BROWN

Human Research Protection Program

Plan[1]

Revised 02/09/2026

[1] This document satisfies AAHRPP elements I.1.A-G, I-2, I-3, I.4.B-C, I.5.A, I.5.C, I.5.D, I.6.B, I.7.A, I.7.C, I-9, II.1.B, II.2.C, II.2.G, II.2.H, II.2.E-II.2.E.2, II.3.C-II.3.C.1, II.3.E, II.3.F, III.1.A, III.1.C, III.2.A, III.2.D

Table of Contents

Scope

Throughout this document, the term “Institutions” may refer to Brown University or any of the institutions within the Brown University Health or Care New England systems. Where this plan varies for a specific institution, such variations will be explicitly noted in the relevant sections below.

Purpose

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

The 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 the Institution 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 Institution for purposes of engagement in Human Research when that individual is on-duty in any capacity as an employee of the Institution.

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

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

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 effects of the interventions on biomedical or behavioral health-related outcomes.

Engaged in Human Research

In general, the Institution is considered engaged in Human Research when the Institution’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 or identifiable biospecimens from the subjects of the research; or (3) the informed consent of human subjects for the research. The Institution follows OHRP guidance on “Engagement of Institutions in Research”[2] to apply this definition and exceptions to this definition.

[2] http://www.hhs.gov/ohrp/policy/engage08.html

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.[3]

The following activities are not considered Research as Defined by DHHS:

1 Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2 Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.

2.1 Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.

2.2 Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.

2.3 Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3 Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4 Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.

5 Secondary research involving non-identifiable newborn screening blood spots.

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

[3] 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.

- 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 the Institution's Human Research protection program plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by the Institution.

Ethical Requirements

In the oversight of all Human Research, the Institution (including its investigators, research staff, students involved with the conduct of Human Research, the Institution's institutional review boards (IRBs), IRB members and chairs, IRB staff, the Institutional Official/Organizational Official (IO/OO), 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

the Institution commits to apply its ethical standards to all Human Research regardless of funding.

All Human Research must undergo review by one of the institutionally designated IRBs. Activities that do not meet the definition of Human Research do not require review and approval by one of the Institution's IRBs and do not need to be submitted to one of the Institution's IRBs unless there is a question regarding whether the activity is Human Research.

When the Institution 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 Institution commits to apply the regulations of that agency relevant to the protection of Human Subjects.

When the Institution is engaged in FDA Human Research, the Institution 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 IRB obtains consultation or training.

All policies and procedures are applied identically to all research regardless of funding or 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

For clinical trials, the Institution commits to apply the “International Conference on Harmonisation – Good Clinical Practice E6” (ICH-GCP) when required by industry-sponsored studies.

The Institution 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.”)

The Institution utilizes the IRB to review and approve the use of a Humanitarian Use Device (HUD) before it can be used at a facility for clinical care (with the exception of emergency use).

When Human Research is conducted or funded by the Department of Justice (DOJ), the Institution commits to apply 28 CFR §22 and 28 CFR §46. When Human Research is conducted with the federal Bureau of Prisons (DOJ), the Institution commits to comply with 28 CFR §512.

When Human Research is conducted or funded by the Department of Defense (DOD), the Institution 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[4]. the Institution 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), the Institution 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), the Institution commits to applying the Department of Energy (DOE) O 443.1C which includes the requirements to apply 10 CFR §745 and Subparts B, C, and D of 45 CFR §46, as applicable, and additional DOE requirements outlined in HRP-318 - WORKSHEET - Additional Federal Agency Criteria.

DOE requirements apply to all research conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research.

When research involves contractors, DOE “Contractor Requirements Document” describing contractor responsibilities for protecting human research participants must be included in contracts.

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

---

[4] Quick applicability table for DHHS Subparts:

	DHHS DOD DOE ED EPA VA
Subpart B	X X X X X
Subpart C	X X X X
Subpart D	X X X X X X

(EPA), the Institution 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), the 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. Note that not all institutions may permit research under GDPR.

Sponsored Human Research

For both sponsored and non-sponsored Human Research the Institution 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)
    - DOD research involving Experimental Subjects
    - DOD classified research
    - Research on DOD personnel
    - DOD research involving chemical or biological agents under an exception
- 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)
    - Department of Energy (DOE) human terrain mapping research
- 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 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.
- Research using the short form of consent documentation.

The categories of Human Research not overseen include:

- 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.)
- Research conducted or funded by the Veteran Administration (VA)
- Research that includes processing or holding personal data of subjects residing in the European Union.

Human Research Protection Program Policies and Procedures

Policies and procedures for the Human Research Protection Program are available on the following Web site:https://division-research.brown.edu/research-cycle/conduct-research/human-subjects-research/policies/toolkit | https://www.brown.edu/research/guidance-policies

Human Research Protection Program Components

Institutional Official/Organizational Official (IO/OO)

Deputy Vice President for Research is designated as the IO/OO for Brown University.

Senior Vice President of Research is designated as the IO/OO for Brown University Health.

The Chief Clinical Officer is designated as the IO/OO for Care New England.

An Institutional Official Council ("IOC") has been created and chartered to oversee aspects of the reorganized Brown HRPP Unit.

The IO/OO 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 Institution 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 Institution.
- Suspend or terminate research approved by one of the Institution's IRBs.
- Disapprove research approved by one of the Institution's IRBs.
- Establish a contingency plan for transferring oversight of one or more studies to another institution or IRB in the event the IRB is unable to continue oversight of the studies in an emergency/disaster scenario (e.g., natural disasters, man-made disasters, infectious disease pandemics, etc.).

The IO/OO 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 Institution cannot approve research that has not been approved by one of the IRBs designated by the Institution.
- 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, 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 (FWA) and addenda.
- Fulfill educational requirements mandated by OHRP.

Department of Energy (DOE) Institutional Official

The DOE IO:

- Resides within Office of Science (SC) and serves both as the Associate Director of Science for Biological and Environmental Research (BER) and the Senior DOE Official responsible for overseeing and monitoring DOE-supported and conducted HSR (or for designated an SES-level manager in DOE to do so). Specifically, the DOE IO oversees the Departmental implementation of the requirements of DOE O 443.1C Chg.1, 10 CFR §745, 45 CFR §46 (Other Subparts),and related Executive Orders (E.O.s), Presidential Memoranda, and other Presidential directives and international requirements, as applicable, in consultation with the NNSA, as appropriate.
- Reports to the Secretary of Energy for purposes of this function and determines what constitutes Departmental HSR, in consultation with the NNSA.
- Allocates resources for the DOE Human Subjects Protection Program (HSPP).
- Assures policies are in place that require that the research review process be independent and free of coercion and undue influence.

- Establishes a process to receive and act on complaints and allegations regarding the DOE HSPP.
- Oversees the Central DOE IRBs and formally appoints all members of the Central DOE IRBs.
- Must approve classified research to be conducted at DOE sites/laboratories after IRB approval and prior to initiation.
- Reviews and adjudicates IRB member appeals of IRB approval determination for classified project.
- Must concur on all requests for partial or full exemptions from the requirements of DOE O 443.1C Chg. 1.
- Approves and rescinds authorization agreements with other DOE and outside institutions for IRB review.

Department of Energy (DOE) Human Subjects Protection (HSP) Program Manager

The DOE HSP Program Manager:

- Resides within the DOE SC's BER and reports to the DOE IO.
- Develops procedures for the HSP program in consultation with the NNSA HSP Program Manager, as appropriate.
- Prepares and updates guidance to be followed for obtaining approval for HSR in consultation with the NNSA HSP Program Manager, as appropriate.Reviews and coordinates with DOE site Offices and site IRBs regarding plans to correct any noncompliance or mitigate adverse study events, ensuring they comply with applicable HSP requirements.

- Reviews and approves statements of work for Human Terrain Mapping (HTM) projects submitted by DOE's non-NNSA sites. Ensures compliance with DOE requirements, and, for HTM projects that are Strategic Partnership Projects (SPPs) and Strategic Intelligence Partnership Program (SIPP) projects, coordinates with appropriate Headquarters SPP/SIPP leads prior to approving such statements of work for initiation. Ensures site Offices and M&O contractors are aware of decisions concerning proposed HTM work.
- Provides advice and guidance on evolving Departmental and national bioethics and regulatory issues regarding human research subject protection and helps identify and resolve program/project concerns in consultation with the NNSA HSP Program Manager, as appropriate.
- Develops and conducts educational programs on bioethics and human research subjects protection requirements, practices, and procedures relevant to DOE employees, DOE contractor personnel, financial assistance recipients, and the public in consultation with the NNSA HSP Program Manager, as appropriate.
- Regularly (at least every three years) conducts institutional performance reviews, or quality assurance consultations, to assess compliance with human research subject

protection requirements, in consultation with the NNSA HSP Program Manager, as appropriate.

- Serves as the Chair of the DOE Human Subjects Working Group and as official DOE representative to groups with bioethics and HSP interests. The NNSA HSP Program Manager shall co-chair meetings, as appropriate.
- Reviews and, in coordination with the NNSA HSP Program Manager and the DOE-IN, approves requests for waivers, on a project by project basis, from the DOE requirements for classified research if the reviewing IRB determines that a project that is classified, in whole or in part, can be reviewed in an unclassified manner.
- Makes recommendations to the Secretary after concurrence from the IO, regarding exemptions from any other requirements of DOE O 443.1C Chg. 1, and satisfies the advance notice and publication requirements of 10 CFR §745.101(i) prior to the granting of any exemption (in consultation with the NNSA HSP Program Manager, as appropriate).
- Concurs on human participant provisions in interagency agreements, in consultation with the NNSA HSP Program Manager, as appropriate.
- Maintains the DOE HSR (HRSD), the list of unclassified intelligence-related HSR projects, and the unclassified list of classified HSR projects for DOE.
- Serves as the Co-Chair of the Central DOE IRB-C.

Department of Energy (DOE) National Nuclear Security Administration Human Subjects Protection Program Manager

When an NNSA element or project is involved, the responsibilities of the NNSA HSP Program Manager are identical to those of the DOE HSP Program Manager. The NNSA HSP Program Manager:

- Resides within NNSA NA-10.1, the Office of · Policy and Strategic Planning and reports functionally to the DOE IO.

- When a NNSA element or project is involved, the responsibilities of the NNSA HSP Program Manager are identical to those of the DOE HSP Program Manager.
- Ensures compliance with the DOE/NNSA requirements.
- Works with the DOE HSP Program Manager, as outlined above.
- Serves as one of the Co-Chair of the Central DOE IRB-C.

Responsibilities of the other DOE HRPP components are described in DOE Order 443.1C Chg. 1.

All members of the Institution

All individuals within the Institution 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 an IRB designated by the IO/OO.
- 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/OO.
- 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.

IRBs

The list of IRBs designated by the IO/OO 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 IRB Office. IRB members and IRB staff have the responsibility to follow Human Research Protection Program policies and procedures that apply to IRB members and staff.

Relying on an External IRB

The Institution may rely upon IRBs of another institution or organization provided one of the following is true:

- The IRBs are part of an AAHRPP accredited institution or organization.
- The IRBs are not part of an AAHRPP accredited institution or organization, but where reasonable steps have been taken to ensure that subjects are adequately protected. For example, for research that is no greater than Minimal Risk, there may be an assurance that the IRBs will adhere to applicable ethical standards and regulations. For research that is greater than Minimal Risk, the institutions may agree on more extensive oversight.
- The IRBs are part of an established reliance network (e.g., Smart IRB) that has established contractual and SOP-level procedures to clarify the roles and responsibilities associated with IRB reliance and to establish mechanisms to ensure quality and consistency in the review process among institutions.
- The sIRB has been pre-determined by study sponsor or grant or established by prior arrangement.
- The Institution's investigator is a collaborator on Human Research that is primarily conducted at another institution or organization and the investigator's role does not include interaction or intervention with subjects.
- The Institution 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.)

Reliance on an external IRB requires an Authorization Agreement and an active Institutional Profile, as well as a local review for compliance with local policies of the Institution. When Human Research carried out at the Institution or by its agents is reviewed by an IRB at another institution or organization, this HRPP will follow established policies and procedures

that specify which studies are eligible for reliance, how reliance is determined, and will provide information to researchers about reliance criteria and the process for seeking IRB reliance.

The IRBs relied upon by the Institution have the authority to:

- Approve, require modifications to secure approval, and disapprove all Human Research overseen and conducted by the Institution. All Human Research must be approved by one of the IRBs designated by the IO/OO. Officials of the Institution may not approve Human Research that has been disapproved by the IRB of record.
- 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.

the 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.

Serving as the IRB of Record

When the 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.

Investigators and Research Staff

Investigators and research staff have the responsibility to:

- Follow the Human Research Protection Program requirements described in HRP-103 - INVESTIGATOR MANUAL.
- Comply with all determinations and additional requirements of the IRB, the IRB chair, and the IO/OO.
- Develop and implement emergency/disaster response procedures for their research depending on location and nature of the research.

Legal Counsel

Legal Counsel has the responsibility to:

- Provide advice upon request to the IO/OO, IRB, and other individuals involved with the Human Research Protection Program.
- Determine whether someone is acting as an agent of the Institution.
- 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 citizens 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.

Grants and Contracts & Clinical Trials

Grants and Contracts & Clinical Trials Offices has the responsibility to review contracts and funding agreements for compliance with Human Research Protection Program policies and procedures.

Education and Training

This plan is made available to the human research community via the IRB website. To maintain awareness of HRPP policies and procedures, new information, revised materials and opportunities for continuing education are communicated to the research community by way of various email list-serve groups targeted to appropriate audiences.

IRB members, IRB staff, and others involved in the review of Human Research, including the IO/OO, must complete initial and continuing training utilizing the Collaborative Institutional Training Initiative (CITI) human subjects online training program. Training is valid for a three-year period, after which time refresher training must be completed.

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

HRPP staff will coordinate with organizational officials in the development and implementation of training materials related to emergency preparedness and response plans specific to human research conducted at the organization. The HRPP emergency preparedness plan will be made available to the human research community via the IRB website. The organization is responsible for notifying research teams when the organization's emergency response plan is activated.

Continuing Planning for HRPP Disruptions

The organization routinely assesses potential emergency scenarios, disruptive events and threats to the institution to improve its business continuity plan. The HRPP Director, or their designee, collaborates with organizational leadership to develop, implement, and assess, continuity planning procedures for the HRPP.

Depending on the nature of the event, the HRPP Director will collaborate with the IO/OO, other institutional leadership, and vendors, as appropriate, to:

- Determine the types of research that might continue and the types that the organization may need to temporarily postpone. The organization proactively identifies external IRBs on which it can rely on temporarily during an emergency.
- Identifies external IRBs on which it can rely on temporarily during an emergency.
- Ensure continuity of operations in the event that electronic systems and/or records are inaccessible or not operational

Implement alternative review procedures, including leveraging online and virtual platforms, to ensure that IRB meetings can continue in scenarios where the IRB cannot meet in person. In instances where the convened IRB is unable to meet and IRB approval for a study may lapse, the IRB Chair can determine whether subjects can continue to participate in research activities if it is in the best interest of already enrolled subjects.

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:

Alexandra Boutros, BS, CIP
Director, Human Research Protection Program
Brown University
Box 1986
Providence, RI 02912
Email: irb@brown.edu
401-863-3050

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/OO, 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/OO 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 IO/OO or designee.

To make such reports, contact the IO/OO:

J. Martin Scholtz, PhD
Deputy Vice President for Research
Brown University
Email: marty_scholtz@brown.edu

Bharat Ramratnam, MD
Senior Vice President of Research
Brown University Health
Email: BRamratnam@brownhealth.org

William Grobman, MD, MBA
Chief Scientific Officer
Care New England
Email: wgrobman@kentri.org

Monitoring and Auditing

In order to monitor and ensure compliance, internal or external auditors who have expertise in federal and state statutes, regulations and institutional 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/OO 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 BIRCH IO Council. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The IO/OO has the responsibility to review this plan to assess whether it is providing the desired results.

[1] This document satisfies AAHRPP elements I.1.A-G, I-2, I-3, I.4.B-C, I.5.A, I.5.C, I.5.D, I.6.B, I.7.A, I.7.C, I-9, II.1.B, II.2.C, II.2.G, II.2.H, II.2.E-II.2.E.2, II.3.C-II.3.C.1, II.3.E, II.3.F, III.1.A, III.1.C, III.2.A, III.2.D

[1] http://www.hhs.gov/ohrp/policy/engage08.html

[1] 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.

[1] Quick applicability table for DHHS Subparts:

	DHHS	DOD	DOE	ED	EPA	VA
Subpart B	X	X	X		X	X
Subpart C	X	X	X			X
Subpart D	X	X	X	X	X	X