B. University Policy on Human Research Protection

Purpose

The promotion of scholarship and the discovery of new knowledge through research are among the major functions of Case Western Reserve University (CWRU) as an ins

Human subject is defined in 45 CFR 46 as "a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2)

Per the applicable regulations, IRBs have the authority to review allegations of human research non-compliance for studies they oversee. An IRB may receive allegations in several different ways, including quality assurance auditing reports, subject complaints, internal allegations, or investigator self-reporting.

The CWRU IRB is required to report serious or continuing non-compliance to federal regulatory entities and to funding agencies or other sponsors. Additionally, CWRU is required to report serious or continuing non-compliance to federal regulatory entities when the research is federally funded and when one of CWRU's affiliated hospital IRBs is the IRB of record.

e. Faculty Advisor Responsibility for Student Research

A faculty member advising student research projects* involving human subjects is responsible for assuring that the rights and welfare of the subjects of student research are adequately protected. CWRU expects that advisors will take an active part in preparing students for the role of researcher, instructing them in the ethical conduct of research and assisting in the preparation of IRB applications. After protocol approval, the advisor should meet regularly with his/her students in order to review their work and progress. While a student serves as the primary researcher for the protocol, the faculty advisor is ultimately responsible for the protection of the student's human subjects. A faculty member's electronic "signature" on the application indicates his/her acceptance of responsibility to comply with all administrative and federal regulations.

* Simulated research activities in a

prior approval by the IRB*. Investigators wanting to change a procedure in a study that has already been approved by an IRB must prepare a written description of the proposed change and the reason for the change. Upon review of the proposed amendment, the IRB will then reassess the balance of risks to benefits.

*In the unusual situation where a protocol change is required to avoid an immediate apparent hazard to a subject, the investigator may make the change prior to obtaining IRB approval but must immediately inform the IRB of the occurrence.

Adverse Events. An adverse event is defined as any undesirable and unintended (although not necessarily unexpected) impact on the subject, as a result of a study intervention.[4] Investigators must report in writing to the relevant IRB all adverse events in accordance with the IRB's policies and procedures for reporting such events.

[3] (45§46.110)

[4] http://www.hhs.gov/ohrp/policy/advevntguid.html

3. Studies Eligible for CWRU IRB Review

The CWRU IRB reviews social/behavioral/educational studies and biomedical research not conducted in a hospital setting. The CWRU IRB does not review biomedical research protocols that involve patients, employees, data, and/or equipment at one of the below affiliated hospitals:

- University Hospitals Cleveland Medical Center
- MetroHealth System
- The Cleveland Clinic

Per Central VA policy, the Louis Stokes Cleveland Veterans Affairs Medical Center IRB cannot be the IRB of record for CWRU research. When research conducted at the LSCVAMC is funded through CWRU, a CWRU IRB must be the IRB of record, and that approval must be supplemented by LSCVAMC IRB approval. Investigators planning research to take place at LSCVAMC that will be funded through CWRU, should consult with the CWRU Research Compliance Officer in order to determine which IRB will be the IRB of record.
Any questions about whether a research activity can be submitted to the CWRU IRB should be referred to the CWRU IRB Office (see https://case.edu/research/faculty5(/f)-U Id3(e)-3f-3.9(e3.7(ch1.6(o)-229c(h)-h.63C)7.9(1h)-5. Tw[12.eir

searh7 -ion(C)17.iotalo.3((C)17.io)-5.2(w,-1-15(42c8f)-6onti.6(h)nuind Med)ga (C)

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5.

[5] The organizational official can make a determination about whether CWRU will enter into an inter-institutional agreement to rely on another IRB for review and approval of research.

CWRU Investigators and Study Staff

Investigators and research staff have the responsibility to:

- Understand the definition of Human Research.
- Consult the relevant IRB when there is uncertainty about whether an activity is human research.
- Not conduct human research or allow human research to be conducted without review and approval by an IRB designated in the CWRU FWA.
- Comply with institutional, federal, state and local requirements, as well as the ethical principles promulgated by The Belmont Report.
- Follow HRPP requirements.
- Follow IRB policies and procedures.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the Organizational Official.
- Report allegations of undue influence regarding the oversight of the HRPP or concerns about the HRPP to the Organizational Official.
- Report allegations or findings of non-compliance with the requirements of the HRPP to the IRB.

Institutional Review Boards (IRB)

Reliance on an IRB that is not at a cooperating institution requires an Institutional Authorization Agreement for IRB review (IAA) executed by the Institutional or Organizational Official.

The CWRU IRB, as well as any IRBs relied upon by CWRU, has the authority to, for the studies they are monitoring:

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- Affirm that each human research study proposed to be conducted in their department or school can be done responsibly by the study team using the resources described in the proposal.

Office of Research Administration

The Office of Research Administration (and similar offices with delegated authority, such as the School of Medicine Office of Grants and Contracts) has the responsibility to review contracts and funding agreements for compliance with HRPP policies and procedures.

6. Education and Training

IRB members, IRB staff, and others involved in the review of human research must complete initial and continuing training on the protection of human subjects.

Investigators and research staff must complete the initial and continuing training on the protection of human subjects.

7. Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of noncompliance, or input regarding the HRPP may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Office, the IRB Chair, the Organizational Official, Office of General Counsel, Integrity Hotline, Internal Audit Department, Deans, or Department Chairs.

The relevant IRB has the responsibility to investigate allegations and findings of non-compliance related to conduct of research for studies under its jurisdiction and take corrective actions as needed. The Organizational Official has the responsibility to investigate all other reports and take corrective actions as needed. In some instances, the IRB and the Organizational Official may, for different purposes, both be required to investigate the same matter, or may collaborate or share resources as necessary.

Employees who report in good faith possible compliance issues shall not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Organizational Official or designee.

To make such reports, contact:

The Office of the Associate Vice President of
Research Sears Library Building, 6th Floor.
2083 Martin Luther King, Jr.
Drive Cleveland, Ohio 44106-
7230
216-368-0143

8. Monitoring and Auditing

In order to monitor and assure compliance, auditors who have expertise in federal and state statutes, regulations and organizational requirements will conduct periodic not-for-cause audits.

9. Disciplinary Actions

The IRB and the Institutional Official may terminate or suspend IRB approval. In addition, the IRB and/or the Institutional Official and/or Organizational Official may place limitations or conditions on an investigator's or research staff's privilege to conduct human research whenever, in the opinion of the IRB and/or the Institutional Official and/or Organizational Official, such actions are required to

maintain the integrity of the HRPP.

** approved by the Faculty Senate 2/27/2018; approved by the Board of Trustees 4/17/2018*