



## INFORMATION FOR IRB MEMBERS

### WELCOME

Thank you for volunteering to serve on the university's Institutional Review Board (IRB). The review board works closely with investigators and the university to help ensure the safety and welfare of the individuals participating in human subject research.

The Board's sole concern is protecting the safety, welfare and rights of human subjects. The IRB reviews to ensure:

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is obtained or appropriately waived from all prospective subjects and documented
- The research protocol includes a plan for data and safety monitoring
- Subjects' privacy and confidentiality are protected
- Appropriate additional safeguards are incorporated for any vulnerable subjects

Research methodology will not be evaluated so long as it does not impact risk and ethical issues. Approval of this Board is not an endorsement of the research techniques, results, or conclusions drawn from the research.

### IRB Composition

- Each IRB will consist of at least five members
- Each IRB will include at least one member whose primary concerns are in scientific areas
- Each IRB will include at least one member whose primary concerns are in nonscientific areas, at least one member who represents the perspective of research participants, and at least one member who is not otherwise affiliated with CHS and who is not part of the immediate family of a person affiliated with CHS.

### ROLES OF IRB MEMBERS

The primary job of an IRB member is to help protect the rights and welfare of research subjects. Most members are Oklahoma State University Center for Health Sciences (CHS) faculty members are knowledgeable about science and research methods. Other board members are CHS staff and/or non-affiliated community volunteers.

Members of the IRB have been appointed to ensure a variety of expertise and diversity. All members have an equal vote. Please do not hesitate to give your comments during the Board discussions. Each member brings a special set of skills and insights that are important for a thorough IRB review. It is important that all members actively participate.

There are faculty members from a variety of disciplines on each IRB. Diverse expertise is needed to evaluate a wide variety of research studies. If the IRB determines there was a major study design flaw, the IRB would be concerned that the investigator would not be able to answer the study question. As a result, the IRB could not approve the research since the study risks would outweigh the potential benefit (new knowledge) to be gained.

The IRB members must also reflect racial, gender and cultural diversity. This is desired to promote sensitivity to community attitudes and respect for the Committee's decisions. Some members also have specific advocacy roles (for prisoners and children involved in research). For others, their primary concern is in non-scientific areas. Non-scientist members provide very important checks to determine if study materials and consent forms are in a language that will be understandable to potential study participants. The role of the non-scientist is so critical that there is a regulatory requirement for a non-scientist to be present at each convened board meeting.

Whenever possible, each IRB member has an alternate. This is done to reduce the frequency of meetings that members must attend. It also helps to ensure that sufficient members are available to reach the required meeting quorums. Although some members are officially designated as alternates, all members have equal voting privileges. If for some reason a member and his/her alternate wished to attend the same meeting, only one member of the team would be able to vote on a protocol action.

## **EDUCATION**

By reviewing protocols and participating in board discussions, you will become knowledgeable about the wide spectrum of CHS research and you will gain information about the latest research methods. Since science and technology is rapidly advancing, you will be taking part in lively committee discussions about evolving research ethics.

New IRB members must complete a web-based human subjects protections training course, designed specifically for their role, before serving as protocol reviewers. The course is comprehensive and includes information on ethical principles and regulatory requirements. National experts developed the course with funding from the National Institutes of Health. It is considered a continuously updated, topical, relevant course and is currently used by thousands of institutions and organizations worldwide. Please inform staff of your course completion.

As an IRB member you will also receive periodic additional education.

## ADMINISTRATIVE SUPPORT

The Human Subject Research (IRB) office provides support to the IRB and are pleased to assist you in your role as an IRB member. Your primary contact will be with the Research Compliance Coordinator or the Asst. Director. Please do not hesitate to contact either if you ever have any questions or concerns.

The IRB staff work closely with the investigators and with the committee members. The office staff pre-reviews the protocol submissions for completeness, and ensures regulatory criteria are met before placing them on a meeting agenda. The IRB staff members also answer investigators' questions and assign protocols IRB members. Members of the IRB staff attend the IRB meetings to provide regulatory guidance, prepare IRB meeting minutes, and forward IRB correspondence to investigators.

<b>ORRP Staff</b>			
<b>IRB Operations</b>			
Director, Research Compliance	Amber Hood, MS	918-561-1413	<a href="mailto:Amber.hood@okstate.edu">Amber.hood@okstate.edu</a>
Asst Director, IRB	Elisa Jolls, EdD	918-281-2756	<a href="mailto:ejolls@okstate.edu">ejolls@okstate.edu</a>
Research Compliance Coordinator	Daniel Angel	918-815-4144	<a href="mailto:Daniel.angel@okstate.edu">Daniel.angel@okstate.edu</a>

Please visit the Human Subjects section of the Office of Research [website](#) for the most up to date information on IRB procedures, IRB guidance, meetings and regulatory requirements.

## OKLAHOMA STATE UNIVERSITY: CENTER FOR HEALTH SCIENCES INSTITUTIONAL REVIEW BOARD

The university has one internal IRB.

<b>IRB</b>		
Chair	Anil Kaul, MD, DDS, MPH	Director, High Complexity Clinical Laboratory Clinical Professor, Health Care Administration

The ORRP staff monitors board assignments to ensure that the IRB with the most applicable expertise reviews the research. The ORRP may change a protocol board assignment if IRB members have significant conflicts of interest.

Research (clinical trials) that are industry sponsored, and not designed by CHS researchers may be reviewed by an independent, Association for the Accreditation of Human Research Program (AAHRPP) certified, board (e.g., the Western IRB).

**OTHER REVIEW COMMITTEES**

For some types of research, other institutional committee approvals are also required. The following university committees have specific responsibilities as mandated by federal regulations, state law and university policies.

<b>CHS Committee</b>	<b>Research Involving</b>
Biological Safety	Gene manipulation, infectious agents, toxins

**ASSURANCE FOR HUMAN SUBJECTS RESEARCH**

As part of the university’s Federal Wide Assurance (FWA), CHS has documented its intent to ensure that human subjects research is done properly. This is done through the university’s assurance. Each organization conducting human subjects research must have an assurance filed with the federal Office for Human Research Protections (OHRP). By signing this document, the institutional official has documented the university’s commitment that:

- All human subjects research will be reviewed and approved by the IRB before it is undertaken;
- Legally effective informed consent or a consent waiver will be obtained for all human subject research.
- Written procedures for human subject protections will be followed.
- Serious non-compliance with human subject requirements will be reported to OHRP.
- Sufficient IRB resources will be provided.
- IRB members, researchers, and research support staff will receive human subjects training; and
- Human subjects research will be limited to locations for which the university has authority and oversight responsibility.

The university’s FWA is: **#00005037**

## THE NINE BASIC IRB MEMBER RESPONSIBILITIES

- Conducting Protocol Review
- Applying Discipline & Regulatory Knowledge
- Attending Meetings
- Avoiding Conflict of Interest
- Developing IRB Policy
- Completing Mandatory Education Requirements
- Handling Allegations or Reports of Noncompliance
- Maintaining Confidentiality
- Determining Whether Federal Reports are Required

### Responsibility 1: Conducting Protocol Review

#### TYPES OF IRB REVIEW

1. Initial Review (IR)– Occurs when a research protocol is first submitted for IRB review. IR may take place at a meeting of the convened IRB (Full Review) or through Expedited or Exempt review mechanisms.
  - i Expedited Review – The study meets the regulatory requirement to be reviewed outside of a convened meeting by one or more IRB members delegated by the Chair
  - ii Exempt Review – The study meets the regulatory requirements to be exempt from review by the IRB, as verified by the IRB Office. (additional information on page 17)
2. Continuation Review (CR) or Administrative Annual Review (AAR) – CR occurs at least once every year, or at a greater frequency based on degree of risk as determined by the IRB. Select Expedited Review protocols are eligible for AAR.
3. Revisions/Modification Requests –The IRB has the authority to require revisions be made to a research protocol and is responsible for reviewing the revisions that are submitted by the investigator. Also, a researcher may submit a request to revise an already approved research protocol.

#### OTHER REVIEWS

4. Protocol deviations/violations and Unanticipated problems/adverse events – Unforeseeable events may arise when conducting research with human subjects.
5. Alleged or Reported Noncompliance – IRB reviews alleged or reported incidents of noncompliance, including the initial allegation/reports, any subsequent quality assurance reviews, investigation committee reports, or correspondence or information submitted in the course of handling the alleged or reported incident of noncompliance.

### Responsibility 2: Applying Discipline and Regulatory Knowledge

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

- Specialized experience – Many IRB members have scientific, medical, or other professional backgrounds and are expected to apply this knowledge in the review of research. This often proves useful to the IRB in its review of research that involves vulnerable subject populations such as children, prisoners, economically or educationally disadvantaged, or individuals with impaired consent capacity. Other members of the IRB are members of the community and not affiliated with CHS. These members serve as a rich resource to the IRB by reflecting the interests of the community including the interests of many prospective and current research participants.
- CHS policies and procedures – The IRB member must exhibit knowledge and application of CHS policies and procedures.
- Federal regulations – There are several sets of federal regulations that apply to the review of research involving human subjects. It is the responsibility of the IRB member to be familiar with these regulations and understand when each set applies to protocols based upon the nature of the research. A summary of the core regulations is included in the IRB Resource Guide (i.e. 45 CFR 46 Subpart A, 21 CFR 50).

### **Responsibility 3: Attending Full Review Meetings**

In order for an IRB meeting to be officially convened for full review, a quorum of at least half of the IRB member roster plus an additional member must be present. If a quorum is not established, no final actions can be taken upon the research protocols to be reviewed at that meeting and vital research may be greatly delayed. Also, Continuing Review approvals may lapse if a quorum is unavailable. In addition, each IRB member brings expertise to the review of research protocols. Each member has an important and unique contribution to make in the overall conduct of full reviews. Even if a quorum is obtained, the full review cannot be conducted without a nonscientist, scientist and, for FDA regulated studies, a physician.

### **Responsibility 4: Avoid/Disclose IRB Member Conflict of Interest**

No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Conflicts of interest include, but may not be limited to, the following:

1. The IRB member is currently engaged, or expects to be engaged, in the human subjects' research project under review.
2. The IRB member has a direct financial interest in the principal investigator or the entity funding the research proposed by the principal investigator.
3. The IRB member and the principal investigator of the application under consideration share an immediate (rather than extended) familial relationship.

4. The IRB member has other reasons to feel that she or he cannot render an independent assessment of an application.

The IRB member shall disclose the conflict of interest at the following time(s):

1. When the IRB member is contacted to participate in the review of a project from a Principal Investigator with whom the IRB member has a conflict of interest.
2. Prior to the discussion at a convened meeting of a project for which the IRB member has a conflict of interest.
3. Immediately upon discovery of the conflict of interest if at other than the foregoing times.

*Significant financial interest* is anything of monetary value, including, but not limited to:

- Salary or other payments for services (e.g., consulting fees or honoraria);
- Equity interests (e.g., stocks, stock options, or other ownership interests);
- A proprietary interest in the research such as a patent, trademark, copyright, or licensing agreements including royalties from such rights;
- A financial interest in the sponsor, product or service being tested;  
A position as an executive director or director of the agency or company sponsoring the research regardless of the amount of compensation;
- Any compensation that could be affected by the outcome of the research regardless of the amount of compensation.

*Significant financial interest* does NOT include:

- Salary, royalties, or other remuneration from the University;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or non-profit entities;
- An equity or financial interest that when aggregated for the IRB member or consultant and the IRB member's or consultant's spouse and dependent children meets both of the following tests: does not exceed \$5,000 in value as determined through reference to public prices or other reasonable measures of fair market value and does not represent more than a 5% ownership interest in any single entity;
- Salary, royalties or other payments that when aggregated for IRB member or consultant and the IRB member's or consultant's spouse and dependent children over the next 12 months are not expected to exceed \$5,000.

### **Responsibility 5: Developing IRB Policies**

The IRB role in developing policy usually focuses upon specific protocol review issues. IRB members may be asked to serve on IRB policy subcommittees or to review and comment on selected proposed policies.

### **Responsibility 6: Mandatory Education Requirements**

The CHS requirement for education in human subjects' protection was initially implemented in response to the National Institute of Health (NIH) requirements (effective with October 2000 awards) of training. All investigators/key personnel conducting research involving human subjects, or data or biological specimens derived there from, are required to be trained in the protection of human subjects. Likewise, each IRB member is required to complete this education requirement and seek recertification every three years.

IRB members are provided with ongoing continuing education opportunities.

### **Responsibility 7: Handling Allegations or Reports of Noncompliance – What is the IRB member role in handling alleged or reported cases of noncompliance?**

Incidents of alleged noncompliance with federal or IRB policy and procedures are periodically reported to the IRB by subjects, family members, research staff, colleagues, IRB staff or other individuals at CHS or within the community. Also, researchers report incidents of noncompliance with either approved IRB protocol procedures or University policy and procedures. The IRB Chair, Research Compliance Director, IRB Assistant Director, Legal Counsel, and IRB members may be involved in serving on investigation committees, collecting information, interviewing respondents or complainants, reviewing and/or inspecting research records. The IRB makes a final determination regarding whether noncompliance occurred and if so, what sanctions or protocol/informed consent revisions are needed.

### **Responsibility 8: Maintaining Confidentiality**

IRB members must maintain the confidentiality of any subject data that is presented to them in the review of research protocols. In addition, IRB members should maintain the confidentiality of all information collected from the researchers during the review. The IRB committee also handles sensitive information regarding noncompliance issues, and members are asked not to discuss these topics in their department, family, or any other outside settings.

### **Responsibility 9: Determining When Federally Mandated Reports are Required – When must the IRB submit reports to federal regulatory agencies?**

The IRB is subject to federal requirements to report certain issues that arise in the conduct of research. Per federal regulation, the Food and Drug Administration (FDA) and/or the Office for Human Research Protections (OHRP) should be notified when any of the following are directly related to the conduct of federally funded or FDA regulated research protocol:

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



The IRB is responsible for making a determination whether an incident meets these federal criteria for reporting to FDA, OHRP, or other applicable institutional or external agency.

### **IRB MEETING ATTENDANCE**

A quorum of the full IRB membership must be present to hold a convened meeting. Most IRB members have another member with whom they alternate their meeting attendance. However, the teams may split their coverage as best fits their schedule. While it is recognized that both members might occasionally be unavailable for a meeting, this should be rare. Researchers (including students on graduation timelines) count on all IRB meetings being held as scheduled.

If a member is unable to attend a scheduled meeting, the member should notify the IRB team as soon as possible.

### **MEETING LOGISTICS**

#### **Advance Materials**

Approximately 6 days prior to each convened meeting, the analyst will provide meeting material by email. The material will include an agenda and information about all the protocols the committee will consider. Specific meeting contents are described below.

For new protocols or those undergoing continuing review, **all IRB members review the following:** 1) IRB application summarizing the research; 2) informed consent and assent documents, as applicable; 3) questionnaires to be used for data collection (e.g., questionnaires, interview questions, or assessment scales); and 4) recruitment materials, including any advertisements to be seen or heard by potential subjects.

Those designated to be a **primary or secondary reviewer** of the research will also review: 1) complete copy of the research proposal; 2) complete copy of the sponsor's protocol or grant application for externally funded applications, as appropriate; 3) copies of the applicable drug / device information for research involving medications or devices.

Please notify the compliance coordinator if you are missing any materials.

The complete IRB file and minutes from previous reviews are also available to all IRB members prior to and during the convened meeting upon request.

## **PREPARING FOR THE MEETING**

Review and prepare for all studies on the agenda. Some helpful hints about preparation follow:

1. Begin by reviewing the meeting agenda. Look for your name to determine which protocols you have been assigned. These materials are your priority; start by reviewing them. You may be assigned to review a new protocol, an ongoing study that is due for a continuing review, or an amendment.
2. Many protocols are reviewed during a convened IRB meeting; however, some IRB submissions may qualify for expedited review. New members are not assigned to perform expedited reviews on the medical IRBs.
3. The primary reviewer should prepare a short summary for each of their assigned protocols. The summary should emphasize the procedures, risks, benefits, and consent process. Try to be concise and avoid giving excessive study details as each committee member receives a research summary and consent form in their materials.
4. Remember that the IRB member's job is to help protect the rights and welfare of research subjects. As you review your materials, look for problems and unanswered issues, but also try to suggest solutions. It is most helpful if you can come to the meeting ready to recommend specific modifications that the IRB can require the investigator to make.
5. The primary reviewer is encouraged to contact the principal investigator to resolve questions in advance of the meeting.
6. At times, ad hoc consultants may be desired to provide additional professional expertise to assist the Committee in its review. Should you identify the need for a consultant, please contact the Research Compliance Coordinator who will work with the Chair to make the necessary arrangements.
7. Members should ensure that any meeting materials are not copied or circulated. Please ensure that any printed IRB meeting materials are shredded when disposed.

## **ATTENDING THE MEETING/REVIEWING**

### **Guests**

Guests may include investigators CHS staff, and students. After the PI is excused, the IRB will complete discussion of any controversial issues and their resolution prior to voting.

### **Meeting Agenda**

The Chair will call the meeting to order and will usually follow the prepared agenda. Sometimes when there are conflicts of interest or other schedule conflicts, agendas must be rearranged. Ongoing research (i.e., continuing reviews, amendments, and event reports) is usually discussed before new protocols. This is done to avoid lapses in IRB approval and protocol interruptions should the IRB not be able to complete its entire agenda.

### **Disclosing Conflicts of Interest**

As an IRB member, you are required to disclose all potential and actual conflicts of interest before a protocol is reviewed. IRB members with conflicts of interest may be in the meeting room to answer questions about the protocol but must leave the room prior to final discussion and voting. The name of the board member with a conflicting interest is recorded in the IRB meeting minutes.

The members of the IRB retain the right to question other IRB members regarding their potential conflicts of interest at the time of protocol submission and bring discussions of such potential conflicts forward to the committee.

A Chair with a conflict of interest will not conduct those discussions.

### **Confidentiality**

IRB members must maintain the confidentiality of any subject data that is presented to them in the review of research protocols. In addition, IRB members should maintain the confidentiality of all information collected from the researchers during the review. The IRB committee also handles sensitive information regarding noncompliance issues, and members are asked not to discuss these topics in their department, family, or any other outside settings.

### **Protocol Reviews and Discussions**

The following procedures will be used for each protocol reviewed (new submission, continuing review, or amendment):

- 1) The Chair will ask all members to disclose any potential/actual conflicts of interests and excuse those with a potential conflict;
- 2) The primary reviewer will read their review emphasizing issues impacting subject welfare and safety with recommendations for modifications to improve subject protections when appropriate;
- 3) The secondary reviewer will present their comments;
- 4) The discussion will be opened to the full committee; and
- 5) At the conclusion of the group discussion, the Chair will ask the primary reviewer to offer a motion.

### **Making a Motion**

In their motion, the primary reviewer should propose:

- 1) Recommended Board action;
- 2) And for new and continuing reviews,
  - a. the risk level associated with the study; and
  - b. recommended length for IRB approval (up to one year).

### **Risk Level**

Study risk level is defined as either minimal risk or greater than minimal risk. Please use the following general guidance to make determinations:

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

The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults. Additional requirements apply when the research is greater than minimal risk, particularly for vulnerable populations (children, prisoners, fetuses, adults with decisional impairment).

IRB ACTION	REQUIREMENTS	OUTCOMES (next steps)
<p><b>APPROVAL</b></p>	<p>The IRB has determined that all criteria for approval have been met, as follows:</p> <ul style="list-style-type: none"> <li>• Risks to subjects are minimized;</li> <li>• Risks are reasonable in relation to reasonably anticipated benefits;</li> <li>• Selection of subjects is equitable;</li> <li>• Consent will be obtained &amp; documented (or regulatory criteria for waiver of consent have been met);</li> <li>• Proposed consent form(s) contains all the required elements;</li> <li>• Consent language is not exculpatory;</li> <li>• Information is presented in a language that is understandable to potential subjects;</li> <li>• Written consent will be obtained from adults who are able to consent;</li> <li>• Written assent will be obtained from: adults who are unable to consent and children 14-17 years old;</li> <li>• Verbal assent will be obtained from children younger than 14;</li> <li>• Separate parental permission will be obtained for subjects under 18;</li> <li>• Confidentiality is safeguarded;</li> </ul>	<p>Investigator receives an IRB approval letter for the period specified by the board.</p> <p>Letter informs the investigator of responsibilities for:</p> <ul style="list-style-type: none"> <li>• study oversight;</li> <li>• reporting serious adverse events and unanticipated problems;</li> <li>• for seeking IRB approval before initiating study changes; and</li> <li>• for seeking continuing IRB approval.</li> </ul>

	<ul style="list-style-type: none"> <li>Monitoring is adequate to assure subject safety and data integrity The IRB has determined whether an independent data and safety monitoring board or committee is required.</li> </ul> <p>When applicable, the IRB has:</p> <ul style="list-style-type: none"> <li>determined that regulatory criteria for inclusion of vulnerable populations have been met (additional safeguards have been included);</li> <li>determined whether an IND or IDE is required if a protocol involves the use of investigational new drugs or devices</li> </ul>	
<p><b>MODIFICATIONS REQUIRED</b></p>	<p>The criteria for approval have been met based on the review materials and explicit revisions that require simple concurrence by the investigator.</p> <p>Note: The federal agency (Office for Human Research Protections – OHRP) has made findings against boards when they inappropriately approve research contingent upon substantive modifications or clarifications.</p>	<p>The chair designates expedited IRB members who will subsequently review the investigator responses under expedited procedures outside the convened meeting.</p> <p>The reviewer approves the revised research protocol on behalf of the IRB.</p> <p>Research may not begin until the IRB member indicates that the required modifications have been made.</p>

<p><b>DEFERRAL</b></p>	<p>The criteria for approval have not been met. Additional information including substantive changes to the research proposal, consent form(s), application, or other materials is required before the board can make a determination.</p>	<p>Investigators are notified of deficiencies.</p> <p>One or more members of the IRB may be appointed to discuss the deferral with the principal investigator.</p> <p>After revising the protocol and/or consent form(s), the investigator will resubmit their response to the IRB.</p> <p>The application is then rescheduled for review at a convened meeting.</p> <p>The IRB may request that the investigator attend the convened IRB meeting at which the revised protocol will be reviewed.</p> <p>If the changes are approved, an approval letter that will document the approval period is sent to the investigator by the IRB staff.</p>
<p><b>DISAPPROVAL</b></p>	<p>Risks of the procedures outweigh any potential benefit to be gained.</p>	<p>IRB notifies the principal investigator by letter of the reasons for disapproval.</p> <p>The principal investigator will be given an opportunity to respond in person or in writing.</p> <p>No research may be initiated without approval of the IRB.</p> <p>The board's vote is final.</p> <p>No other office or official of the institution may approve a research activity that the IRB has disapproved.</p>

### **Length of IRB Approval**

The IRB may approve research for up to one year. The approval period should be appropriate to the degree of risk and the Committee may set a shorter approval period (i.e., more often than annually) for high or unusual risk protocols or protocols with a high risk/benefit ratio.

Examples of research that may require more frequent review include “novel” research (e.g., gene manipulation), Phase I studies, or projects conducted by investigators who have previously failed to comply with the requirements of the IRB. The approval period will be documented in the minutes of the IRB meeting.

### **Voting**

Show of hand votes are used or, in the case of meeting via Zoom, verbal votes are used. Members with disclosed conflicts may not vote and do not count towards the meeting quorum. The IRB member and their alternate may not both vote at the same meeting.

Members may vote for or against the motion or may choose to abstain from the vote. Only one action is voted on at a time.

If the quorum is lost at any time during the meeting (e.g., loss of members through absence or abstention), the IRB may not take further actions unless and until a quorum is restored.

## **FOLLOWING THE MEETING**

The IRB and IRB leadership work together to prepare and finalize the meeting minutes. Standard turnaround times have been developed to try to ensure prompt preparation of investigator correspondence.

Within three working days of the meeting, the ORRP staff will send correspondence to the principal investigator documenting the board’s actions. When modifications are required, the ORRP staff will pre-review investigator responses and will forward complete responses to the designated IRB reviewer.

The ORRP staff will write the meeting minutes within five working days following the convened meeting. The minutes will be sent to the IRB members for review and any necessary discussion or corrections, to be submitted within 5 business days. Minutes are finalized and uploaded to IRBManager within 14 days following the convened meeting.

## **REVIEWS PERFORMED OUTSIDE THE CONVENEED MEETING**

Protocols that meet specific regulatory criteria may be reviewed outside the convened IRB meeting. This is defined as expedited review. The IRB chairperson designates the IRB members



who may perform expedited reviews. The IRB members are notified of expedited reviews by email through IRBManager

### **New Protocols**

The IRB chairperson designates members with an appropriate level of experience to conduct these types of reviews. A single IRB member will review each submission. The reviewer should contact the compliance coordinator immediately if they feel the research does not qualify for expedited review or if they are unable to complete and return their review within one week.

The reviewer may approve the research, request modifications, or refer the research to the convened IRB for review but may not disapprove the research. The reviewer must document the specific research category under which the research qualifies for expedited review. Completed reviewer sheets should be uploaded to IRBManager.

### **Investigator Responses to IRB Required Modifications**

The coordinator will post investigator responses and revised supporting documents for the designated modifications reviewer. The reviewer should ensure that the investigator has made all the modifications requested by the board. Reviewers are asked to limit their review to the Board's specific requests.

### **Continuing Reviews & Amendments**

Only administrative and editorial amendments and continuing review applications that meet the requirements for expedited review may be reviewed outside of the convened IRB meeting. The chairperson delegates these responsibilities to a limited number of experienced IRB members who have undergone additional training. The expedited reviewer may approve the research, request modifications, or refer the research to the convened IRB for review but may not disapprove the research.

## **EXEMPT RESEARCH**

Some human subjects research may be exempt from review by the IRB. At CHS, investigators may not make this determination. IRB staff review applications for exemption to determine whether the proposed research meets the regulatory requirements for exemption. Review should be made prior to the beginning of study activities.