UB Human Research Protection Program Plan

Revised July 5, 2024

Effective July 12. 2024

[1] Prior to this current version, the Human Research Protection Program Plan was revised July 20, 2023 and effective August 31, 2023.

Purpose

This organization is committed to protect 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 the all individuals in the 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 the organization for purposes of engagement in Human Research when that individual on on-duty in any capacity as an employee of the organization.

An individual who is not an employee is considered an agent of the organization for purposes of engagement in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of the organization.

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

Clinical Trial

Human Research intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of a drug or biologic, to identify any adverse reactions to a drug or device, to evaluate the safety or effectiveness of a drug, biologic, or device, or to study absorption, distribution, metabolism, and excretion of a drug or biologic with the object of ascertaining its safety or efficacy.

Engaged in Human Research

The organization is engaged in Human Research when its employees or agents are interacting or intervening with Human Subjects for the purpose of conducting research. The organization follows OHRP guidance on "Engagement of Institutions in Research" to apply 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 the Department of Health and Human Services (45 CFR §46.102(e1-6))

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) 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 of identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable Private Information is 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 is 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 the Department of Defense (32 CFR §219.102(e))

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human Subject as Defined by Federal Drug Administration (21 CFR §50.3(g))

Human subject means an individual who is or becomes a participant 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.

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 (45 CFR §46.102(l))

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research as Defined by FDA (21 CFR §56.102(c))

Any experiment that involves a test article and one or more human subjects, and that either

Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520 (g) of the act, or

Need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but 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 conducted or overseen by this organization.

Ethical Requirements

In the conduct of all Human Research this organization (including its investigators, research staff, students involved with the conduct of Human Research, IRB members and chairs, IRB staff, the Authorized Institutional Official, Associate Authorized Institutional Official, employees, and students) 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 an organizationally designated IRB. Activities that do not meet the definition of Human Research (e.g., most classroom activities, quality improvement activities, program evaluation, and surveillance

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

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

When the organization is engaged in FDA Human Research, the 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 Chair who will provide a determination.

Other Requirements

All policies and procedures that are applied to Human Research conducted domestically are applied to Human Research conducted in other countries. Further, other countries may require adherence to additional policies and procedures. Contact the IRB Chair for more information.

The 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 the organization becomes engaged in federally-conducted or -supported Human Research to which the Federal Wide Assurance applies, the organization and the institutional review boards (IRBs) designated under the organization's Assurance will comply with the Federal Policy for the Protection of Human Subjects:

7 CFR part 1c	Department of Agriculture
10 CFR part 745	Department of Energy
14 CFR part 1230	National Aeronautics and Space Administration
15 CFR part 27	Department of Commerce
16 CFR part 1028	Consumer Product Safety Commission
22 CFR part 225	Agency for International Development
24 CFR part 60	Department of Housing and Urban Development
28 CFR part 46	Department of Justice
32 CFR part 219	Department of Defense
34 CFR part 97	Department of Education

38 CFR part 16	Department of Veterans Affairs
40 CFR part 26	Environmental Protection Agency
45 CFR part 46	Department of Health and Human Services
45 CFR part 46 (by Executive Order 12333)	Central Intelligence Agency
45 CFR part 690	National Science Foundation
49 CFR part 11	Department of Transportation
29 CFR part 21	Department of Labor
6 CFR Part 46	Department of Homeland Security
20 CFR Part 431	Social Security Administration

Note that as of January 21, 2019, the Department of Justice (DOJ) has not become an official signatory. Guidance on DOJ human subjects research can be found at: https://www.nij.gov/funding/humansubjects/pages/human-subjects.aspx

When Human Research is conducted or funded by the Department of Justice (DOJ), the organization commits to apply 28 CFR part 46. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the organization relies on the Bureau Research Review Board to ensure compliance with 28 CFR §512.

When Human Research is conducted or funded by the Department of Defense (DOD), the organization commits to apply DOD Directive 3216.02. When Human Research is conducted or funded by the Department of the Navy, the organization commits to apply SECNAVINST 39000.39D.

When Human Research is conducted or funded by the Department of Education (ED), the organization commits to applying 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), the organization commits to applying DOE O 443.1B Chg1 (PgChg) for the Protection of Human Research Subjects and to applying DOE N 443.1 for the Protection of Human Subjects in Classified Research.

When Human Research is conducted or funded by, or when the results of research are intended to be submitted to the Environmental Protection Agency (EPA), the organization commits to applying 40 CFR §26.

When Human Research is subject to Veterans Administration (VA) oversight, the organization commits to apply VHA Handbook 1200.05(2) requirements, and all

regulations pertaining to the participation of veterans as subjects including requirements for indemnification in case of research-related injury pertained to non-veteran subjects enrolled in Veterans Administration (VA) approved research.

Sponsored Human Research

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

Scope of Human Research Protection Program

The categories of Human Research conducted include:

- Research involving fetuses.
- Research involving *in vitro* fertilization.
- Veteran's Administration (VA) Human Research involving prisoners as subjects unless a waiver has been granted by the Chief Research and Development Officer.
- Veteran's Administration (VA) Human Research involving children as subjects unless a waiver has been granted by the Chief Research and Development Officer.
- 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 approval 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.

Generally, UB's IRB reviews human research involving children as subjects, veterans, pregnant women, and incarcerated populations using the expedited and full board review process. For the most part, a good number of studies meet exemption categories and the exempt review process applies.

Human Research Protection Program Policies and Procedures

Policies and procedures for the Human Research Protection Program are available to University of Bridgeport employees and students on the portal.

Human Research Protection Program Components

Authorized Institutional Official (AIO) and Associate AIO

The Provost and Vice President for Academic Affairs is designated as the Authorized Institutional Official.

The Authorized Institutional Official, assisted by the Associate Authorized Institutional Official, has the authority to:

- Create the Human Research Protection Program budget.
- Allocate resources with 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 IRB authorization agreements.
- 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 IRB approval of research.
- Disapprove research approved by the IRB.

The Authorized Institutional Official, assisted by the Associate Authorized Institutional Official is responsible 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 an IRB designated by the organization.
- Implement a process to receive and act on complaints and allegations regarding the Human Research Protection Program.
- 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, including IRBs 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 and addenda.
- Fulfill educational requirements mandated by Veterans Administration (VA) Office of Research and Development and OHRP.

All members of the organization

All faculty, staff, and students within the organization are responsible 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 an IRB designated by the Authorized Institutional Official.
- Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the Authorized Institutional Official or Associate Authorized Institutional Official.
- Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB.

IRBs

The list of IRBs designated by the Organization Official to be the IRBs relied upon by the Human Research Protection Program and the scope of review of these IRBs is listed in the IRB rosters available from the Associate Authorized Institutional Official.

The organization may rely upon the IRB of another organization provided one of the following is true:

- The IRB is the IRB of an organization with an HHS active Federalwide Assurance (FWA) and the IRB is recognized under the FWA.
- This organization's investigator is a collaborator on Human Research to be primarily conducted at another organization and the investigator's role does not include interaction or intervention with subjects.
- The organization is engaged in the Human Research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.)

The IRBs relied upon by the Authorized Institutional Official have the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the organization[2]. All Human Research must be approved by an IRB designated by the Authorized Institutional Official. Officials of the organization 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 the IRB's requirements or that has been associated with unexpected serious harm to subjects, or is not being conducted in accordance with *45 CFR 46* or the Committee's decisions, conditions, or requirements.
- 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.

IRB member and IRB staff are responsible to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.

Committee meetings are conducted in accordance with Roberts Rules of Order. At a minimum, the Chair, in conjunction with the Administrator, conducts the meeting, there is a predetermined agenda, the minutes from the prior meeting will consist of a list of proposals reviewed, the outcome, date of meeting and members in attendance.

The IRB may vote to approve, disapprove, or modify a research proposal. These actions require the vote of a majority of the members present at the meeting. The Chair does not vote, except to break a tie. If the vote is not unanimous, the minority opinion must be recorded in or attached to the minutes. A committee member may abstain from voting for any reason, without explanation. A member may change his/her vote until the time the vote is finally announced by the Chair. After that, a member's vote may be changed only by permission of the Committee which may be given by general consent.

The Expedited Research Review process requires only one IRB member to review a research proposal and this member may be the IRB Chair. The Expedited review process may also be used to review and approve minor changes to previously reviewed research during the period for which original approval is authorized. In both cases, the

IRB Chair, or designated representatives conducting the Expedited review, informs the IRB Administrator of research which has been approved by this procedure in Mentor IRB. The Administrator will then update members at the next scheduled IRB meeting via Mentor IRB's agenda function.

IRB Membership

Committee criteria include (but is not limited to):

- The IRB will have a membership greater than five individuals; and one member will not be affiliated with UB.
- Individuals will have varying backgrounds to promote complete and adequate review of research.
- They will be knowledgeable and compliant to UB commitments and regulations; applicable law and federal regulations; standards of professional conduct and practice.
- They will serve for a period of three years.

The IRB may, in its discretion, invite individuals (*ad hoc members*) with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the committee. *Ad hoc members* may not vote with the IRB to determine approval or disapproval of research.

Full IRB actions require the presence of a quorum of the voting members, defined as a majority (i.e., >50%) of the IRB members. As part of the meeting, at least one scientist member, at least one member whose concerns are nonscientific and one member who is not affiliated with UB/community representative must be present for quorum to be established.

IRB Training

The IRB Chair, its members and Department Directors receive a copy of the *UB Human Research Protection Plan*, links to The Belmont Report *Ethical Principles and Guidelines for the Protection of Human Subjects Research*, April 18, 1979 and 45 CFR 46 *Protection of Human Subjects*. Additional training will be required as prescribed by the IRB, and may include, but is not limited to CITI training on:

- Biomedical Research and/or Social & Behavioral Research
- Biomedical Responsible Conduct of Research and/or Social & Behavioral Responsible Conduct of Research
- IRB Chair/Member
- Conflicts of Interest

IRB Documentation of Activities

UB utilizes this plan, the forms and application materials to document the following:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- IRB meeting minutes which shall be in sufficient detail to show attendance, actions taken by the IRB, the vote on these actions including the number of members voting for, against and abstaining; the basis for requiring changes in or disapproving research.
- Records of continuing review activities.
- Copies of all correspondence between the IRB and the investigators.
- As list of IRB members as described in §46.108(a)(2).
- Written procedures for the IRB as described in §46.108(a)(3)(4).
- Statements of significant new findings provided to subjects as described in §46.116(c)(5).

Investigators and Research Staff

Investigators and research staff are responsible to:

- Follow the Human Research Protection Program requirements described in the Investigator Manual.
- Follow the Human Research Protection Program policies and procedures that apply to IRB members and staff.
- Comply with all determinations and additional requirements of the IRB, the IRB Chair, and the Authorized Institutional Official.

Legal Counsel

Legal Counsel is responsible to:

- Provide advice upon request to the Authorized Institutional Official, Associate Authorized Institutional Official, 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 DHHS and FDA definitions of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures.
- Resolve conflicts among applicable laws.

Deans/Department Chairs

Deans and Department Chairs are responsible 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 Authorized Institutional Official or Associate Authorized Institutional Official.

- Ensure that each Human Research study conducted in their department or school has adequate resources.

Office of Instruction Based and Sponsored Research

The Office of Instruction Based and Sponsored Research is responsible to review sponsor contracts and funding agreements for compliance with Human Research Protection Program Policies and procedures.

Education and Training

All new employees are to review this plan as part of initial orientation. Human Resources 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 must complete the online Collaborative Institutional Training Initiative (CITI) human subjects online training program for IRB members. See the UB portal 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 online Collaborative Institutional Training Initiative (CITI) human subjects online training program. See the UB portal 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.

Questions and Additional Information for the IRBs

The IRB wants your questions, information, and feedback. Contact information for the IRB is irb@bridgeport.edu. The current faculty serving as the IRB Chair(s) and IRB Administrator are available on UB's Research Compliance page and on myUB portal's Research Compliance page.

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, Authorized Institutional Official, Associate Authorized Institutional Official, Legal Counsel, Deans, or Department Chairs.

The IRB is responsible to investigate allegations and findings of non-compliance and take corrective actions as needed. The Authorized Institutional Official is responsible 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 Authorized Institutional Official or the Associate Authorized Institutional Official.

Contact information for the Authorized Institutional Official is as follows:

Provost and Vice President for Academic Affairs
University of Bridgeport
126 Park Avenue
Bridgeport, CT 06604
Email: provost@bridgeport.edu
(203) 576-4685

Contact information for the Associate Authorized Institutional Official is as follows:

Director, Instruction-Based and Sponsored Research
University of Bridgeport
126 Park Avenue
Bridgeport, CT 06604
Email: irb@bridgeport.edu
(203) 576-4974

Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and University requirements may 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 Authorized Institutional 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 Authorized Institutional Official 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 Authorized Institutional Official. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The Authorized Institutional Official, assisted by

the Associate Authorized Institutional Official, is responsible to review this plan to assess whether it is providing the desired results.

Approved:

Manyul Im, Ph.D.
Authorized Institutional Official
Provost and Vice President for Academic Affairs
July 12, 2024