AAHRPP TRAINING SERIES

IRB Member Responsibilities

What are the responsibilities of an IRB chair or vice chair?

The Chair is a voting members of the IRB and assumes all the responsibilities of regular IRB Members. In addition to their responsibilities as voting IRB members, the IRB Chair or Vice Chair (when the Chair is not present) will oversee IRB meetings to ensure reviews and approvals meet the criteria for approval and comply with other regulatory requirements, ethical principles, or university policy. In addition, chairs can guide discussions on controverted issues and propose resolutions to the issues, form sub-committees for inquiries, request post approval monitoring activities and provide input on IRB member evaluations.

What are responsibilities of an IRB Member?

As an IRB member, your responsibilities include:

1) Attending the majority of convened IRB meetings
2) Applying disciplinary knowledge and regulatory knowledge
3) Reviewing the IRB application materials and informed consent form for all research proposals on the meeting agenda to a depth to where you can determine whether the criteria for approval is met.
4) When assigned as a primary reviewer, after reviewing the application and all supporting documents such as the protocol, surveys, questionnaires, advertisements, drug or device brochures and informed consent documents, present a summary for the board in sufficient detail to facilitate a discussion about whether or not the research meets the criteria for approval.
5) Conducting assigned expedited reviewers
6) Avoiding conflict of interest
7) Completing required training and education
8) Maintaining confidentiality of board proceedings and of research protocols
9) Knowing when to ask for a consultant

What is Quorum?

Quorum is determined by the number of IRB members on the official IRB roster. Alternate members do not add to the quorum count. It is important that the member or the alternate attend each meeting so that quorum can be achieved. A quorum is the minimum number and type of IRB members that must be present at a convened meeting. In order to review proposed research at a convened meeting, a majority of the members of the IRB must be present, including at least one member whose primary concerns are in nonscientific areas (45 CFR 46.108(b); 21 CFR 56.108(c)). If a majority of the IRB membership is not present, or if a nonscientist is not present, then quorum has not been met. Note: Studies involving FDA regulated drugs or devices require a **physician or dentist** (when appropriate) to be involved in the review.

The attendance information must be documented in the minutes for determining whether the nonscientist was present, and whether proposed research received enough votes (i.e., a majority of those present) to be approved.

Quorum is calculated by using the "half-plus-one" technique. . For example, if the total IRB membership is 10, then the majority is 6 (half of 10 is 5, plus 1 equals 6). However, for an odd number of members, the majority should be calculated by taking half of the total number of IRB members, and rounding up to the next whole number. For example, if the IRB membership is 15, then majority is 8 (half of 15 is 7.5, and rounding up to the next whole number is 8)

A quorum must be maintained throughout the meeting. If quorum is lost during a meeting, then the IRB may not vote on proposed research (45 CFR 46.108(b); 21 CFR 56.108(c)). Because IRB members may occasionally enter or leave the room at various times during a convened meeting (e.g., arrive late, depart early, or leave the meeting temporarily), the minutes provide sufficient information to indicate that a quorum is maintained.

http://rcb.tamu.edu/humansubjects/forms/HRP305WORKSHEETQuorumandExpertise.pdf

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

Each IRB member has expertise in a particular area and is expected to apply that knowledge in the review of research protocols. There are three primary areas of expertise that an IRB member should utilize. These are as follows:

Specialized experience – Many IRB members have scientific, medical, or other professional backgrounds and are expected to use this knowledge in the review of research. Other members may have experience with vulnerable subject populations such as children, prisoners, pregnant women, or individuals with impaired decision making capacity. Community members or those not affiliated with TAMU serve as a valuable resource to the IRB by reflecting the interests of the community including the interests of many prospective and current research participants.

TAMU policies and procedures – The IRB member must exhibit knowledge and application of TAMU policies and procedures. The TAMU HRPP standard operating procedures can be found at the following website:
http://rcb.tamu.edu/humansubjects/forms

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.

The Common Rule for Human Research Protections, **45 CFR Part 46**, is the primary regulation used for

the review of research at TAMU.

The Common Rule is divided into subparts.

Subpart A – Is the core regulation that cover the following areas:

- Definitions
- IRB Membership
- IRB authority, functions and operations
- Review of Research
- Criteria for Approval
- IRB Records
- Requirements for Informed Consent and Documentation of Consent
- Use of federal funds for research requires a Federal Wide Assurance (FWA)

Additional protections for vulnerable populations in Subpart B, C, and D.

Subpart B – Pregnant Women, Human Fetuses and Neonate
http://rcb.tamu.edu/humansubjects/forms/HRP412CHECKLISTPregnantWomen.pdf

Subpart C – Prisoners
http://rcb.tamu.edu/humansubjects/forms/HRP415CHECKLISTPrisoners.pdf

Subpart D – Children
http://rcb.tamu.edu/humansubjects/forms/HRP416CHECKLISTChildren.pdf

Subpart E – Registration of Institutional Review Boards

Please be aware that many federal agencies that adopted the Common Rule may have other specific regulations that have to be satisfied. The agencies include DOJ, EPA, DOD, DOE, Dept. of ED. See Worksheet HRP-318.
http://rcb.tamu.edu/humansubjects/forms/HRP318WORKSHEETAdditionalFederalAgencyCriteria.pdf

The IRB also encounters studies of test articles (drugs, devices and biologics). These studies fall under the scope of **FDA** regulations. The FDA has numerous sets of regulations but the primary regulations used for research at TAMU include:

- Protection of Human Subjects - Informed Consent (21 CFR Part 50)
- Institutional Review Boards (21 CFR Part 56)
- IND - Investigational New Drug Application (21 CFR Part 312)
  http://rcb.tamu.edu/humansubjects/forms/HRP306WORKSHEETDrugs.pdf
- IDE - Investigational Device Exemptions (21 CFR Part 812)
  http://rcb.tamu.edu/humansubjects/forms/HRP307WORKSHEETDevices.pdf

What materials do all IRB members need to review before they attend a board meeting?

The electronic system iRIS contains all the necessary protocol related materials required for review which includes the following items as applicable to the study.

*Application form with local context and protocol procedures
*Consent/Assent document(s) and script(s)
HIPAA Authorization
Recruitment materials – ads, flyers, emails
Survey instruments
Investigator drug brochure or device manual
Contract or Grant – (IRB staff will verify congruency)

The primary reviewer will present a summary of the materials to the board for discussion of how the study does or does not meet the criteria for approval.

When a study does not go to the full board and is reviewed through expedited procedures, the primary reviewer is responsible for reviewing all research materials for that submission.

See HRP-045 SOP: Member Review Expectations.
http://rcb.tamu.edu/humansubjects/forms/HRP045SOPIRBMemberReviewExpectations.pdf

What do you need to know about avoiding conflict of interest?

IRB members are responsible for knowing when they have a conflicting Interest and for disclosing such interests. Financial conflicts of interest are disclosed in accordance with Texas A&M University System Regulation 15.01.03 Financial Conflicts of Interest in Sponsored Research and University Rule 15.01.03.M1 Financial Conflicts of Interest in Sponsored Research.

IRB members are to notify the Chair at an IRB meeting prior to the review of any research for which they have a conflict of interest. The IRB member must leave the meeting for the discussion and vote of the research. The IRB member should notify the IRB staff immediately if they are assigned a non-committee review of any research for which they have a conflict of interest and ask for the review to be reassigned. Conflicts of interest include non-financial as well as financial conflicts, because non-financial interests can also come into conflict with a reviewer's commitment to maintain objectivity. See HRP-050 SOP: Conflicting Interest of IRB Members.

http://rcb.tamu.edu/humansubjects/forms/HRP050SOPConflictingInterestsofIRBMembers.pdf

What education do you have to complete before reviewing human subjects research for the IRB?

IRB Member Required Training		
	Course	Timeline
Initial Training	CITI IRB Members Basic	Within 45 days of appointment
	TRAINTRAQ Financial Conflicts of Interest in Research - 211716	Within 45 days of appointment
	TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Within 45 days of appointment
	New IRB Member Orientation	Prior to voting and review assignments;
Refresher Courses	CITI IRB Members Refresher	Every 5 years
	TRAINTRAQ Financial Conflicts of Interest in Research - 211716	Every 4 years or upon change
	TRAINTRAQ HIPAA Privacy and Security for Human Research - 2112435	Annually or as required

Additional sources of ongoing education include: PRIM&R conferences (or equivalent professional meetings), IRB member education during IRB meetings and webinars. See HRP-002 SOP: Education http://rcb.tamu.edu/humansubjects/forms/HRP002SOPEducation.pdf

What are IRB member responsibilities for maintaining confidentiality?

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

When should the IRB use a consultant?

Both the Common Rule and the FDA regulations state that the IRB can use consultants (internal or external) when the review of research requires expertise beyond what is available through the current IRB membership. Certain protocols require specific knowledge in scientific areas such as medical research, research involving vulnerable populations, or community participatory research. Consultants may provide a written report or attend board meetings to present their scientific review but they are never allowed to vote. Whether or not the criteria for approval is met is never deferred to a consultant. The board retains this responsibility after they consider the consultant's information. Consultants are subject to the conflict of interest disclosure. Reviewers should contact the IRB staff when the assigned review requires additional expertise

especially when the research is greater than minimal risk. See SOP HRP-051.
http://rcb.tamu.edu/humansubjects/forms/HRP051SOPConsultation.pdf

Evaluation of IRB members:

A periodic analysis of IRB committee member meeting attendance and review assignments is conducted to evaluate the membership and composition of the committees and to ensure members are fulfilling the requirements including education requirements. Member contributions and attendance are evaluated before reappointments are made. The evaluation is conducted by the IRB Chair and the HRPP office. See HRP-060 Evaluations of the HRPP.
http://rcb.tamu.edu/humansubjects/forms/HRP060SOPAnnualEvaluationsoftheHRPP.pdf