

# HUMAN RESEARCH PROTECTION PROGRAM PLAN

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## **Purpose**

The Harvard Longwood Campus (HLC) Human Research Protection Program (HRPP) is responsible for the review and oversight of Human Research conducted by agents of Harvard Longwood Campus (HLC) Schools including Harvard Faculty of Medicine (Harvard Medical School and Harvard School of Dental Medicine) and Harvard T.H. Chan School of Public Health (Harvard Chan School). The purpose of this document is to describe the HLC HRPP plan to comply with ethical and regulatory requirements for the conduct and oversight of Human Research.

The HLC HRPP is a comprehensive system to ensure the protection of the rights and welfare of participants in Human Research. It is comprised of the Harvard Chan School-based Office of Regulatory Affairs and Research Compliance (ORARC), which serves as the essential administrative unit supporting the HLC HRPP; institutional and School leadership; IRB Operations that manages the HMS and HSPH IRB panels; Quality Improvement Program (QIP); investigators and their study staff; Department Chairs, and other relevant offices. The HLC HRPP is dependent on all above-mentioned parties fulfilling their roles and responsibilities described in this plan.

## **Key Definitions and Terms**

### **Agent**

An individual, who is an employee or student, is considered an agent of Harvard Faculty of Medicine or Harvard Chan School Health for purposes of engagement in Human Research when that individual is on-duty in any capacity as an employee or student of the HLC Schools. Specifically, an agent is an individual who, by agreement or otherwise, may act on behalf of the HLC Schools and bind it by words or actions; a person who represents the HLC Schools by its authority or delegated authority.

An individual who is not an employee is considered an agent of Harvard Faculty of Medicine or Harvard Chan School for purposes of engagement in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of HLC Schools.

The Office of Regulatory Affairs and Research Compliance (ORARC) will consult with the Office of General Counsel (OGC) to determine whether someone is acting as an agent of the School when it is unclear whether the individual meets this definition.

### **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, Harvard Faculty of Medicine or Harvard Chan School is considered engaged in Human Research when its employees or agents, for the purposes of the Human Research, obtain: (1) data about the participants of the research through intervention or interaction with them; (2) identifiable private information about the participants of the research; or (3) the informed consent of human

participants for the research. The Office of Regulatory Affairs and Research Compliance follows the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP)<sup>1</sup> to apply this definition and exceptions to this definition

## Human Research

Human Research is considered any activity that either:

- Is “Research” as defined by Department of Health and Human Services (DHHS) and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or
- Is “Research” as defined by Food and Drug Administration (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 (for example, survey administration).
- **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 site, the investigator is the responsible leader of the team and may be called the Principal Investigator (PI).

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<sup>1</sup> <http://www.hhs.gov/ohrp/policy/engage08.html>

## Research as Defined by DHHS

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.<sup>2</sup>

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

- 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.
- 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.
  - Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
  - Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
  - 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).
- 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.
- Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.
- 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 both of the following:

1. Must meet the requirements for prior submission to the Food and Drug Administration under
  - a. 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; OR
  - b. section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; AND
- 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.

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<sup>2</sup> 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.

## **Mission and Goal**

The mission of the Harvard Longwood Campus Human Research Protection Program is to protect the rights and welfare of participants in Human Research that is overseen by the Harvard Longwood Campus IRBs.

The Office of Regulatory Affairs and Research Compliance aims to promote a culture of compliance with the highest legal and ethical standards for the conduct of Human Research. It is also committed to education of its research community and outreach to collaborating institutions participating in research.

## **Requirements**

### **Ethical**

Each Harvard Longwood Campus (HLC) School 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

In addition, when engaged in non-exempt international Human Research, the HLC IRBs follow applicable international and local ethical guidelines.

### **Legal**

Each Harvard Longwood Campus (HLC) School commits to apply its ethical standards to all Human Research regardless of funding.

All Human Research conducted by an agent of HLC Schools must undergo review by the HLC IRB. Activities that do not meet the definition of Human Research do not require 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 Harvard Faculty of Medicine or Harvard Chan School 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 Harvard Faculty of Medicine or Harvard Chan School is engaged in FDA-regulated Human Research, the institution commits to apply the FDA regulations.

When Human Research is conducted or funded by the following Departments, the institution commits to comply with relevant regulations:

Departments	Regulations
Department of Justice (DOJ)	28 CFR §22
Federal Bureau of Prisons (DOJ)	28 CFR §512
Department of Defense (DOD)	DOD Directive 3216.02, which includes the requirement to apply 45 CFR §46 Subparts B, C, and D <sup>3</sup> DFARS clause or comparable language used in the agreement with the DOD Component supporting the research involving human subjects
Department of Education (ED)	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
Department of Energy (DOE)	DOE O 443.1A and to use “Checklist for IRBs to Use in Verifying that HS Research Protocols are in Compliance with the Department of Energy (DOE) Requirements.” DOE Institutional Review Board Template for Reviewing Human Subjects Research Protocol that Utilize Personally Identifiable Information (PII)”
Environmental Protection Agency (EPA), or when the results of research are intended to be submitted to or held for inspection by EPA	40 CFR §26, which includes the requirement to apply 45 CFR §46 Subparts B and D

## Other Requirements

When reviewing research that involves Community-Based Participatory Research (CBPR), the IRB considers the following core principles:

- Facilitates collaborative, equitable partnerships in all phases of research
- Integrates and achieves balance between research and action for benefit of all partners
- Recognizes a community as unit of identity
- Builds on community strengths/resources
- Promotes co-learning and capacity building among all partners
- Involves a long-term process and commitment
- Emphasizes local relevance of public health problems and multiple determinants of health
- Disseminates findings and knowledge gained to all partners and involves all partners in that process

<sup>3</sup> 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

For research involving investigational products, when required by the sponsor, the institution commits to apply the International Conference on Harmonisation – Good Clinical Practice E6(R2) (ICH-GCP).

For research involving the collection of personal data about individuals located in (but not necessarily citizens of) European Union member states; Norway; Iceland; Liechtenstein, and Switzerland, the institution commits to apply the EU General Data Protection Regulations (GDPR).

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

### **Sponsored Human Research**

For both sponsored and non-sponsored Human Research, the HLC Schools abide by ethical principles, regulatory requirements and HRPP policies and procedures.

### **Scope of Human Research Protection Program**

The categories of research conducted at Harvard Faculty of Medicine and Harvard T.H. Chan School of Public Health include:

- Research involving human subjects
- Research involving pregnant women as subjects
- Research involving non-viable neonates
- Research involving neonates of uncertain viability
- Research involving fetuses
- Research involving in vitro fertilization
- 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
- 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
- International research
- Community-Based Participatory Research (CBPR)
- Research conducted or funded by the Department of Defense (DOD)
  - DoD research conducted in countries other than the US
  - Surveys performed on DoD personnel
- 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)



The categories of research not reviewed by HLC IRBs include:

- 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
- Classified research
- Exemption categories 7 and 8

## **Human Research Protection Program Policies and Procedures**

Policies and procedures for conducting Human Research at Harvard Faculty of Medicine and Harvard Chan School are available in the [ESTR Library](#) (HUID and PIN required) or by [request](#). Changes to policies and procedures may be communicated to the research community in the following ways including direct email to affected parties, posted to the ORARC and/or other HLC research-based websites, and/or QIP educational/training session.

## **Human Research Protection Program Components**

### **Institutional Officials**

The Harvard University *Chief Research Compliance Officer* is designated as the Institutional Official (IO) for Harvard Faculty of Medicine.

The *Associate Dean of Regulatory Affairs and Research Compliance* is designated as the IO for Harvard T.H. Chan School of Public Health, and also serves as the Responsible Organizational Official on file with the Association for the Accreditation of Human Research Protection Programs, Inc.

The IOs share responsibility for the approval of the HLC Schools' Human Research Protection Program plan.

Each IO has the authority to take the following actions or delegate these authorities to a designee for their respective Harvard LMA School(s):

- Sign federal assurances.
- Suspend or terminate IRB approval of research.
- Place limitations or conditions on an investigator's or research staff's privilege to submit and/or conduct Human Research.
- Establish a contingency plan for transferring oversight of one or more studies in an emergency/disaster scenario (e.g., natural disasters, man-made disasters, infectious disease pandemics, etc.).

The IOs share responsibility (unless otherwise noted) to:

- Approve policies and procedures governing Human Research.
- Determine, or designate to another staff to determine what institutions their respective HLC School(s) will rely upon for IRB review and approval.
- Approve the HLC HRPP budget (approved by the Harvard Chan School IO).
- Allocate resources among each unit within the Human Research Protection Program.

- Appoint and remove IRB members and IRB chairs for their respective HLC School(s).

### **Director, Office of Regulatory Affairs and Research Compliance**

The Director for the Office of Regulatory Affairs and Research Compliance (ORARC) has overall responsibility for the Harvard Longwood Campus (HLC) Human Research Protection Program (HRPP).

The ORARC Director is responsible to:

- Develop and implement policies and procedures governing Human Research at the HLC Schools.
- Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
- Hire and fire ORARC staff.
- 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 requirements.
- Establish policies and procedures for collaborating international sites to increase the likelihood that Human Research will be reviewed and conducted in accordance with relevant US and local ethical the legal requirements.
- Institute regular, effective, educational and training programs for all individuals involved with the HRPP, including collaborators at international sites.
- Ensure that the research review process is independent and free of coercion or undue influence, and ensure that Harvard Faculty of Medicine or Harvard Chan School officials cannot approve research that has not been approved by an IRB designated by the School.
- Oversee a process of receiving and responding to complaints and allegations associate with reviewing and conducting Human Research.
- Oversee the HLC Quality Improvement Program (QIP) to monitor compliance, identify problem areas, and to assist investigators in improving study site performance.
- Ensure that the Human Research Protection Program has sufficient resources, including the number of IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Fulfill educational requirements mandated by Harvard Faculty of Medicine or Harvard Chan School and the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP).
- Report unanticipated problem involving risks to participants or others, serious or continuing non-compliance, and/or a suspension or termination of IRB approval to institutional officials within 5 business days and to applicable external agencies, including OHRP, within 20 business days.

### **All Members of the Harvard Longwood Campus Schools**

All individuals within the research community 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 HLC IRB review and approval (or formal determination from the IRB that the proposed Human Research is exempt).
- Report allegations of undue influence regarding the oversight of the HRPP or concerns about the HRPP to the ORARC Director or Institutional Official.
- Report allegations or finding of non-compliance with the requirements of the HRPP to the IRB and/or Quality Improvement Program.

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

### **Institutional Review Board (IRB)**

The Harvard Faculty of Medicine IRB and Harvard Chan School IRB panels are each designated by their respective Dean of Faculty and serve as the IRBs for the HLC Schools. These two IRBs are collectively referred to as the Harvard Longwood Campus IRBs (HLC IRBs), which is supported and managed by the Office of Regulatory Affairs and Research Compliance.

Harvard Faculty of Medicine and Harvard Chan School may rely upon another institution for IRB review provided that the institution has a current, unexpired Federalwide Assurance on file with the DHHS OHRP and one of the following is met:

- The IRB is the IRB of an [AAHRPP accredited institution](#).
- 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 HLC School investigator is a collaborator on Human Research primarily conducted at another institution and the investigator's role does not include interaction or intervention with subjects.
- The HLC School is engaged in the Human Research solely because it is receiving federal funds. (The local HLC School investigator does 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](#) (unless requested through [Smart IRB](#)) and an active Institutional Profile, as well as a local review for compliance with local policies of the HLCs School(s). When Human Research carried out by agents of Harvard Faculty of Medicine or Harvard T.H. Chan School of Public Health, is reviewed by an IRB at another institution or organization, the HLC 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 HLC Schools 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 Institutional Official. Officials of this Institution may not approve Human Research that has not been approved by one of the Institution's IRBs.
- 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 HLC IRBs 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 a HLC IRB provides IRB review for other institutions, the HLC HRPP will follow established policies and procedures to ensure that the composition of the HLC IRB is appropriate to review the research and will comply with applicable laws and regulations of the relying site. This includes ensuring the HLC 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 HLC IRB separates business functions from ethical review.

The HLC 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 HLC 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 HLC 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.

IRB chairs, members and staff are responsible to follow applicable HRPP policies and procedures.

The HLC Schools may choose, on a case-by-case basis, to provide Human Research protection oversight for another institution, or to delegate responsibility for Human Research protection oversight to another institution. In each case, a formal relationship must be established between the School and the other institution through an Authorization Agreement. This relationship must be formalized before the School will accept any human research proposals from another institution, or delegate responsibility for IRB review to another institution.

In the conduct of cooperative research projects, HLC Schools acknowledge that each institution is responsible for safeguarding the rights and welfare of human subjects and complying with applicable federal regulations. When an Authorization Agreement exists, the HLC School may enter into a joint review arrangement, rely on the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. When doing so, HLC Schools will ensure that the review arrangement is approved, in writing, by the appropriate officials of the institutions involved, and the particular characteristics of its local research context are considered, either (i) through knowledge of its local research context by the HLC IRB or (ii) through subsequent review by appropriate designated institutions officials, such as the Chair and/or other IRB members.

When a HLC School is the coordinating center for a multi-center protocol, the HLC IRB will require the PI to ensure that IRB approval has been obtained at each participating site prior to institution of the research at that site. At the time of initial review, the HLC IRB will assess the procedures for dissemination of the protocol information (e.g., unanticipated problems involving risks to participants or others, modifications, interim findings) to all participating sites.

## Quality Improvement Program

The Quality Improvement Program (QIP) is one of the units within the Office of Regulatory Affairs and Research Compliance and a key component of the HLC HRPP. QIP provides quality assurance and quality improvement (QA/QI) support to the research community.

Quality Assurance (QA) activities involve routine review and for cause audit, investigator self-assessment, continuous and systematic monitoring and evaluation in an effort to ensure applicable standards are met, including HHS and FDA regulations, NIH guidelines, local laws and regulations, and institutional policy. Quality Improvement (QI) activities strive to improve the overall efficiency and effectiveness, and promote best practice beyond mere compliance.

QIP is independent of the HLC IRB, and its scope includes ensuring, assessing, and facilitating both investigator and IRB compliance; providing ongoing education and training; and offering human research support services to the research community.

To meet its compliance and education goals, QIP is responsible for and has the authority to:

- Perform not-for-cause reviews of any human research protocol approved by the HLC IRB.
- Perform for-cause audits at the request of the HLC IRB, ORARC Director, and/or Institutional Officials.
- Perform not-for-cause reviews and for-cause audits of HLC IRB records and offer recommendations to ensure compliance, as needed, and/or best practices.

- Provide investigators with quality improvement recommendations to ensure that research is conducted in accordance with best practice standards, such as good clinical practice guidelines.
- Recommend action to the IRB, based on observations obtained during for-cause audits.
- Provide training and education to the research community.
- Investigate allegations and findings of non-compliance.
- Report potential serious and/or continuing non-compliance to the ORARC Director.

QIP offers the following human research support services:

- Assist investigator with IRB submission preparation by offering review and edit of submission materials and technical support navigating the IRB review process.
- Provide investigator/study staff with study management tools and, when appropriate, training on how tailor such tools to support their protocol.
- Provide floating short-term regulatory support (equivalent to study coordinator/project manager type) for any HLC IRB-approved Human Research protocol.
- Provide routine monitoring (available onsite and/or remotely).
- Offer regular education and training opportunities to the research community, and as requested by investigators and their study 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.
- Comply with all determinations and additional requirements of the IRB, the IRB Chairs, ORARC Director, and the Institutional Officials.
- Develop and implement emergency/disaster response procedures for their research depending on location and nature of the research.

### **Department Chairs**

Department Chairs have the responsibility to:

- Review non-exempt Human Research Initial Review Applications and certify the following:
  - The Principal Investigator is qualified by education, training and experience to personally conduct and/or supervise the research described in the protocol.
  - The Principal Investigator has completed all applicable institutional credentialing processes to conduct this research.
  - The Principal Investigator has sufficient resources to carry out this research as proposed.
  - The protocol is scientifically valid and employs research procedures which are consistent with sound research design.
- Oversee the review and conduct of Human Research in their department.
- Forward complaints and allegations regarding the Human Research Protection Program to the ORARC Director and/or Institutional Official.
- Department Chair review is a requisite of IRB approval for non-exempt Human Research.

### **Committee on Microbiological Safety (COMS)**

COMS has the responsibility to:

- Review all research involving recombinant DNA as well as work involving biohazards. COMS registration is a requisite of IRB approval when the human research involves specific COMS regulated materials, namely, biological toxins subject to the National Select Agent Registry Program; bacteria, virus, fungi, yeast, parasites or prions.

### **Embryonic Stem Cell Research Oversight Committee (ESCRO)**

ESCRO Committee has the responsibility to:

- Review all research use of embryos, human embryonic stem cell (hESC) lines, and hESC derivatives.

### **Information Technology (IT)**

Harvard Medical School (HMS) IT; Harvard School of Dental Medicine (HSDM) IT; Harvard Chan School Department of IT; Harvard University IT have the responsibility to:

- Assist investigators and IRBs in identifying the appropriate data security level as necessary per research protocol.
- Assist investigators in implementing the appropriate data security level requirements.
- IT Certification is a requisite of IRB approval when the Human Research is classified by the IRB as involving Sensitive research data.

### **Office of the Vice Provost for Research**

The Office of the Vice Provost for Research has the responsibility to:

- Review of new research proposals that pose management challenges and/or reputational risk, see policy at <http://osp.finance.harvard.edu/provost-criteria> Provostial review is a requisite of IRB approval for non-exempt Human Research that meet criteria listed in the policy.

### **Office of Technology Development (OTD)**

OTD has the responsibility to:

- Negotiate intellectual property (IP) issues in Clinical Trial Agreements (CTAs) and Sponsored Research Agreements (SRAs), and approve Material Transfer Agreements (MTAs) with institutions that may receive Human Research samples collected at Harvard Medical School, Harvard School of Dental Medicine, and Harvard T.H. Chan School of Public Health.

### **Radiation Safety Committee (RSC)**

RSC has the responsibility to:

- Review research procedures that involve the use of “radiation sources” in Harvard owned or controlled facilities. Radiation sources include ionizing and non-ionizing radiation sources or devices, e.g., radioactive materials; lasers; x-rays. RSC approval is a requisite of IRB approval.

### **Sponsored Programs/Grants & Contracts Administration (Negotiating Offices)**

Harvard Medical School Office of Research Administration (ORA); Harvard Chan School Sponsored Program Administration (SPA) has the responsibility to:

- Review contracts, grants, and funding agreements, including data use agreements, for compliance with HRPP policies and procedures, as well as any applicable external laws or regulations.

## **Office of General Counsel (OGC)**

OGC has the responsibility to:

- Provide advice upon request from the ORARC leadership, IRB Chairs, Institutional Officials, and other individuals involved with the HRPP.
- Assist in determining whether someone is acting as an agent of Harvard Faculty of Medicine and/or Harvard Chan School.
- Assist in determining who meets the definition of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures.
- Assist in the resolution of conflicts among applicable laws.

## **Additional HRPP Components for Harvard University Faculty of Medicine Program in Medical Education (PME) within the Office of Education Scholarship at Harvard Medical School**

The Academy has the responsibility to:

- Provide scientific review and approval of research involving HMS MD students and/or faculty as participants (either via interaction or secondary data). PME approval is a requisite of IRB determination and/or approval.

## **Office of Academic and Research Integrity (ARI)**

ARI has the responsibility to:

- Implement policies adopted by the Harvard Faculty of Medicine as well as the policies and regulations promulgated by the federal government and its agencies in the areas of conflict of interest, research integrity, and scientific misconduct.
- Serve as a resource for research administration in the resolution and enforcement of research compliance issues; facilitates and coordinates training, education, and outreach initiatives.

## **Scholars in Medicine Office (SMO)**

SMO has the responsibility to:

- Work with ORARC to ensure all SMO-sponsored student Human Research projects are reviewed by the IRB.

## **Monitoring and Auditing**

Quality Improvement Program (QIP) is available to conduct not-for-cause audits and/or provide onsite and/or remote monitoring, as well as for-cause audits. Not-for-cause reviews may focus on compliance concerns previously identified through federal, state and/or institutional bodies.

## **Education and Training**

All new investigators and study staff and IRB members are to review this plan as part of their initial orientation. QIP offers frequent and regular educational sessions open to the entire research community throughout the academic year, and/or by request.



IRB members, IRB staff, and others involved in the review of Human Research must complete the Collaborative IRB Training Initiative (CITI) modules or acceptable equivalent every three years.

Investigators, research staff, and others involved in the conduct of Human Research must complete the CITI modules or acceptable equivalent every three years.

HRPP staff will coordinate with IOs in the development and implementation of training materials related to emergency preparedness and response plans specific to human research conducted at the HLC Schools. The HRPP emergency preparedness plan will be made available to the human research community through ORARC's [website](#). Each LMC-school is responsible for notifying research teams when the school's emergency response plan is activated.

The ORARC Director in conjunction with QIP will identify and implement additional educational and training, as needed.

### ***Emergency Preparedness***

The HLC Schools routinely assess potential emergency scenarios and threats to the institution to improve its emergency preparedness and response plan. The ORARC Director collaborates with institutional leadership to develop, implement, and assess, emergency preparedness procedures for the HLC HRPP.

Depending on the nature of the event, the ORARC Director will collaborate with institutional leadership to determine the types of research that might continue and the types of research that the school may need to temporarily postpone. The ORARC Director proactively identifies external IRBs on which HLC Schools can rely on temporarily during an emergency, first considering the Harvard University Area IRB.

The IRB staff will work with IT resources and/or electronic system vendors to ensure continuity of operations in the event that electronic systems are inaccessible or not operational for extended periods of time during an emergency/disaster. The ORARC Director will collaborate with the vendor of the ESTR to ensure that records are maintained on a secure server that is accessible in the event of an emergency.

The HLC Schools will 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.

## General Questions

For questions, requests for additional information from the HLC IRBs, and/or to provide feedback relating to the HLC HRPP, contact ORARC during normal business hours, Monday through Friday 8:30 am – 4:30 pm, as follows:

Mailing Address: Harvard T.H. Chan School of Public Health  
Office of Regulatory Affairs and Research Compliance  
90 Smith Street, Suite 335  
Boston MA 02120

Phone: 617-432-2157

Fax: 617-432-2165

IRB Email: [irb@hsph.harvard.edu](mailto:irb@hsph.harvard.edu) or [irb@hms.harvard.edu](mailto:irb@hms.harvard.edu)

QIP Email: [qip@hsph.harvard.edu](mailto:qip@hsph.harvard.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 or students are permitted to report concerns on an anonymous basis. Concerns may be reported to the Quality Improvement Program, IRB Chair, ORARC Director, Institutional Official, and/or the Office of General Counsel.

The Quality Improvement Program has the responsibility to investigate allegations of non-compliance when requested by the IRB, IRB Chair, or ORARC Director. The ORARC Director or IRB will evaluate and manage all allegations and findings of non-compliance.

Employees or students 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 ORARC Director or Institutional Official. To make such reports, their contact information is as follows:

### ORARC Director:

- Name: Leslie Howes, MPH
- Phone: 617-432-2153
- Email: [lhowes@hsph.harvard.edu](mailto:lhowes@hsph.harvard.edu)
- Mailing Address:

Harvard T.H. School of Public Health  
Office of Regulatory Affairs and Research Compliance  
90 Smith Street, Office 338  
Boston, MA 02120

### Harvard University Faculty of Medicine Institutional Official:

- Name: Ara Tahmassian, Ph.D.  
Harvard University Chief Research Compliance Officer
- Phone: 617-495-9797
- Email: ara\_tahmassian@harvard.edu
- Address: The Richard A. and Susan F. Smith  
Campus Center, Suite 839  
1350 Massachusetts Avenue  
Cambridge, MA 02138

**Harvard T.H. Chan School of Public Health Institutional Official:**

- Name: Delia Christiani, MD, JD, MSCI  
Associate Dean, Regulatory Affairs and Research Compliance
- Phone: 617 432-2148
- Email: dwchristiani@hsph.harvard.edu
- Address: Harvard T.H. Chan School of Public Health  
Office of Regulatory Affairs & Research Compliance  
90 Smith Street, Office 337  
Boston, MA 02120

**Disciplinary Actions**

The Institutional Official (IO) may place limitations or conditions on an investigator or research staff's privilege to conduct Human Research whenever in the opinion of the IO such actions are required to maintain the Human Research Protection Program.

**Approval and Revisions to this Plan**

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