**Human Research Protection Program Plan**

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| Version | Date | Revisions |
| R00 | 7/31/17 | Original issue |
| R01 | 12/12/19 | Logo, document number in footer, add institutions that approve studies to local sites, change IRBNet to Click, change organizational official to IO, remove SR. Assoc VPRED as IO, change to single IRB, remove IRB roster is available, remove AAHRPP accreditation for sIRB, remove no interaction with subjects, remove federal fund requirement for sIRB, remove phrase on IO approving studies, remove CEO |
| R01 | 12/17/2020 | Annual review, no changes |
| R02 | 5/27/2022 | Updated to Revised Common Rule |
| R03 | 12/28/22 | Added Community involvement, internal audit, sIRB responsibilities |
| R04 | 6/29/23 | Revised the number of recipients of the Investigator Quality Improvement Assessments |
| R05 |  | Annual review, change title of IO, update building address |

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## Scope

Throughout this document “Organization” refers to University at Buffalo, The State University of New York.

## Purpose

This Organization is committed to protecting the rights and welfare of subjects in Human Research. The purpose of this plan is to describe this Organization’s plan to comply with ethical and legal requirements for the conduct and oversight of Human Research.

This Organization’s Human Research Protection Program is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The Human Research Protection Program is based on all individuals in this Organization along with key individuals and committees fulfilling their roles and responsibilities described in this plan.

## Definitions

### Agent

An individual who is an employee 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 an employee is considered an agent of this Organization for purposes of engagement in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of this Organization.

Legal counsel has the ultimate authority to determine whether someone is acting as an agent of this Organization.

### Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effect of the interventions on biomedical or behavioral health-related outcomes.

### Engaged in Human Research

In general, this Organization is considered engaged in Human Research when this Organization’s employees or agents for the purposes of the Human Research obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research. This Organization follows OHRP guidance on “Engagement of Institutions in Research”[[1]](#footnote-1) to apply this definition and exceptions to this definition.

### Human Research:

Any activity that either:

* Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or
* Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Research”).

### Human Subject as Defined by DHHS

A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through Intervention or Interaction with the individual, and uses studies, or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:

* **Intervention** means both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
* **Interaction** means communication or interpersonal contact between investigator and subject.
* **Private Information** means 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 that the individual can reasonably expect will not be made public (for example, a medical record).
* **Identifiable Private Information** means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
* **Identifiable Biospecimen** means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

### Human Subject as Defined by FDA

An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

### Investigator

The person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

### Research as Defined by DHHS

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.[[2]](#footnote-2)

### Research as Defined by FDA

Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

* Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
* Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
* Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

## Mission

The mission of this Organization’s Human Research protection program plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by this Organization.

### Ethical Requirements

In the oversight of all Human Research, this Organization (including its investigators, research staff, students involved with the conduct of Human Research, the Organization’s institutional review boards (IRBs), IRB members and chairs, IRB staff, the Institutional Offical (IO), and employees) follows the ethical principles outlined in the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research titled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” also known as “The Belmont Report”:

* Respect for Persons
* Beneficence
* Justice

### 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 organizational designated IRB (UB IRB). Activities that do not meet the definition of Human Research do not require review and approval by the UB IRB and do not need to be submitted 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 Organization commits to apply the FDA regulations relevant to the protection of Human Subjects.

Any questions about whether an activity meets the regulatory definitions of Human Research should be referred to the IRB Office who will provide a determination.

### Other Requirements

When reviewing research that involves community based research, the UB IRB obtains consultation or training.

All policies and procedures are applied identically to all research regardless of whether the research is conducted domestically or in another country, including:

* Confirming the qualifications of investigators for conducting the research
* Conducting initial review, continuing review, and review of modifications to previously approved research
* Post-approval monitoring
* Handling of complaints, non-compliance, and unanticipated problems involving risks to subjects or others
* Consent process and other language issues
* Ensuring all necessary approvals are met
* Coordination and communication with local IRBs or institutions required for approval of human subjects studies

For clinical trials, this Organization commits to apply the “International Conference on Harmonization – Good Clinical Practice E6.” (ICH-GCP)

This Organization prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)

When Human Research is conducted or funded by the Department of Justice (DOJ), this Organization commits to apply 28 CFR §22. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the Organization commits to comply with 28 CFR §512.

When Human Research is conducted or funded by the Department of Defense (DOD), this Organization commits to apply the Department of Defense (DOD) Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D[[3]](#footnote-3). This Organization will comply with the terms of the DFARS clause or comparable language used in the agreement with the Department of Defense (DOD) Component supporting the research involving human subjects.

When Human Research is conducted or funded by the Department of Education (ED), this Organization commits to applying 34 CFR §97 Subpart D (equivalent to 45 CFR §46 Subpart D), 34 CFR §98.3, 34 CFR §98.4, 34 CFR §356.3, and 34 CFR §99.

When Human Research is conducted or funded by the Department of Energy (DOE), this Institution commits to applying the Department of Energy (DOE) O 443.1B and to use “DOE Institutional Review Board Template for Reviewing Human Subjects Research Protocol that Utilize Personally Identifiable Information (PII).”

When Human Research is conducted or funded by, or when the results of research are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA), this Organization commits to applying 40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D.

When Human Research is subject to the European Union General Data Protection Regulations (GDPR), this Institution coordinates with legal counsel to ensure that the research activities conform to broader institutional policies related to GDPR, where applicable, as well as legal counsel’s interpretation of study-specific GDPR requirements.

### 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 categories of Human Research overseen include:

* International research
* Research conducted or funded by the Department of Defense (DOD)
* Research conducted or funded by the Department of Justice (DOJ)
* Research conducted or funded by the Department of Education (ED)
* Research conducted or funded by the Department of Energy (DOE)
* Research conducted, funded, or subject to oversight by the Environmental Protection Agency (EPA)
* Federally funded research
* Research involving fetuses.
* Research involving *in vitro* fertilization.
* FDA-regulated research.
* Research involving drugs that require an IND.
* Research involving devices that require an abbreviated IDE.
* Research involving devices that require an IDE issued by FDA.
* Investigator held abbreviated IDE.
* Investigator held IND or IDE.
* Research involving pregnant women as subjects.
* Research involving non-viable neonates.
* Research involving neonates of uncertain viability.
* Research that plans to or is likely to involve prisoners as subjects.
* Research involving children as subjects.
* Research involving children, pregnant women, fetuses, or neonates that is not otherwise approvable without approvable of an agency secretary or director.
* Research involving a waiver of consent for planned emergency research.
* Emergency use of a test article in a life threatening situation.
* Activities involving humanitarian use devices.
* Research using the short form of consent documentation.

The categories of Human Research not overseen include:

* Research conducted or funded by the Veteran Administration (VA)
* Classified Research (Classified research is secret research to which access is restricted by law to a particular hierarchical class of people. A security clearance is required to review classified research.)

### Human Research Protection Program Policies and Procedures

Policies and procedures for the Human Research Protection Program are available on the following Web site: <http://www.research.buffalo.edu> and the Click Library.

## Human Research Protection Program Components

### Institutional Official

The Associate Vice President for Regulatory Support is designated as the Institutional Official (IO).

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

* Create the Human Research Protection Program budget.
* Allocate resources within the Human Research Protection Program budget.
* Appoint and remove IRB members and IRB chairs.
* Hire and fire research review staff.
* Determine what IRBs the Organization will rely upon.
* Approve and rescind authorization agreements for IRBs.
* Place limitations or conditions on an investigator’s or research staff’s privilege to conduct Human Research.
* Create policies and procedures related to the Human Research Protection Program that are binding on the Organization.
* Suspend or terminate research approved by one of the Organization’s IRBs.
* Disapprove research approved by the IRB.

The IO has the responsibility to:

* Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
* Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed.
* Establish policies and procedures designed to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirement.
* Institute regular, effective, educational and training programs for all individuals involved with the Human Research Protection Program.
* Ensure that the research review process is independent and free of coercion or undue influence, and ensure that officials of the Organization cannot approve research that has not been approved by the IRB.
* Ensure that the IRB Chair(s) and members have direct access to the IO for appeal if they experience undue influence or if they have concerns about the function of the IRB.
* Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.
* Follow-up on findings of serious or continuing non-compliance of IRB staff and IRB members.
* Implement an auditing program to monitor compliance and improve compliance in identified problem areas.
* Investigate and remediate identified systemic problem areas, and where necessary removal of individuals from involvement in the Human Research protection program.
* Ensure that the Human Research Protection Program has sufficient resources, appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
* Review and sign federal assurances (FWA) and addenda.
* Fulfill educational requirements mandated by OHRP.

### All members of the Organization

All individuals within the Organization have the responsibility to:

* Be aware of 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 the IRB.
* Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the IO.
* Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.

Individuals who are responsible for business development are prohibited from carrying out day-to-day operations of the review process.

### IRB

This Organization may rely upon IRBs of another organization provided one of the following is true:

* The IRB has proper expertise.
* This Organization’s investigator is a collaborator on Human Research that is primarily conducted at another organization.

Reliance on an external IRB requires an Institutional Reliance Agreement for IRB review and a local review for compliance with local policies.

When following DHHS requirements: Records must include documentation specifying the responsibilities that a relying organization and an organization operating an IRB or EC each will undertake to ensure compliance with the requirements of the Common Rule. UB is a member of the Smart IRB, and utilizes the Smart IRB master reliance agreement to document reliance on external IRBs.

The IRBs relied upon by this Organization have the authority to:

* 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. Officials of this Institution may not approve Human Research that has not been approved by the IRB.
* Suspend or terminate approval of Human Research not being conducted in accordance with an IRBs’ requirements or that has been associated with unexpected serious harm to subjects.
* Observe, or have a third party observe, the consent process and the conduct of the Human Research.
* Determine whether an activity is Human Research.
* 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.
* Serve as the Privacy Board, as applicable, to fulfill the requirements of the HIPAA Privacy Rule for use or disclosure of protected health information for research purposes.

This institution will comply with the determinations of the reviewing IRB, follow reporting and conflict of interest disclosure requirements as specified in the authorization agreement, conduct monitoring, identify an appropriate contact person, ensure researchers have appropriate qualifications and provide local context information (and any updates) to the reviewing IRB.

When this institution provides IRB review for other institutions, this HRPP will follow established policies and procedures to ensure that the composition of the IRB is appropriate to review the research and will comply with applicable laws of the relying site. This includes ensuring the IRB is appropriately constituted, members are appropriately qualified, members will not participate in the review of research in which they have a conflict of interest; and that the IRB separates business functions from ethical review.

The IRB will review the research in accordance with established policies and procedures to determine that research is ethically justifiable, according to all applicable laws, including initial review, continuing review, review of modifications to previously approved research and unanticipated problems involving risks to subjects or others. The IRB will also have the ability to suspend or terminate IRB approval; as well as have the final authority to decide whether researcher or research staff conflict of interest and its management, if any, allows the research to be approved and request audits of research reviewed.

The IRB will notify the researcher (and organization) of its decisions, make relevant IRB policies and records available to the relying institution or organization and specify an IRB contact for communication.

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| IRB member and IRB staff have the responsibility to follow Human Research Protection  Program policies and procedures that apply to IRB members and staff. |

### Investigators and Research Staff

Investigators and research staff have the responsibility to:

* Follow the Human Research Protection Program requirements described in the INVESTIGATOR MANUAL (HRP-103).
* Comply with all determinations and additional requirements of the IRB, the IRB chair, and the IO.

### Legal Counsel

Legal Counsel has the responsibility to:

* Provide advice upon request to the IO, IRB, and other individuals involved with the Human Research Protection Program.
* Determine whether someone is acting as an agent of the Organization.
* Determine who meets the definition of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures.
* Resolve conflicts among applicable laws.
* Determine whether any Human Research involving personal data about individuals located in (but not necessarily citizen of) European Union member states, Norway, Iceland, Liechtenstein, and Switzerland conforms with EU General Data Protection Regulations (GDPR).

### Deans/Department Chairs

Deans and Department Chairs have the responsibility to:

* Oversee the review and conduct of Human Research in their department or school.
* Forward complaints and allegations regarding the Human Research Protection Program to the IO/OO.
* Ensure that each Human Research study conducted in their department or school has adequate resources.

### University at Buffalo Internal Audit Office

The Internal Audit Office provides a variety of services to the Institution including audits & follow-up and consulting services with the goal of assisting the university in meeting its compliance objectives through quality evaluation of risk and controls.

**The Research Foundation (RF) for the State University of New York (SUNY) Office of Internal Audit Services**

The SUNY RF Auditing services conduct periodic internal audits of components of the SUNY system including a review of the IRB to assesses the administrative structure, processes and controls including campus policies, IRB composition, and documentation, compliance with 45 CFR 46 and investigator compliance with campus policies, IRB approvals and determinations of record maintenance. Recommendations of any notes process observations are provided.

**Quality Assurance Improvement Program**

The HRPP Quality Assurance Improvement Program is a component of the HRPP that evaluates compliance of the Human Research Protection Program through systematic evaluation of Human Subjects research activities and documents.

The goal of the quality assurance improvement plan is to achieve and maintain compliance and to achieve targeted levels of quality, efficiency, and effectiveness of the HRPP by achieving the following objectives:

•Improving the compliance of investigators with their responsibilities

•Improving compliance of minutes with regulatory compliance

•Increase efficiency of recording and finalizing minutes

The following documents are utilized to measure the accomplishment of the objectives of the HRPP Plan:

•CHECKLIST: Investigator Quality Improvement Assessment (HRP-430).

•CHECKLIST: Minutes Quality Improvement Assessment (HRP-431).

In order to achieve the goal of assessing the compliance of the Human Research Protection Program as well as the quality, effectiveness and efficiency fo the HRPP program, the Quality Assurance Improvement Program strives to:

• Send the Investigator Quality Improvement Assessment to up to ten investigators monthly

• Complete the Minutes Quality Improvement Assessment on the minutes of every IRB Meeting conducted each month.

•Track compliance and assess any significant trends

•Work with the IRB Manager and Organizational Official to implement an intervention in the event that any evaluations indicate performance outside of the target range.

### Sponsored Projects Services (SPS)

The Sponsored Projects Services (SPS) has the responsibility to review contracts and funding agreements for compliance with Human Research Protection Program policies and procedures.

## Education and Training

All new employees involved in the design, conduct or reporting of human subject research are to review this plan as part of initial orientation. The human resources department is to conduct refresher training on current employees as needed to maintain awareness of this policy.

IRB members, IRB staff, and others involved in the review of Human Research, including the IO/OO, must complete the online Collaborative Institutional Training Initiative (CITI) human subjects online training program. See the IRB Web site for a link to this training. This training is valid for a three-year period, after which time a refresher CITI course or additional training must be completed. Investigators and research staff must complete the initial and continuing training described in the INVESTIGATOR MANUAL (HRP-103).

Investigators and research staff must complete the initial and continuing training described in the INVESTIGATOR MANUAL (HRP-103).

## Community Involvement

The University at Buffalo’s Clinical and Translational Science Institute (CTSI) engages the community in clinical and translational research. The CTSI seeks to improve the health of Western New York residents through innovative research across the full T1 through T4 translational spectrum including the alignment of community and research, education, and service learning to more quickly assimilate findings from evidence-based research into clinical and community practice.

Consultations

The CTSI’s Community Engagement Core is a resource available to all researchers. It offers a consultation service to assist with:

* Linking researchers with community partners through its extensive community network
* Brainstorming community-based recruitment strategies, particularly among underrepresented communities,
* Understanding cultural nuances of intended communities
* Providing community demographic data
* Discussing health disparities related to topics and communities
* Preparing grant submissions

The Buffalo Research Registry

The Buffalo Research Registry (BRR) is a local registry of people who are interested in learning more about research studies. Each member completes a profile that allows them to be matched with studies that may be of interest. It also asks if members are interested in being informed of local events or becoming a member of a research team. The goal is to have this registry reflect the demographics of the Buffalo area and has a specific focus on enrolling underrepresented groups. To date, the BRR has 5,723 members. 51% of members are from an underserved community defined by ZIP codes with high poverty levels. 46% identify as a racial/ethnic minority.

Community Partnership Development Seed Grants

Two seed grants are awarded annually to support the planning of community-based participatory research partnerships and engagement of communities on research teams. The goal of these awards is to prepare community-academic partnerships to successfully collaborate on the design of research projects, address health equity, and generate a research plan for submission of larger grants. The review process includes academic and community reviewers.

CIRTIfication

UB is an official adaptor of CIRTIfication, a community friendly human subjects research training program, developed by the Dr. Emily Anderson form the University of Illinois. This training is offered to community partners and can be done individually or in a small group setting.

Community Engagement Studios

The Community Engagement Core is trained to facilitate Community Engagement Studios, a model of engagement developed by Meharry-Vanderilt that facilitates project-specific input from community stakeholders to enhance research design, implementation, and dissemination. CE Studios create a space where stakeholders (or Community Experts) provide immediate, focused feedback to a researcher on specific areas of  
concern for a given research study. It’s a quick, yet in-depth, method for researchers to get genuine input from the intended community.

## Questions and Additional Information for the IRB

The IRB Office wants your questions, information, and feedback.

Contact and location information for the IRB Office is:

Clinical and Research Institute on Addictions

1021 Main Street

Buffalo, NY 14203

716-888-4888

ub-irb@buffalo.edu

## Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of non-compliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees are permitted to report concerns on an anonymous basis. Concerns may be reported to the IRB Chair, IRB Office, IO, Legal Counsel, Deans, or Department Chairs.

The IRB has the responsibility to investigate allegations and findings of non-compliance and take corrective actions as needed. The IO has the responsibility to investigate all other reports and take corrective actions as needed.

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

To make such reports, contact:

Office of Research Compliance

Clinical and Research Institute on Addictions

1021 Main Street

Buffalo, NY 14203

716-888-4888

ub-irb@buffalo.edu

## Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and organizational requirements will conduct periodic audits. Audits will focus on areas of concern that have been identified by any entity, i.e., federal, state or institutional. Random audits may also be conducted.

## Disciplinary Actions

The IO may place limitations or conditions on an investigator’s or research staff’s privilege to conduct Human Research whenever in the opinion of the IO/OO such actions are required to maintain the Human Research Protection Program.

## Approval and Revisions to the Plan

This Human Research Protection Program Plan is to be approved by the IO. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The IO has the responsibility to review this plan to assess whether it is providing the desired results.

Or

This Human Research Protection Program Plan is to be approved by the Chief Executive Officer. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The IO has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the IO, the Chief Executive Officer has the authority to amend this plan as deemed necessary.

1. <http://www.hhs.gov/ohrp/policy/engage08.html> [↑](#footnote-ref-1)
2. For research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research. [↑](#footnote-ref-2)
3. Quick applicability table for DHHS Subparts:

   |  |  |  |  |  |
   | --- | --- | --- | --- | --- |
   |  | DHHS | DOD | ED | EPA |
   | Subpart B | X | X |  | X |
   | Subpart C | X | X |  |  |
   | Subpart D | X | X | X | X |

   [↑](#footnote-ref-3)