IRB Member Manual

A basic training guide designed to support board members as they learn the IRB process.

Board Member Handbook: A Basic Training Guide to Assist New Board Members with the IRB Process Provided by:

Case Western Reserve University Institutional Review Board
Sears Library, Suite 622
2095 Martin Luther King Jr. Dr.
Cleveland, OH 44106
Email: cwru-irb@case.edu
https://case.edu/research/faculty-staff/compliance/institutional-review-board-cwru-irb/cwru-guidance

CASE WESTERN RESERVE UNIVERSITY EST. 1826

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Kimberly Volarcik
Executive Director, Human Research Protection Program
Office of Research & Technology Management
10900 Euclid Avenue
Cleveland, Ohio 44106-7340
Phone: 216.368.0134
kav6@case.edu

Dear IRB Board Member,

The Case Western Reserve University (CWRU) Institutional Review Board is pleased to welcome you as you begin your service on the IRB. We hope that you will enjoy an interesting and fulfilling term with us.

This document is designed to guide you through membership expectations and related information for your service on the IRB at the CWRU. New CWRU IRB members always have many questions regarding IRB practices and the use of SpartaIRB, our electronic research submission software. We encourage you to let staff know about your training needs as a new Board member.

Over time, you will be exposed to a multitude of differing research studies--some with unique sets of circumstances that require use of additional federal guidelines. At IRB meetings you will learn about regulations that pertain to vulnerable subjects such as children, pregnant women and, and prisoners.

As an **IRB member you are not required to become an expert in these federal regulations. The IRB Chair and administrative staff will be able to assist you with questions that you may have as a reviewer. Just remember that <u>your expertise and unique perspective as a reviewer is valued</u> even if you** do not have experience in any of the special circumstances described.

Executive Director for the Human Research Protection Program

Chapter 1: The IRB Administrative Office

Office Location

The IRB Administrative Office is located on the 6th floor in Nord Hall, Suite 615. The IRB administrative staff is available to assist you in your role as an IRB Member.

Contact Lists

The contact lists for the IRB administrative staff may be found on the CWRU IRB website https://case.edu/research/faculty-staff/compliance/institutional-review-board-cwru-irb

IRB Administrative Staff

The administrative staff for the IRB consists of paid professionals who write procedures and guidance, handle correspondence with relevant federal agencies, process applications for review, request progress reports from researchers, conduct training for researchers and IRB members, arrange IRB meetings, and generally provide support services needed for the oversight of research at CWRU. The IRB, not the professional staff, makes final decisions regarding a research project that has been submitted for consideration. Thus, the IRB and the administrative staff have differing roles and responsibilities, and their relationship with researchers will therefore differ.

Chapter 2: Introduction, Definitions, and History

Introduction

The Case Western Reserve University (CWRU) Institutional Review Board (IRB) reviews social/behavioral/educational and low-risk biomedical Human Research studies conducted by CWRU faculty members, staff and students. The CWRU IRB is constituted to review research involving Human Research according to Code of Federal Regulations at 45CFR46 and the U.S. Food and Drug Administration (FDA) regulations at 21CFR Parts 50 and 56. The CWRU IRB is an appropriately constituted administrative body established to protect the rights and welfare of human subjects. The IRB functions independently. Attempts to coerce or otherwise unduly influence the actions of the IRB are forbidden. Federal regulations at 45 CFR 46.107 outline the requirements for the composition of institutional review boards:

The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural

backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB based on gender. No IRB may consist entirely of members of one profession.

The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

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. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Definitions

Affiliated member is an employee or agent of CWRU (or a member of that person’s immediate family) who is appointed to the IRB as a full member or alternate, either scientific or non-scientific. Affiliated members include but are not limited to individuals who are: Full- or part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; CWRU pensioners; emeriti; health care providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB.

Faculty Member is a tenured, tenure track or non-tenure track person holding a full-time academic appointment at the ranks of professor, associate professor, or assistant professor in the constituent faculty whose obligations to the University include at least two of the following: 1) teaching, 2) research and scholarship, and 3) service to the University community.

Member is a person who is appointed to the IRB with the right to participate in all discussions. A member of the IRB may be voting or ex officio.

Voting Member is a person who is appointed to the IRB with the right to vote and count in determining the quorum at a convened meeting.

Non-Affiliated Member is a person who is appointed to the IRB as a full member or alternate, either scientific or non-scientific, but not connected or associated with Case Western Reserve University or its affiliate institutions in any way other than as an IRB member or alternate. Non-Affiliated members are also not part of the immediate family of someone who is affiliated with the CWRU or its affiliates. Non-affiliated members cannot work for the university, or receive any funds from the university (i.e., pension, stipend, contract, etc.). This connection includes children, spouses, partners, and/or working relationships.

Alternate member is an individual who has the experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member(s) whom the alternate would replace.

A Scientific member is an individual who has formal education and training as a physician or other healthcare professional, A Master's or Doctoral-level physical, biological, or social/ behavioral scientist, or significant post-baccalaureate work experience in a physical, biological, or social-behavioral sciences.

A Non-Scientific member is an individual who may have formal education and training in a discipline generally considered to be non-scientific (e.g., humanities, law, business) and/or is engaged in an occupation or role that is generally considered to be non-scientific (e.g., law enforcement, management, minister/rabbi/imam).

A Scientific and/or Cultural Reviewer or Consultant is an individual with competence in a special area whom the IRB has invited to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB as per 45 CFR 46.107(e).

Ex Officio Member is a person who is appointed to the IRB with the right to participate in all discussions, but who does not vote or count in the quorum.

Conflicting Interest or **Conflict of Interest** means the existence of one or more concerns that might influence an IRB member in the performance of their Board responsibilities. Conflicting interests are factors that can cloud judgment, such as personal relationships between an IRB member and an investigator, and financial relationships with sponsor companies.

Brief History of Human Subjects Research Regulations

The modern history of ethical standards for human subject's research began in the 1940s with the Nuremberg Code. Since then, the U.S. federal government has increased awareness for protecting the rights and welfare of human subjects by establishing regulatory codes and regulations. This section provides a brief background on the history of the regulations and ethics that are required when human subjects are involved in research.

Nuremburg Code

The Nuremberg Code was developed following the Nuremberg Military Tribunal which judged Nazi doctors conducting human experimentation. The Code encompasses many of the basic principles governing the ethical conduct of human subject's research today. The Nuremberg Code states that "the voluntary consent of the human subject is absolutely essential" and it further explains the details implied by this requirement: capacity of participants to consent, participants' rights to participate or not, freedom from coercion, no penalty for withdrawal, and comprehension of the risks and benefits involved.

Declaration of Helsinki

In 1964, the World Medical Association established recommendations to guide medical doctors in biomedical research involving human subjects. The Declaration governs international research ethics and defines rules for "research combined with clinical care" and "non-therapeutic 6 research." The Declaration of Helsinki was revised in 1975, 1983, 1989, 1996, 2000, and 2008 and is the basis for Good Clinical Practices used today. Issues addressed in the Declaration of Helsinki include:

- Research involving medical interventions with humans should be based on the results from laboratory and animal experimentation.
- Research protocols should be reviewed by an independent committee prior to initiation.
- Informed consent from research participants is necessary.
- Research should be conducted by medically/scientifically qualified individuals.
- Risks should not exceed benefits.

Belmont Report

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research wrote "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The Belmont Report sets forth the basic three ethical principles expected to be followed when doing research involving human subjects: respect for persons (autonomy), beneficence, and justice.

Respect for Persons: "Respect for persons incorporates at least two ethical convictions: first, individuals should be treated as autonomous agents, and second, persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy." In short, this states that the person must be capable of making the decision on whether or not to participate in a human subject's research project.

Beneficence: "Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In [the Belmont Report], beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms."

Justice: "Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some 7 burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit."

Federal Policy for the Protection of Human Subjects (Common Rule)

In 1981, the Department of Health and Human Services codified the Policy for the Protection of Human Subjects (Title 45, Part 46). These regulations, called the "Common Rule," provide for the basic foundation of Institutional Review Boards. This Federal Policy has been codified by the 18 federal agencies that conduct, support, or otherwise regulate human subjects research, hence the title "Common Rule." The Policy also provides additional protections to specific populations, such as pregnant women, fetuses, and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D) involved in human subjects research. In January 2019, a revised Common Rule went into effect. United States Food and Drug Administration Regulations The U.S. Food and Drug Administration, within the Department of Health and Human Services, regulates drugs, medical devices, and biologics. FDA regulations 21 CFR Part 50 (Protection of Human Subjects), and 21 CFR Part 56 (Institutional Review Boards) must be adhered to when studies are conducted using drugs, medical devices, or biologics. Although FDA regulations are similar to the regulations found in the Common Rule, there are some differences. Heath Insurance Portability and Accountability Act (HIPAA) Privacy Rule The Health Insurance Portability and Accountability Act Privacy Rule (HIPAA) is a federal law that generally prohibits health care providers (such as physicians or other health care practitioners, hospitals, nursing facilities and clinics) from using or disclosing "protected health information" (PHI) without written authorization from the patient. If an investigator intends to create, use, or release to others (e.g., sponsors, other investigators, collaborators) any identifiable health information in connection with their research, he/she must indicate that in the IRB application. When reviewing proposed research, the IRB serves as the Privacy Board and can approve waivers or alterations of HIPAA authorization for use of PHI. Protected Health Information (PHI) is health information transmitted or maintained in any form or medium that includes ALL of the three following parts:

- identifies or could be used to identify an individual; and
- is created or received by a healthcare provider, health plan, or healthcare clearinghouse; and
- relates to the past, present, or future physical or mental health or condition of an individual.

The provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual. The full text of the updated HIPAA Privacy Rule can be found at the Office for Civil Rights (OCR) website: http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html.

Chapter 3: Board Composition

All standard operating procedures and policies apply to all members and alternates of the CWRU IRB.

The Case Western Reserve University Institutional Review Board (CWRU IRB) will be constituted according to the federal regulations governing IRB membership, as outlined in 45 CFR 46.107.

Composition of IRB

The CWRU IRB is a board comprised of faculty members, a prisoner representative, a non-scientist, and a non-affiliated member.

On an annual basis, the IRB Chair and the Executive Director for the Human Research Protection Program shall review the membership and composition of the IRB to determine if they continue to meet regulatory and institutional requirements. Members will receive documented feedback on their performance as reviewers following this annual review.

Who Cannot Sit on the IRB and IRB Member Conflict of Interests

University Faculty, Deans, Administrators or Other Personnel with on-going conflict of interests cannot sit as IRB members. Individuals from the CWRU Office of Research and Technology Management may not serve as voting members of the IRB. Individuals from these offices may provide information to the IRB and attend IRB meetings as guests or ex officio members. No individual with responsibility for the business and financial interests of the organization may serve on the IRB.

No IRB member may participate in the review (initial, continuing, or modification) of any project in which the member has a conflicting interest, except to provide information requested by the IRB. It is the responsibility of each IRB member to disclose any COI in a protocol submitted for review and recuse him/herself from the deliberations and vote by leaving the room.

All members and alternate members of the IRB who are affiliated with the University CWRU annual COI Disclosure form, those who are not affiliated complete the CWRU Outside Interests Disclosure Form - Community Partners and annually thereafter. These forms are submitted to the Executive Director for HRPP or an Associate Director for the IRB who shares information regarding IRB member COIs with IRB staff. The IRB staff, in turn, ensure that IRB members and alternates are not assigned to conduct reviews of

protocols for which they have a conflict and to ensure appropriate recusal during convened meetings.

An IRB member, alternate, or consultant may be considered to have a conflicting interest requiring recusal when they, or immediate member of their family, have any of the following:

1. Substantive involvement in the design, conduct, and reporting of the research.
2. Significant financial interests (See 2012 Policy on Individual Conflict of Interests and Institutional Conflict of Interests for a definition of significant financial interests) related to the research being reviewed
3. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.

The IRB Chair will query IRB members at each convened meeting to determine if a COI exists regarding any research protocols to be considered during the meeting and remind them that they should recuse themselves by leaving the room during the discussion and vote of the specific research study. If a conflicted member is participating by conference call, videoconference or web meeting the member's participation is terminated for discussion and voting.

IRB members with a conflicting interest are excluded from being counted towards quorum. All absences of members with COIs are recorded in the minutes.

If the Conflict of Interests status of an IRB member changes during the course of a study, the IRB member is required to declare this to the IRB Chair and/or Executive Director for HRPP.

Consultants and the investigator-as-member cannot participate in the review and approval process for any project in which he or she has a present or potential conflict of interests. Where the investigator-member has a conflicting interest, he or she should be present only to provide information requested by the IRB. He or she should be absent from the meeting room during the discussion and voting phases of the review and approval process; IRB minutes will reflect whether or not these requirements have been met.

Appointment of IRB Members

Members are appointed annually by the Senior Vice President for Research and Technology Management.

The qualities considered for leadership appointments [Chair and Vice-chair] include academic status and record of leadership; academic expertise; willingness to commit the time required; experience with IRB and human research protection issues; administrative

abilities; and personal capacity to listen and guide multiple opinions expressed in a meeting format. Appointments may be renewed annually. Continuing membership is contingent upon satisfactory performance on the IRB, which includes, but is not limited to, reliable attendance and participation.

Non-Affiliated IRB Members

As with Affiliated members, Non-Affiliated members are questioned about whether their immediate family members are affiliated with the institution. They are interviewed by the Executive Director for HRPP or an Associate Director of the IRB and/or IO to inform them about the obligations of being a Board member and to determine suitability for Board membership.

Alternates

All alternates must be officially appointed and their role as a substitute member must be listed on the membership roster. Each alternate is only permitted to substitute for a specific IRB member or a class of IRB members for whom they are listed and have similar background and expertise.

Alternate members will be subject to the same appointment, terms of service, conflict of interest review and responsibilities as regular voting members of the IRB. If an IRB member cannot attend a meeting, his or her alternate will be contacted by the IRB member he/she represents to determine if he or she can attend. When an alternate member substitutes for a primary member, the alternate member receives and reviews the same material that the primary member receives.

Prisoner Representative

When the IRB reviews research that involves prisoners, at least one voting member present at the convened IRB meeting must be a prisoner representative with the appropriate background and expertise to serve in that capacity. If a prisoner representative is selected to serve on the IRB, the person must have a close working knowledge, understanding and appreciation of prison conditions from the perspective of a prisoner.

Suitable individuals could include present or former prisoners; prison chaplains; prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience. The prisoner representative must be officially appointed and be listed on the membership roster, and will be subject to the same appointment, terms of service, conflict of interests review and responsibilities as regular voting members of the IRB.

Terms and Conditions of Service

Members of the IRB may be reappointed annually by the Senior Vice President for Research and Technology Management. Upon appointment to the IRB, a current copy of each member's Curriculum Vitae (CV) must be provided to the IRB and maintained on file. Updated copies of members' CVs are requested at the beginning of each academic year and as re-appointments are made to the IRB.

Members of the IRB are expected to attend all scheduled meetings of the IRB and participate in the discussion and review of all protocols. Members of the IRB who are not able to attend a scheduled meeting of the IRB should provide sufficient advance notice (at least five working days) to an Associate Director of the CWRU IRB of the intended absence(s). If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he or she should notify the IRB at least 30 days in advance so that an appropriate replacement can be obtained. If the member has a designated alternate, the alternate can serve during the primary member's absence.

Orientation and Education of IRB Members

The Office of Research Administration and the IRB office have qualified IRB leadership and said leadership are annually reviewed and reappointed. New members of the IRB will receive a letter of appointment and meet with Executive Director for HRPP or an Associate Director of the IRB (or designee). The orientation session will review the functions of IRB members, discuss the confidentiality rules of the IRB, and review the member conflict of interest policy. Each new member is provided with an extensive outline of important topics and given various references for information on those topics. IRB members will receive training in the use of the IRB electronic submission and review system.

Opportunities for additional education are also provided. Until new IRB members have been sitting on the IRB for 6 months they will not be assigned as a primary or secondary reviewer for protocols. Prior to the new IRB member's first review presentation, the member will maintain an on-going relationship to meet with and work with the IRB staff to discuss the review process, to answer any questions prior to the scheduled IRB meeting, to discuss any concerns, to review policies and review processes.

IRB members must have Human Subjects' Protection or CREC certification. Relevant articles are routinely distributed to IRB members to further their knowledge and educational opportunities are provided by the CWRU Continuing Research and Education Credit (CREC) Program and the IRB Advisory Committee to enhance members' knowledge of regulations and information relating to protection of human

subjects. IRB members who have served for 1 year are awarded Continuing Research Education Credits applicable toward Human Subjects' Protections recertification.

What are the expectations for an IRB Member?

As an IRB Member, you are expected to do the following:

- Prepare for IRB meetings by reviewing all agenda items.
- Utilize this manual and other HRPP Toolkit documents in preparation for IRB meetings.
- Contribute to the collegial discussion of agenda items at IRB meetings.
- Confirm attendance for and attend approximately 85% of scheduled IRB meetings.
- Communicate well in advance to your assigned IRB Analyst when you cannot attend an IRB meeting or when you need assistance with accessing or interpreting submission or review materials.
- Report any Conflicting Interest for IRB Members to your assigned IRB Analyst, IRB Chair or Panel Chair, and the HRPP Director (see "SOP: Definitions (HRP-001)" for a definition).
- Become a designated reviewer at the time of 1 year of service or sooner if requested due to gaps in expertise.
- Stay current with all training requirements.
- Treat all oral and written information obtained as part of the review process as confidential; IRB members must not disclose or use confidential information without prior authorization, which includes refraining from communicating review results to Investigators separately from any official IRB communication.
- Unless asked to do so by the Executive Director or Institutional Official, refrain from issuing statements about HRPP or IRB operations, policies, tools, systems, or other related topics in a manner that would appear to be speaking on behalf of the HRPP or IRB.

IRB Performance and Evaluation

The IRB is routinely assessed for performance, composition, and attendance. Annual reappointment of the Chair and Vice Chair is contingent upon satisfactory review by the Associate Vice President for Research.

IRB members are sent a self-evaluation form annually. IRB Member performance is reviewed by the Associate Vice President for Research and the Executive Director for HRPP on an annual basis. The major criteria for the assessment are knowledge of IRB regulations, attendance at Board meetings and other IRB committees, leadership, and ability to conduct expedited reviews.

If a performance review identifies a problem, which cannot be resolved, a replacement will be appointed.

Chair of the IRB

CWRU's Institutional Official (IO), in consultation with the Executive Director for HRPP, appoints a Chair and Vice Chair of the IRB to serve for renewable annual terms. Any change in appointment, including reappointment or removal, requires written notification.

Roles and Responsibilities

- The IRB Chair should be a highly respected individual, from within CWRU, fully capable of managing the IRB, and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the Chair.
- The IRB Chair will represent the CWRU IRB as a voting member of the IRB Advisory Committee (IAC).
- The IRB Chair is responsible for conducting the meetings and may serve as signatory for correspondence generated by the IRB.
- The IRB Chair is authorized to take immediate action to suspend a study or studies if information is presented regarding subject safety or for any other reason where such action would be deemed appropriate, pending review by the convened IRB.
- The IRB Chair advises the Institutional Official and the Executive Director for HRPP about IRB member performance and competence.

The performance of IRB Chair will be eviewed on an annual basis by the Executive Director for HRPP in consultation with the IO. Feedback from this evaluation will be provided to the Chair. If the Chair is not acting in accordance with the IRB's mission, following these policies and procedures, has an undue number of absences, or not fulfilling the responsibilities of the Chair, he/she may be removed.

Vice Chair of the IRB

The Vice Chair serves as the Chair of the IRB in the absence of the Chair and has the same qualifications, authority, and duties as Chair.

IRB Members

The role of an IRB member is to ensure that human research activities comply with federal regulations, state and local laws, and institutional policies and procedures, by:

1. Completing member education and training, both initial and on-going.
2. Maintaining the confidentiality of IRB deliberations and the research reviews.

3. Conducting and documenting reviews of research as assigned in a timely fashion.
4. Attending IRB meetings as scheduled.
   Members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, they should inform the IRB Chair, Vice Chair, or an IRB Office staff member. If an IRB member is to be absent for an extended period of time, such as for a sabbatical, he or she should notify the IRB at least 30 days in advance so that an appropriate replacement can be obtained. If the member has a designated alternate, the alternate can serve during the primary member's absence.
5. Participating in subcommittees of the IRB if requested and available.
6. Conduct him/herself in a professional and collegial manner.

The performance of IRB members will be reviewed on an annual basis by the Research Compliance Officer. IRB members will receive formal documented feedback on the results of this review. Members who are not acting in accordance with the IRB's mission or policies and procedures or who have an undue number of absences may be removed.

Alternate Members

The appointment and function of alternate members is the same as that for primary IRB members, and the alternate's expertise and perspective are comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The IRB roster identifies the primary member(s) or class of members (e.g., physician scientist) for whom each alternate member may substitute. The alternate member will not be counted as a voting member unless the primary member is absent. The IRB minutes will document when an alternate member replaces a primary member.

Scientific and/or Cultural Reviewers/Consultants

If a primary or secondary reviewer with the appropriate scientific, scholarly, or cultural expertise and background is not available, the IRB office will seek out a reviewer within or outside of CWRU to serve as a consultant and utilize that person as the appropriate reviewer. The IRB utilizes non-IRB or CWRU reviewers or consultants when it is determined that members do not have the expertise necessary to review a particular protocol.

When the need for a consultant is established, the Executive Director for HRPP or an Associate Director of the IRB will identify an appropriate consultant, arrange for the review, and ask the consultant to provide written documentation of his/her review. A copy of the written communication is provided to each Board member prior to the meeting for their review. In

addition, all written communications between the consultant and the IRB are included in the protocol file.

When a consultant is scheduled to review a protocol, they are asked by the Executive Director for HRPP or an Associate Director of the IRB, to disclose to the IRB any conflict of interests related to the protocol. If a conflict exists, the consultant will be excused from the review of the protocol and the IRB will identify another consultant without a conflict.

Written comments of consultants will be kept in IRB records. Key information provided by consultants at meetings will be documented in the minutes. Written reviews provided by the outside reviewer also will be filed with the study application. While it is often sufficient for a consultant to provide his/her comments in writing after reviewing the protocol, the IRB may request a consultant's presence at a full board meeting. If in attendance, these individuals will provide consultation to IRB members but may not participate in the vote.

Liability Coverage for IRB Members

The insurance coverage that CWRU carries that applies to employees and any other person authorized to act on behalf of CWRU for acts or omissions within the scope of their employment or authorized activity applies to IRB members conducting their normal duties.

Reporting and Investigation of Allegations of Undue Influence

If an IRB chair, member, or staff person feels that the IRB has been unduly influenced by any party, they shall make a confidential report to the Executive Director for HRPP or Institutional Official (IO) depending on the circumstances. The IO will ensure that a thorough investigation is conducted and, if the allegation is determined valid, that corrective action is taken to prevent additional occurrences. In the event that the allegation is regarding the IO, the matter will be referred to the President for investigation and any necessary action.

Undue influence means attempting to interfere with a normal functioning and decision making of the IRB or to influence an IRB member, or staff outside of the establish processes or normal and accepted methods in order to obtain a particular result, decision or action by the IRB or one of its members or staff.

IRB Member File Documentation

A file (hard copy and/or electronic) on each member of the IRB, including consultants, will be maintained and kept in the IRB Administrative Office. These files will be maintained indefinitely.

Each IRB member's file will include the following information or documentation:

- Updated Curriculum Vita or resume
- Appointment/Reappointment Letters
- Documentation of Human Subjects Regulation Training and Certification
- Documentation of Continuing Education
- Related Correspondence

IRB Registration Updates

Changes in CWRU IRB will be reported to the OHRP as follows:

1. Within 90 days after changes regarding the IRB chairperson or the contact person who provided the IRB registration information.
2. Within 90 days of a change in the membership roster.
3. Within 30 days after CWRU's decision to disband as a registered IRB or permanent cessation of the IRB's review of HHS-conducted or -supported research.
4. Promptly to register any additional IRB before it is designated under an FWA and reviews research conducted or supported by HHS.

References or Regulatory Citations

45 CFR 46.107
Case Western Reserve University Faculty Handbook
CWRU Conflict of Interests Policy