Community College of Rhode Island: Institutional Review Board: Research Proposal Submission Policy

Policy Title: Institutional Review Board: Research Proposal Submission Policy

PROCEDURE NUMBER: TBA

EFFECTIVE: TBA

BACKGROUND:

The Community College of Rhode Island is working in collaboration with the University of Rhode Island Institutional Review Board to allow the CCRI fulltime faculty to submit research proposals to the URI IRB for research consideration. CCRI Vice President of Finance and Strategy and the URI Vice President of Research and Economics Development signed an IRB Authorization Agreement (IRB AA) on December 5, 2019. This agreement agrees that CCRI may rely on the URI IRB for review and continuing oversight of its human subject research and applies to human subjects research covered by the CCRI FWA. This agreement excludes subjects under the age of 18 and prisoner subjects.

The review performed by URI IRB will meet the human subject protection requirements of CCRI Institution OHRP-approved FWA. The IRB at URI Institution/Organization will follow written procedures for reporting its findings and actions to the CCRI IRB Institutional Director. Relevant minutes of IRB meetings will be made available to CCRI Institution upon request. CCRI Institution remains responsible for ensuring compliance with the URI IRB's determinations and with the Terms of its OHRP-approved FWA.

The IRB Authorization Agreement will be kept on the CCRI internal shared drive and provided to Office of Human Research Protection (OHRP) upon request. The IRB AA agreement may be terminated by either party on sixty (60) days-advance written notice-effective as of-the-expiration of-the·notice period; Unless earlier-terminated as provided in this agreement, this agreement shall terminate one (1) year following the effective date (later of the two signatory dates).

The mission of the Community College of Rhode Island: The state's only public comprehensive associate degree-granting institution. We provide affordable open access to higher education at locations throughout the state. Our primary mission is to offer recent high school graduates and returning adults the opportunity to acquire the knowledge and skills necessary for intellectual, professional and personal growth through an array of academic, career and lifelong learning programs. We meet the wide-ranging educational needs of our diverse student population, building on our rich tradition of excellence in teaching and our dedication to all students with the ability and motivation to succeed. We set high academic standards necessary for transfer and career success, champion diversity, respond to community needs, and contribute to our state's economic development and the region's workforce.

POLICY STATEMENT:

This policy establishes CCRI to work in collaboration with the University of Rhode Island Institutional Review Board (URI, IRB) for the protection of human subjects and describes the ethical standards and institutional commitments applicable to research proposals to the University of Rhode Island IRB to conduct human subject research at CCRI.
In order to strengthen and improve CCRI's collaboration with URI IRB, the Vice President of Academic Affairs and CCRI IRB Institutional Director shall ensure that all research proposals sent to URI IRB be reviewed every year through the office of the Dean of Health and Rehabilitative Science.

Policy Guiding Principles
When CCRI collaborates with the URI IRB, in research using human subjects, the ethical principles expressed in the Belmont Report shall apply, unless properly authorized federal departments, agencies, or foreign states that have controlling jurisdiction over the research call for other appropriate ethical standards.

Policy Scope of Authority
This policy applies whenever CCRI collaborates with URI IRB in research that engages in human subject research as described by the Federal Policy for the Protection of Research Subjects (the "Common Rule"). CCRI holds a Federalwide Assurance (FWA) with the Department of Health and Human Services. Under its FWA, CCRI extends the applicable regulations of the Department of Health and Human Services in Title 45 Part 46 of the Code of Federal Regulations to all research involving human subjects as defined by DHHS regulations regardless of sponsorship.
This assurance applies to all research involving human subjects being conducted by investigators acting as agents of CCRI regardless of the site of the activity; to all human research involving any CCRI personnel, patients, students, or facilities owned and operated by CCRI or CCRI affiliated entities; research that is supported by extramural funds granted to (or applied for through) CCRI; or for research conducted using CCRI funding at non-CCRI sites. CCRI holds a Federalwide Assurance Addendum with the Department of Defense (DoD). Under this Addendum FWA, CCRI extends the regulations of the Department of Defense in Title 32 Part 219 of the Code of Federal Regulations to all applicable research involving a human being as an experimental subject.
In addition, this policy applies to clinical investigations and other clinical activities requiring IRB review under FDA regulations, and to human subject research regulated by other federal agencies. Research studies involving humans not covered by CCRI's FWA will not be accepted under the URI/CCRI IRB AA.

Policy Jurisdiction

A. Activities Involving CCRI Investigators. All fulltime faculty paid by CCRI, who are conducting studies involving human subjects within the course and scope of their duties, regardless of the source or amount of funding, are required without exception to have prior approval from the CCRI IRB Committee before research is submitted to the URI IRB.
    - The fulltime faculty must have prior approval from the CCRI IRB Committee and URI IRB, without exception, when studies conducted by CCRI faculty, when the human subjects research is supported either by extramural funds granted to (or applied for through) CCRI, or for research conducted with CCRI funding at non-CCRI sites, or when URI IRB has a written agreement to provide IRB review for research studies.
B. CCRI fulltime faculty member must serve as a Principal Investigator,
    - Whether the study can be certified as exempt or otherwise not fall under human subjects regulation, and/or
    - Whether the study will require additional institutional review and approval.

Determinations of whether or not CCRI fulltime faculty is engaged in research for any study will be made through URI IRB review process.

Procedure
Full-Time Faculty from the Community College of Rhode Island will complete a submission application that will be reviewed by the CCRI IRB Committee. An application template will be located on the CCRI IRB webpage. The submission checklist is as follows:

Submission Procedures Checklist:

- Complete the CCRI/ URI IRB Exempted Application Form (If research does not fall into the exempt categories, the researcher needs to submit an initial IRB application as a new study (refer to CCRI IRB committee for directions).
- CITI training certificates for all investigators

If applicable:

- Grant application
- Questionnaires, surveys
- Recruiting letter, email, or flyer
- Letter of Agreement to participate in research from a collaborating agency, organization or institution
- MA/PhD Proposal and signed copy of MA/PhD Proposal Approval Sheet
- Informed Consent

The application will be reviewed by the CCRI IRB Committee according to the review date calendar. After notification of approval from the committee, the researcher will submit the following information to the URI IRBNet link.

- Approved CCRI IRB acceptance letter
- CCRI/IRB Exempted Application Form

POLICY APPLIES TO:

Full-Time Faculty from the Community College of Rhode Island

EXCEPTIONS:

Exceptions to this policy will be made at the discretion of the Vice President of Academic Affairs.

RESPONSIBILITIES:

The office of the Vice President of Academic Affairs is responsible for implementing and maintaining this policy

RELATED POLICIES: TBA

DEFINITIONS:

The definitions in this policy apply to all other policies established for the Protection of Human Subjects in Research.

Agent – Person authorized to act on behalf of CCRI. This includes an individual performing CCRI designated activities or exercising CCRI-delegated authority or responsibility.

Clinical Investigation – See definition for Research (as defined by FDA regulations).

Code of Federal Regulations (CFR) – A codification of federal agency regulations which has the force and effect of law.

DHHS- The Department of Health and Human Services was the first federal agency to codify regulations governing human research protection. The Code of Federal Regulations at 45 CFR 46 describes the DHHS requirements for the protection of human subjects. The DHHS regulations require that research involving human participants be subject to oversight by an IRB to ensure that the rights and welfare of research participants are protected and meets regulatory and institutional requirements.

Federal Guidance – Information published by federal agencies on the topic that represents the agency's current thinking or view but does not have the effect or force of law.

Federalwide Assurance (FWA) – A document filed with the Office for Human Research Protections (OHRP) of the Department of Health and Human Services expressing an institution's commitment to comply with the department's regulations for the protection of human subjects.

FTE – Full-time equivalent appointment.

Generalizable Knowledge – Information derived from a systematic investigation that can be applied to: other facilities or institutions; existing body of knowledge on a topic, disease or disorder disseminated through publication or scientific meeting; or a change in the standard of care.

Human Subject (as defined by DHHS regulations) – A living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Human Subject (as defined by FDA regulations) – An individual who becomes a participant in research regulated by the Food and Drug Administration (FDA), either as a recipient of a test article or as a control. A subject may be either a healthy human or a patient. In the case of research involving medical devices, a human subject includes an individual on whose specimen a medical device is used.

Human Subjects Research – Any activity that is either (a) "research" as defined by DHHS regulations that involves "human subjects" as defined by DHHS regulations or (b) "research" as defined by FDA regulations that involves "human subjects" as defined by FDA regulations.

Human Subjects Research (as defined by DOE 443.1A) – Any systematic investigation (including research development, testing, and evaluation) utilizing living individuals or personally identifiable information or materials, designed to develop or contribute to generalizable knowledge. (See DOE P 443.1A for examples and exclusions.)

Research Involving a Human Being as an Experimental Subject (as defined by DoDD 3216.02) – an

activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction.(32CFR219.102(f).

IRB – Institutional Review Board established in accord with and for the purposes expressed in federal regulations to protect the rights and welfare of human research subjects.

OHRP- Office of Human Research Protection. The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP is part of the Office of the Assistant Secretary for Health in the Office of the Secretary of HHS.

Research (as defined by DHHS regulations) – A systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.

Systematic Investigation – an orderly collection to obtain information about which conclusions can be drawn and so that others can review those conclusions.

CCRI Facilities – Facilities owned and operated by CCRI; does not include facilities leased by the CCRI to private entities.

CCRI Institutional Official – Individual authorized to act for CCRI and, on its behalf, obligates CCRI to the Terms of its Federalwide Assurance with the Department of Health and Human Services and OHRP.

APPROVED:

Date:

Signature on record at college. Email pbardsley@ccri.edu for assistance.