PURPOSE: This document outlines how University Hospitals of Cleveland IRB may rely on the Cleveland Clinic to serve as the IRB of Record for a University Hospitals study or Investigator within the Case Comprehensive Cancer Center.

SCOPE: All human subjects research protocols meeting the criteria for IRB review, being conducted at University Hospital locations or for which University Hospitals professional staff or employees have research responsibilities under the University Hospital’s Human Subject Research Protection Program and for which the Cleveland Clinic IRB is the IRB of record.

RESPONSIBLE INDIVIDUALS: All University Hospitals IRB Administration Staff and University Hospitals professional staff or employees with research responsibilities for clinical research protocols falling under the scope of this SOP.

DEFINITIONS:

Institutional Review Board (IRB): A specifically constituted review body established or designed by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral or social science research

Federalwide Assurance (FWA): A formal, written, binding attestation in which an institution ensures to the Department of Health and Human Services (HHS) that it will comply with applicable regulations governing research with human subjects

IRB Authorization Agreement (IAA): A formal, written agreement in which the reviewing IRB agrees to serves as the IRB of record for a relying institution, including an academic institution. Agreements are generally used to cover a single research study, categories of research studies or research studies within a research program

Association for the Accreditation of Human Research Protection Program (AAHRPP): The Association of the Accreditation of Human Research Protection Programs, Inc. (AAHRP) promotes high-quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs (HHPPs).

Office for Human Research Protections (OHRP): The office under the Department of Health and Human Services responsible for implementing HHS regulations (45 CFR 46) governing biomedical and behavioral and or social science research involving human subjects
Reliant Review: “Reliant Review” often referred to as “Facilitated Review” is a model that allows investigators to make a single Institutional Review Board (IRB) to serve as the “IRB of Record” for protocols conducted by any organization (or multiple organizations) while at the same time allowing each site to retain local context review and oversight. Through written contracts called “IRB Authorization Agreements (IAA)” participating institutions may allow Institution A to act as the “IRB of Record” for Institution B “Relying IRB”

IRB of Record: “IRB of Record” is a reviewing IRB that assumes IRB responsibilities for another institution and is designated to do so through an approved FWA on file with the Federal Office for Human Research Protections.

Relying IRB: “Relying IRB” is an Institutional Review Board with whom University Hospitals has entered into as part of a cooperative research project

Reliant Review Form: A “Reliant Review Form” is a modified version of the UH IRB electronic smart form used for reliant studies.

Collaborative Institutional Training Initiative (CITI): CITI is a web-based program providing online courses designed to satisfy human subjects research requirements for faculty, staff, and students involved in human subjects. Initial and continuing education (every 3 years) are required for the Principal Investigator and any key personnel obtaining research informed consent.

POLICY STATEMENT: University Hospitals may rely on the Cleveland Clinic IRB provided investigators at both institutions are participating as investigators on a research project and the IRB of Record, in this case the Cleveland Clinic IRB is the lead Clinical Research Site.

When relying on the Cleveland Clinic IRB, whether it is for a single research project or a portion of University Hospital’s research portfolio in which the Cleveland Clinic is the lead site, the Cleveland Clinic IRB must meet Federal regulations for the conduct of research and IRB review. The Cleveland Clinic IRB must have a Federalwide Assurance and will be accredited by an independent accrediting body, such as the Association for the Accreditation of Human Research Protection Program.

When University Hospitals relies on the Cleveland Clinic IRB to serve as the IRB of Record, the Cleveland Clinic IRB has been evaluated by the University Hospitals IRB and determined to meet specific criteria for the protection of human subjects. A formal written Institutional Review Board Authorization Agreement (IAA) exists between University Hospitals and the Cleveland Clinic delineating the roles and responsibilities of each party.
UNIVERSITY HOSPITALS (Relying IRB) INVESTIGATOR RESPONSIBILITIES:

- Comply with the IRB of Records requirements and directives per the IAA
- Provide the IRB of Record with any local context issues relevant to the research protocol
- Submit a “Reliant Review Form” documenting local context information relevant to the research protocol in the Relying IRB’s electronic system
- Ensure the safe and appropriate performance of the research. This includes, but is not limited to ensuring the qualifications of research staff; monitoring protocol compliance, maintaining compliance with state, local or institutional requirements related to the protection of human subjects; providing a mechanism to receive and address concerns from local study subjects and others about the conduct of the research; and investigating, managing, and providing notification to the IRB of Record of any study-specific incidence, experience, or outcome that rises to the level of an unanticipated problem and/or serious or continuing non-compliance
- Will provide to the IRB of Record any data and safety monitoring reports they receive, either at continuing review, upon request by the Relying IRB, or on an emergent basis, if appropriate.

CLEVELAND CLINIC (IRB of Record) RESPONSIBILITIES:

- Conduct review of research according to all applicable regulations and laws, including initial review, continuing review, and review of modifications to previously approved research.
- Conduct review of potential unanticipated problems, adverse events, and/or serious or continuing non-compliance
- Provide notification to University Hospitals researcher staff and Relying IRB in writing of its determinations and decisions
- Make available relevant IRB minutes, IRB membership rosters, and standard operating procedures to the Relying IRB upon request
- When appropriate, conduct on-site or remote post-approval monitoring or adults, unless delegated to the Relying IRB
- Maintain an IRB membership that satisfies the requirements of 45 CFR 46.107 and 21 CFR 56.107 and which provides special expertise as needed to adequately assess all aspects of each study
- Promptly notify the University Hospital’s IRB if there is a suspension or termination of the external IRB’s authorization to review a study
- Promptly notify the University Hospital’s IRB of any audits
- Maintain appropriate documentation per record retention policies, including an OHRP-approved Federalwide Assurance for human subjects research
PROCEDURES:
When the Cleveland Clinic serves as the IRB of Record for University Hospitals, the University Hospital’s investigator (or designee) is responsible for:
- Completing a “Reliant Review Form” in the IRB electronic system to document the IRB of Record reliance and the research study for institutional oversight purposes
- Uploading the following supporting documentation and correspondence in the University Hospital’s IRB electronic system “Reliant Review Form”
  - Current IRB approved research study protocol, IND/IDE FDA documentation, investigator’s brochure, etc.
  - Cleveland Clinic IRB Approval Letter
  - Consent form(s) approved by the IRB of Record
  - Cleveland Clinic approved Recruitment materials
  - Current Human Subjects Protection Certification (CITI) expiration dates for key study personnel
  - Completion of UH Research Credentialing for non-UH personnel. This is a requirement for any non-UH personnel accessing Protected Health Information (PHI) at UH or UH entity, or UH systems containing PHI.
  - Disclosure of Conflict of Interest (COI) as per UH and Case policy (COI Management plan as applicable)
  - Department Review and Approval
  - Any Additional UH Required Reviews/Approvals
    - Examples of additional review may include, but are not limited to the following: Special Care Units (intensive care, newborn nursery, emergency room, etc.), Electrical Safety Office, Department of Pharmacy Services, Case Biosafety Committee, Protocol Review & Monitoring Committee (PRMC), Radiation Safety Committee, Department of Radiology, Department of Pathology, Conflict of Interest Committees at Case and UH, Research Finance Office, and/or Grants and Contracts Office

UNIVERSITY HOSPITAL INSTITUTIONAL REVIEW BOARD (UH IRB)
RESPONSIBILITIES AND ACTION:
When a new Reliant Review Form is received by the IRB, an IRB Specialist will conduct a review of the application/checklist and protocol, informed consent documents, recruitment materials, any relevant grant applications and the investigator’s brochure (if applicable).
If the Reliant Review Form and other submission requirements are appropriate, the IRB may “accept the submission in accordance with the executed IRB Authorization Agreement in effect between the two institutions.

Under this agreement the University Hospitals Cleveland Medical Center Institutional Review Board may rely upon the Cleveland Clinic IRB as the IRB of Record. In addition, the University Hospitals Cleveland Medical Center IRB will grant such reliance for approval, amendment and continuing review with a one-time acceptance letter.

REFERENCES: None

FORMS OR ATTACHMENTS: None

APPROVALS

Approved by Dr. Grace McComsey, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center– July 17, 2017