IRB Advisory Committee (IAC) Charter

Case Western Reserve University
(CWRU)

University Hospitals Cleveland Medical Center
(UHCMC)

MetroHealth System
(MHS)

Cleveland Clinic
(CC)

VA Northeast Ohio Healthcare System
(VA)

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Policy Administered By:

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History and Mission

The IRB Advisory Committee (IAC) was created in 1999. In 2003, the Office for Human Research Protections (OHRP) changed its assurance requirements, mandating that each organization within the Case Western Reserve University (CWRU) system have a separate assurance (Federalwide Assurance (FWA)). As the IRB system itself did not change in that member institutions still relied upon each other to provide IRB review in accordance with federal regulations, the mission of the IAC did not change, but was strengthened through required IRB Authorization Agreements between the member institutions. CWRU and the Cleveland Clinic entered into a new affiliation agreement in 2003, as well, and consistent with other affiliates, the Cleveland Clinic became a member institution of the IAC.

The core mission of the IAC is to ensure that the oversight of research involving human participants is appropriate and in accordance with institutional policies, federal regulations, and state and local laws, as well as The Belmont Report. The secondary mission of the IAC is to share resources and best practices among member institutions to facilitate multi-institutional research.

Applicability and Jurisdiction

These policies and procedures (hereafter referred to as "policy") cover all human research conducted by any student, employee, or faculty member of Case Western Reserve University (CWRU), University Hospitals Cleveland Medical Center (UHCMC) and the MetroHealth System (MHS) as part of his or her job responsibilities with that organization, or any human research conducted by an independent contractor of these organizations as part of the organization's contract. In addition, for any human research in which CWRU acts as the grantee, employees of the VA Northeast Ohio Healthcare System (VA) and the Cleveland Clinic (CC) are also responsible for complying with this policy.

CWRU and each member institution have agreed to utilize the IAC as a means to meet oversight responsibilities between member institutions with signed IRB authorization agreements. Institutional Officials at each member institution have empowered their voting members to act on behalf of their institutions.

Definitions

- **IRB Advisory Committee (IAC)**: Committee consisting of voting and non-voting representatives from CWRU, UHCMC, MHS, VA and the CC.

- **Member Institution**: An organization represented on the IAC, for example, University Hospitals Cleveland Medical Center.

- **Institutional Review Board (IRB)**: An administrative body established to protect the rights and welfare of human research participants as defined by federal regulations that is listed on one or more member institution's Federalwide Assurances (FWAs).

- **IRB Chair:** The head member of the IRB who serves as a voting member.

- **IRB Authorization Agreement**: A formal agreement between /among one or more member institutions that identifies the IRB of record for research review.

- **IAC Chair**: The Associate Vice President for Research (AVP) at CWRU or an appointed alternate. The IAC Chair is normally a non-voting member of the IAC, but can vote in the case of a tie.

- **CWRU Research Compliance Officer (RCO)**: CWRU's Executive Director of Research Compliance or appointed alternate who serves as the administrator for the IAC. The RCO is normally a non-voting member of the IAC, but acts on behalf of the IAC Chair in his/her absence.

- **Office of Research Administration (ORA)**: The CWRU office that provides administrative support for the IAC.

- **IRB Administrative Office (IAO)**: The office at each member institution that provides administrative support to that institution's IRB(s).

- **IAO Head:** A voting member who acts as the administrator or other official who is responsible for the IAO.

Responsibilities

IAC members are responsible for presenting member institution-specific concerns, as well as providing input for continuing improvement and regulatory awareness within the IRB system. Members are also responsible for maintaining awareness of policies within each institution when applicable. The IAC does not establish institutional human subject protection and IRB policies for the institutions, although it serves as an advisory resource. However, this policy and all other policies of the IAC are established by the institutions.

The IAC will determine what projects it will undertake, such as policy revision or process coordination (e.g., conflict of interest or electronic submission), based on needs and availability of resources within the IAC. Typically, the Chair will create sub-committees that will then be responsible for preparing recommendations for the full committee.

Membership and Alternates

Each IRB shall be represented by the IRB Chairperson and head of the respective IRB Administrative Office (IAO) Head. The IAO Head is the person responsible for overseeing the administrative activities of the IRB and possesses regulatory expertise. Each member's IRB shall formally appoint both representatives and their alternates and shall notify the CWRU Research Compliance Officer (RCO) of any changes of its voting representatives. Each member may identify one alternate. Alternates must have comparable levels of expertise and be empowered to act on behalf of their regular member.

Ex Officio membership will be documented through the roster. Guests (investigators, administrators, students, etc…) may attend a meeting of the IAC by invitation of the IAC Chair. Guests may be asked to leave the meeting upon request of an IAC member. Such instances may occur when there is a potential conflict of interest or when confidentiality is limited to members of the IAC only. Guests will not normally participate during discussions involving non-compliance.

Meetings and Voting

The IAC will generally meet quarterly, but not less frequently than twice per annum. The Office of Research Administration will schedule meetings and provide members with meeting materials. However, IAC members may request a committee meeting outside of the official schedule as needed.

In general, the IAC develops programs and policies based on consensus of all committee members as one of the core functions is to facilitate collaboration. However, formal decisions of the committee are always supported by an official vote; therefore, achieving quorum for each meeting is essential. Electronic voting for a specific action of the committee (e.g. revision to policy) outside of a convened meeting is allowable unless one or more members request the vote occur during a convened meeting. Members and appropriate institutional officials will be provided with an updated roster at least annually.

In matters requiring a vote, each IAC member will have one vote. The Chair and the RCO are normally non-voting members of the IAC; however, in the case of a tie, the Chair has the deciding vote. In the absence of the Chair, the RCO will act in his/her place.

Referral of Matters to the IAC

IRBs and member institutions may utilize the IAC as a board to make recommendations or provide counsel on matters involving research with human participants. There is an expectation that each member institution's IRB(s) will normally resolve matters independently. However, in the event that an IRB presents reasonable justification for the use of the IAC to provide a more independent or multi-institutional assessment, the IAC will review the matter and provide appropriate recommendations or feedback.

Requests to utilize the IAC should be submitted to the RCO who will determine whether the matter should be addressed by the IAC. The RCO will assess whether the scope of the issue warrants the expertise and input of IRB professionals at more than one member institution. Examples of matters warranting review by the IAC include, but are not limited to: recommendations for policy improvements applicable to all institutions, the perception of a conflict of interest by a member IRB, assistance with resolution of an issue affecting researchers at more than one member institution, etc. The RCO will forward his/her assessment to the IAC Chair for final acceptance or denial of the referral. An institution may appeal the decision of the Chair to the full IAC. The decision of the IAC would not be subject to further appeal.

If the request for IAC review is accepted, the RCO, in consultation with the IAC Chair, may create a subcommittee of the IAC to examine the issue. However, the subcommittee may interview members of that IRB on a case by case basis.

IAC review of allegations of non-compliance must be conducted in accordance with the *IAC Policies and Procedures Regarding Allegations of Non-Compliance.* In addition, following an IRB's final determination that non-compliance has occurred, that IRB may request that the IAC provide recommendations on how to address matters identified during their review process.

Subcommittee recommendations will be distributed to the referring IRB and to all IAC members (if appropriate). As any review would likely require significant time and resources, it is expected that the member institution requesting review of a matter will accept and implement the recommendations of the IAC. In addition, if a recommendation is made that affects all member institutions, it is normally expected that the institutions will implement the recommendation.

IRB Member Training

The IAC will assure that regular training sessions for IRB members are offered as part of its mission to share resources, address current research/regulatory challenges, and promote collaboration among member institutions. The IAC is responsible for determining the content of such training with the assistance of the CWRU Office of Research Administration, which is responsible for organization and implementation.

Institutional Non-Compliance

Institutional non-compliance is defined as a member institution's failure to address investigator non-compliance, failure to meet federal regulatory requirements, or failure to comply with its IRB Authorization Agreements.

If the IAC Chair identifies possible *institutional non-compliance*, he/she will work directly with the IRB Chair, IAO head and appropriate member institution official(s) to resolve the issue. If the possible non-compliance cannot be resolved in this manner, it will be brought to the full IAC for discussion and resolution. Specific written agreements between the member institutions, if any, that provide alternative mechanisms for dispute resolution and other matters shall supersede this policy.

IAC Membership Requirements

Institutional Compliance:

In accordance with the IRB Authorization Agreements, each institution must act in compliance with regulatory and applicable institutional requirements. To document this compliance, each institution should maintain or be in the process of obtaining accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). External audits of IRB operations at least once every five years can be substituted for AAHRPP. Documentation of accreditation or results of audits must be provided upon request of the IAC Chair through the CWRU Office of Research Administration. All materials will be kept confidential.

Quality Improvement Reviews:

Quality Improvement (QI) Review compares the implementation of the protocol by the investigator to the specifics of the IRB-approved protocol. The IAO or another office within the institution may perform this type of review as designated by the IAO of each institution. Individuals performing this task must have access to research and/or medical files. Quality Improvement Reviews should occur on a continuing basis and reports shall be made available to the respective institutions bound by IRB Authorization Agreements, as needed.

Educational Responsibilities:

The CWRU Office of Research Administration, in conjunction with the IAC, will identify and review new information that might affect the IRBs, including laws, regulations, policies, procedures, and emerging ethical and scientific issues. IAC members will disseminate this information to the appropriate offices (i.e. IRB, Grants and Contracts, etc…) within their institutions. The information will then be communicated to the investigators and their research staff, and the IRB members and IRB staff, through written communication (i.e., letter and/or IRB websites) or verbal presentations. In addition, the IAC members may further disseminate this information to other individuals when appropriate.

Each member's institution will require appropriate personnel to participate in a continuing education program that meets the minimum requirements of the Continuing Research Education Credit (CREC) Program administered by the CWRU Office of Research Administration.

Cleveland Clinic and VA investigators and researchers who are current with their required human subjects training through their institutions will be provided 12 continuing CREC credits in the CREC program. In turn, CWRU, MHS and UHCMC investigators, who are current with their required human subjects training through their institutions, will be entered in the CC Human Subject Training Program.

The CREC Program policy addresses how a new investigator/faculty member coming from another institution, who has documented training accepted by his/her previous institution, will be entered into the CREC Program. Individuals who have performed CITI training within one year and whose prior training has been reviewed for congruence with the required CREC training can be enrolled in the CREC Program directly without any additional training requirements.

The IAC is responsible for approving the content and administration of the CREC Program in order to ensure compliance with applicable regulations and grant requirements. The IAC will determine whether any of the new information described above will be incorporated into the CREC Program.

In accordance with this responsibility, on November 13, 2020, the IAC voted and approved the motion that due to educational trainings provided during IRB meetings, IRB members in good standing would receive the required 12 CREC credits for a three year cycle. However, less credits may be given for those IRB members who do not consistently attend or engage

in the IRB Meetings. The IRB IAO will determine how many CREC credits each IRB member receives based on their standing Community Outreach Programs:

Community Outreach Activities are evaluated periodically. Each institution will host web content to provide contact information to solicit from prospective participants' concerns, complaints, and input.

CTSC IRB Task Force

CWRU is a site of a Clinical and Translational Science Award (CTSA) and was approved for funding by the National Center for Advancing Translational Sciences (NCATS) and the National Institutes of Health (NIH). The goal of the Clinical and Translational Science Collaborative (CTSC) is to provide full service and integrated clinical translational research capability within the Cleveland community that will improve the health of patients in Northeast Ohio through patient-based research. As part of this award, the collaborative institutions developed twelve resource groups organized by area of expertise or interest called "Core Resources". One of the Cores is the "Regulatory and Knowledge Support Core" (RKS). The RKS' area of focus is on issues related to research administration, RCR training and education, bioethics, program evaluation, pilot awards, community-based research (including practice based research networks) and bioinformatics support. In an effort to utilize already existing institutional infrastructures, the IAC agreed to provide the base membership for a RKS subcommittee called "IRB Task Force" on July 15, 2011. The IRB Task Force advises the RKS and other Cores of the CTSC on matters related to the protection of Human Subjects in participating in research. When requested, IAC members (as part of their membership on the task force) will review and provide opinion regarding human subject protection issues that may arise as part of the RKS initiatives under the CTSC.

Confidentiality of Compliance Activity

Compliance activity information, including Quality Improvement Reviews, institutional IRB auditing, compliance initiatives, and all other compliance activities shared with the IAC per this policy and other IAC policies, will be kept in confidence by the member institutions unless superseded by the reporting requirements of each institution's Federalwide Assurance or by the respective IRB Authorization Agreements, as applicable.

Policy Review

Policies and procedures of the IAC are reviewed at least once per year and can be revised per a majority vote by the committee.