Human Research Protection Program Plan

September 2023

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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 institution of higher learning. If this research is to be meaningful and beneficial to humanity, involvement of human subjects as study participants is necessary. It is imperative that investigators in all disciplines protect the rights, welfare and privacy of human research subjects.

University policy and federal regulations mandate compliance with all applicable requirements. Moreover, faculty investigators also have a moral obligation to humankind. The interests of society and the rights of individual subjects must be protected as investigators carry out the mandate to advance knowledge. Research may entail risks to human subjects. Therefore, investigators are obligated to weigh those risks in light of potential benefits to the subject and/or to society.

The CWRU HRPP Policies are outlined in the Human Research section of the Faculty Handbook.

Definitions

Agent: An individual who is faculty member, employee, or student is considered an agent of this Organization for purposes of engagement in Human Research when that individual is on-duty in any capacity as an employee of this Organization

- An individual who is not a faculty member, employee, or student is considered an agent of this Organization for purposes of

Principal Investigator: The person responsible for the conduct of a human research study at one or more sites, whether on- or off-campus. If the human research study is conducted by a team of individuals, the principal investigator (PI) is the responsible leader of the team. A principal investigator can assign a PI Proxy or multiple Proxies to perform responsibilities on behalf his/her behalf in communicating with the CWRU IRB for the research protocol submissions. The principal investigator is held accountable for ensuring that the team complies with all rules and regulations and engages with human subjects properly and ethically.

Co-Investigator: An individual involved with the principal investigator in the scientific development or execution of a project. A co-investigator typically devotes a specified percentage of time to the project.

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Mission

The mission of CWRU's Human Research Protection Program (HRPP) is to protect the rights and welfare of human research subjects by ensuring that the oversight of human research is appropriate and in accordance with institutional, federal, state and local requirements, as well as the ethical principles promulgated by the Belmont Report.[2]

Scope

The CWRU HRPP covers all human research conducted by any student, employee, trainee, or faculty member (whether paid or unpaid) of CWRU ("CWRU investigator"). It includes any human research conducted at cooperating institutions pursuant to a grant, contract, cooperative agreement, or other award to CWRU. Cooperating institutions include University Hospitals of Cleveland (UHC), MetroHealth System (MHS), Veterans Affairs Northeast Ohio Healthcare System (VANEOHS) and the Cleveland Clinic Foundation (CCF). Reliance agreements in place allow CWRU to defer to the IRBs at these institutions for local protocol review. Hereafter, these institutions shall be referred to as "member institutions" under the CWRU HRPP.

Ethical Principles and Regulatory Mandates

Human research conducted under the auspices of the CWRU HRPP must be carried out in an ethical manner and in accordance with the principles promulgated by the Belmont Report: respect for persons, beneficence, and justice. In addition, investigators must comply with all applicable federal, state and local requirements related to the protection of human subjects, including Department of Health and Human and Services (DHHS) regulations (i.e., 45 CFR 46) and all relevant requirements of other regulatory and funding agencies. CWRU maintains a Federalwide Assurance (FWA) with DHHS.

Research must not begin until investigators have received review and approval or verification of exemption by one of the Institutional Review Boards (IRBs) listed on the CWRU FWA. CWRU applies its ethical standards to all human research regardless of funding.

All human research, except as explicitly exempted in 45 CFR 46.101(b), must undergo review by an appropriate designated IRB(s). Activities that do not meet the definition of human research (e.g., most classroom activities, quality improvement activities, non-scholarly program evaluation, and certain health surveillance activities) do not require review and approval by one of the IRBs within the CWRU HRPP. When CWRU is engaged in human research that is conducted, funded, or otherwise subject to regulations by a federal department or agency, it will apply the regulations of that agency relevant to the protection of human subjects.

Legal Requirements

This Organization commits to apply its ethical standards to all Human Research regardless

of funding. All Human Research must undergo review by the CWRU IRB.

Activities that do not meet the definition of Human Research do not require review and approval by the CWRU IRB and does not need to be submitted to the IRB unless there is a question regarding whether the activity is Human Research.

When this Organization is engaged in DHHS Human Research that is conducted, funded, or otherwise subject to regulations by a federal department or agency who is a signatory of the Common Rule, the Organization commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When this Organization is engaged in FDA Human Research, this

Policy Oversight Committee

Leadership of the CWRU HRPP will review and approve policies and SOPs as the Policy Oversight Committee. The Committee is constituted with the Associate Vice President for Research, Executive Director for the HRPP, and as applicable IRB administrators.

Institutional Review Board Advisory Committee (IAC)

CWRU and its affiliated hospitals comprise the largest human subject research center in Cleveland, Ohio. The CWRU Human Research Protection Program (HRPP) covers all human research conducted by any student, employee, or faculty member of Case Western Reserve University (CWRU), University Hospitals of Cleveland (UHC) and 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 Veterans Affairs Northeast Ohio Healthcare System

Sponsored Human Research

For both sponsored and non-sponsored Human Research this Organization abides by its ethical principles, regulatory requirements and its policies and procedures.

Scope of Human Research Protection Program

The Case Western Reserve University Institutional Review Board reviews social science, behavioral, and educational, and low-risk biomedical research for CWRU faculty, staff, and students.

Any questions about whether a research activity is considered

ensures that CWRU evaluates Conflict of Interests in research and conducts education on the responsible conduct of research.

The Institutional Official has the authority to take the following actions or delegate these authorities to a designee:

- Allocate university resources within the HRPP budget
- Appoint and remove CWRU IRB members and IRB chairs
- Approve and rescind authorization agreements for CWRU IRB
- Suspend or terminate research approved by the CWRU IRB
- Disapprove research approved by the CWRU IRB

The Senior Vice President for Research meets bi-monthly with his Leadership Committee which is composed of the Associate Vice President for Research, Assistant Vice President for

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will be conducted in accordance with all applicable ethical and legal requirements.

- Institute regular, effective, educational and training programs for all individuals involved with the HRPP
- Ensure that the research review process is independent and free of undue influence and ensure that officials of the organization cannot approve research that has not been approved by one of the IRBs designated by the organization.
- Implement a process to receive and act on complaints and allegations regarding the HRPP.
- Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
- Investigate and remediate identified systemic problem areas and, where

regulations for the performance of reach activities that involve human subjects (21 CFR 50 and 56) as required.

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 an Organizational Official.

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

- Determine whether an

listed on CWRU's FWA requires an Institutional Authorization Agreement (IAA) or Reliance Review Agreement (RRA) for IRB review and local review for compliance with local polices of the university. The IAA is executed by the Institutional Official and the RRA is executed by the Institutional Official or Executive Director for the HRPP and a local review for compliance with local policies of the university.

The IRBs relied upon by CWRU have the authority to, for the studies they are monitoring:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Organization. All Human Research must be approved by one of the IRBs designated by the Institutional Official or Executive Director for the HRPP. Officials of this Organization may not approve Human Research that has not been approved by the CWRU IRB.
- Suspend or terminate approval of human research not being conducted in accordance with an IRB's requirements or that has been associated with unexpected serious harm to subjects
- Observe, or have a third party observe, the consent process.
- Determine whether an activity is human research
- Determine whether additional protections are warranted for studies involving vulnerable subject populations.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan, if any, allow the human research to be approved. (http://www.case.edu/president/facsen/frames/handbook/conflicts_of_interest.ht)

IRB members and IRB staff have the responsibility to follow HR--2 (bi)-2(l)-2 (o1tj/TT0 1)-2 (e)4 ( )-10 (a)w -2

School of Dental Medicine, the Frances Payne Bolton School of Nursing, the School of Medicine and the School of Engineering. Individuals working in any central administrative units at the university may also submit a social, behavioral, educational or low-risk biomedical protocol submission to the CWRU IRB.

Investigators and research staff have the responsibility to:

- Follow the HRPP requirements described in the (HRP-103)
- Understand the definition of Human Research
- Consult the 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
- Follow IRB policies and procedures
- Comply with institutional, federal, state and local requirements, as well as the ethical principles promulgated by the Belmont Report
- Comply with all determinations and additional requirements of the IRB, the IRB chairperson, and the Institutional 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.

Legal Counsel

The IRB considers and adheres to all applicable state and local laws in the jurisdictions where the research is taking place. The HRPP and IRB rely on CWRU's Office of General Counsel for the interpretation and application of Ohio law and the laws of any other jurisdiction where research is conducted as they apply to research involving human participants. The IRB will also ensure that informed consent forms are consistent with applicable state and local laws.

- Legal counsel has the

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Office of Research Administration

The Office of Research Administration's Sponsored Projects Office and the School of Medicine Grants and Contracts Office, with delegated authority, have the responsibility to review contracts and funding agreements for compliance with HRPP policies and procedures.

The Executive Director for HRPP and the Associate Vice President for Sponsored Projects and Director for SOM Grants and Contracts Office meet on an ad-hoc basis to discuss and develop new or updated policies or procedures as changes in requirements occur and disseminat0.04 (t)-6 (s)]TJ0 T(e)-6 (s

Employees who report in good

study.

3. Once the RCO gives permission for CWRU to rely on the external IRB, the CWRU investigator completes a through the CWRU SpartaIRB system. The review of this request will entail t 0.044 g12 0 0 1 [illegible]