reasonably be expected to result from the research.

> **Minimal Risk**: the risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. These are risks that reflect background risks that are familiar and part of the routine experience of life for an average person in the general population.
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> **Greater than Minimal Risk**: The probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Research that is greater than minimal risk is reviewed at full board meetings.

What are exempt and expedited reviews, and when are they used?

If the study is minimal risk, the designated reviewer considers whether the research falls into an exempt or an expedited review categories. Only the HRPP may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt.

Expedited Review: Research that falls within the scope of one of the expedited categories of research defined by federal regulation may be reviewed via expedited review, meaning by a single IRB member (45 CFR 46.110, 21 CFR 56.110 and 38 CFR 16.110). Expedited review categories applies to research that involves no more than minimal risk: OHRP Expedited Review Categories (1998) | HHS.gov

Exempt Review: Typically research may be granted exempt status by the HRPP if all research activities involve procedures listed in one or more of the specific categories under 45 CFR 46.101(b): Exemptions (2018 Requirements) | HHS.gov

What is the difference between exempt and not human subjects research?

Certain activities have characteristics of research but do not meet the regulatory definition of human subjects research. Some studies fall in gray areas and it is difficult to determine if in fact they are human subjects research and require IRB review. To be considered research, a study must involve human subjects and be research. Below are the federal definitions of each.

Does a study involve Human Subjects?

To involve human subjects, a study must involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual OR the study must involve a living individual about whom an investigator conducting research obtains identifiable private information.

Is the activity Research?

To be considered research, the activity must be a systematic investigation including research, development, testing and evaluation, AND the activity must be designed to develop or contribute to generalizable knowledge. If a study does not meet both definitions, it is not human subjects research (NHSR) and does not require IRB review.

Who makes the not human subjects research determination?

The designated IRB reviewer makes determinations of whether or not activities constitute human subjects research

- HRP 310 Worksheet Human Research

Who can perform an administrative review of an IRB submission?

Experienced HRPP personnel designated by the HRPP Director can make exempt, not engaged, and non-human subjects research determinations (the former only after consulting with an IRB member), as well as perform other administrative reviews. Administrative reviewers can be designated the by the IRB Chair to verify study closures and responsive materials on protocols given a determination of 'Modifications Required to Secure Approval' by the IRB.

Who do you go to for help on review issues (ethical or regulatory)?

You may contact the HRPP staff or IRB Chair for assistance with any questions pertaining to your review.

What is an adverse event? What is an unanticipated problem (UAP)?

Adverse Events (AE): Any unfavorable and unintended event, including an abnormal laboratory finding, symptom, or disease associated with the research or the use of a medical investigational test article. It does not necessarily have to have a causal relationship with the research.

Unanticipated Problem (UAP): An unanticipated problem involving risk to participants or others is defined by meeting ALL 3 of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol-related documents and the characteristics of the subject population being studied;
2. Related or possibly related to participation in the research; and
3. Suggests that the research places participants or others at a greater risk of harm than was previously known or recognized.

UAPs are "unanticipated" and therefore are generally not previously identified in the consent document. Anticipated problems occurring at a greater severity or frequency than previously expected may qualify as unanticipated problems reportable to the IRB.

- HRP 024 SOP New Information Process
- HRP 029 SOP Reportable New Information
- HRP 321 Worksheet Review of Information Items

How are unanticipated problems reviewed by the HRPP and the IRB?

The IRB requires principal investigators to promptly report a summary of each UAP involving risks to subjects and others to the IRB. Upon receipt, HRPP staff will screen the report. The report, with the HRPP staff's recommendation, is then reviewed by the IRB Chair, Vice Chair, or HRPP Director who will determine whether the report likely represents an unanticipated problem.

If the reported problem clearly does not meet the unanticipated problem criteria the report will be acknowledged. All reports will also be reviewed to determine if there are issues of possible noncompliance. If initial review indicates that the report is likely an unanticipated problem involving risks to subjects or others, study documents such as the protocol and consent form will be provided to the IRB members for review prior to the convened meeting.

The IRB will consider whether the event meets all three criteria for an unanticipated problem involving risks to subjects or others. If after reviewing the information, the IRB determines that the event was not an unanticipated problem, the issue will be returned to the HRPP to be handled administratively.

What is noncompliance? What is considered serious and/or continuing noncompliance?

Noncompliance means the failure to follow the regulations governing human research, the requirements and determinations of the IRB, or the HRPP, University or System Policies rules or procedures.

> **Serious noncompliance** is such that the failure to comply could adversely affects the rights, safety, or welfare of a subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.
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> **Continuing noncompliance** is a pattern of noncompliance that suggests the likelihood that without intervention, the instances of noncompliance will recur, a repeated unwillingness to comply, or an apparent persistent lack of knowledge of how to comply.

Findings of serious and/or continuing noncompliance must be reported to regulatory authorities and the sponsor.

How is noncompliance reviewed by the HRPP/IRB?

Upon receipt of a report or allegation of noncompliance or upon identifying noncompliance as part of the review process, HRPP staff will assign the review to the HRPP Director, IRB Chair or other designated reviewer to make an assessment of whether or not immediate action is necessary in advance of the IRB meeting.

The HRPP initiates fact-finding activities in accordance with HRP 024 SOP New Information to determine whether the allegation of noncompliance is sustained. This investigation may include reviewing study documents, corresponding with the Principal Investigator and other research personnel, requesting a post-approval monitoring visit, and/or forming an investigative subcommittee. The IRB Chair/ IRB reviewer(s) may reach out to the HRPP as needed during this process. In the event that the investigation finds evidence that serious and/or continuing noncompliance has occurred, the new information will be referred to the convened IRB. If the new information requires immediate action to protect the rights and welfare of subjects in advance of the meeting, the IRB Chair or HRPP Director may suspend the research in accordance with HRP 026 SOP Suspension or Termination Issued Outside of the Convened IRB.

Who determines when serious or continuing noncompliance has occurred?

The full board determines when serious or continuing noncompliance has occurred at a convened meeting. The IRB will also determine what restrictions, conditions, or other remedial actions are necessary to resolve the noncompliance and the procedures required to prevent future occurrences. The researcher is notified in writing of the IRB's determination and of any required corrective actions. Regulatory agencies will also be notified as applicable.

What is the difference between a continuing review and an administrative check in?

Due to the Revised Common Rule, continuing review is not required for minimal risk research. HRPP policy states that all non-exempt research not requiring continuing review must still undergo an annual administrative check in. Annual administrative check in's are administratively verified by HRPP staff.

Generally, if a protocol was approved at a convened IRB meeting at initial review, it must be reviewed at a convened IRB meeting for its continuing review. However, if the research initially did not qualify for expedited review, the IRB may designate the protocol as minimal risk and determine that the protocol may undergo an expedited review process under Category 9. This determination can be made at the time of initial review or at a subsequent continuing review. Furthermore, no research may continue after approval has expired, and may only resume after the IRB has approved the continuation for that study.

- HRP 032 SOP Non-Committee Review Conduct
- HRP 322 Worksheet Administrative Check In Process

What training/education have you had as an IRB member?

The answer will be member-specific, but all IRB members are required to maintain up to date CITI certification and attend new member orientation. Additionally, HRPP staff provide educational presentations and materials as needed at the beginning of meetings.

How do you learn of new or revised policies or procedures?

Members are informed by the HRPP staff of new or revised policies or procedures at the beginning of full board meetings. New policies or procedures are also sent out via email and/or updated on the HRPP website.

Who is responsible for evaluating the scientific merit of studies?

Scientific merit is evaluated by funding agencies, at the departmental level by departmental reviewers, and by the IRB. Detailed scientific review is outside of IRB scope. However, the IRB has to assess whether or not the research is scientifically sound to ensure the risk are minimized. The Criteria for IRB Approval (46.111) specify that risks to subjects must be minimized by using sound research design, and that risks to subjects are reasonable in relation to anticipated benefits and the importance of the knowledge to be gained. To fulfill this requirement, the IRB must ensure that the investigator offers sufficient background information to support the proposed research, describes the importance of the knowledge expected to result, and provides a clear and detailed research protocol that adequately tests the proposed research hypothesis.

Who do you go to if you are feeling pressured by undue influence as a reviewer?

Typically, the first step would be to speak to the HRPP Director or IRB Chair. You may also report to the Institutional Official (IO). All individuals in the institution are required to ensure that allegations of undue

influence of the HRPP or review process are reported to the Institutional Official within 5 days of becoming aware of the allegation.

- HRP 015 SOP Undue Influence

Who is the Institutional Official (IO)? What do they do?

At Texas A&M University the Vice President for Research, Dr. Jack Baldauf, is the IO. The IO is responsible for ensuring that the human research protection program has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research; and, ensure that the IRB functions independently and that its chair(s) and members have direct access to the IO for appeal if they experience undue influence. The IO is legally authorized to represent the institution, is the signatory official for all Assurances, and assumes the obligations of the institution's Assurance. IRB membership is appointed by the IO in accordance with HRP 006 SOP Institutional Official.

As an IRB member, what do you have to do with respect to potential conflicts of interest (COI)?

Before reviewing research, IRB members are to determine whether they have a Conflicting Interest (COI) with the research. If an IRB member has a COI in connection with a review outside a meeting (e.g., expedited process), he or she is to notify the IRB/HRPP staff and return all materials so the submission can be re-assigned. If an IRB member has a COI in connection with a review of a submission for which he or she has been assigned as a primary or scientific reviewer, he or she is to notify the IRB/HRPP staff so the submission can be re-assigned. If an IRB member has a COI in connection with a review of research at a meeting, he or she is to notify the meeting chair, stay in the meeting room only to answer questions about the research, and to leave the meeting room for discussion and voting regarding that research. The IRB member with a COI will not count towards quorum.

- HRP 050 SOP Conflict of Interest of Members

How do you know if the PI or other research personnel have a COI on a study?

During the application process, investigators are prompted to disclose all interests that may be perceived as conflicting with the best interest of the participants engaged in human subjects research. The HRPP refers individual financial interests to the TAMU Conflicts of Interest Official to assists with the development of a COI management plan. Once the COI Official approves the management plan, it is shared with the IRB. The IRB has the authority to decide whether a financial interest and its management allows the research to meet the criteria for approval.

- HRP 055 SOP Financial Conflict of Interests
- Texas A&M University System Regulation 15.01.03 Financial Conflicts of Interest in Sponsored Research
- University Rule 15.01.03.M1 Financial Conflicts of Interest in Sponsored Research

How is your IRB service evaluated and do you ever receive feedback?

The IRB chair or HRPP Director evaluate the knowledge, skills, and performance of each regular and alternate IRB member on a yearly bases. The results of the evaluation are communicated to each individual IRB member. Members in need of improvement will be contacted to identify areas that need to be developed or strengthened.

- HRP 060 SOP Evaluations of the HRPP
- HRP 327 Worksheet Performance Evaluation for IRB Members

Does the IRB ever utilize consultants to assist with reviews?

The IRB invites consultants with competence in special areas to assist in the review of issues requiring expertise beyond or in addition to that available on the IRB. HRPP staff provide consultants with all documents necessary for the consultant to provide the IRB with the additional expertise needed. Information (oral or written) provided by the consultant is shared with the IRB committee, or the designated reviewer for non-committee review. Consultants are to disclose to the IRB/HRPP when the consultant, or their immediate family have a financial interest in the sponsor, product, or service being tested or are involved in the design, conduct, or reporting of the research. Consultants with a Conflicting Interest may not perform reviews for the IRB.

- HRP 051 SOP Consultant
- HRP 301 Worksheet Review Materials
- HRP 320 Worksheet Scientific or Scholarly Review

Who determines when an Investigational New Drug (IND) application is needed?

The FDA defines a drug, in part, as “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals” (section 201(g) of the Federal Food Drug and Cosmetic Act). TAMU is primarily a social and behavioral campus, and it is very rare to receive an IRB application that requires an Investigational New Drug (IND). In the rare instance that an application is received requiring an IND, the investigator is responsible for obtaining the IND number and providing it to the IRB. Studies that involve FDA-regulated products that are submitted without an IND number will be reviewed by the HRPP with respect to determining the need for an IND, based on federal requirements and the investigator's response to questions contained in the protocol. If the HRPP determines that the study does not require an IND and the IRB approves the study, the study may begin. If the HRPP determines that an IND is needed, the investigator must submit an IND application to the FDA and provide documentation of the outcome of the FDA determination (IND number) before the IRB gives approval to enroll subjects in the study.

- HRP 306 Worksheet Drugs and Biologics

When is an Investigational Device Exemption (IDE) needed?

All clinical evaluations of investigational devices, (investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices) unless exempt, must have an

approved Investigational Device Exemption (IDE) before the study is initiated. Clinical evaluation of devices that have not been cleared for marketing in the United States requires:

1. An investigational plan approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by FDA;
2. Informed consent from all patients;
3. Labeling stating that the device is for investigational use only;
4. Monitoring of the study and;
5. Required records and reports

The IDE regulations (21 CFR 812) describe three types of device studies: significant risk (SR), nonsignificant risk (NSR), and exempt studies. SR device studies must have an IDE application approved by the FDA and have IRB approval before they proceed, and they must follow all of the IDE requirements. NSR device studies must follow the abbreviated IDE requirements at 21 CFR 812.2(b), including informed consent and IRB review, and do not require submission of an IDE application to FDA.

- HRP 307 Worksheet Devices

Who makes a significant/non-significant risk determination on research involving an investigational device?

The sponsor or investigator makes the initial significant/non-significant risk (SR/NSR) device determination for research involving an investigational device. The IRB then makes its own assessment, and the device determination is documented in the minutes with the rationale used by the IRB. The IRB will notify the PI of its determination and the study may begin without submission of an IDE application to the FDA.

If the IRB disagrees with the sponsor's or PI's assessment that a device study is "non-significant risk" and determines that the study using the device is "significant risk," it will notify the PI, and where applicable, the sponsor (21 CFR 812.66) and document its determination in the IRB minutes. The study will be deferred, the sponsor or PI must apply for an IDE, and the study may not begin until the FDA approves the IDE application and the IRB approves the study. Upon receipt of FDA approval, the sponsor or PI must provide the IRB with the FDA's approval letter or conditional approval letter as part of the re-submission process.

FDA has the ultimate decision in determining if a device study is SR or NSR. If the FDA does not agree with an IRB's decision that a device study presents a NSR, an IDE application must be submitted to FDA. The FDA becomes informed of the NSR determination indirectly by the sponsor(s), who must file "abbreviated IDE requirements" {21 CFR 812.2(b).}

- HRP 418 Checklist Non-Significant Risk Device

How do you identify additional requirements from federal funding agencies?

The PI is responsible for identifying the funding source in the initial submission. During the pre-review of the IRB Application, the HRPP staff will complete the HRP 318 Worksheet Additional Federal Guidance to ensure all applicable federal criteria are met. HRPP staff will communicate to reviewers any additional criteria that must be considered during their review.

Does the HRPP have an emergency preparedness plan?

The HRPP has an emergency preparedness and response plan that addresses how continuity of operations will be maintained to ensure human participant protections during an emergency. The plan is enacted when an emergency or disaster situation impacting the HRPP has occurred, or in preparation for scenarios where a potential emergency situation is imminent (e.g., natural disaster, man-made disaster, infectious disease pandemic, etc.) and HRPP operations and/or the ability of investigators to conduct Human Research is, or is likely to be, adversely impacted. In such instances, the HRPP leadership will defer to designated institutional leadership and institution-wide disaster and emergency response planning, and limit HRPP-specific disaster and emergency response planning only to those areas of operations or human research protections not otherwise covered by institution-level plans.

- HRP 065 SOP Response Plan for Emergencies-Disasters Impacting the HRPP
- HRP 351 Worksheet Protocol Specific Emergency Disaster Risk Mitigation Planning
- HRP 352 Worksheet Additional Emergency-Disaster Review Considerations