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 (a)4 ()5 (C)10.a9 (A)iT (gr)3 .revis4 (e m)-6 (em)-62 (a)4 (s)-1 (ed)-2 (a)-2 (or)3 (a6, 4 (ti)-2

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Ex Officio membership will be documented through the roster. Guests (investigators, administrators, students, etc…) may attend a meeting of the IAC

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 researcht 76.1 (i)-5002 Twd, 9 (tim w)4 (t is)1 (n)2tio(r)5 (t o2 (f)5 ((wh)-2 ((r)

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