AAHRPP Site Visit

Ochsner IRB Members: Prepare to be Interviewed!

As a member of the Ochsner IRB, you are an important part of the accreditation process. AAHRPP accreditation is a gold standard that will contribute to increased interest in research being performed at Ochsner.

Ochsner’s accreditation largely depends on these interviews. We are counting on the commitment you make as an IRB member to ensure that research participants are protected. To obtain accreditation, all interviews must be successful.

This material was created to help you succeed should you be asked for an interview. The IRB staff is also available for single or group prep sessions. In addition, educational information will be provided at the end of each panel meeting leading to the site visit. This guidance is not intended to be memorized; it is intended to focus your thinking to prepare for the interview.

1. Do you know what AAHRPP accreditation is and why Ochsner is seeking it?

   AAHRPP is the Association for the Accreditation of Human Research Protection Programs. Through the accreditation process, Ochsner’s human subject protection program will be examined and evaluated. We can also further improve our current human research protection program and attain greater public trust by demonstrating that Ochsner goes beyond minimal legal requirements in protecting research participants.

   **AAHRPP’s Mission & Vision**

   AAHRPP accredits high-quality human research protection programs in order to promote excellent, ethically sound research. Through partnerships with research organizations, researchers, sponsors, and the public, AAHRPP encourages effective, efficient, and innovative systems of protection for human research participants.

   AAHRPP, through accredited research programs worldwide, will ensure that all human research participants are respected and are protected from unnecessary harm.

2. What is the “Common Rule”? The Belmont Report? FDA? OHRP? HIPAA?

   **Common Rule:** In 1991, 16 federal departments and agencies adopted a common set of regulations, called the “Common Rule”, governing human subject research sponsored by the federal government. As is implied by its title, the Federal Policy is designed to make uniform the human subject protection system in all relevant federal agencies and departments. The Common Rule was derived from the first of four subparts of the Department of Health and Human Services (DHHS) regulations for the protection of human subjects (Subpart A- Basic HHS
Policy for Protection of Human Research Subjects). Under the Common Rule, Federal Regulations define the authority and function of the IRB.

**The Belmont Report:** The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was asked by the Congress to “identify the basic principles which should underlie the conduct of biomedical and behavioral research involving human subjects.” The Commission wrote a report commonly called the “Belmont Report”, which describes three ethical principles. These principles are: 1) Respect for person; 2) Beneficence; 3) Justice. For further information, and a link to the entire report go to: [http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm)

**FDA:** Food and Drug Administration

**OHRP:** Office for Human Research Protection

**HIPAA:** The “Privacy Rule”, also known as the Health Insurance Portability and Accountability Act went into effect April 14, 2003 ([http://www.hhs.gov/ocr/hipaa](http://www.hhs.gov/ocr/hipaa)). Its purpose is to establish minimum Federal standards for safeguarding the privacy of individuals’ identifiable health information. The law generally prohibits health care providers such as health care practitioners, hospitals, nursing facilities and clinics from using or disclosing "protected health information" without written authorization from the individual.

Ochsner is committed to conducting research involving human subjects under rigorous ethical principles. The IRBs have been established to comply with existing regulations of the federal government in accordance with U.S. Department of Health and Human Services (HHS) regulations ([46 CFR Part 46](http://www.hhs.gov/ocr/archive/46CFR46)), the Food and Drug Administration (FDA) regulations ([21 CFR 50](http://www.hhs.gov/ocr/archive/21CFR50), [56](http://www.hhs.gov/ocr/archive/21CFR56), [21 CFR 312](http://www.hhs.gov/ocr/archive/21CFR312), and [21 CFR 812](http://www.hhs.gov/ocr/archive/21CFR812). In addition, the IRBs comply with HIPAA and its Regulations as set forth in [45 CFR 160 and 164](http://www.hhs.gov/ocr/archive/45CFR160_and_164).

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

The IRBs’ main mission is to protect the rights, safety and welfare of research subjects. There are three IRB Panels at Ochsner. These IRBs review and approve human subjects research in accordance with Department of Health and Human Services (DHHS) regulations in [45 CFR 46](http://www.hhs.gov/ocr/archive/45CFR46). In addition, for studies involving products regulated by the Food and Drug Administration (FDA), the Ochsner IRB review research and comply with the requirements set forth in [21 CFR 50](http://www.hhs.gov/ocr/archive/21CFR50), [21 CFR 56](http://www.hhs.gov/ocr/archive/21CFR56), [21 CFR 312](http://www.hhs.gov/ocr/archive/21CFR312), and [21 CFR 812](http://www.hhs.gov/ocr/archive/21CFR812). In addition, the IRBs comply with HIPAA and its Regulations as set forth in [45 CFR 160 and 164](http://www.hhs.gov/ocr/archive/45CFR160_and_164).

As an IRB member, 1) You will attend the majority of convened IRB meetings; 2) Review the IRB application and informed consent form for all research proposals; 3) Review all expedited actions of the Chair and Vice Chairs and all Convened Board Meeting Minutes.
4. **Are community members heard? Are you?**

Each IRB meeting will include at least one member whose primary concerns are nonscientific, or non-affiliated. If you are a community member, please express your concerns freely.

5. **Is the IRB workload fair?**

Please answer based on your experience.

6. **Why were you chosen for IRB service or why did you choose to become a member of the IRB?**

Depending on your situation, answers to this question will vary.

7. **Do you have a written checklist for review? Written guidance? Do you use them?**

Each scientific (primary) and consent form reviewer is provided with a reviewer checklist for each type of submission – new study, amendment, and continuing review. These checklists are developed by IRB staff and the IRB Chair and are based on current regulations. The review sheets are provided to each reviewer as part of the meeting agenda packet. The review sheets will eventually be incorporated into ERSA.

8. **Do you know what minimal risk is and how it is 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 definition of minimal risk serves as the starting point for the IRB chair’s determination of the category of review. If a project meets the definition of minimal risk, and falls into an exempt or expedited category as described below, the Chair alone, Vice Chair, or designated IRB member may review and approve the project.

The categories of exempt and expedited are mutually exclusive. If the study is minimal risk, the chair considers whether the research falls into an exempt category. If the research does not fall into one of the exempt categories, then the expedited review categories are considered.

9. **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.
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.

Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).

10. What is meant by exempt and expedited and when are these categories used?

Exempt Human Subjects Research

The Ochsner IRB will review all human subjects research activities under its jurisdiction to determine whether the research meets one or more of the exemption categories described in the Federal regulations and that it complies with Ochsner’s ethical standards.

Exempt Eligibility:

Research activities involving human subjects that are exempt from the requirement that they receive IRB full or expedited review are identified in 45 CFR 46.101(b)(1)-(6), 45 CFR 406.301(a), 45 CFR 46.401(b) and 21 CFR 56.104(d). The IRB may not create new categories of this exempt research. Only the IRB Chair 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 and must contact the IRB concerning the status of proposed research or changes in ongoing research.

An Investigator may request a particular category of exemption, but the final determination of applicability will be made by the IRB.

Research may be granted exempt status by the IRB if all research activities involve procedures listed in one or more of the specific categories under 45 CFR 46.101(b). **NOTE:** These categories do not apply to research involving prisoners and categories 1-5 do not apply to FDA regulated research.

Exempt Categories [45CFR46.101 (b)]:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as ...

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless ...
(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under 45 CFR 46.101(b)(2) if...

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects...

(5) Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine...

(6) Taste and food quality evaluation and consumer acceptance studies...

Expedited Review

The Ochsner IRB will review all human subjects’ research activities under its jurisdiction to determine whether the research meets one or more of the expedited categories described in the Federal regulations.

Expedited Eligibility:

I. Federal regulations (45 CFR 46.110, 21 CFR 56.110 and 38 CFR 16.110) allow the IRB to review certain applications on an expedited basis if they meet specified criteria.

An IRB may use the expedited review procedure to review either or both of the following:

(a) Some or all of the research appearing on the Expedited Category list and found by the reviewer(s) to involve no more than minimal risk.

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

Expedited Review Categories: The IRB may use an expedited procedure to conduct initial review of research provided all research activities do not fall under any of the general restrictions, present no more than minimal risk to human subjects, and involve procedures listed in one or more of the following categories (45CFR46.110 &21CFR56.110):

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met...

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows...

(3) Prospective collection of biological specimens for research purposes by noninvasive means.
(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications)...

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). **NOTE:** Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR46101.b.2 and b.3. This listing refers only to research that is not exempt.

(6) Collection of data from voice, video, digital, or image recordings made for research purposes

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and human factors evaluation, or quality assurance methodologies. **NOTE:** Some research in this category may be exempt from the requirement that it obtain IRB approval

(8) Continuing review of research previously approved by a full IRB as follows:
   a. Where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
   b. Where no subjects have ever been enrolled (at any site, if multi-center trial) and no additional risks have been identified; or
   c. Where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (b) through (h) do not apply but the IRB has determined and documented at a convened full IRB meeting that the research involves no greater than minimal risk, and no additional risks have been identified.

Only the Chair and Vice Chair’s (or designee) normally deal with approving Expedited and Exempt research.

11. **To whom can you go to for help on regulatory or ethical review issues?**

Help is available from: 1) IRB website (https://ersa.ochsner.org) 2)IRB educational materials (distributed at the IRB meetings and at the bi-annual education suppers); 4) IRB members, Chair, Vice Chairs and staff; 5) IRB policies and procedures (distributed bi-annually via email to all members and available online at https://ersa.ochsner.org.
12. Can an Informed Consent be waived, and if so, when?

In some situations, the IRB may waive the requirement for obtaining a signed Informed Consent Document (45 CFR 46.117(c)). Investigators may request that the IRB waive the requirement for a signed written informed consent. The IRB may waive the requirement for a signed consent if it finds:

a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (the subjects would be placed at risk by documents linking them with an illegal or stigmatizing characteristic or behavior). [Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern]; or

b. The research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived the IRB may require the investigator to provide subjects with a written statement regarding the research.

Examples of types of studies that fall into the first category are survey or interview studies that contain highly sensitive questions (e.g., criminal behavior, sexual behavior).

Examples of studies that fall into the second category are mail-out surveys about topics that could not reasonably damage a participant’s reputation or employability, or be otherwise stigmatizing.

Waiver of documentation of consent may mean that no written document is provided to the subject at all, for example, in a random-dial telephone survey study. In this type of study, the telephone interview would begin with a script that includes all of the required elements of consent, but the study subjects would receive no written information about the study, either before or after the interview. The telephone script containing the elements of consent must be included in the ERSA New Study Application.

On the other hand, the waiver of documentation of consent may mean only that the subject’s signature does not have to be obtained. The regulations stipulate that the IRB chair may still require that the investigator provide the subject with a written statement about the research when granting a waiver of documentation. For example, in a mailed-out survey study or in a web-based survey, the chair may determine that it is reasonable for the investigator to provide the subjects with an Information Sheet containing all of the basic elements of consent. The Information Sheet would simply have a statement that returning the survey or questionnaire via mail or the web or responding to the interview questions would constitute the subject’s consent/agreement to participate in the research study.
13. What do you know about serious adverse events? Serious and continuing noncompliance? Unanticipated problems?

**Serious Adverse Event:** An event is defined as being *serious* if the event adversely alters the relationship between risks and benefits and includes events that either result in or require intervention to prevent:

- Inpatient hospitalization or prolongation of hospitalization
- Life-threatening reactions
- Result in persistent or significant disability/incapacity or permanent harm or disability (either physical or psychological)
- Jeopardize the subject
- Congenital anomaly/birth defect in the offspring of research participant
- Breach of confidentiality that may have a negative consequence
- Death

**Unexpected Adverse Event:** An event is defined as being unexpected if the event exceeds the nature, severity, or frequency described in the protocol or the Investigator’s Brochure

**Possibly related:** An event is defined as reasonably related to the research if it is more likely to be caused by the research procedures than not.

**Serious Non-compliance:** An action or omission taken by an Investigator that any other reasonable Investigator would have foreseen as compromising the rights and welfare of a participant.

**Continuing Non-compliance:** A pattern of repeated actions or omissions taken by an Investigator that indicates a deficiency in the ability or willingness of an Investigator to comply with Federal regulations, Ochsner IRB Policy, or determinations or requirements of the Ochsner IRB.

**Unanticipated problems** involving risks to subjects or others: Untoward events that are serious, unexpected, and reasonably related to the research.

For further information regarding Adverse Event Reporting (Internal & External), and time frame for reporting requirements, refer to the IRB Written Procedures at:

https://ersa.ochsner.org/OchsnerMaint/Doc/0/12AQCRG7TNR4T2HDRB99L26LCE/IRB_SOPs_August%202011.pdf
14. What are the primary concerns/issues when reviewing a consent form?

The answer to this is person dependent, but should include a review for the inclusion of the essential elements of consent.

- A statement that the study involves research;
- An explanation of the purposes of the research;
- The expected duration of the participant's participation;
- A description of the procedures to be followed;
- Identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the participant;
- A description of any benefits to the participant or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- If the research is subject to FDA regulation, a statement that notes the possibility that the FDA may inspect study records (Research is FDA regulated if it involves the use of any drugs or medical devices other than the use of approved drugs and medical devices in the course of medical practice, or if the data will be submitted to or held for inspection by the FDA.)
- For research involving more than minimal risk, an explanation as to whether any compensation is available;
- An explanation as to whether any medical treatments are available if injury occurs; If so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights;
- Whom to contact in the event of a research-related injury to the participant;
- A statement that participation is voluntary;
- A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled; and
- A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

In addition, the consent document may contain the following items when appropriate:

- A statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable;
- If the participant is or may become pregnant, a statement that the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable;
- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent;
- Any additional costs to the participant that may result from participation in the research;
• The consequences of a participant's decision to withdraw from the research;
• Procedures for orderly termination of participation by the participant
• A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant
• The approximate number of participants involved in the study.

15. What are the primary concerns when reviewing a protocol?

The answer to this is person-dependent but should include a review of the following:

• Risks to subjects are minimized
• Risks to subjects are reasonable
• Equitable selection of subjects
• Adequate provisions for monitoring data collection
• Adequate provisions to protect privacy
• Adequate provisions to maintain confidentiality
• Adequate safeguards to protect vulnerable populations (children, pregnant women, etc)

16. What constitutes continuing review and why is it done?

The IRB is required to review all non-exempt research projects at intervals appropriate to the degree of risk, but not less than once a year (45 CFR 46.109(e)). This is called "continuing review." If a project initially received expedited review and risks to subjects remain minimal, the continuing review may be expedited (reviewed by the chair, Vice Chair or designated IRB member, generally within two weeks of receipt in the IRB Office). If a project initially received full board review, the project generally requires full board continuing review. Investigators are encouraged to submit progress reports (Continuing Review forms) 1 to 2 months before expiration to allow for full board review and approval. It is the Principal Investigator's responsibility to submit an application for continuing review in sufficient time to permit the IRB chair/vice chair or full board, as the case may be, to review and approve the application prior to its expiration date. NO HUMAN SUBJECTS ACTIVITY MAY TAKE PLACE AFTER THE EXPIRATION DATE unless there is an over-riding safety concern. Investigators must submit a request in writing, by telephone or email for IRB approval to continue studying subjects currently on the trial, and continue data analysis. Continuing review information should be submitted on the Progress (Continuing Review) Report Form in ERSA.

17. Do you think IRB reviews are fair? Correctly done?

Response to this question will vary depending on the individual’s experience.