THE OHIO STATE UNIVERSITY

INFORMATION FOR IRB MEMBERS

WELCOME

Thank you for volunteering to serve on one of the university's Institutional Review Boards (IRB). The review boards work closely with investigators and the university to help ensure the safety and welfare of the individuals participating in human subject research. Currently Ohio State investigators are conducting more than 3,000 projects that involve human subjects.

Your appointment letter is very important. Please keep your copy and make sure that you have returned a signed original. This is the official record documenting your acceptance of the IRB member role on behalf of the university.

ROLES OF IRB MEMBERS

Your primary job as an IRB member is to help protect the rights and welfare of research subjects. Most members are Ohio State faculty members who are knowledgeable about science and research methods. Other board members are Ohio State 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 Committee 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. When a study has not been reviewed for scientific merit prior to the IRB meeting, the scientist members on the committee must evaluate the study plan. The IRB must know that the scientific question is important and that the proposed study design can yield the information required to answer the research question. 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 Ohio State 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.

This guide is provided as your reference to the Ohio State IRB procedures. New members are required to observe an IRB meeting before beginning to review protocols. In addition, all members are given the *Institutional Review Board Member Handbook* that you should also find very helpful as you perform your reviews.

New IRB members must complete a web-based CITI human subjects protections training course before serving as protocol reviewers. The CITI 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 state of the art course and is currently used by thousands of institutions and organizations worldwide. Please inform staff of your course completion. Details on the required training are found at http://orrp.osu.edu/irb/training-requirements/.

As an IRB member you will also receive periodic updates. The IRB chairs and vice chairs also attend local, regional, and national conferences to help the boards stay current on human subjects protections issues.

ADMINISTRATIVE SUPPORT

The Office of Responsible Research Practices (ORRP) provides support to the university review committees. The ORRP staff members are pleased to assist you in your role as an IRB member. Your primary contact will be with the IRB analysts. Please do not hesitate to contact the analyst if you ever have any questions or concerns.

The ORRP staff work closely with the investigators and with the IRBs. The office staff pre-reviews the protocol submissions for completeness before placing them on an IRB meeting agenda. The ORRP staff members also answer investigators' questions, and assign protocols to the most appropriate IRB. Members of the ORRP staff attend the IRB meetings to provide regulatory guidance, prepare IRB meeting minutes, and forward IRB correspondence to investigators. ORRP staff also work with the IRB leadership to develop quality improvement initiatives and to

investigate allegations of non-compliance with human subjects requirements. ORRP also conducts post-approval monitoring to ensure compliance with IRB approved protocols.

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Please visit the Human Subjects section of the ORRP website for the most up to date information on IRB procedures and regulatory requirements. The ORRP website contains Ohio State policies, IRB guidance, meeting calendars, and regulatory guidelines. The website can be accessed at **http://orrp.osu.edu/irb/.**

OHIO STATE INSTITUTIONAL REVIEW BOARDS

The university has three internal IRBs. A listing of the boards and the current leadership follows.

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.

Behavioral & Social Sciences IRB (Research that does not involve biomedical procedures)			
Chair	Daniel Strunk	Associate Professor	Clinical Psychology
Vice Chair	Jesse Fox	Assistant Professor	Communication
Vice Chair	Howard Klein	Professor	Management and Human Resources
Biomedical Sciences IRB			
Chair	Karla Zadnik	Professor/Dean	Optometry
Vice Chair	Jan Clark	Specialty Practice Pharmacist	Infectious Diseases
Vice Chair	Tom Raasch	Professor	Optometry
Vice Chair	Cynthia Shellhaas	Professor	Obstetrics & Gynecology
Cancer IRB			
Chair	William Carson	Professor	Surgical Oncology
Vice Chair	Floor Backes	Assistant Professor	Gynecologic Oncology

Research (clinical trials) that is industry sponsored, and not designed by Ohio State researchers is reviewed by an independent board (e.g., the Western IRB) unless the ORRP triage determines that the research should be reviewed by one of the local Boards.

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.

Ohio State Committee	Research Involving
Clinical Scientific Review Committee (CSRC)	Cancer-related activities
Institutional Biosafety Committee (IBC)	Gene manipulation, infectious agents, toxins
Maternal-Fetal Welfare Committee	Pregnant women and fetuses
Human Subjects Radiation Committee	Radioactive drugs or research exposure to external radiation
Privacy Board	Protocols that are exempt from IRB review and involve protected health information (PHI) (HIPAA compliance)

ASSURANCE FOR HUMAN SUBJECTS RESEARCH

As part of the university's Federalwide Assurance (FWA), Ohio State 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 non-exempt 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 subjects research;
- Written procedures for human subjects protections will be followed;
- Serious non-compliance with human subjects 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.

A copy of the university's FWA (#00006378) is posted at http://orrp.osu.edu/files/2012/02/FWA-042521.pdf.

RESEARCH PERFORMANCE SITES

An Ohio State IRB may only approve human subjects research activities at locations for which the board has an understanding of the local research context and the university has oversight and control mechanisms in place.

Persons are considered to be "engaged" in human subjects research when they:

1) Intervene or interact with living individuals for research purposes;
OR
2) Obtain individually identifiable private information for research purposes;
OR
3) Receive a direct federal grant to support human subjects research.

Some limited use of non-Ohio State facilities is permitted for research activities. However, the facilities and the personnel at the non-Ohio State sites must not be "engaged" in the research activities. Additional guidance on this topic is available at: http://www.hhs.gov/ohrp/policy/engage08.html. Questions may also be directed to the IRB analyst.

Since Ohio State is automatically "engaged" in human subjects research whenever it receives a direct federal grant, generally the Ohio State IRB must review and approve research whenever an Ohio State faculty member receives a federal grant. This is required even if there will be no human subject activities at any Ohio State sites. In some situations, IRB review may be ceded to a collaborating institution through the use of an IRB Authorization Agreement facilitated by ORRP staff.

If a principal investigator proposes:

- Limited use of another institution's facilities (e.g. schools, nursing homes, businesses) for research activities that do not engage the facility or the facility personnel in the research, the IRB should require the investigator to submit letter(s) of support from the institution(s).

- More than limited use of the outside facilities or involvement by individuals who are not Ohio State employees or students (that would engage them in the research activities), the IRB should ask the investigator to provide documentation that there are arrangements in place for IRB oversight.

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 first contact their alternate to determine if their alternate can attend an additional meeting or trade scheduled meeting dates. The member that has initiated the schedule change must inform the IRB analyst of their team's plan for meeting coverage with as much advance notice as possible so materials can be properly posted.

Should the university close for severe weather or other emergencies, please phone ORRP at 614-292-3748 for voice mail instructions regarding meeting cancellations.

MEETING LOGISTICS

Schedules / Locations

Please refer to your board's specific schedule for meeting location and dates. Meetings are held every two or three weeks and usually last from two to three hours.

Parking

Free parking tokens are provided for individuals who are not affiliated with Ohio State to use in Ohio State visitor garages. See the IRB analyst at the meeting for a parking pass.

Advance Materials

Approximately 6 days prior to each convened meeting, the analyst will notify you via email that materials for the meeting are posted on BuckeyeBox. The material will include an agenda and information about all the protocols the committee will consider. The member's convened folder will contain reviewer sheets and a research proposal for your assigned protocols and other detailed information as applicable (e.g., grant proposal, drug information). 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 IRB analyst 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

Plan on spending several hours reading and preparing your protocol reviews.
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 (which means they are reviewed outside of the meeting by one or more IRB members delegated by the Chair). 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. The secondary reviewer should also be prepared to fill in (give a verbal summary of the study) if the primary reviewer is unexpectedly absent.

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 Operations Manager or Senior Protocol Analyst who will work with the Chair to make the necessary arrangements.

7. All assigned reviewers are required to turn in reviewer sheets. You may make changes directly on the protocol materials (e.g. a consent form) when major revisions are required. Please also turn these in to the analysts. BuckeyeBox-posted reviews are preferred and encouraged to avoid transcription problems; these can be uploaded prior to the meeting or after. Remember to date and note the IRB action(s) on your reviewer sheet(s), type your name, and upload the sheet in your "convened" protocol-specific folder.

8. Members should also 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

Guests

All guests will sign in, and each will complete a confidentiality agreement for the proceedings of the meeting. Guests may include investigators, Ohio State staff, and students. For each protocol that is reviewed with the principal investigator present during the convened IRB meeting, the IRB will review the application and begin discussion of the criteria for approval. 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.

Chairs and Vice Chairs with conflicts of interest will not conduct those discussions.

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 a determination:

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)
APPROVAL	The IRB has determined that all criteria for approval have been met, as follows: • Risks to subjects are minimized; • Risks are reasonable in relation to reasonably anticipated benefits; • Selection of subjects is equitable; • Consent will be obtained & documented (or regulatory criteria for waiver of consent have been met); • Proposed consent form(s) contains all the required elements ; • Consent language is not exculpatory; • Information is presented in a language that is understandable to potential subjects; • Written consent will be obtained from adults who are able to consent; • Written assent will be obtained from: adults who are unable to consent and children 14-17 years old; • Verbal assent will be obtained from children younger than 14; • Separate parental permission will be obtained for subjects under 18; • Confidentiality is safeguarded;	Investigator receives an IRB approval letter for the period specified by the board. Letter informs the investigator of responsibilities for: • study oversight; • reporting serious adverse events and unanticipated problems; • for seeking IRB approval before initiating study changes; and • for seeking continuing IRB approval. Research that has been approved by the IRB may be subject to further review by the Senior Vice President for Research (SVP). If approved by the IRB but not permitted by the Senior Vice President for Research, the SVP will promptly convey notice to the investigator and the IRB Chair.

	• 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. When applicable, the IRB has: • determined that regulatory criteria for inclusion of vulnerable populations have been met (additional safeguards have been included); • determined whether an IND or IDE is required if a protocol involves the use of investigational new drugs or devices	
MODIFICATIONS REQUIRED	The criteria for approval have been met based on the review materials and explicit revisions that require simple concurrence by the investigator. 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.	The chair designates an IRB member who will subsequently review the investigator responses under expedited procedures outside the convened meeting. The reviewer approves the revised research protocol on behalf of the IRB. Research may not begin until the IRB member indicates that the required modifications have been made.

DEFERRAL	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.	Investigators are notified of deficiencies. One or more members of the IRB may be appointed to discuss the deferral with the principal investigator. After revising the protocol and/or consent form(s), the investigator will resubmit their response to the ORRP. The application is then rescheduled for review at a convened meeting of the appropriate IRB. The IRB may request that the investigator attend the convened IRB meeting at which the revised protocol will be reviewed. If the changes are approved, an approval letter that will document the approval period is sent to the investigator by the ORRP staff.
DISAPPROVAL	Risks of the procedures outweigh any potential benefit to be gained.	ORRP notifies the principal investigator by letter of the reasons for disapproval. The principal investigator will be given an opportunity to respond in person or in writing. No research may be initiated without approval of the designated IRB. The board's vote is final. Neither the Senior Vice President for Research or any other office or official of the institution may approve a research activity that the IRB has disapproved.

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. 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.

A motion passes when no more than one IRB member of the duly convened IRB casts a dissenting vote. 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 ORRP 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.

The ORRP staff will write the meeting minutes and the IRB Chair, Vice Chair, or member chairing the meeting will review and approve the minutes within five working days following the convened meeting. Within three working days of receiving the approved minutes, 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.

REVIEWS PERFORMED OUTSIDE THE CONVENED 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 in the BuckeyeBox Archives Folder.

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. Reviews are posted on a weekly basis. The reviewer should contact the IRB analyst 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 BuckeyeBox.

Investigator Responses to IRB Required Modifications
The analyst 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 Ohio State, investigators may not make this determination. ORRP staff review applications for exemption to determine whether the proposed research meets the regulatory requirements for exemption.

IRB MEMBER PROTECTIONS

The University Regulatory Counsel has provided ORRP with the following information. IRB service is clearly within the scope of responsibility for Ohio State employees. As such, employees are granted a qualified immunity from liability in civil actions related to their university duties that are filed in state courts. If IRB members perform their duties in good faith and in a reasonable manner, the risk for personal liability is negligible.

Although community volunteers are not provided the specific statutory protection granted by state law to university employees, the University Regulatory Counsel has indicated that Ohio law may give community IRB members some protection. Since they are formally appointed to the committees by the institutional official, the university would urge a court to afford community IRB members a similar level of protection to that granted to state employees. This reasoning, however, has never been tested in an Ohio court.

The University Treasurer's Office has also informed the University Regulatory Counsel that the university's comprehensive risk insurance policy provides coverage for university volunteers. As with employees, community members must be acting within the scope of their IRB responsibilities in good faith and in a reasonable manner.