I. Introduction

Ochsner has adopted these Institutional Review Board (IRB) Written Procedures to ensure the protection of the rights and welfare of human subjects participating in research conducted under the authority of the institution. These supersede previous versions and collections of policies for the IRB.

Institutional Authority Under Which the IRB is Established and Empowered (45 CFR § 46.103)(21 CFR § 56.109(a))

The IRB (hereinafter called the “Board”) is one or more standing Panels of Ochsner (hereinafter called the Institution). The Board acts under the authority of the CEO.

A. Purpose of the IRB

The purpose of the Board is to protect the safety, rights and welfare of humans who are subjects of research. The Board shall review and has the authority to approve, disapprove, or require modifications to all research activities involving human subjects.

The Board has adopted these Written Procedures to comply with the United States Department of Health and Human Services (DHHS) Regulations on research with human beings (www.ecfr.gov, Title 45, Part 46), the United States Food and Drug Administration (FDA) Regulations on research with human beings (www.ecfr.gov, Title 21, Parts 50 & 56), and, when applicable, the International Conference on Harmonization (ICH) “Guidance for Industry- E6 Good Clinical Practice: Consolidated Guideline” (http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf).

The institution wants to promote and encourage research while protecting human subjects. Administratively, the IRB is charged with protecting human subjects, and reports directly to the Executive Vice President & Chief Academic Officer, as does Research Operations, from which the IRB is independent.

Revision History for Auditors

Sep 2012 Updated weblinks. “Office of Research Operations” changed to a generic term, “Research Operations” so revisions as its name changes over time will not be necessary.


B. Statement of Ethical Principles

The Board is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled, *The Belmont Report; Ethical Principles and Guidelines for the Protection of Human Subjects of Research* ([http://www.hhs.gov/ohrp/policy/belmont.html](http://www.hhs.gov/ohrp/policy/belmont.html)).

The Board subscribes to the basic generally accepted principles governing research, as outlined in the Belmont Report: Respect for Persons, Justice, and Beneficence.

The ethical guidelines of the Belmont Report are considered in the review of all research activities, including informed consent, risk/benefit analysis and the selection of subjects for research. The Board strives to maintain sensitivity to community attitudes and to take into consideration the racial and cultural backgrounds of research subjects.

II. Authority of the IRB

A. Scope of Authority Defined

Under the terms of Ochsner’s Federal Wide Assurance (Number FWA00002050), entered into with the DHHS (Department of Health and Human Services) Office for Human Research Protections (OHRP), Ochsner has given the Board the authority to protect all human subjects involved in research at Ochsner, or in all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:

1. The research is sponsored by the institution, or
2. The research is conducted by or under the direction of any employee or agent of the institution in connection with his or her institutional responsibilities, or
3. The research is conducted by or under the direction of any employee or agent of the institution using any property or facility of the institution or
4. The research involves the use of the institution’s non-public information to identify or contact human research subjects or prospective subjects.

Ochsner has entered into both Inter-Institutional Agreements and Cooperative Agreements that expand upon defined scope of authority. These documents may be found in the FWA documents located at http://ochpoint/academics/research/IRB/SitePages/fwa.aspx

B. Duty to Report Undue Influence

The IRB review process and the implementation of policies and procedures are to be conducted objectively and without undue influence over deliberations or process. Individual IRB members, whether employed by the institution or an affiliate or community members, have both the obligation and right to report any undue pressure upon them to make decisions at the convened IRB meetings that would favor an individual investigator or the institution over the welfare and safety of the research subject.

Reports regarding undue pressure of an IRB member can be made orally or written (with or without identity) to any of the following:

- Executive IRB Chair
- Vice President for Research

Revision History for Auditors

11/15/2012 “Appendix 7” changed to http://ochpoint/academics/research/IRB/SitePages/fwa.aspx

3/20/2003 “Cooperative Amendments” changed to “Cooperative Agreements” to correct a typo.
• The Director of Ochsner's Office of Research Integrity
• Chief Academic Officer

The Director of Ochsner's Office of Research Integrity will be informed by the individual that has been made aware of undue influence of an IRB member and will be responsible for an official investigation of the reported undue pressure. In a timely manner, the Director of Ochsner's Office of Research Integrity will inform the IRB member of the investigation findings and actions taken to alleviate the undue pressure. Outcome of the review will be documented, the complainant provided with a response, and a corrective action plan instituted if deemed necessary.

Revision History for Auditors
11/15/2012 Added “Chief Academic Officer” to the list of people who can receive reports regarding undue pressure on an IRB member

C. Authority of the Board to Act on Proposed Studies

The Board has authority to approve, require modifications in (to secure approval) or disapprove all research activities involving human subjects. This can be done by either the Ochsner IRB Board or any other IRB Board that is on the Ochsner Federal Wide Assurance. The statutory bases for these authorities are as follows:

a. DHHS regulations pertaining to rights and welfare of subjects and/or patients.

b. U.S. Food and Drug Administration (FDA) regulations pertaining to rights and welfare of subjects and/or patients participating in research involving investigational drugs, devices or biologics.

D. Authority to Require Progress Reports and to Oversee the Study

The Board has the responsibility and the authority to review progress of studies at least yearly and more often when deemed necessary. The Board also has the authority from the institution to observe or have a third party whom the Board determines is qualified and appropriate observe the consent process or any aspect of the research. The Board has the authority from the institution to independently develop and use its own forms.

E. Authority to Suspend or Terminate Approval of Research

The Board has the responsibility and the authority to suspend or terminate approval of any study that has an unanticipated problem involving risks to human subjects, serious or continuing
noncompliance with any federal regulation or serious or continuing noncompliance with the requirements or determinations of the IRB. Such actions will be determined at a convened meeting of the full board with a quorum present and will be incorporated into the minutes of the meeting.

As expedited review cannot disapprove studies, all suspensions and terminations must be done by the convened Board. In urgent situations, the Executive IRB Chair or designee can call a special IRB meeting and/or request the institution to immediately suspend the institutional approval for a study.

When a study is suspended or terminated, the IRB will always consider actions to protect the rights and welfare of currently enrolled participants. If currently enrolled participants must be withdrawn, this will include what the plan is for making arrangements for medical care if needed off a research study. If participants do not need to be withdrawn, then the IRB will consider whether their supervision needs to transfer to another investigator/site, or continuing in the research study with additional monitoring. The IRB will consider whether research participants need to be informed of the suspension or termination.

Revision History for Auditors

4/21/2008 Added "As expedited review cannot disapprove studies, all suspensions and terminations must be done by the convened Board. In urgent situations, the IRB Chair or designee can call a special IRB meeting and/or request the institution to immediately suspend the institutional approval for a study."

4/21/2008 Added “When a study is suspended or terminated, the IRB will always consider actions to protect the rights and welfare of currently enrolled participants. If currently enrolled participants must be withdrawn, this will include what the plan is for making arrangements for medical care if needed off a research study. If participants do not need to be withdrawn, then the IRB will consider whether their supervision needs to transfer to another investigator/site, or continuing in the research study with additional monitoring. The IRB will consider whether research participants need to be informed of the suspension or termination."

F. Authority to Restrict Research

The Board has the responsibility and the authority to restrict any study it determines to warrant such action. If one aspect of a study fails to comply with federal regulations or Board requirements or determinations, the Board must restrict the study so as to restrict the portion found in noncompliance until it is brought into compliance.
III. IRB Relationships

A. The Top Administration of the Institution

The Executive IRB Chair reports directly to the Executive Vice President of System Medical Affairs & Chief Academic Officer, who reports to the CEO of Ochsner on IRB matters.

Revision History for Auditors

11/15/2012 Changed “The IRB Chair serves as the Chair of each review panel, and…” to “The Executive IRB Chair…” to reflect evolving changes in responsibilities. Removed the reference: (Http://ochweb/documents/Academics/irb/HSP_org_chart.pdf) as it is under revision

B. Other Committees and Department Chairs Within the Institution

The Board is a standing committee, which is independent of any other Committee, Department or Division of the Institution. The Board may require projects to be reviewed and approved by the Radiation Safety Committee, Biosafety Committee and other regulatory committees prior to the IRB Panel reviewing the study. It is the responsibility of each department chair, and other institution officials, to ensure that the determinations of the Board are followed. The Board requires all initial applications to be reviewed by the Principal Investigator’s Department Chair or delegate before they are submitted to the Board.

The institution may disapprove research approved by the Board. However, the institution, its departments, divisions and committees may not approve research that has been disapproved by the Board. Further, officials of the organization may not approve research that has not been approved by the IRB.

Revision History for Auditors

11/15/2012 At the end of the first paragraph, deleted “This means of institutional control to improve human subject protection will be signified by a signature line for the Department Chair on initial applications.” This is now done electronically through ERSA.

11/17/2004 Deleted “Effective April 1, 2002” as an introductory phrase to the Board requires all initial applications to be reviewed by the Principal Investigator’s Department Chair before they are submitted to the Board.
C. Research Investigators

Only Ochsner scientific staff (in the generic sense of the term, e.g., physicians, nurses, Ph.D., etc.) may serve as Principal Investigators on protocols. Protocols approved from other IRBs may have PIs from those institutions as PIs on Ochsner IRB applications. The Board recognizes only one Principal Investigator for each project. The Principal Investigator has ultimate responsibility for his/her research project and all official IRB correspondence is addressed to the Principal Investigator. No studies involving human subjects may be conducted without IRB approval.

In order to submit a protocol to the Ochsner IRB, all who are principal and sub-investigators must complete research and human protection education. Proof of the educational training must be provided to the IRB Office. For Ochsner employees, this training is the CITI course. For non-Ochsner employees it may be the CITI course or whatever their institution requires for research and human subject protection training.

Revision History for Auditors

11/3/2005 Changed “…investigators must complete the research and human protection education module as specified by the Office of Research Administration. Principal Investigators must present proof of completion of the educational module to the IRB Office” to “…investigators must complete research and human protection education. Proof of the educational training must be provided to the IRB Office. For Ochsner employees, this training is the CITI course. For non-Ochsner employees it may be the CITI course or whatever their institution requires for research and human subject protection training.” (Note: this was discussed and recommended by the Clinical Research Advisory Committee at their July 6 and November 3, 2005 meetings)

11/17/2004 Deleted the phrase “effective September 1, 2002” as serving no useful purpose years after the IRB re-engineering in 2002.

6/11/2002 Added “Protocols approved by other IRBs may have PIs from those institutions as PIs on Ochsner IRB applications.” (Note: Approved by: IRB Chair (Dr. Breault) and EVP/CAO (Dr. Pinsky) on 6/11/2002)

D. Student Research

Students, residents and fellows may not serve as principal investigators on clinical protocols. Student protocols must be submitted under Staff supervision.

E. Other Institutions

The Board may act as liaison with the IRBs of other institutions as necessary to assist in the approval of joint and cooperative projects involving multiple sites and/or investigators. The Board may agree to permit another federally sanctioned IRB to act as the IRB of record for studies to be conducted
by, or with the assistance of Ochsner personnel, at the facilities of a second institution. The Board may agree to function as the IRB of record for another investigator and/or institution if the project involves material collaboration from Ochsner personnel. Such agreements will require written letters of agreement and may include the completion of a Federal Wide Assurance, Single Project Assurance, a Cooperative Project Assurance, Cooperative Agreement, or Inter-Institutional Agreement to the Ochsner Federal Wide Assurance documentation.

1. **NCI CIRB** Ochsner follows the independent review model with the NCI CIRB. The NCI CIRB is the sole IRB of Record responsible for both study review as well as review of local context considerations. The delineation of responsibilities between the NCI CIRB and the Ochsner IRBs is specified in the [Independent Model Information](http://www.ncicirb.org) link on the NCI CIRB website. Additional operational details can be found in the NCI CIRB Handbook for Local Sites available at the CIRB Website (http://www.ncicirb.org).

2. For new studies, the NCI CIRB coordinator submits NCI CIRB studies via the ERSA website for tracking purposes. The Principal Investigator and all sub-investigators on the original submission must submit conflict of interest disclosures prior to Ochsner IRB submission. The final submission is acknowledged by the Ochsner IRB office and the approved consent form(s) is posted in ERSA for tracking purposes once the study specific worksheet approval is received from the NCI CIRB. The approved consent form(s) approval date is the date in which the NCI CIRB approves the study specific worksheet to open a new study.

3. For amendments, the NCI CIRB coordinator only submits changes to the Ochsner IRB when the amendment involves changes to the consent form. When the amendment includes the addition of sub-investigators or a change in the PI, the new investigators being added must submit conflict of interest disclosures prior to submission to the Ochsner IRB. The final amendment is acknowledged by the Ochsner IRB office and the approved revised consent form(s) is posted in ERSA for tracking purposes. The approved consent form(s) approval date is the date in which the NCI CIRB approves the amendment. The NCI CIRB approval date is retained even if there are additional changes to the local consent form(s) such as study team changes. Protocol amendments that only involve a version date change to the consent form are not submitted to the Ochsner IRB.

4. Continuing reviews are not submitted to the Ochsner IRB. The submissions of annual reports for continuing review are covered in the NCI CIRB SOPs.

5. External safety reports do not need to be submitted to the Ochsner IRB. Please refer to the following memo to Sponsors. Local potential unanticipated problems, including serious adverse events that meet the [definition of unexpected, serious and related](http://www.ncicirb.org) are reported to the NCI CIRB and the Ochsner IRB. In addition, instances of serious or continuing non-compliance are submitted to the NCI CIRB and the Ochsner IRB.
6. The NCI CIRB coordinator submits the study specific worksheet to the NCI CIRB to close the study. When the approval of the study closure is received via email by the Ochsner IRB, the Ochsner IRB office closes the study in the electronic submission system.
Revision History for Auditors

4/6/2016 Added NCI CIRB procedures

7/31/2002 Added the NCI CIRB section:
The Central Institutional Review Board (CIRB) Initiative is a pilot project sponsored by the National Cancer Institute (NCI) in collaboration with the DHHS Office of Human Subjects Protection (OHRP) to develop an innovative approach to human subjects protection for national multi-center trials in cancer. CIRB’s primary function is initial and continuing review of protocols and the local institution’s primary function is consideration of local context and oversight of local performance for these protocols. After the NCI’s Central IRB (CIRB) has approved a protocol, an OCF investigator who wishes to enroll subjects in a CIRB-approved protocol downloads the protocol, informed consent documents, and the CIRB application, from the CTSU web site and submits these documents to the OCF IRB office.
The local institutional procedure is that detailed on their website at http://www.ctsu.org/frameit.asp?url=http://www.ncicirb.org. OCF assigns the local facilitated review to the Ochsner IRB Chair or his designee among the vice-chairs of the OCF IRB Panels. This facilitated review is more than a "yea or nea" authority—the facilitated reviewer may propose/approve additions to the protocol or word substitutions in the informed consent (see next paragraph). The Ochsner IRB Chair or his designee has the option to accept the CIRB approval "as is", accept it with de minimus modifications (see below), or they may decide not to accept the CIRB review and require that the investigator submit the protocol for full IRB Panel review at OCF. If the Ochsner IRB Chair or his designee does not accept the CIRB review, they may still utilize CIRB written materials as resources for the OCF Panel review. As part of this "facilitated review", the Ochsner IRB Chair or his designee may add stipulations or local requirements to protocols, particularly to increase subjects' safety, to clarify procedures, etc, but may not delete or contradict any protocol contents. Local boilerplate additions or deletions to the informed consent, dealing with state and local law, institutional requirements, or IRB policies, may be considered.
The Ochsner IRB Chair or his designee may also make minor word substitutions or additions in the informed consent document, particularly to facilitate better comprehension by the local population, as long as the proposed changes do not alter the meaning of the CIRB approved contents. When the protocol and/or the informed consent document has only these minor or boilerplate changes (accepted with de minimus modifications by the Ochsner IRB Chair or his designee), then the study, the investigators and informed consent are considered to be approved by the CIRB with local facilitated review that involved an OCF full panel for review or entry into the minutes. OHRP has agreed that this process does not require OCF full Panel review.
Current OHRP/NCI guidance states “any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document must be justified in writing by the investigator and approved by the IRB. The justification for and approval of such deletions or modifications must be reflected in the IRB minutes. For trials sponsored by the National Cancer Institute (NCI), investigators must forward copies of such IRB-approved changes, with their justifications, to the appropriate Cooperative Group headquarters.” Therefore, if there are any changes that meet the definition of the previous paragraph, the Ochsner IRB Chair or his designee will bring their recommendations to an OCF full panel for review, with the justification for and approval of such deletions or modifications documented in the IRB minutes. This study is still considered to be approved by the CIRB with local facilitated review that involved an OCF full panel. It is recognized that this process is evolving as NCI, OHRP, and local institutions gain more experience with it. The latest rules and guidance on the CIRB website should be used if they are updated and contradict any of these written procedures. The responsibilities of OCF (through ORA and the IRB office) as detailed on the CIRB website on July 17, 2002 are to:---continued on next page
Revision History for Auditors – continued from previous page

1) Ensure the safe and appropriate performance of the research at OCF. This includes, but is not limited to, monitoring protocol compliance, any major protocol violations, and any serious adverse events occurring at the institution, and providing a mechanism by which complaints about the research can be made by local study participants or others. Any actions taken as a result of problems that are identified in these areas should be shared with the CIRB and reported as required by the procedures established by the protocol’s sponsoring Group [Therefore local adverse events that are related, serious, and unexpected must be reported to the OCF IRB office in addition to CIRB.];

2) Ensure that the investigators and other staff at the local institution who are conducting the protocol are appropriately qualified and meet the institution’s standards for eligibility to conduct research [Therefore, the local facilitated review will include the approval of the investigators];

3) Provide to the CIRB and keep current the names and addresses of local contact persons who have authority to communicate for the local IRB, such as the local IRB administrator;

4) Establish a procedure by which the local IRB will receive and review the CIRB materials for protocols to be performed at the local institution. For each CIRB reviewed protocol (approval or disapproval) that is submitted to the local IRB by a local investigator: - Review the CIRB’s materials; - Determine if there are any local context issues that must be addressed by the local IRB; and - Decide whether to accept the CIRB review or conduct a separate local IRB review. Report to the CIRB the decision about local acceptance/rejection of the CIRB review. Notify the CIRB if there is ever a change in the acceptance/rejection of the CIRB review [The details for implementing this are in the beginning of this section.];

5) As appropriate, add local restrictions, stipulations, or substitutions to CIRB approved informed consents. Deletion of CIRB approved requirements in the protocol and Informed Consent Form is not allowed, and substantive changes that affect the meaning of CIRB approved requirements are not allowed;

6) If the local IRB accepts the CIRB approval of a protocol, maintain in the local IRB records documentation of the decision and evidence that it has received and considered all CIRB material relevant to the protocol [For the most reviews done by the IRB Chair or designee, this will be documented in the letter sent to the PI and CIRB. For the occasional studies that use an OCF full panel facilitated review as noted above, this will be reflected in the panel’s minutes as well as the letter sent to the PI and CIRB.];

7) Maintain an OHRP approved Assurance for human subjects research;

8) Maintain a local IRB whose membership satisfies the requirements of 45 CFR 46;

9) Maintain a human subjects protection program, as required by the DHHS OHRP;

10) Ensure that local IRB members and local investigators receive proper initial and continuing education on the requirements related to human subjects protections;

11) Notify the CIRB immediately if there is ever a suspension or restriction of the local IRB’s authorization to review protocols; and

12) Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects.

(Note: Approved by IRB Chair (Dr. Breault) on 7/31/02 after consultation with the CIRB and approval from Dr. Pinsky to proceed with the CIRB project and adding them to our FWA.)
F. Regulatory Agencies

The Board is subject to regulation by federal oversight agencies, including the FDA, OHRP, and all other applicable federal, state and local agencies with oversight of any aspect of the research.
IV. Organization and Membership of the IRB

The Board will consist of at least two separate review panels, each with its own vice-chair(s), and chaired by the IRB Executive Chair or designee. The IRB Executive Chair will be administratively responsible to the Executive Vice President & Chief Academic Officer and will have direct access to the CEO on IRB issues. The Executive Vice President & Chief Academic Officer will be responsible for providing support for the operation of the Board panels.

A. Membership

The Ochsner IRB will be comprised of the following panels:

<table>
<thead>
<tr>
<th>Panel</th>
<th>Status</th>
<th>Type of Review</th>
<th>Number of Members</th>
<th>Number of Alternates</th>
<th>Minimum Meeting Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Active</td>
<td>Not Specialized</td>
<td>9</td>
<td>12-50</td>
<td>Monthly</td>
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<td>B</td>
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</table>

Once a panel has approved a protocol, all additional oversight and actions will generally be performed by that same panel (i.e., continuing review, expedited review, adverse event considerations) except in urgent situations. Each panel will be distinct and separate from the other panels. If an issue affects more than one panel (e.g., an investigator with studies open under more than one panel is failing to comply with regulations), each panel will address the issue separately. However, one panel may review a previous panel’s decisions, and concur with those decisions if they believe the previous panel’s decisions are appropriate.
B. Qualification of Members

The membership of each review panel will include individuals with varying backgrounds. Each panel will possess appropriate professional competence to review the diverse types of protocols that are received. The IRB will be able to ascertain the acceptability of the research in terms of institutional commitments and regulations, all applicable laws, and standards for professional conduct and practice.

Each IRB panel will include at least one member who has no affiliation with Ochsner (and no immediate family member with an affiliation with Ochsner) other than his/her IRB membership. There will be one member at every meeting whose interests and background are non-scientific. Each IRB has at least one member who represents the perspective of research participants. The unaffiliated member, the member representing the general perspective of subjects, and the non-scientific member may be the same person or they may be represented by two or three different persons. In addition, each panel that reviews FDA-regulated products (drugs, biologics, and devices) will have at least one member present who is a physician.

C. Membership Diversity

Membership is selected to assure appropriate diversity, including representation by multiple professions, multiple ethnic backgrounds, both genders, and both scientific and non-scientific members.

D. Alternate Members

An alternate member exists for each category of members of the Panel. The guidelines presented above will also pertain to the alternates who must have like qualifications to the members for whom they are the alternates.
The IRB roster will identify the primary member(s) for whom each alternate member may substitute in the categories of physician scientist, other scientist, and non-scientist. To ensure maintaining an appropriate quorum, the alternate's qualifications should be comparable to the primary member to be replaced, and attention paid to roster notations of gender and affiliation so as to maintain a quorum. The IRB minutes will document when an alternate member replaces a primary member. When alternates substitute for a primary member, the alternate member should have received and reviewed the same material that the primary member received or would have received.

**Revision History for Auditors**

Feb 2005 Removed “(medical)” from “other (medical) scientist” based on OHRP revised IRB registration forms on Feb 2005 that no longer allows a non-scientist to be interpreted as a non-medical scientist.
V. Management of the IRB

A. Chair

1. Selection and Appointment

The Executive Vice President & Chief Academic Officer appoints the Executive IRB Chair, obtaining the approval of the CEO. Only people with sufficient expertise and experience will be considered for these IRB positions. The Executive IRB Chair will select separate Vice-Chairs and/or Chairs for each Panel from among the Panel members.

Revision History for Auditors
Oct 2012 – The IRB Chair is now referred to as the Executive IRB Chair since one or more others can be the acting Chair of an IRB panel. Added that the Executive IRB Chair will select separate Vice-Chairs and/or Chairs for each Panel from among the Panel members.
Jan 2016 – replaced “Ochsner Staff” with “people” to clarify it is possible the CAO might appoint a person from outside Ochsner to be hired as the Executive IRB Chair/

2. Length of Term/Service

The Executive IRB Chair will serve three-year renewable terms. The Executive Vice President & Chief Academic Officer, considering input from Board members, investigators, and other administrators, will evaluate him or her formally on an annual basis. Results of FDA audits and communications from FDA, OHRP and AAHRPP will be considered in his or her evaluation.

Revision History for Auditors
Oct 2012 – added AAHRPP

3. Duties

a. The individual chairing the meeting has the responsibility to ensure the compliance of the Panel with all federal regulations. The Chair manages his/her review panel(s) and the matters brought before it according to FDA and DHHS regulations pertaining to the rights and welfare of research subjects. The Chair or delegate is responsible for conducting the Panel’s meetings.
b. The Executive IRB Chair advises the Executive Vice President & Chief Academic Officer of Board activities and has direct access to him for all IRB matters. The Executive IRB Chair ensures that the Executive Vice President & Chief Academic Officer is providing adequate resources and support to the IRB through the standard Ochsner annual budget process that determines the IRB budget for the following year.

c. The Executive Vice President & Chief Academic Officer is responsible for ensuring that adequate resources (i.e. staff, equipment, space) are available to the Executive IRB Chair and IRB Office to support the activities of the Executive IRB Chair and review panels.

d. The IRB Chair, Vice-Chairs and delegates will make evaluations, when necessary, to determine if research is exempt from the federal regulations for the protection of human subjects. The responsible individual determines whether the research is exempt, qualifies for expedited review or requires convened Panel review.

e. The IRB Office Staff reviews all protocol submissions to screen completeness and to triage into tentative categories for the IRB Chair to review. The IRB Office Staff are the primary persons to receive human subject calls when they have questions or concerns about a research study.

f. The IRB Administrator is responsible for supervision of the IRB office and the effective allocation of resources to various activities of the chair and review panels. The IRB Administrator will perform or delegate these duties.

Revision History for Auditors

Oct 2012 updated to clarify that IRB Chairs, Vice-Chairs or delegates can complete exempt reviews

e. The IRB Office Staff reviews all protocol submissions to screen completeness and to triage into tentative categories for the IRB Chair to review. The IRB Office Staff are the primary persons to receive human subject calls when they have questions or concerns about a research study.

f. The IRB Administrator is responsible for supervision of the IRB office and the effective allocation of resources to various activities of the chair and review panels. The IRB Administrator will perform or delegate these duties.

Revision History for Auditors

Sep 2006 change from the program manager will perform or delegate these duties to the IRB administrator will perform or delegate these duties.

4. **Removal**

After consultation with those involved in the selection of the Executive IRB Chair, the Executive Vice President & Chief Academic Officer may remove the Executive IRB Chair with concurrence of the CEO.

5. **Remuneration**

The Chair may be remunerated for services as appropriate.

**B. IRB Members**

1. **Selection and Appointment**

   The Executive IRB Chair recommends candidates for appointment as IRB Panel members or alternate members, and the Executive Vice President & Chief Academic Officer appoints them. Members will be selected in a manner that will ensure that all requirements of these procedures are followed.

2. **Length of Term/Service**

   Members serve indefinitely pending results of annual IRB member evaluations.

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**Revision History for Auditors**

10/4/2012 B.2 -removed statement that members serve a three-year renewable term and changed to indicate that members serve indefinitely pending results of annual evaluations.

3. **Duties**

   Members independently evaluate project submissions prior to the IRB meeting, participate in appropriate discussions, and vote to approve, disapprove, require modifications, or table each submission during the IRB meeting. These actions apply to: (a) initial reviews, (b) continuing reviews, (c) amendments, (d) adverse events that are serious, unexpected, and related, which may require changes in the protocol or informed consent as determined by the PI or IRB Office experienced clinical reviewer (e) serious unanticipated protocol deviations, and (f) advertisements.
Members also review and vote on other pertinent business that the Chair includes on the agenda. Experienced members may be appointed by the Chair to review research activities that qualify for expedited review.

4. Participation Requirements

Members are required to attend the meetings of their assigned IRB panel. The Chair is responsible for counseling members if they do not meaningfully and fully participate, and problematic trends in this area may result in removal from the panel. Members are required to fulfill the education requirements outlined in section C of this procedure.

Revision History for Auditors

3/28/2007 removed statement that three consecutive absences by a member may result in removal from the Panel.
10/4/2012 added statement to indicate that members are required to fulfill the continuing education requirements as outlined in section C of this procedure

5. Removal, Resignation

The Executive IRB Chair in conjunction with the IRB Office may remove members. Recommendations of the Chair, other members of the Board, investigators or other institution officials will be considered. Resigning members should notify the Chair or IRB Administrator.

Revision History for Auditors

Mar 2003 Added, “…resigning members must notify the Chair, Chair of their department if in a department…”
Sep 2006 changed resigning members must notify to should notify
Oct 2008 removed that resigning members should notify the Chair, Chair of their department if in a department, and the Executive Vice President & Chief Academic Officer of their intentions in writing. Replaced with “Resigning members should notify the IRB Chair or IRB Administrator”
Jan 2016 changed who may remove IRB members from the EVR&CAO to the IRB Executive Chair in conjunction with the IRB Office to match current practice.

C. Training of IRB Chairs and Members

1. Core Training

All IRB Chairs, members and alternates must complete a core educational program prior to serving on the IRB. The core training track consists of training in Federal Regulations and Board Operating Procedures.
Regulatory training provides the basic foundation for protecting human subjects in research, and includes FDA Regulations, HHS Regulations, the differences between them, the historical background to the Federal Regulations, and the Belmont Report.

Operational Procedure Training focuses on the Ochsner IRB policies and procedures and builds upon the content of the regulatory training by reinforcing the regulations as applied to the policy and procedures of the Ochsner IRB. Both regulatory and operational training must be completed prior to serving on the IRB.

Those serving as IRB Chair or a Panel Vice-Chair will receive additional training provided at the Vice Chairs meetings.

Revision History for Auditors

Sep 2006 changed from those serving as IRB Chair or Vice Chairs will receive additional training such as session at WIRB or by teleconference sessions with their panels, or similar training to: “…will receive additional training provided at the Vice Chair meetings

2. Orientation of New Members

In addition to core training, new members will attend two meetings as an observer prior to becoming a voting member. IRB meetings attended in the past can substitute for this. They will be oriented to the Ochsner IRB web site. Each new member will be provided a list of applicable websites from the SOP appendix. In addition, they will receive a copy of Institutional Review Board Member Handbook (Robert Amdur and Elizabeth A. Bankert), Third Edition.

Revision History for Auditors

Sep 2006 added – In addition to core training, new members will attend two meeting as an observer prior to becoming a voting member. IRB meetings attending in the past can substitute for this.

Jul 2010 Updated weblink to Ochsner Federal Wide Assurance

Oct 2012 updated reference material and core training for IRB members

3. Continuing Education

a. Board training seminars will be held periodically (at least annually)
b. Continuing education information will be distributed from time to time via the IRB Panel Agendas and / or posted to the website on an ongoing basis to keep the Board informed.

c. Ochsner provides one relevant journal subscription, such as *IRB - Ethics and Human Research* to each IRB panel member, and maintains a copy in the IRB Office.

### Revision History for Auditors

Sep 2006 deleted “IRB members are encouraged to attend national meetings on protection of human subjects”

Jul 2008 Board training seminars will be held periodically (at least twice a year) was changed to (at least annually)

### 4. Reference Materials

A list of reference materials is available on the IRB website.

### Revision History for Auditors

Oct 2012 removed references to books, periodicals and video cassettes to indicate that reference materials are available on the IRB website.

### D. Compensation of IRB Members

IRB members may be remunerated for services as appropriate.

### E. Liability Coverage for IRB Members

IRB members and chairs are protected from personal liability under the Ochsner self-insurance policy, which protects individuals serving on all Institution committees.

### F. Use of Consultants

The Board may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available on the Board. These individuals may not vote with the Board (HHS 45 CFR § 46.107(f); FDA 21 CFR § 56.107(f); ICH § 3.2.6). No individuals will be selected as a consultant if they have a conflict of interest, defined as any conflict that would exclude an IRB member from the room during discussion and voting.

Reference: Guideline: Consultant Review
G. IRB Office Support Staff

1. Support

The Executive Vice President & Chief Academic Officer will provide sufficient secretarial/administrative support and adequate resources to ensure all federal, state and Institution regulations are followed in the timely conduct of IRB matters. The commitment of staff for the IRB is evaluated on a continual basis and additional help will be provided as needed.

2. Resources

Adequate meeting and office space shall be provided for the IRB and staff. Office equipment and supplies, including file cabinets, computers with Internet access and copy machines, shall be made available to the IRB and staff.

3. Duties

The IRB staff shall prepare an agenda, maintain minutes of each IRB meeting, and store records according to regulations. The agenda, protocols, full grant applications (as applicable), consent forms, and subject recruitment materials shall be provided to each Panel Member and Alternate (as appropriate) approximately a week in advance of a meeting. The meeting material(s) is provided via email and/or ERSA. Staff shall collect all other meeting documents at the end of the meeting. Staff shall prepare, store and maintain files required by regulation and these Written Procedures.

Revision History for Auditors

Oct 2012 clarified to indicate that members receive all agenda items and review materials vie e-mail and access to the ERSA system

4. Training

The IRB Staff will complete the same core educational program provided to board members. This includes training on the regulations and the Ochsner IRB policies and procedures. The IRB staff will also be provided ongoing and continuing education opportunities (IRB seminars, workshops; distribution of continuing education information; and access to the IRB website and library).

Revision History for Auditors

Sep 2006  removed journal clubs as part of IRB staff training
H. Conflict of Interest

There will be no selection of IRB members by investigators. Individuals who are responsible for business development are prohibited from serving as members or ex-officio members on the IRB and from carrying out day-to-day operations of the review process.

Neither the sponsor, nor the investigator, or any individual involved in the conduct of the research activity under review will participate in the Panel review or conclusions except to provide information. No member may participate in the Panel’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the Panel. Members having a conflict of interest shall announce the conflict and disqualify themselves from participation during review of that research project except to provide information on request. Persons identified in this section shall leave the meeting during the discussion and the vote on any motion to approve or disapprove the research in question. When a person with a conflict of interest leaves the room he/she cannot be counted towards a quorum. If the quorum is lost, the protocol will be tabled (HHS 45 CFR § 46.107(e); FDA 21 CFR § 56.107(e); ICH § 3.2.3)). These conflict of interest exclusions for IRB members also apply to expedited review, and reviews of unanticipated problems or non-compliance.

Institutional researchers with a large volume of research studies may not be the best choice for IRB members due to the appearance of potential conflict of interests and frequent leaving of the meeting when their protocols are discussed. Rather than specifying a rigid limit, this principle will be kept in mind when the Executive Vice President & Chief Academic Officer appoints IRB members. In so far as possible, research studies will be directed to the panel least likely to have IRB members with conflict of interests regarding that study.
VI. Functions of the IRB
A. Conducting Initial Review

The Board shall follow DHHS and FDA regulations and, when applicable, ICH guidance, concerning institutional review boards and the requirements of its Written Procedures for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator, and when applicable, to the institution (HHS 45 CFR §§ 46.108; 46.103(b)(4); 46.103(b)(5); FDA 21 CFR § 56.108 (a)(1); ICH § 3.3).

Each Panel must determine that the following requirements are satisfied before it approves research:

1. Risks to subjects are minimized by:
   a. using procedures which are consistent with sound research design; and
   b. which do not unnecessarily expose subjects to risk; and
   c. whenever appropriate, using procedures already being performed on the subjects for diagnostic or treatment purposes (HHS 45 CFR § 46.111(a)(1); FDA 21 CFR § 56.111(a)(1)).
   
   Risks to subjects are reasonable in relationship to anticipated benefits, if any, to subjects; and
   the importance of the knowledge that may be expected to result.

2. In evaluating risks and benefits, the Panel should consider only those risks and benefits that may result from the research as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research. The Panel should not consider possible long-range effects of applying knowledge gained in the research (e.g. the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility (HHS 45 CFR § 46.111(a)(2); FDA 21 CFR § 56.111(a)(2); ICH § 2.2).

3. Selection of subjects is equitable, taking into account the purposes of the research and the setting in which the research will be conducted. Determine that necessary additional safeguards have been included to protect the rights and welfare of vulnerable subjects, if all or some of the subjects are children, prisoners, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons (HHS 45 CFR § 46.111(a)(3) and (b); FDA 21 CFR § 56.111(a)(3) and (b)).

4. Determine that informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with HHS 45 CFR § 46.116, FDA 21 CFR Part 50, and as outlined in these Written Procedures (HHS 45 CFR § 46.111(a)(4); FDA 21 CFR § 56.111(a)(4); ICH § 2.9).
5. Determine that informed consent will be appropriately documented in accordance with and to the extent required by HHS 45 CFR § 46.117 and FDA 21 CFR § 50.27.

6. Determine that there are adequate provisions in the research plan, where appropriate, for monitoring the data collected to ensure the safety of subjects (HHS 45 CFR § 46.111(a)(6); FDA 21 CFR § 56.111(a)(6)).

7. Determine that there are adequate provisions to protect privacy of subjects and to maintain the confidentiality of data, where appropriate (HHS 45 CFR § 46.111(a)(7); FDA 21 CFR § 56.111(a)(7); ICH § 2.11).

8. Determine that plans for subject recruitment that involve advertising or other direct contact with potential subjects outside the doctor-patient relationship are consistent with the protocol, the consent form, and FDA Guidelines found in the FDA Information Sheets.

Calculation of Initial Approval Date

The IRB calculates the date of initial IRB approval in the following manner:

When a research study is approved at a convened meeting, the date of the convened meeting is the date of IRB approval.

When the research study is approved subject to modifications at a convened meeting, the date of IRB approval is the date that the requested changes are verified by the Chair, Vice Chair, or his/her designee.

Calculation of Expiration Date

Initial Approval

The IRB calculates the date of expiration in the following manner:

When a research study is fully approved at a convened meeting, the date of expiration is based on the date of the convened meeting (minus one day). For example, if the committee meeting date is 10/17/10, then the date of IRB expiration is 10/16/11 for an annual approval or 4/16/11 for a six month approval.

When a research study is approved subject to modifications, the date of expiration is one year from the date of the convened meeting (minus one day). It is not calculated from the date that the Chair, Vice Chair, or his/her designee verifies the requested changes and grants final approval. For example, if the committee approves a research study subject to modifications on 10/17/10 and the response is verified by the Chair, Vice Chair, or his/her designee on 10/20/10, then the date of IRB approval is 10/20/10 and the expiration is 10/16/11 for an annual approval or 4/16/11 for a six month approval.
Modification Dates

The IRB calculates the date of modification approval in the following manner:

When a modification is approved through an expedited review mechanism, the modification approval date is the date that the Chair, Vice Chair or his/her designee reviews and approves the modification.

When a modification is reviewed at a full board meeting and is approved at the meeting, the modification approval date is the date of the IRB meeting.

When a modification is reviewed at a full board meeting and is approved subject to modifications, the modification approval date is the date that the response is verified by the Chair, Vice Chair, or his/her designee.

Expiration dates are maintained as the date assigned upon initial or continuing review unless the IRB determines that there has been a significant change to the risk/benefit ratio which would require a more frequent continuing review. If this change occurs, the IRB will notify the principal investigator of the study of the new expiration date. The new date must never exceed the original expiration date.

Reference: Guideline: Advertising Review

Revision History for Auditors

December 2016 – added section to clarify calculation dates for approvals and expirations

9/13/2006 A.9 – removed repeated information about additional safeguards for vulnerable subjects

7/28/2008 Removed reference to Initial Review Packet guideline being sent to the Investigator since the implementation of ERSA

VI. Functions of the IRB

B. Informed Consent

The Panel shall require that information given to subjects as part of informed consent is in accordance with HHS 45 CFR § 46.116; ICH § 4.8 and FDA 21 CFR § 50.25.

The Panel may require that information, in addition to that required by regulations, be given to subjects when in the Panel's judgment the information would meaningfully add to the protection of the rights and welfare of subjects (HHS 45 CFR § 46.109(b); FDA 21 CFR § 56.109(b); (ICH § 3.1.5)).

The Panel has authority to observe or have a third party observe the consent process and the research (HHS 45 CFR § 46.109(e); FDA 21 CFR § 56.109(f); ICH § 5.15.1). The IRB Administrator will designate a third party, such as a QA Specialist, to conduct a site visit when appropriate.

Reference: Guideline: Site Visits

The Panel shall ensure that informed consent is documented in accordance with and to the extent required by HHS 45 CFR § 46.116, FDA 21 CFR § 50.27, and ICH § 4.8, unless documentation is waived by the Panel as provided in HHS 45 CFR §§ 46.109(c) and 46.117, and in FDA 21 CFR § 56.109(c).

Consent Form Requirements

1. The consent form must be:

   • approved by the Panel;
   • signed and dated by the subject or the subject's legally authorized representative (HHS 45 CFR 46.117(a)); FDA 21 CFR § 50.27(a); ICH § 4.8.8);
   • signed and dated by the person who conducted the informed consent discussion (ICH § 4.8.8);
   • a signed and dated copy must be given to the person signing the form (HHS 45 CFR §§ 46.117(a)); FDA 21 CFR § 50.27(a); ICH § 4.8.11).

Revision History for Auditors

Oct 2004 deleted “signed and dated by the investigator” (IRB Executive Chair and Vice-Chairs deleted this requirement on 4/23/03. This was inadvertently missed in the SOP revisions since. It is now deleted after being queried by a sponsor in their review of the IRB SOPs.)
2. The consent form must be either:

- A written consent document that embodies the elements of informed consent required by HHS 45 CFR §§ 46.116 and 46.117(b)(1); or FDA 21 CFR §§ 50.25 and 50.27(b)(1); or
- A "short form" written consent document, in accordance with HHS 45 CFR § 46.117(b)(2) or FDA 21 CFR 50.27(b)(2), which states that the elements of informed consent required by HHS 45 CFR § 116 or FDA 21 CFR § 50.25 have been presented orally to the subject (or legal representative), in which case:
  - there shall be a witness to the oral presentation;
  - the Panel shall approve the written summary of what is to be said to the subject or subject's representative;
  - the subject or representative shall sign the short form;
  - the witness shall sign both a copy of the summary and the short form;
  - the person actually obtaining the consent shall sign a copy of the summary; and
  - a copy of the summary and a copy of the short form shall be given the subject (or representative).

3. Elements of Consent

Informed consent shall include the following elements:

- A statement that the study involves research; (HHS 45 CFR § 46.116(a)(1); FDA 21 CFR § 50.23(a)(1); ICH § 4.8.10(a));
- An explanation of the purposes of the research (HHS 45 CFR § 46.116(a)(1));; FDA 21 CFR § 50.23(a)(1); ICH § 4.8.10(b));
- The expected duration of the subject's participation in the research (HHS 45 CFR § 46.116(a)(1); FDA 21 CFR § 50.23(a)(1); ICH § 4.8.10(s));
- A description of the procedures to be followed (HHS 45 CFR § 46.116(a)(1); FDA 21 CFR § 50.23(a)(1); ICH § 4.8.10(d));
- Identification of any procedures which are experimental (HHS 45 CFR § 46.116(a)(1); FDA 21 CFR § 50.25(a)(1); ICH § 4.8.10(f));
- A description of any reasonably foreseeable risks or discomforts to the subject (HHS 45 CFR § 46.116(a)(2); FDA 21 CFR § 50.25(a)(2); ICH § 4.8.10(g));
- A description of any benefits to the subject or to others which may reasonably be expected from the research (HHS 45 CFR § 46.116(a)(3); FDA 21 CFR § 50.25(a)(3); ICH § 4.8.10(h));
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject (HHS 45 CFR § 46.116(a)(4); FDA 21 CFR § 50.25(a)(4); ICH § 4.8.10(i));
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, and a statement that the IRB, the Food & Drug Administration, and the Office of Human Research Protections may inspect the records (HHS 45 CFR § 46.116(a)(5); FDA 21 CFR § 50.25(a)(5); ICH § 4.8.10(n) and (o));
- For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs; and whether any medical treatments are available if injury occurs; and if
so, what they consist of, or where further information can be obtained (HHS 45 CFR § 46.116(a)(6); FDA 21 CFR § 50.25(a)(6); ICH § 4.8.10(j));

• An explanation of whom to contact for answers to pertinent questions about the research, and research subject's rights; and whom to contact in the event of a research related injury to the subject (HHS 45 CFR § 46.116(a)(7); FDA 21 CFR § 50.25(a)(7); ICH § 4.8.10(q)); and

• A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled (HHS 45 CFR § 46.116(a)(8); FDA 21 CFR § 50.25(a)(8); ICH § 4.8.10(m)).

• For applicable clinical trials, the subject will be informed of the clinical trial registry databank at www.ClinicalTrials.gov along with an explanation of what this means as required by FDA (FDA 21 CFR § 50.25(a)(9)).

When APPROPRIATE, one or more of the following elements of information shall also be provided to each subject:

• A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable (HHS 45 CFR § 46.116(b)(1); FDA 21 CFR § 50.25(b)(1));

• Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent (HHS 45 CFR § 46.116(b)(2); FDA 21 CFR § 50.25(b)(2); ICH § 4.8.10(r));

• Any additional costs to the subject that may result from participation in the research (HHS 45 CFR § 46.116(b)(3); FDA 21 CFR § 50.25(b)(3); ICH § 4.8.10(l));

• The consequence(s) of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject (HHS 45 CFR § 46.116(b)(4); FDA 21 CFR § 50.25(b)(4));

• A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue will be provided to the subject (HHS 45 CFR § 46.116(b)(5); FDA 21 CFR § 50.25(b)(5); ICH § 4.8.10(p));

• The approximate number of subjects involved in the study (HHS 45 CFR § 46.116(b)(6)); FDA 21 CFR § 50.25(b)(6); ICH § 4.8.10(t)); and

• The trial treatment(s) and the probability of random assignment to placebo or to each treatment (ICH § 4.8.10(c)).

The Panel may require that information in addition to that required in Federal Regulations (HHS 45 CFR Part 46); FDA 21 CFR Part 50 and ICH § 4.8) be given to research subjects when in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects (HHS 45 CFR § 109(b); FDA 21 CFR § 56.109(b); ICH § 3.1.5).

Reference: Guideline: Consent Forms - Required Signature Lines
4. Waiver of Documentation of Consent

The Panel, for some or all subjects, may waive the requirement that the subject or the subject's representative sign a written consent document if it finds that:

- the research presents no more than minimal risk of harm to subjects; and
- the research involves no procedures for which written consent is normally required outside the research context (HHS 46 CFR § 45.117(c)(2); FDA 21 CFR § 56.109(c)).

If the Panel waives the requirement of documentation of informed consent as identified above, it may require the investigator to provide subjects with a written statement regarding the research (HHS 46 CFR § 45.117(c)(2); FDA 21 CFR § 56.109(c)).

For research under HHS jurisdiction, but not FDA jurisdiction, the Panel may also waive the requirement for a signed written consent document if the only link between the subject and the research would be the consent document and the main risk of harm is breach of confidentiality (HHS 46 CFR § 45.117(c)(1)).

5. Waiver of Consent

The Panel may waive the requirement for informed consent per 45 CFR 46.116 (d) (or allow an alteration of some or all of the elements of informed consent) only if the Panel finds that each of the following four elements is met. This is different than waiving the requirement of documentation of informed consent, as identified directly above in Section (B)(4) of these Written Procedures.

- the research involves no more than minimal risk to subjects; and
- the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation (45 CFR § 46.116(d)).

If the research involves an FDA regulated article under 21 CFR Parts 50 and 56, the Panel may waive the requirement for prior consent only if the research involves the individual emergency use of a test article, as provided for in FDA 21 CFR §§ 50.23 (a)-(c), 56.104(c), and 56.102(d) and these Written Procedures (if such emergency use is reported to the Panel after the waiver has already occurred, the Panel will acknowledge rather than approve the waiver).

The obtaining of informed consent shall be deemed feasible unless, before use of the test article (except as provided below), both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

Revision History for Auditors

Aug 2008 In the last para of VI.B.4, changed NIH to HHS: “For research under HHS jurisdiction, but not FDA jurisdiction,…” to make clear HHS jurisdiction that the regulation applies to is broader than NIH though it includes NIH.
• The human subject is confronted by a life-threatening situation necessitating the use of the test article.
• Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from the subject.
• Time is not sufficient to obtain consent from the subject’s legal representative.
• There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

If immediate use of the test article is, in the investigator’s opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in the above paragraph of this section in advance of using the test article, the determinations of the clinical investigator shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

The documentation required in this section shall be submitted to the IRB within 5 working days after the use of the test article.

6. Revised Consent Forms

When an IRB approved consent form is submitted for revision, the IRB Panel (or expedited reviewer) will specify in the approval letter if there is to be
• no new enrollment until the revised consent with the IRB stamp is posted for use in the ERSA system
• re-consenting of all active subjects with the revised consent form

If these are not specified in the approval letter, then they are not required by the IRB. In these cases the IRB does not consider it a GCP or IRB violation to
• enroll a subject using the currently approved consent form during the brief gap time between the IRB approving a revised consent form and posting it in ERSA with the IRB stamp making it available for use.
• not re-consent a subject using the revised consent form with written signatures

For most studies, the situation described will not occur since there will not be subjects enrolling during the few day gap between IRB approval of a revised consent and the revised consent being posted in ERSA. If you submitted a consent revision to the IRB and you have a subject you want to enroll in the gap time, then check the IRB approval letter in ERSA. If your letter is not available in ERSA, call the IRB Office to find out if you are allowed to do so. If the above applies, you may call the IRB Office to ask for the revised consent to be rushed—often it can be turned around in an hour if you know there is a subject to enroll and plan ahead during the gap.

Sponsors or PIs may want to do more than the IRB requires, such as formally re-consenting when the IRB does not require it, or holding off enrollment in the gap until a revised consent is ready when the IRB did not require them to. These are acceptable and are not violations of the IRB directions.
7. Foreign Languages

When a subject does not understand English, the investigator should use an IRB approved version of the consent form in that person’s native language, that is, in a language understandable to the subject [45 CFR 46.116; ICH 4.8.6.]. It is the investigator’s responsibility to have the foreign language consent form developed and submitted to the IRB for approval.

It is not permissible to enroll a subject by using the IRB approved English consent form and formally or informally translating it into the subject’s native language. The formal, written foreign language version must be specifically approved by the IRB after consultation with an appropriate independent expert, prior to it being used to enroll subjects.

In some situations a short form approved by the IRB might be used in this setting, see section VI.B.2 above.

Revision History for Auditors

Dec 2004 Added this new section on Foreign Languages. Note: This was already clear in IRB actual practice and forms, but we noticed they were not in the written procedures. Occasional questions come up about these items, and it would be best to add this information to the procedures.

Feb 2013 Added the last para of this section
VI. Functions of the IRB

C. Emergency Research Consent Waiver

The Board may waive the requirement for informed consent for research involving emergency medical situations if it finds and documents that the requirements of 21 CFR §50.24 are met.

1. In order to approve an emergency research consent waiver study, the Board shall find and document that:
   a. The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

2. Obtaining informed consent is not feasible because:
   a. Subjects will not be able to give informed consent because of their medical condition;
   b. The intervention under investigation must be administered before consent from the subject’s legally authorized representative is feasible; and
   c. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.

3. Participation in the research holds out the prospect of direct benefit to the subjects because:
   a. Subjects are facing a life-threatening situation that necessitates intervention;
   b. Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence supports the potential for the intervention to provide a direct benefit to the individual subjects; and
   c. Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

4. The clinical investigation could not practicably be carried out without the waiver.

5. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative for consent within that window rather than proceeding without consent. The investigator will summarize the efforts made to contact legally authorized representatives and make this information available to the Board at the time of continuing review.

6. The Board has reviewed and approved informed consent procedures and an informed consent document consistent with 21 CFR §50.52. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The Board has reviewed and approved procedures and information to be used
when providing an opportunity for a family member to object to a subject’s participation in the clinical investigation consistent with paragraph 7e of this section.

7. Additional protections of the rights and welfare of the subjects will be provided, including, at least:
   a. Consultation (including, where appropriate, consultation carried out by the Board) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn.
   b. Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits.
   c. Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results.
   d. Establishment of an independent data-monitoring committee to exercise oversight of the clinical investigation.
   e. If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, then the investigator commits, if feasible, to attempt to contact within the therapeutic window, a family member of the subject who is not a legally authorized representative, and asking whether he or she objects to the subject’s participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the Board at the time of continuing review.
   f. For the purposes of this waiver “family member” means any one of the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the participant is the equivalent of a family relationship.

The Board will ensure that there are procedures in place to inform at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject’s inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. The Board shall also ensure that there are procedures in place to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject’s participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is informed about the clinical investigation, and the subject’s condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject’s legally authorized representative or family member, if feasible.

The Board will require that a separate Investigational New Drug Exemption (IND) or Investigational Device Exemption (IDE) will be obtained by the sponsor, even for marketed products.
The Board will promptly notify in writing the investigator and sponsor when it determines that it cannot approve an emergency consent exception study. The notice shall include the reasons for the disapproval.

The Board may require additional protections for subjects in an emergency research consent waiver study as appropriate.

Revision History for Auditors

none
VI. Functions of the IRB

D. Research Involving Children

When the Panel reviews research involving children, the Panel will determine which of the four following risk/benefit categories the research fits into. The Panel’s designation will be entered into the minutes for that meeting. The four possible categories are:

**Category 1 (45 CFR 46.404; 21 CFR 50.51) - Research not involving greater than minimal risk.**

For category 1 research to be approved, the Panel must find that:

(a) No greater than minimal risk is presented. 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.

(b) Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians

**Revision History for Auditors**

Feb 2016 deleted examples of minimal risk, and will defer to OHRP/FDA guidance documents for examples. Wording revised to more exactly conform to regulatory wording.

Mar 2003 deleted "550 ml in an 8 week period for adults, or for children" in the first bullet of examples of minimal risk in children. The adult reference is irrelevant since this section is specific to children’s regulations.

**Category 2 (45 CFR 46.405; 21 CFR 50.52) – Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.**

For category 2 research to be approved, the Panel must find that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians
Revision History for Auditors
Feb 2016 Wording revised to more exactly conform to regulatory wording.

Category 3 (45 CFR 46.406; 21 CFR 50.53) – Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition.

For category 3 research to be approved, the Panel must find that:

(a) The risk represents a minor increase over minimal risk;
(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
(d) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

Revision History for Auditors
Feb 2016 Wording revised to more exactly conform to regulatory wording.

Mar 2003 clarification of adding the 21 CFR reference, and deleted the sentence “Nontherapeutic research may be conducted in children with the consent of a legally authorized representative provided the following conditions are met” since this wording was not in the regulations.

Category 4 (45 CFR 46.407; 21 CFR 50.54) – Research not fitting into categories 1 through 3, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Category 4 research under HHS jurisdiction cannot be performed without review by the Secretary of the Department of Health and Human Services as outlined in 45 CFR 46.407.

Category 4 research under FDA jurisdiction cannot be performed without review by the Commissioner of Food and Drugs as outlined in 21 CFR 50.54.
Assent Determination

After the Panel makes the risk/benefit determination, they must consider the issue of child assent, as described in 21 CFR § 50.55 and 45 CFR Part D, § 46.408(a). The panel must decide whether assent is necessary, and also whether and how it will be documented if it is necessary.

Among the assent possibilities the Panel can consider are the following:

• Waived assent (45 CFR § 46.408(a));
• Verbal assent, without documentation;
• Verbal assent, with documentation by the investigator and/or the legally authorized representative(s);
• Written assent form, with subject signature; or
• Subject signature block on consent form (for older children only).

Unless otherwise specified by the Panel, the method for assent documentation will be the Pediatric assent signature box at the end of the LAR consent form for those 13-17 years old and a separate assent sheet for the person obtaining assent to sign for those younger than 12. These forms are on the IRB website.

Children who are wards of the State or any other agency, institution, or entity can be included in research approved under category 3 and 4 only if the research is:

1) related to their status as wards; or
2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

The IRB will appoint an advocate for each child who is a ward in Category 3 or 4 research, in addition to any other individual acting on behalf of the child as guardian or in loco parentis

1) The advocate will be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child’s participation in the research.

2) The advocate will not be associated in any way (except in the role as advocate or member of the IRB) with the research, the investigators, or the guardian.
3) No new enrollment of such subjects should occur until the IRB has appointed an advocate.

Revision History for Auditors

Jan 2013  Added the phrase “in Category 3 or 4 research” to clarify that appointing an advocate for wards only applies in Category 3 or 4 research.
VI. Functions of the IRB
E. Research Involving Pregnant Women, Fetuses, & Neonates
(45 FR 46, Subpart B)

E. Research Involving Pregnant Women, Fetuses, & Neonates (45 CFR 46, Subpart B)

1. When the Board considers research involving pregnant women and fetuses, it shall ensure that:
   a. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
   b. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
   c. Any risk is the least possible for achieving the objectives of the research;
   d. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of 45 CFR 46 subpart A;
   e. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of 45 CFR 46 subpart A, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
   f. Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
   g. For children who are pregnant, assent and permission are obtained in accord with the provisions of 45 CFR 46 subpart D and/or 21 CFR 50, subpart D;
   h. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
   i. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
   j. Individuals engaged in the research will have no part in determining the viability of a neonate.

2. When the Board considers research involving neonates, it shall ensure that:
   a. Neonates of uncertain viability may be involved in research if all of the following conditions are met:
      1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
      2. Individuals engaged in the research will have no part in determining the viability of a neonate.
3. The IRB determines that:
   (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
   (ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

4. The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

b. Nonviable neonates may not be involved in research unless all of the following additional conditions are met:
   1. Vital functions of the neonate will not be artificially maintained;
   2. The research will not terminate the heartbeat or respiration of the neonate;
   3. There will be no added risk to the neonate resulting from the research;
   4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
   5. The legally effective informed consent of both parents of the neonate is obtained in accord with 45 CFR 46, subpart A, except that the waiver and alteration provisions of 45 CFR Sec. 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

c. Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of 45 CFR 46 subparts A and D.

3. The Board may consider approval of HHS-funded research not otherwise approvable under parts 1 and 2 of this written procedure which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates if:
   The Secretary of HHS, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:
   (1) That the research in fact satisfies the conditions of Sec. 46.204, as applicable; or
   (2) The following:
      (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
      (ii) The research will be conducted in accord with sound ethical principles; and
(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

Revision History for Auditors
none
VI. Functions of the IRB

F. Research Involving Prisoners
(45 CFR 46, Subpart C)

The purpose of this section is to provide additional safeguards for the protection of prisoners involved in research. Prisoners may be under constraints because of their incarceration, which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research.

Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Each Panel that reviews research involving prisoners will have at least one prisoner representative, a member who is or was a prisoner or who has the appropriate background and experience to represent the rights and welfare of the prisoners. When a convened Panel reviews research involving prisoners, the prisoner representative will be present at the meeting.

In addition to its other responsibilities prescribed in these Written Procedures, the Panel shall review research involving prisoners only if it finds that:

1. The research under review represents one of the categories of the research permissible under 46.306(a)(2);

2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

3. The risks involved in the research are commensurate with the risks that would be accepted by non-prisoner volunteers;

4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Panel justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

5. The information is presented in language which is understandable to the subject populations;
6. Adequate assurance exists that parole panels will not take into account a prisoner’s participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

7. Where the Panel finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing participants of this fact.

Biomedical or behavioral research may involve prisoners as subjects only if the Panel has approved the research considering the above requirements and the proposed research involves solely the following:

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice in the Federal Register, of his intent to approve such research; or

4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well being of the subject. In cases in which studies require the assignment of prisoners to control groups, which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice in the Federal Register, of his/her intent to approve such research.

If a participant is incarcerated temporarily while enrolled in a study:

- If the temporary incarceration has no effect on the study, the participant can remain enrolled.
- If the temporary incarceration has an effect on the study, the information must be submitted to the IRB for review as described in the procedures above.

Revision History for Auditors

None
VI. Functions of the IRB

G. Research Involving Employees

An Ochsner employee signing a consent form for an Ochsner research study that poses greater than minimal risk to participants will also be required to sign the Employee Non-Coercion statement. This includes an employee signing a research consent form as a legally authorized representative for a minor child participating in a research study at Ochsner. The form should be kept with the informed consent. A witness with no direct connection to the research study will also sign this form. Every study will be considered by IRB policy to potentially involve employees, and the extra safeguard mandated for greater than minimal risk studies will be signing the witnessed Employee Non-Coercion Statement that is posted on the IRB website. The Employee Non-Coercion statement may be modified as needed by the IRB Chair based on feedback from IRB members, federal or state regulations, and institutional concerns. The major purpose of using this safeguard in this population vulnerable to coercion is to make clear that:

- Employees are not required to volunteer in research studies to maintain employment, nor will their employment status be damaged in any way if they choose not to be a research subject.
- There has been no undue influence by the employer to have the employee participate in research as a subject (or have the employee’s child participate).
- There have been no statements, threats or implied threats that the employee’s job performance evaluations will be affected in any way whether or not the employee (or the employee’s child) participates in a research study.
- If an employee research subject chooses to withdraw their (or their child’s) participation at any time, this will not affect their employment or their performance evaluation.

For research studies that pose no greater than minimal risk to participants where consent has been waived, no Employee Non-Coercion statement is required.

For research studies that pose no greater than minimal risk to participants and have a consent form, the IRB, with input from research compliance, will make a case-by-case determination whether to require the signing of the non-coercion statement or waive the requirement. The IRB’s determination will be based upon a careful review of the study protocol, with particular emphasis on the proposed participant recruitment procedures.

Revision History for Auditors

Jan 2016 Clarifications, and adjust need for Employee Non-Coercion statement for minimal risk w/consent studies to a case-by-case evaluation
Jan 2012 The employee paragraphs in a larger section on vulnerable adults were extracted into their own section
Feb 2005 Typo corrections
VI. Functions of the IRB

H. Vulnerable Adults Needing an LAR

When all or some of the subjects in proposed research are vulnerable adults (such as patients who may be desperate for any treatments because of their dismal prognosis, mentally or cognitively limited, etc.), the Board will ensure the review of the research is in compliance with ICH Guidelines (e6, 1.61).

The Board will consider additional safeguards for the research subjects on a case-by-case basis (FDA 21 CFR § 56.111(b); HHS 45 CFR § 46.111(b)).

For studies involving the possibility of consent by legally authorized representatives for adult subjects, the Board must consider the issue of subject assent. The Board must determine whether assent is necessary, and how it will be documented if it is necessary (ICH § 4.8.12).

For research purposes, Ochsner follows Louisiana state law for persons who may consent to surgical or medical treatment. Questions regarding the state law should be directed to Ochsner legal affairs.

Revision History for Auditors

December 2016 – Added state law sentence and link

Feb 2016 – Deleted: “and default to a line in the approval letter reminding the PI to take extra caution in the consent process unless additional safeguards are determined by the Board” – because new IRB letter format is linking all requirements to IRB website to shorten letters.

Dec 2012 Separated the Vulnerable adult section from the employee section, making each of these their own section

Jul 2012 Deleted the Category 1-4 characterization of vulnerable adults that made it parallel to children. Based on discussions stemming from the AAHRPP visit, we concluded that the nonfederal vulnerable category of possible coercion based on disease did not warrant having the children’s categories assigned to them.
VI. Functions of the IRB

I. Review of Devices

1. Review of research involving medical devices.

Before reviewing research involving a medical device for human use, the Board will determine if the device is a Significant Risk (SR) Device or a Non-Significant Risk (NSR) Device. (See http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf).

a. If the Board determines that the device is NSR, this finding will be included in the minutes and the Board may proceed to review the research activities and investigator under its normal procedures for reviewing research projects.

b. If the FDA has issued an Investigational Device Exemption (IDE) for the proposed use of the device, then it is automatically a SR device. This finding will be noted in the minutes.

c. If FDA has not issued an IDE for the proposed use of the device, then the Board shall consider the following elements in determining if the device is SR:

   i. An explanation provided by the sponsor of why the device is not a significant risk device, and

   ii. Whether the use of the device might cause harm to any of the subjects, and the
       nature of the harm that may result from use of the device.

Note: If the subject must undergo a medical procedure as part of the study, and that medical procedure is not one that the subject would otherwise undergo as part of standard medical care, the Board must consider the risks associated with the procedure as well as the use of the device. If potential harm to subjects could be life-threatening, could result in permanent impairment of body function, or permanent damage to body structure, the device should be considered SR.

d. If the Board determines the device is SR, and there is no IDE assigned, it will provide the investigator and, if appropriate, the sponsor, with its finding. The sponsor is responsible for notifying the FDA of the Board’s SR determination. The Board will not review the research until the sponsor provides proof that the FDA has granted an IDE to the sponsor. If the FDA has not responded to the IDE application, as described in FDA 21 CFR § 812.30, this proof may consist of a letter showing that an IDE application was submitted at least 30 days prior to the date on which the Board reviews the research.

e. If the Board determines the device is SR, and there is no IDE assigned, and that the investigation meets one of the IDE exemptions listed at 21 CFR 812.2(c), this finding
will be noted in the minutes, and the Board will not make an SR/NSR determination. The exemptions are:

(1) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

(2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

(3) A diagnostic device, if the sponsor complies with applicable requirements in Sec. 809.10(c) and if the testing:
   (i) Is noninvasive,
   (ii) Does not require an invasive sampling procedure that presents significant risk,
   (iii) Does not by design or intention introduce energy into a subject, and
   (iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

(4) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

(5) A device intended solely for veterinary use.

(6) A device shipped solely for research on or with laboratory animals and labeled in accordance with Sec. 812.5(c).

(7) A custom device as defined in Sec. 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.

Also, if the investigation involves a device that is cleared for marketing through the PMA process, and the device is being studied for the purpose(s) for which the device is labeled, the Board will consider the investigation exempt from the IDE regulations. This finding will be noted in the minutes, and the Board will not make an SR/NSR determination.

2. Reference Information regarding Medical Device Approval

Research involving a medical device for human use that qualifies as a Non-Significant Risk (NSR) Device (unless the device is banned), may begin upon approval by an IRB and does not require the issuance of an Investigational Device Exemption (IDE) by the FDA (FDA 21 CFR, 812.2 (b)(1)).
Research involving a medical device for human use that does not qualify as NSR device is classified as a Significant Risk (SR) Device. Research involving SR devices (unless the device is banned) cannot begin until the FDA issues an IDE and approval is granted by an IRB (FDA 21 CFR, 812.30 (a)).

A significant risk device means an investigational device that meets any of the following criteria (FDA 21 CFR, § 812.3(m)):

a. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.
b. Is purported or represented to be for use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.
c. Is for a use of substantial importance in diagnosis, 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
d. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

3. Review of Humanitarian Use Devices (HUD)

IRB review of humanitarian use devices is required under Federal Regulation (FDA 21 CFR Part 814). Before reviewing a HUD, the Board shall:

a. Determine that the FDA has granted a Humanitarian Device Exemption (HDE) to the sponsor.
b. Determine whether the investigator intends to use the HUD according to its FDA approved use, and if off-label use is planned what the reasons and safeguards are.

After the Board has determined that the FDA has granted an HDE, the Board may proceed to review the use of the HUD at Ochsner and those applying to use it by using its normal procedures for reviewing research projects. HUDs are intended to benefit subjects in the treatment or diagnosis of diseases or conditions that affect or manifest in fewer than 4000 individuals in the United States per year. HUDs are considered by the FDA to be approved for marketing. Federal regulations do not require informed consent for use of a humanitarian use device when used as treatment (not research). However, the Board may require consent in such instances at its discretion. The Board requires that any information packets that come with the HUD be provided to the patient prior to the use of the HUD. The Board will require a brief consent addendum to the surgical consent when there is off label use, that explains what off label HUD use means and provides an opportunity to assure the patient is fully aware of the off label use. The Board will require informed consent for research use of the HUD, however research use will almost always require an IDE from FDA and thus is treated as any other clinical investigation with an IDE.
Revision History for Auditors

Sep 2008 Added "The Board will require a brief consent addendum to the surgical consent when there is off label use, that explains what off label HUD use means and provides an opportunity to assure the patient is fully aware of the off label use. The Board will require informed consent for research use of the HUD, however research use will almost always require an IDE from FDA and thus is treated as any other clinical investigation with an IDE." Rationale: after their review of the issue raised at Panel A on 6/3/08 (see below change to this section dated 6/3/08, superseded by this change), and review of the new draft FDA guidance on this matter at http://www.fda.gov/cdrh/ode/guidance/1668.pdf dated 8/5/2008. The IRB Vice Chairs met on 8/27/08 to discuss this and decided unanimously (including the IRB Executive Chair) that this would be the SOP change. Details of the IRB HUD Guidance paper and 1 page template were finalized, reviewed by the Vice-Chairs by email, and sent to the IRB members by email soon after 9/25/2008.

Mar 2008 Removed “The Board will require informed consent for off label use of the HUD” - after discussion of this at the Panel A meeting on 6/3/2008. A specific HUD was approved for use at that meeting for both on label and off label treatment use. An extensive discussion concluded the IRB should not mandate a consent form for treatment use even when off label, at least in this specific HUD and circumstances. The SOP is reworded to allow for this.

Mar 2003 Added clarification "and the Board will not make an SR/NSR determination." after the text: "If the Board determines the device is SR, and there is no IDE assigned, and that the investigation meets one of the IDE exemptions listed at 21 CFR 812.2(c), this finding will be noted in the minutes"

Mar 2003 Added clarification "Also, if the investigation involves a device that is cleared for marketing through the PMA process, and the device is being studied for the purpose(s) for which the device is labeled, the Board will consider the investigation exempt from the IDE regulations. This finding will be noted in the minutes, and the Board will not make an SR/NSR determination."
VI. Functions of the IRB

J. Emergency Use & Expanded Access of a Test Article

Emergency Use of a Test Article

The Panel will review, at convened Panel meetings, the treatment use (FDA 21 CFR §§ 312.34 and 312.35), and the emergency use (FDA 21 CFR §§ 56.102(d), 56.104, and 312.36) of a test article under applicable FDA regulations and the principles of research ethics presented in Ethical Principles and Guidelines for the Protection of Human Subjects of Research (The Belmont Report, http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html).

Emergency use is defined as the use of an investigational drug, biological product or medical device with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRBV approval (21 CFR § 56.102(d)). This does not include the “off-label” uses of approved medical products in the practice of medicine (i.e., not in a research context). Within 5 working days after emergency use, the physician responsible for the use must notify the Panel of its use. This notification report should indicate if additional uses are anticipated, in which case a protocol and consent form must be submitted for Panel approval. When emergency use is reported to the Panel before the use occurs, the Panel will review and approve or disapprove the use. When emergency use is reported to the Panel after the use has already occurred, the Panel will acknowledge rather than approve the use. Waiver of informed consent in conjunction with emergency use is discussed under Informed Consent above.

Under FDA regulations, the emergency use of a test article is considered a clinical investigation / investigational device use, the patient is considered a research participant, and the FDA may require data from an emergency use to be reported in a marketing application. However, patients receiving a test article in an emergency use as defined by FDA regulations may not be considered to be a research subject when following DHHS regulations. DHHS regulations do not permit data obtained from patients to be classified as human subjects research, nor permit the outcome of such care to be included in any report of a research activity subject to DHHS regulations.

Expanded Access of a Test Article

FDA expanded access rules should be used by all physicians prescribing drugs that are not commercially available and being used outside of clinical trials. If a non-commercially available drug is being used for treatment, it is still considered investigational use by FDA. On June 2, 2016, FDA issued three final guidances for industry related to expanded access. Expanded access is FDA’s process to facilitate the availability of investigational treatment options to patients with serious or immediately life-threatening diseases or conditions who lack therapeutic alternatives.

The first guidance, “Individual Patient Expanded Access Applications: Form FDA 3926” describes a streamlined option for licensed physicians to request use of an investigational new drug to treat individual patients who have exhausted other treatment options, including for emergency use. When Form FDA 3926
is substituted for the current Forms FDA 1571 and 1572, the agency estimates that each submission will take only 45 minutes, resulting in a significant burden reduction. Based on comments received from the public, the new form can also be used for follow-up submissions.

The second guidance, “Expanded Access to Investigational Drugs for Treatment Use -- Questions and Answers,” responds to frequently asked questions about the implementation of FDA’s regulations on expanded access to investigational drugs.

The third guidance, “Charging for Investigational Drugs Under an IND -- Questions and Answers” responds to frequently asked questions about the implementation of FDA’s regulation on charging for investigational drugs under an investigational new drug application (IND) in the context of clinical trials or expanded access for treatment use.

FDA also developed patient and physician fact sheets to further inform stakeholders about expanded access.

Revision History for Auditors

Jul 2016: Based on revised regulations, special exception section replaced with expanded access section. The new expanded access section taken with edits form a public FDA email about their new guidance. Title of SOP changed from “Emergency Use of a Test Article” to “Emergency Use & Expanded Access of a Test Article.” Some clarifications added to the Emergency Use paragraphs.

Mar 2003: clarified that when a SR device trial without an IDE meets an IDE exemption, that the Board will not make an SR/NSR determination

Mar 2003: added “Also, if the investigation involves a device that is cleared for marketing through the PMA process, and the device is being studied for the purpose(s) for which the device is labeled, the Board will consider the investigation exempt from the IDE regulations. This finding will be noted in the minutes, and the Board will not make an SR/NSR determination”

Jul 2002: Added the section on special exception use after IRB Chair (Dr. Breault) consulted with Dr. John Martin of the FDA. See the file on Protocol #2002.308.A for the background information that required clarification of this. Dr. Breault received a final follow-up phone call from John Martin at the FDA (Division of Scientific Investigations, Human Subject Protections Group, 301-827-7279) on 8/20/02 about whether the IRB Chair can make these decisions or it must be a full panel. He agreed that this was a gray area with some conflicting opinions, but since this is more than minimal risk, it would probably be best to be a full board decision. This will be our policy at Ochsner. The FDA recommended adding our policy into the SOPs.
VI. Functions of the IRB
K. Conducting Continuing Review

Ochsner IRB Panels shall conduct continuing review of all Ochsner IRB approved research activities.

1. Approved projects shall be reviewed at intervals appropriate to the degree of risk to which subjects are exposed. In no case will the interval between reviews be longer than one calendar year. Except in cases where the federal regulations allow expedited review, continuing review shall be conducted at a convened meeting of the IRB Panel (HHS 45 CFR §§ 46.108(b); 46.109(e); ICH § 3.1.4)).

Factors that affect the IRB’s decision about whether intervals should be shorter than a year include:

- The nature of and risks posed by the clinical investigation;
- The degree of uncertainty regarding the risks involved;
- The vulnerability of the subject population;
- The experience of the clinical investigator and/or sponsor;
- The projected rate of enrollment; and
- Whether the studies involve novel therapies.

2. IRB approval of research automatically expires at the end of the designated approval period determined at the initial review of any subsequent review. The IRB may approve research for a defined time period of not more than one year minus one day, or for a limited number of subjects. The IRB will calculate the approval period for research per the following example: A protocol is reviewed and approved (or approved with administrative changes) on August 1, 2011. Since the IRB’s approval of the study will expire on August 1, 2012, the IRB must complete its continuing review no later than that date minus one day – July 31, 2012. This applies to protocols receiving either convened or expedited review.

3. Each IRB Panel has authority to determine which research activities need verification – from sources other than the investigator – that no material changes in the research have occurred since the previous IRB review. Sources other than investigators may include copies of FDA audits, site visits conducted by authorized personnel, reports from “whistleblowers,” etc (HHS 45 CFR §§ 46.103(b)(4); FDA 21 CFR § 56.108(a)(2)). Criteria that Panels will consider in determining which studies need such additional verification include multiple protocol violations, research activities or events that have harmed subjects, or patterns of lateness with regulatory deadlines such as continuing review paperwork, adverse events that are serious and unexpected and related.

4. Notification that continuing review is to take place will be sent to investigators and their CRCs by the ERSA system 60, 30, 15, and then every day prior to the continuing review expiration date until the continuing review is submitted or the study is expired. Investigators will submit appropriate reports to the IRB Office on ongoing research activities at least ten working days prior to the scheduled continuing review.
5. All changes in approved research are to be promptly reported to and approved by the IRB Panel (HHS 45 CFR §§ 46.103 (b)(4) before being initiated by the investigator (FDA 21 CFR § 56.108(a), except where necessary to eliminate apparent immediate hazards. In this latter case, changes should be promptly reported to the IRB Panel.

6. Each IRB Panel has authority to suspend or terminate the approval of research that is not being conducted in accordance with federal regulations or in accordance with stipulations imposed on the research activity by the IRB Panel. Any suspension or termination will be reported promptly to the investigator and the Chair will inform the Executive Vice President & Chief Academic Officer (CAO) and the System VP for Research. The CAO or his designee will notify the FDA, the Office for Human Research Protections, and any other federal agencies that require separate reporting of the suspension or termination (HHS 45 CFR §§ 46.108(a); FDA 21 CFR 46.113)

7. Continuing review may be conducted through an expedited review procedure when permitted by the regulations (HHS 45 CFR §§ 46.110 (8)(9).

If IRB approval of a specific study expires before continuing review and approval occur, investigators must stop all research activities involving human subjects related to that study (45 CFR 46.103 (b)), except where they judge that it is in the best interests of already enrolled subjects to continue to participate. When investigators make this judgment, they must promptly notify the IRB (45 CFR 46.103(b)(5)). When the IRB reviews the investigator’s decision, it may decide whether it is in the best interests of already enrolled subjects to continue to participate in the research by considering the best interests of subjects either one at a time or as a group. If an IRB determines that it is not in the best interests of already enrolled subjects to continue to participate, investigators must stop all human subjects research activities, including intervening or interacting with subjects, or obtaining or analyzing identifiable private information about human subjects (45 CFR 46.103 (b)). Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred.

Some or all of the following methods will be used to determine which projects needs verification from sources other than the investigators that no material changes have occurred since the previous IRB review as required by 45 CFR 46.103 (b)(4)(ii).

A. Random audits of Ochsner studies that are conducted by the Institution.

B. Study audits for cause can be requested by the IRB. Audit requests and their frequency would be at the discretion of the IRB Chair, Administrator, or the majority vote of an IRB Panel responsible for that study. The Research Quality Assurance team is also free to audit for cause any study their own procedures direct them to.

C. For cause audits mandated by the IRB will generally be limited to studies that have some or all of the following characteristics:
   - high risk study,
   - a greater than minimal risk investigator-sponsored study
   - high enrollment,
   - vulnerable population,
projects conducted by investigators who previously have failed to comply with the requirements of the federal regulations or the requirements or determinations of the IRB, and/or

- projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

Revision History for Auditors

Apr 2016 – In #1 above clarified that CR can be expedited when federal regulations permit, not just when initial review was expedited.

Feb 2013 – deleted Item #7 and replaced with statement that continuing review can occur under the expedited review procedure as long as it is within the regulations. Updated the VP of Academics to the System VP of Research. Clarified that for cause audits will be conducted by the Research Quality Assurance team. Clarified that audits may include greater than minimal risk investigator-sponsored studies.

Jul 29, 2010 – removed 90 day ERSA notification of study expiration. Notifications are no longer sent this far out of date in ERSA. Removed reference to random audits being conducted by Compliance Office since this function was moved to a part of Research Administration.

Feb 4, 2010 – added the factors that affect the IRB’s decision about whether continuing review intervals should be shorter than a year.

Apr 21, 2008 – added that any other applicable federal agencies (in addition to FDA and/or OHRP) will be notified of IRB suspensions or terminations.

Oct 26, 2006 – added that continuing review notifications will be sent by the ERSA system at 90, 60, 30, 15 and then every day prior to the expiration date. Added that a continuing review report must be submitted 10 working days prior to the expiration date.

Feb 14, 2006 – added clarification that if IRB approval lapses and the PI believe it is in the best interests of the subjects to continue, then the IRB chair must be notified to make a determination and the continuing review must be submitted within 5 working days.

Feb 11, 2004 – added section to indicate the methods that will be used to determine which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review as required by 45 CFR 46.103(b)(4)(ii).
VI. Functions of the IRB

L. Review of Amendments

The Ochsner IRB shall conduct review of amendments for all approved research that has IRB approval that is current (i.e., not lapsed).

1. Amendments shall be reviewed by the IRB. Investigators must obtain pre-approval from the IRB of any changes in the research activity. However, purely administrative changes that have no effect on protection of human subjects or the scientific aspects of the study do not need IRB approval. Examples of the latter include change of phone numbers or personnel, minor administrative and typo corrections to the protocol, packaging and mailing instructions for samples, etc. (HHS 45 CFR §§ 46.103(b)(4); FDA 21 CFR § 56.108(a)(4)).

2. An exception to changes in research being pre-approved by the IRB before they occur is when such changes are necessary to protect human subjects. In this case investigators should immediately change what is necessary to protect human subjects, but also within ten days thereafter report such changes to the IRB for its concurrence that the change was consistent with ensuring the participants’ continued welfare (HHS 45 CFR §§ 46.103(b)(4); FDA 21 CFR § 56.108(a)(4); ICH E6 3.3.7).

3. Amendments shall be conducted at a convened meeting of the IRB Panel, unless they meet criteria for expedited review. When amendments are reviewed using the expedited procedure, the expedited reviewer may exercise all the authorities of the IRB except that the reviewer may not disapprove the amendment—in this case the expedited reviewer must refer it to the convened Panel for a decision about disapproval (HHS 45 CFR 46.110(b); FDA 21 CFR 56.110(b)).

4. The convened IRB or expedited reviewer must obtain sufficient information to conduct review of modifications to previously reviewed research, and must make a decision based on the same review criteria as initial and continuing review of research. Relevant information generally means the protocol, a change matrix from the sponsor, consent form, and details of the amendment or changes. At times it may also mean Sponsor’s information on the drug/device with updated risk sections, DMC reports or FDA letters that requested changes, or other supporting information. The IRB has the right to obtain additional information if deemed by the IRB to be important information to conduct their review (HHS 45 CFR 46.111 FDA 21 CFR 56.111).

5. If the proposed change in the research is determined by the IRB to affect the participant’s willingness to continue participation (e.g., due to significant new negative findings, or additional burden from the proposed changes) then the IRB will require an appropriate re-consenting process. In cases where subject risk or burdens are not an issue (e.g., additional side effects from a drug that is no longer being taken by anyone in the study that is in follow-up only at our site) the IRB may decide to simply inform subjects verbally at their next clinic visit, or that no communication is necessary pending the circumstances. (HHS 45 CFR §§ 46.116(b)(5); FDA 21, CFR 50.25(b)(5))
Revision History for Auditors

February 14, 2013 – removed reference to the convened IRB including alternate members since this is implied and included in other sections of the SOPs

July 29, 2010 – change made in reference to changes in research being conducted by the Investigator before IRB approval is obtained. Clarified that the regulations require reporting in this situation within 10 days to the IRB. This type of change is usually not considered to be an emergency that triggers the five day notification rule.
VI. Functions of the IRB
M. Review of Adverse Events

These written procedures are based on federal regulations and guidance including:

All adverse events must be reported to the sponsor. Federal IRB guidelines do not require reporting adverse events to IRBs. They do require that Unanticipated Problems Involving Risks to Subjects or Others [21 CFR 56.108(b)] and Unanticipated Adverse Device Events [21 CFR 812.150(a)(1)] be reported to the IRB [45 CFR 46.103(b)(5)].

Some adverse events qualify as unanticipated problems that must be reported to the IRB. Most adverse events do not. When Unanticipated Problems Involving Risks to Subjects or Others or Unanticipated Adverse Device Events are reported to the IRB, and the IRB agrees that they fall into these categories, then the IRB notifies the institution about these events, and the institution notifies both FDA and OHRP that these unanticipated problems have occurred when the studies are under their oversight.

Deciding what events qualify for required reporting to the IRB is discussed at length in the above referenced federal guidance documents. The IRB written procedures, IRB newsletters and guidance documents offer additional, local information and guidance.

Generally, an analysis of adverse event(s) that are serious, related, and unexpected (all three) is the basis for the PI and Sponsor in concluding if there is an unanticipated problem. These unanticipated problems must be reported to the IRB and usually require some change in the study (revised consent, protocol, or investigational brochure; stopping enrollment; terminating an arm of the study; etc.). These types of analyses are often done by Data Monitoring Committees or similar groups set up by the sponsor.

It is NOT helpful to human research subject protection to report all adverse events, especially minor, to the IRB. This practice takes up time that should be spent on the more important issues in protecting subjects and does not provide useful information to that end without additional analysis.

Time Frame for Reporting Unanticipated Problems involving Risks to Subjects or Others

These should be reported within 10 working days of the PI becoming aware of the unanticipated problem. Most often an analysis is required of multiple adverse events to determine there is a signal that is an unanticipated problem for the study. The 10 working days timer starts when the analysis or determination is made that there is an unanticipated problem, which may be more than 10 days past the adverse events that
are some of the data points used in determining there is an unanticipated problem involving risks to subjects or others.

In device studies, the unanticipated adverse device event (UADE) evaluation by the sponsor must be reported by the sponsor to the IRB within 10 working days after the sponsor first receives notice of the UADE. If the UADE occurred at Ochsner, the investigator must report it to the Ochsner IRB and the sponsor within 10 working days.

Within 10 working days means as soon as possible, and in no event more than 10 working days.

An IRB Clinician (a nurse, pharmacist, or physician on the IRB Staff or Panels) will review these reports within 5 working days. If either the PI or the IRB Clinician determines there should be a change in the study, then an IRB physician reviewer (if the IRB Clinician was not a licensed physician) will determine what actions, if any, are required. When brought to a full Panel, it will be with specific recommendations for changes in the study from the physician reviewer; and the Panel will determine if any notice to research subjects or changes to the research are required. If the PI and the IRB Clinician concur that no changes to the research are indicated, then the adverse event will be acknowledged by the IRB Office.

**Local SAEs vs. External (non-local) SAEs / Medwatch Safety Reports**

To maximize subject protection, when local adverse events occur that are in the judgment of the investigator related + unexpected + serious, you should report these along with the investigator opinion/analysis of whether this rises to the level of an unanticipated problem involving risks to subjects or others, and what if anything should change in the study.

To avoid taking valuable time away from more useful subject protection activities, please do not report external adverse events unless there has been an analysis or a judgment made that a particular adverse event or events that are related + unexpected + serious have created a signal that has been determined to be an unanticipated problem involving risks to subjects or others. Generally this will mean that something changes in the study (consent form, protocol, investigator brochure, stop enrollment, one arm will be closed, etc.). This type of analysis is usually done by the sponsor or a Data Monitoring Committee. The local PI will rarely have enough data or a denominator to make appropriate conclusions whether there is a signal that rises to the level of an unanticipated problem involving risks to subjects or others.

**Definitions of types of AEs**

Adverse events in these SOPs should be interpreted as applying to both drug and device trials, even though some definitions and language are rooted in drug studies. Helpful definitions for device-related adverse events can be found at 21 CRF 812.3(s) and 812.150.
Revision History for Auditors

February 14, 2013 – removed outdated reference to newsletters and presentations. Update FDA guidance link and date. Clarified that an analysis of whether an adverse event is an unanticipated problem is generally done by the PI and the Sponsor

October 8, 2008 - Clarified that federal agencies are only notified of unanticipated problems in studies when the studies are under their oversight.

February 10, 2005 - FDA requested clarification (1/19/05 letter to Dr. Pinsky) in our SOPs that the adverse event rules included devices

November 12, 2003 – clarified that serious, related and unexpected adverse events will be reviewed by an experienced clinician in the IRB office, rather than by the convened Panel or a Physician. This is to make clear that not all AEs must be reviewed at a convened meeting and can be reviewed by the appropriate clinicians in the IRB office. Appropriate clinicians means the reviewer has a medical, nursing, or pharmacy degree and they are experienced in their field.
VI. Functions of the IRB

N. Review of Noncompliance and Unanticipated Problems

Reports of unanticipated problems involving risks to human subjects or others and information of serious or continuing noncompliance with Federal Regulations or the requirements or determinations of the Panel, shall be considered at convened meetings of the Panel. The Panel may take action appropriate for the circumstances to protect the safety, welfare and rights of research subjects. In addition, the panel will report this to the institution, which will report it to the OHRP and the FDA as appropriate (21 CFR 56.108b). Unanticipated problems in this paragraph apply to drug trials, device (21 CFR 812.3(s) and 812.150) trials, and non-FDA regulated research.

Ochsner IRB staff will review unanticipated problem submissions and promptly notify the IRB Chair (or designee) if the report merits panel review. The Chair (or designee) will review the ERSA submission and any supporting documentation provided. The review should normally occur within 2 working days of the time the report is received by the IRB Chair (or designee). Based on the review, the IRB Chair (or designee) will determine whether the problem requires convened review and is possibly serious or continuing noncompliance.

Ensuring that research noncompliance is promptly and effectively addressed is essential to protecting the rights and welfare of research subjects. Ochsner requires that employees or agents conducting research under which the Ochsner IRB is the IRB of record report any serious or continuing noncompliance or suspected serious or continuing noncompliance of which they become aware. In addition, federal law requires that the IRB follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials and certain government agencies of the following:

- Serious or continuing violations of federal regulations governing human subjects research, or
- The requirements or determinations of the IRB

1. Reporting Requirements

Principal Investigators and research study staff are required to report each event of serious or continuing noncompliance relating to human subjects research which they are conducting within ten (10) calendar days of learning of the event. If there is any question or possibility that noncompliance could constitute serious or continuing noncompliance, it should be reported.

The following noncompliance events must be reported to the IRB within ten (10) calendar days of learning of the event even if the Principal Investigator, or research study staff, do not believe the event constitutes serious or continuing noncompliance:

- Failure to obtain IRB approval of human subjects research when required
Enrolling a research subject who does not fit the inclusion and exclusion criteria in the protocol, unless it was approved by the Sponsor prior to the enrollment.

Failing to obtain or document informed consent

Administering a drug required by the protocol at a dose or schedule that has not been approved by the IRB except when necessary to eliminate apparent immediate hazards to the research participant.

The IRB will determine if the event constitutes serious or continuing noncompliance. The event should be reported to the IRB via ERSA or email to the IRB Office at irb@ochsner.org

2. Review of noncompliance

Ochsner IRB staff will review reports of noncompliance and promptly notify the IRB Chair (or designee). The Chair (or designee) will review the ERSA submission and any supporting documentation provided. Based on the review, the IRB Chair (or designee) will determine whether the report is possibly serious or continuing.

- If the IRB Chair (or designee) determines the noncompliance is not serious or continuing, correspondence will be sent to the Principal Investigator indicating such.
- If the IRB Chair (or designee) determines the noncompliance is possibly serious or continuing, the item will be schedule for convened IRB review.

The convened IRB is responsible for reviewing noncompliance that is serious or continuing. The IRB staff will provide the following documentation to IRB members in connection with any report of noncompliance that is possibly serious or continuing:

- The ERSA reporting form including the description of the noncompliance
- The most recent protocol
- The current approved consent document(s)

The IRB may request that additional information be collected or that further investigation be conducted if necessary for it to make a final determination.

If the IRB determines that the noncompliance is neither serious nor continuing, then the information will be acknowledged and correspondence will be sent to the Principal Investigator.

If the IRB determines that the noncompliance is serious or continuing, then the IRB will consider the following actions to remedy the noncompliance and protect research subjects and others:

- Requiring additional information from the Principal Investigator with a Corrective Action Plan
- Auditing/monitoring of the protocol
- Auditing/monitoring of the consent process
- Requiring modification of the protocol
- Requiring modification of the consent
• Requiring the re-consenting of and/or providing additional information to current research participants (must occur when such information may affect the willingness of current participants to continue to take part in research)
• Requiring the re-consenting of and/or providing additional information to past research participants
• Requiring more frequent review of the study
• Requiring additional training of study staff
• Prohibiting the use of data collected for publication
• Suspending or terminating the protocol

In appropriate cases, the IRB may refer the matter to the Institutional Official with recommendations to include the following:

• Suspending the right to conduct or participate in human subject research at Ochsner
• Terminating or limiting the right to conduct or participate in human subject research at Ochsner
• Requiring additional supervision of the Principal Investigator
• Terminating employment
• Conducting an investigation into scientific or other misconduct

Upon completion of IRB review, the IRB will notify the Principal Investigator of the IRB’s conclusion and any required actions.

Revision History for Auditors

May 2016 – clarified that for #1 above, second bullet, that enrolling a subject who does not fit the inclusion/exclusion criteria is not considered a noncompliance event if the Sponsor had given prospective approval for it.

Feb 2013 – This section was combined with former SOP section O. Unanticipated Problems. In review with staff and IRB Chair, it was determined that these sections should be combined for clarity as much of the language was identical. Clarified the mechanism to report noncompliance. Removed 48 hour IRB Chair review requirement and changes to 2 working days. Clarified the IRB may refer noncompliance matters to the Institutional Official.

Jan 2012 – new section added to SOPs at request of AAHRPP
VI. Functions of the IRB

O. Protocol Variances

The Ochsner IRB requires the reporting of protocol variances that could adversely affect the safety or welfare of subjects, or could significantly impact the integrity of the research data.

The term protocol variance is synonymous with protocol exemptions, exceptions, deviations, violations, variations and other similar terms used by sponsors and sites.

Any planned variance from the protocol that requires a protocol amendment should be submitted to the IRB for review prior to implementation. The only exception is when changes are necessary to eliminate apparent immediate hazards to subjects.

Any unplanned variance from the protocol must be reported to the IRB within 10 working days of the investigator becoming aware of the variance, if the variance could adversely affect the rights, safety or welfare of subjects or significantly impact the integrity of the research data. The IRB provides a protocol variance template report form in ERSA.

If the sponsor requires reporting of other unplanned variances to the IRB, the investigator may use the IRB variance log and submit it with the next continuing review report.

This policy on reporting protocol variances does not affect the following IRB policies:

- Any changes to the protocol or other written documents composing the research must be approved in advance by the IRB in compliance with 21 CFR 56.108(a) and 312.66.
- Investigators must report to the IRB any related + serious + unexpected adverse events (AE) of any study subject, as required on the IRB’s Letter of Approval.
- The emergency use of a test article must be reported to the IRB in compliance with 21 CFR 56.102(d), 56.104, 312.36, 812.35(a) and 812.150(a)(4), namely within 5 working days.
- If the variance is a result of a reportable AE, reporting should follow the AE rules.
- Unanticipated risks to subjects or others must be promptly reported to the IRB

All protocol variances should be reported to the sponsor.

Revision History for Auditors

February 2013 – clarified that unplanned variances must be reported to the IRB

October 2006 – clarification in procedures that unplanned variances should be reported in ERSA
February 2005 – FDA requested clarification that 5 working day rule applies to reporting emergency use of a test article and should not be confused with non-emergency reporting of unplanned protocol variances within 10 working days.

October 2004 – this section was added to the SOPs after IRB Chair consultation with research compliance, ORA, FDA and final review by the IRB Vice Chairs at their 10/27/2004 meeting.
VI. Functions of the IRB

P. Notification of Panel Actions

The Panel shall notify the investigator and institutional officials (and the sponsor, when appropriate) in writing of its actions in approving, disapproving or requiring changes to (in order to approve) the research. A disapproval notice shall include the basis for the disapproval and provide an opportunity for the investigator to address the Panel in person or in writing regarding its action.

There is no regulatory authority for appeal of Panel decisions in suspending or terminating approval of research, other than an appeal to the Panel itself for a reconsideration of its decision.

Additional Panel actions that will only involve the notification of the investigator are:

1. Tabling a study or item under review when information that appears to be important to having an informed discussion by the panel is missing. The matter will be submitted to a future panel meeting when the important information is received. This does not go to expedited review.

2. An IRB Panel can approve with minor modifications. In this case, a vote for approval with minor modifications means for expedited review by the Chair or the Chair’s designate that can occur after the missing information pieces are obtained. If upon receipt, the information is consistent with the panel’s discussion and no concerns are raised in the mind of the reviewer, then expedited review may approve it. If the information raises concerns or important issues that have not been discussed by the panel, then the reviewer will table the matter for the full panel to review.

Revision History for Auditors

May 2016 – changed the language of #2 above from placing on hold to approve with minor modification. This is based on the most recent AAHRPP surveyor discussion of the language acceptable to AAHRPP. This did not involve a change in practice, just language.
VI. Functions of the IRB

Q. Suspension or Termination of Approval of Research

The Panel has the authority to suspend or terminate its approval of research for any reason it deems appropriate (HHS 45 CFR § 46.113; FDA 21 CFR § 56.113; ICH § 3.1.2), such as:

- the research is not being conducted in accordance with the currently approved protocol; or
- the research is not being conducted in accordance with applicable rules and regulations; or
- the research is not being conducted in accordance with the Panel's requirements; or
- the research has been associated with serious harm to subjects; or
- the research creates a potential threat to the safety and welfare of subjects; or
- the research creates a potential threat to the safety and welfare of others; or
- an FDA or other regulatory audit of the IRB indicates an IRB panel approved the research in a manner that was significantly non-compliant with Federal regulations.

Any suspension or termination of approval shall include a statement of the reasons for the Panel's action and shall be reported promptly to:

- the investigator;
- institutional officials (Institutional Official, System Vice President for Research); and
- the sponsor of the research, and all applicable federal agencies (HHS 45 CFR § 46.113; FDA 21 CFR § 56.113).

Revision History for Auditors

February 2013 – updated titles of intuitional officials for reporting purposes

November 2008 – clarifies that federal agencies are only notified when studies are under their oversight

April 2008 – revised entire section to outline panel authority and reporting requirements to be consistent with AAHRPP Element II.4.D
VI. Functions of the IRB

R. Reporting to the Institution and Government Agencies

The Panel shall report to appropriate institutional officials and through them to the OHRP and FDA when applicable any:

- unanticipated problems involving risks to human subjects or others;

- instances of serious noncompliance (noncompliance that affects the rights or welfare of subjects) or continuing noncompliance (A pattern of noncompliance that indicates a deficiency likely to result in further noncompliance or a circumstance in which an investigator fails to cooperate with investigating or correcting noncompliance) with the Federal Regulations or the requirements and determinations of the Panel; or

- suspension or termination of IRB approval (HHS 45 CFR §§ 46.108(a); 46.103(b)(5)); (FDA 21 CFR § 56.108 (b)).

This will be done by the Chair (or designee) who will draft and send the appropriate letters.

Revision History for Auditors

February 2013 – clarified that Chair or designee will draft the appropriate letters

August 2010 – expanded the definition of serious or continuing noncompliance

November 2008 – clarified that federal agencies are only notified when studies are under their oversight
VI. Functions of the IRB
S. Financial Interests of Investigators

On May 5, 2004 HHS/OHRP issued Final Guidance on *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection*. They recommend “IRBs, institutions, and investigators consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects.” Investigators and sub-investigators must complete a financial disclosure form at the time of each new study submission to the IRB if financial interests in the sponsor exceed certain amounts. In addition, anytime an amendment is created to change the Principal Investigator or add sub-investigators, the new individuals being added to the study must submit a financial disclosure. This applies to principal investigators, sub-investigators, and their immediate family members who are spouses or dependents living with them. If there are significant changes in financial interests during the course of a study, the investigators must notify the IRB.

When the financial disclosure form is triggered, the IRB Chair or IRB Administrator and the Research COI Chair work to develop a management plan that effectively manages, reduces or eliminates the conflict of interest as required by federal regulations while also satisfactorily protecting the rights and welfare of human subjects. The IRB Panel at first review of the study will review the COI management plan with the study materials and determine if the COI management plan is accepted as is, or if additional restrictions should apply. The investigators must fully comply with the determinations of both. The major issues the IRB Panel will be interested in include:

- Whether methods used for management of financial interests of parties involved in the research adequately protect the rights and welfare of human subjects.
- Whether other actions are necessary to minimize risks to subjects.
- The kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.

The results of the Panel’s deliberations will be recorded in the minutes.

*Revision History for Auditors*

February 2013 – clarified that PI’s and sub-I’s must complete a financial disclosure at the time of each new study submission and with an amendment if the PI is being changed or sub-investigators are being added. Clarified that the IRB Chair and IRB Administrator work with the COI Chair to develop management plans. Removed section related to evolution of the Research Conflict of Interest Policy as this is now complete and covered in that policy.

October 2011 – updated to incorporate developing intuitional conflict of interest policy. COI issues will no longer be directly handled by the IRB and instead the Research COI committee will work with the IRB to develop management plans.
November 2008 – reworded to align with reporting via ERSA rather than paper. Corrected to indicate that the financial interest evaluations are limited to spouses and dependents living with them.

February 2005 – created this new section to address financial interests of investigators involved in research
VI. Functions of the IRB

T. FERPA

The Family Educational Rights and Privacy Act (FERPA), is a federal law that protects the privacy of personally identifiable information contained within a student’s educational record. FERPA applies to all schools (K-12 including postsecondary institutions) that receive funds under various programs from the U.S. Department of Education. FERPA defines educational records as records containing information (in any medium – paper, electronic, microfilm, etc) that directly relate to a student and are maintained by an educational institution or by a party acting for the institution. FERPA generally requires written permission of a parent of eligible student before a school can release information from a student’s education record.

Exception may be granted but must be approved by the IRB. These exceptions may include the following:

- An educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:
  - Develop, validate, or administer predictive tests.
  - Administer student aid programs
  - Improve instruction.

A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the investigator conducting the research that specifies:

- The determination of the exception
- The purpose, scope, and duration of the study.
- The information to be disclosed.
- That information from educational records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31 (a)(6) on re-disclosure and destruction of information
- That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization with legitimate interests.
- That the organization is required to destroy or return all personally identifiable information when no longer needed for the purpose of the study.
- The time period during which the organization must either destroy or return the information.
- Education records may be released without consent under FERPA if all personally identifiable information has been removed including:
  - Student’s name and other direct personal identifiers, such as the student’s social security number or student number
  - Indirect identifiers, such as the name of the student’s parent or other family members; the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable; date and place of birth and mother’s maiden name.
• Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting. Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

All instructional material – including teachers’ manuals, films, tapes, or other supplementary instructional material- which will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children engaged in the research.

Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques

Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age of majority as determined under state law

Revision History for Auditors
Dec 2012: This section was extracted from the VI.B. section on Informed Consent and made its own section
VI. Functions of the IRB

U. PPRA

The IRB will comply with the Protection of Pupil Rights Amendment as follows:

For research funded by the U.S. Department of Education: No student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:

- Political affiliations.
- Mental and psychological problems potentially embarrassing to the student or his or her family.
- Sex behavior and attitudes.
- Illegal, anti-social, self-incriminating and demeaning behavior.
- Critical appraisals of other individuals with whom the student has close family relationships.
- Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers.
- Religious practices, affiliations, or beliefs of the student or student’s parent
- Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

Prior consent means:

- Prior consent of the student, if the student is an adult or emancipated minor; or
- Prior written consent of the parent or guardian, if the student is an un-emancipated minor.

Schools and contractors obtain prior written parental consent before minor students are required to participate in any Department of Education funded survey, analysis, or evaluation.

For research not funded by the U.S. Department of Education: The IRB must verify compliance with U.S. Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

- The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student
- Any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.
- Arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items):
  - Political affiliations or beliefs of the student or the student’s parent.
  - Mental or psychological problems of the student or the student’s family.
  - Sex behavior or attitudes.
• Illegal, anti-social, self-incriminating, or demeaning behavior.
• Critical appraisals of other individuals with whom respondents have close family relationships.
• Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
• Religious practices, affiliations, or beliefs of the student or the student’s parent.
• Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

- The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student.
- Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
- The administration of physical examinations or screenings that the school or agency may administer to the student.
- The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure or use.
- The right of a parent or a student to inspect, upon the request of the parent, any instrument used in the collection of personal information administered or distributed to a student.
- Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

Revision History for Auditors

Dec 2012: This section was extracted from the VI.D. section on Research Involving Children and made its own section
VII. Operations of the IRB

A. Scheduling of Meetings

Regularly scheduled meetings of each Panel will be held monthly. Additional meetings may be scheduled as necessary.

The Chair or designee shall conduct all meetings of the Panel. Meetings shall generally be conducted in accordance with the review process explained in VII.B. with the Chair as final arbitrator of procedure.

B. Review Process

1. Each IRB member must be provided with sufficient information to be able to actively and constructively participate in the protocol review.

a. Each protocol will be assigned to a primary scientific reviewer who will be responsible for a full review of all materials, and will lead the discussion of the protocol, the complete grant application (as applicable) and the risk/benefit ratio.

b. Each initial protocol will be assigned to a secondary reviewer, who will be responsible for a full review of all materials and will lead the discussion of subject consent and recruitment procedures.

c. The structure for initial review will be (a) the Chair asks the primary scientific reviewer to present a summary of the protocol / study other than informed consent, (b) the primary scientific reviewer gives their summary, impressions, recommendations, and coordinates the discussion of the study, except for the informed consent, (c) the primary scientific reviewer formulates a recommendation about the panel action about the study, except for the informed consent, after the panel discussion, (d) the Chair asks the secondary reviewer to present a summary of the informed consent, (e) the secondary reviewer gives their summary, impressions, and coordinates the discussion of the informed consent document, (f) the secondary reviewer formulates a recommendation about the panel action about the informed consent, after panel discussion, (h) the Chair takes the vote of the Panel on the motion. Note that continuing reviews only use (d) through (f) if a study continues to have new enrollment. Continuing reviews do not routinely have a secondary reviewer. Most continuing reviews will have the scientific reviewer include the informed consent approval (when applicable) in the one motion with the study re-approval. The continuing review is a presentation primarily of what has occurred in the interim since the last review by a single reviewer.

d. Materials sent to all members for initial, continuing, or amendment review will include (a) the IRB application and/or the continuing review form, (b) the protocol or a summary of it, (c) amendments that have been approved, unless they have been incorporated into the distributed
protocol or protocol summary, (d) a current informed consent document, (e) copies of any other materials the Panel must take a vote on, such as advertising, questionnaires, etc., (f) copies of or a summary of reported unanticipated problems involving risks to subjects or others.

e. Complete documents are available to all members for review in ERSA.

2. Review materials must be received by the membership approximately a week in advance of the meeting to allow for adequate review of the materials.

3. For research funded by the National Institute on Disability and Rehabilitation Research, when an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these research participants.

C. Expedited review process

The Panel may utilize an expedited review procedure as authorized by HHS 45 CFR § 46.110; FDA 21 CFR § 56.110 and ICH § 3.3.5.

The Panel may utilize the expedited review process for the following types of research (HHS 45 CFR § 46.110; FDA 21 CFR § 110):

1. Minor changes in previously approved research during the period of one year or less, for which approval is authorized. Examples of minor changes include investigator changes, HIPAA additions to an informed consent, administrative changes (such as titles, other sites, typo corrections, etc.), pediatric assent forms, protocol changes that do not change the risk-benefit ratio of the study, advertisements that are easily compared to the approved consent document, and foreign language version consent forms that are an accurate translation of the IRB approved English versions (using appropriate expert consultation as needed). NOTE: If the only changes involve sub-investigators or administrative changes that do not affect subject safety, risks, benefits, or consent documents, then these can be administratively approved by the IRB Office without requiring a formal approval through the expedited procedure by an expedited reviewer.

2. Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the categories identified on the respective lists as published by the FDA and the DHHS (see http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm119074.htm).

The Chair or designee may conduct expedited review. The Chair may appoint other experienced reviewers from among the members of the Panel to conduct expedited review. Experienced reviewers are defined as those that have demonstrated an understanding of the regulations and ERSA through training, meeting deliberations, and IRB Office communications.
In reviewing the research, the reviewers may exercise all of the authorities of the Panel except disapproval. If the reviewers do not approve the research being reviewed, they must refer it to the full Panel for action.

A list of research that has been approved under the expedited procedure, including an explanation of the type of research activity and the action taken, shall be provided to the full panel as soon as practical after such expedited approval.

The Panel may not use the expedited procedure if its use of that procedure has been suspended or terminated by the FDA, OHRP or the Institution.

D. Voting Requirements

A quorum of a simple majority is required to conduct business or review research. A quorum requires a majority of the members (or appropriate alternates) of the Panel to be present. Alternates with appropriate backgrounds may replace regular members of similar background to achieve the quorum.

At least one scientific and one non-scientific member must be present at all meetings in which research activities are being considered.

If the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, one or more individuals who are knowledgeable about or experienced in working with such participants will be present.

At least one physician member must be present when research activities involving drugs, biologics or devices are being considered.

Only members (or appropriate alternates replacing individual members) may vote.

No one may vote who has a conflict of interest with respect to the research under consideration.

A favorable vote of the majority of the members/alternates present is required to approve research activities. No votes will be permitted by proxy.

If necessary, IRB meetings may be conducted via telephone conference call, provided each participating member has received all pertinent material prior to the meeting, and can actively and equally participate in the discussion of all protocols. Minutes of such meetings must clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements.

The IRB will ensure and document a quorum for each protocol review.
E. Communication from the IRB Panel

The Panel shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure Panel approval of the research activity. The institution is notified by electronic reports available to Research Administration.

The Panel shall inform all approved investigators in their approval letter that they must comply with the institutional and IRB SOPs related to human subject protection.

F. Appeal of IRB decision

If the Panel decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. (HHS 45 CFR § 46.109(d); FDA 21 CFR § 56.109(e); ICH §§ 3.1.2 and 3.3.9).

Revision History for Auditors

May 2016 – B.1.c was modified to correspond with AAHRPP requirement that there is only one vote per study. C.1 was modified to any investigator change is considered a minor change. C modified so that training replaces one year of service on the IRB is a basis for appointment as an expedited reviewer. E was modified to allow electronic reports to be the means of notifying the institution, and deleting the long list of investigator requirements to be printed on each approval letter. The latter is now be done by a hyperlink in the approval letters.

August 2014 – Removed the following statement as this is already covered to indicate a non-scientist is present at every meeting: At least one member who represents the general perspective of participants is present at convened meetings. This is accomplished by requiring the member who represents the applicable general perspective to be part of the quorum.

March 2013 – Updated to clarify materials sent for convened amendment review and to indicate that all meeting materials are sent to members via ERSA. Update to change name of the Office of Research Operations to Research Administration. Updated information on approval letter to clarify the following: 1) investigators must use the most current non-expired IRB approved consent form; 2) provided link to use of short form consent; 3) a new section on vulnerability was added; 3) when changes are made without IRB approval rather than immediate reporting to the IRB changed to within 5 working days.

August 2010 – Section A was revised to eliminate Robert’s Rules of Order as a procedure guide and to clarify we use the review process outlines in section B.

December 2008 – revised Communications from IRB section to make it more accurate in light of the revised structures in Research Administration and the ERSA programming. Also clarified in the approval letter template section that only unanticipated problems involving risks to subjects or others require reporting to the IRB, not adverse events that are not unanticipated problems (or unanticipated device events). Also added section B.1.d.(f) copies of or a summary of unanticipated problems involving risks to subjects or others. Also added the note in C.1 that certain change requests may be administratively approved by the IRB Office. Also deleted from section c.: “Each panel will perform its own expedited review. Panels are completely separate and responsible for only their own reviewed materials.”
October 2005 - Updated section C.1. as a minor change that can be done by expedited review: “principal investigator changes when the only change is to another person in the same specialty on the Ochsner Staff that is well qualified to be the PI for the study.”

December 2004 - Updated section C.1. as a minor change that can be done by expedited review: “foreign language version consent forms that are an accurate translation of the IRB approved English versions (using appropriate expert consultation as needed).”

November 2003 – Updated section C.1. as a minor change that can be done by expedited review: “advertisements that are easily compared to the approved consent document”

October 2003 – revised the approval letter template information based on WIRB recommendations.
VIII. IRB Record Requirements

The Panel will keep all required records and reports specified by regulation and these Written Procedures (HHS 45 CFR § 46.115; FDA 21 CFR § 56.115; ICH §§ 3.1.2, 3.4).

The IRB maintains records relating to research, including materials submitted by investigators for IRB review (or exemption), documentation of IRB activities, and other required records, such as IRB correspondence, rosters and policies. All records are maintained in a secure manner that allows for a review of the history of IRB actions.

A. Convened IRB discussion and decisions are documented by IRB staff in IRB meeting minutes, which are reviewed and approved by the applicable Panel. The minutes of each IRB convened meeting include:
   • Names of attendees
   • Documentation regarding whether a quorum exists
   • Names of any IRB members who leave the meeting due to a conflicting interest, along with the fact that a conflicting interest is the reason for the absence (as applicable)
   • Actions taken by the IRB, including the number of votes for, against, or abstaining
   • Summary of the discussion of controverted issues (if any) and their resolution
   • Basis for requiring changes in or disapproving research
   • For initial and continuing review, the approval period (not to exceed one year)
   • Determinations required by the regulations and protocol-specific findings justifying those determinations for the following:
     • Waiver or alteration of the consent process
     • Research determinations involving
       o pregnant women, human fetuses, or neonates
       o prisoners
       o children

B. In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of research, IRB staff maintains documentation of Board activities, including the following:
   • Copies of all research proposals reviewed
   • Scientific evaluations, if any, that accompany the proposals
   • Approved consent documents
   • Recruitment materials, if applicable
   • Records of continuing review activities, including progress reports
   • Data and Safety monitoring reports, if any.
   • Modifications to previously approved research.
   • Documentation of non-compliance
   • Reports of injuries to subjects
Human Research Protection Program  
Institutional Review Board  
Written Procedures (SOPs)  
Section: VIII. IRB Record Requirements  
Date Last Reviewed: June 2016

- Unanticipated problems involving risks to subjects or others and documentation of IRB review of these reports
- Statements of significant new findings provided to subjects as required by HHS 45 CFR § 116(b)(5), FDA 21 CFR § 50.25(b)(5) and ICH § 4.8.2.
- Emergency use reports
- Documentation of correspondence between the IRB and the research investigators
- Applicable determinations required by laws, regulations, codes, and guidance

C. For initial or continuing reviews conducted by expedited procedures, records will include the following:
   - Copies of all documentation submitted
   - Specific permissible categor(ies) permitting review by expedited procedures
   - Determinations required by the regulations and protocol-specific findings justifying those determinations for the following:
     - Waiver or alteration of the consent process
     - Research involving pregnant women, human fetuses, or neonates
     - Research involving children
   - Copies of all correspondence between the Panel and the research investigators
   - Applicable determinations required by laws, regulations, codes, and guidance

D. For exempt research, records will include the following:
   - Copies of all documentation submitted
   - Any associated correspondence between investigators and the IRB
   - The justification for exempt determinations, including citations of the specific categor(ies) justifying the exemption
   - Applicable determinations required by laws, regulations, codes and guidance

E. Other records maintained by the IRB office include a list of Panel members and their alternates identified by:
   - Name
   - Earned degrees
   - Representative capacity
   - Indications of experiences such as board certifications, licenses, etc.
   - Information sufficient to describe each member's chief anticipated contribution to the Panel deliberations
   - Any employment or other relationship between the member and the institution

F. Records relating to a specific research activity are maintained for at least 3 years after completion of the research (HHS 45 CFR § 46.115(b); FDA 21 CFR § 56.115(b); ICH § 3.4). This includes research studies that are cancelled without participant enrollment.
Revision History for Auditors

March 2013 – minor editorial changes

December 2008 – Revised as follows: A.6. to clarify that only unanticipated problems involving risks to subjects or others require reporting to the IRB, not adverse events that are not unanticipated problems (or unanticipated device events). An extensive educational process occurred in 2008 about this at Ochsner. A.7.e. the IRB minutes need to summarize the discussion of controverted issues as noted in A.7.d., not every dissenting opinion that does not qualify as a controverted issue.