Harvard Pilgrim Health Care Institute

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Harvard Pilgrim Health Care Institute

I. INTRODUCTION

The Department of Population Medicine (DPM) in the Harvard Pilgrim Health Care Institute is a research and teaching collaboration between Harvard Pilgrim Health Care and Harvard Medical School. Harvard Pilgrim Health Care Institute (HPHCI) is a limited liability corporation of Harvard Pilgrim Health Care, Inc. We are one of 15 Harvard Medical School affiliates. In 2021, Harvard Pilgrim Health Care (HPHC) combined with Tufts Health Plan (Tufts), creating Point32Health, Inc. The Institute is also part of Point32Health and now partners with both health plans.

The Investigator Handbook offers information related to the conduct of sponsored programs and research integrity and compliance, at HPHCI, which apply to faculty and staff of HPHCI, other Point32Health staff conducting research, and external investigators conducting research involving HPHC and Tufts members or data. For specific Policy & Procedures, visit https://www.hphcinstituteosp.org/. This Handbook covers important topics and provides links to information that investigators and staff must understand as they carry out a research project, including but not limited to:

- The missions of sponsored research, education, and service programs at HPHCI, the Office of Sponsored Programs (OSP), and the Office of Research Integrity and Compliance (ORIC);
- The roles and responsibilities of investigators in managing research;
- The structure and functions of the HPHCI OSP and key issues in administering a sponsored program, including financial management;
- Guidelines for establishing agreements with external individuals and organizations that participate in a HPHC sponsored program;
- Key policies that impact the conduct of research as well as the results of research, including intellectual property; and
- The structure and functions of the HPHCI ORIC and key issues in research oversight, including conflicts of interest, export controls, and quality assurance;
- Policies and procedures for the protection of human subjects involved research and of the HPHC Institutional Review Board (IRB).

A. Harvard Pilgrim Health Care Institute

1. Office of Sponsored Programs (OSP)

The OSP ensures that all funded and unfunded programs at HPHCI are carried out effectively, efficiently, and in accordance with all applicable government, sponsor, and institutional guidelines.

Working with HPHCI investigators in all aspects of pre- and post-award administration, OSP's mission is:

- To ensure the appropriate stewardship of sponsored research and teaching activities at HPHCI;
- To confirm that business practices in sponsored research, teaching, and service programs comply with the rules and guidelines of HPHC and all relevant sponsors and regulatory agencies;
- To provide the highest level of service to our internal and external customers;
- To protect the rights and privacy of human subjects involved in research conducted by HPHC/HPHCI investigators; and
- To support the values and goals of HPHCI and Point32Health

The OSP is responsible for the internal review and administration of all sponsored research, teaching, and service activities that are externally funded. In addition, some non-sponsored activities, particularly those that involve human subjects, require review and administration by OSP.

Occasionally, it is not clear whether specific activities should be managed by OSP. In such cases, the activity will receive an advance review by the Director of OSP (DOSP). If the DOSP and the Principal Investigator are unable to agree on the status of the activity, they will present their considerations through the HPHCI Vice President, Administration and Finance, and to the Point32Health Chief Medical Officer, who will make the final determination on the status of the activity.

Visit our website for additional information and resources: https://www.hphcinstituteosp.org/

2. Office of Research Integrity and Compliance (ORIC)

The ORIC oversees all human research projects and compliance issues at HPHCI and Point32Health (including HPHC and Tufts). The office protects the rights and welfare of research participants and provides administrative support to the HPHCI and Point32Health research community. ORIC oversees compliance matters pertaining to public health surveillance as well as research, including, but not limited to conflicts of interest, export controls, IRB operations, research integrity and the quality assurance/quality improvement program.

Our human research protection program is fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), Inc. An independent, non-profit accrediting body, AAHRPP uses a voluntary, peer-driven, educational model to ensure that human research protection programs meet rigorous standards for quality and protection. To earn accreditation, organizations must provide tangible evidence - through policies, procedures, and practices - of their commitment to scientifically and ethically sound research and to continuous improvement. As the "gold seal," AAHRPP accreditation offers assurances - to research participants, researchers, sponsors, government regulators, and the general public- that we are focused first and foremost on excellence.

3. Department of Population Medicine (DPM)

The Department was created in 1992 to focus on research and education as they relate to the care of large defined populations, including individuals who do not seek out care. As the nation's first medical school appointing department based in a health plan, we are strategically positioned to improve population health and health care delivery locally, nationally, and internationally. We're distinctive for our scope, expertise, and collaborations. DPM's mission and activities are highly consonant with the National Academy of Medicine's advocacy for a national Learning Health System – one that incorporates evidence-based practices into routine care, captures new knowledge as part of the ongoing delivery of care, and then applies new knowledge in a timely manner.

B. Investigators Outside of DPM

1. Investigators from Other Point32Health Departments

A variety of staff in other Point32Health departments may conduct externally funded research or teaching activities. Any proposal for an externally funded research or teaching program should be submitted to OSP for prior review. OSP will determine if the project needs to be managed in OSP.

II. RESEARCH ADMINISTRATION

A. Office of Sponsored Programs

The OSP consists of the Director, Assistant Director, Grant and Contract Managers and Associate Grants Administrator. OSP provides comprehensive services in the pre-award and post-award administration of grants, contracts and all other sponsored programs. In order to protect the interests of HPHCI and Point32Health, OSP plays a key role in ensuring compliance with applicable federal and state regulations and with sponsor requirements.

OSP provides services in the following areas:

1. Sponsored Programs Management

- Providing information, guidance, and training to the Harvard Pilgrim research community regarding sponsor guidelines, regulations, and expectations
- Coordinating financial audits of sponsored research activity, including the federal UG audit
- Overseeing and certifying corporate compliance with applicable federal and state regulations
- Developing policies and procedures for research-related issues such as conflicts of interest, scientific misconduct, or intellectual property rights
- Pre-award administration:
    - Providing guidance in the preparation of the administrative sections of a proposal
    - Managing internal review processes, for all proposed projects
    - Endorsing and submitting all applications for external funding
    - Negotiating terms and conditions of awards with sponsors
- Post-award administration:
    - Ensuring that appropriate confidentiality and data use agreements are in place with investigators, research collaborators, and other individuals participating in the research activity, as required
    - Issuing of sub-awards to collaborating organizations
    - Post-award financial administration, including establishing financial accounts, producing financial reports, effort tracking and certification, monitoring expenditures, re-budgeting, and interfacing with sponsors
    - Invoicing prime contractors and payment of subcontractors' invoices
    - Endorsement and timely submission of financial reports to sponsors
    - Supporting investigators in HIPAA compliance as needed

General information for grant/contract submissions, including contact and address information, applicable rates and federal/state identification numbers, can be found on the OSP website at: hphcinstituteosp.org/grants-management-resources.

B. Research Integrity and Compliance

The Office of Research Integrity & Compliance consists of the Director, Research Integrity & Compliance Officer, IRB staff, and Quality Assurance/Quality Improvement Specialists. The RIC team works with investigators and staff members involved in research to ensure compliance with federal and state regulations and institutional policies. The RIC team also provides quality assurance monitoring for OSP

to ensure the appropriate stewardship of sponsored activities. The ORIC oversees all human research projects and compliance issues at HPHCI and Point32Health. The office protects the rights and welfare of research participants and provides administrative support to the HPHCI and Point32Health research community.

The Research Integrity & Compliance (RIC) team provides services in the following areas:

1. Compliance Activities

    - Staffing for the IRB; regulatory oversight over the conduct of research at HPHCI; review of conflict of interest (COI) disclosures of researchers, IRB, and the organization and its key leaders; accreditation activities for AAHRPP accreditation; and export control reviews. The RIC team is also responsible for training and education and quality assurance/quality improvement activities.

2. Institutional Review Board Activities

    - The HPHC Institutional Review Board (IRB) is established in accordance with 45 CFR 46 and is one that performs ethical review of proposed research in order to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. The HPHC IRB assures that all human research activity conducted at HPHCI and Point32Health, or by DPM investigators, affords appropriate protection for the rights, privacy and welfare of research participants as well as for the use of any information or biospecimens related to their involvement in a study. The IRB reviews and approves, disapproves, or modifies all proposals concerning human research. The foundations for this review process are the Ethical Principals described in the Belmont Report (1979), including respect for persons, beneficence and justice, and their appropriate applications in informed consent, assessment of risks and benefits, and the selection of research subjects. Furthermore, federal rules and regulations, as well as other guidance documents, give direction to the review by the IRB Chair and IRB members in reaching decisions regarding the conduct of any human subject research. IRB staff assist Investigators with the preparation of study materials, enables ongoing communication with the IRB Chair and other IRB members, and provides appropriate documentation of the decisions of the IRB.
    - The HPHC IRB also serves as the Privacy Board and reviews all research for compliance with the HIPAA Privacy Rule.

III. SPONSORED RESEARCH AND TEACHING ACTIVITIES

A. Research and Sponsored Research

Federal regulations (CR §46.102) define research in the following way:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Research activities include all activities that would fall under the federal definition, including:

- Activities undertaken primarily to provide a new understanding of diseases, treatments, methods of delivering treatments, enhancing compliance with treatments, or the outcomes of treatments;
- Activities involving clinical care or other forms of direct contact with patients, providers, or other human subjects, except those conducted as part of routine management or operational activities;
- Review of medical records, insurance claims, or other types of existing data collected from or about patients, providers, or other human subjects.

Generally, research includes a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, usually through publication or public presentation of findings. Sponsored research is any research activity that receives funding from an external sponsor.

The following activities are NOT considered sponsored research programs:

- Routine management, operational, or corporate quality improvement initiatives not conducted to produce generalizable knowledge;
- Descriptions of the impact of such initiatives.

B. Sponsored Teaching Programs

Sponsored teaching programs include any teaching program for which funding from an external sponsor is received. Teaching activities carried out by HPHCI faculty or Point32Health staff members without external sponsorship are not covered by this Handbook but must comply with Institutional requirements.

C. Sponsored Service Programs

Some service programs conducted by operational staff at Point32Health receive support from external sponsors. Examples would include externally funded quality improvement initiatives, tests of innovative systems for patient care or disease management, or initiatives to reduce disparities in access to care or clinical outcomes. Sponsored service programs are subject to the same policies for pre-award review as other sponsored research or teaching programs, including human subjects review. Post-award management of sponsored service programs will usually be carried out by the sponsoring Point32Health (HPHC or Tufts) department, subject to all restrictions agreed upon in the pre-award review process.

D. Approval to Conduct Research, Teaching, or Service Programs

Research programs, with or without external sponsorship, and sponsored teaching and service programs may not begin until all approvals, including IRB determination, have been received by the Principal Investigator. Approval to conduct research, sponsored teaching, or sponsored service programs will normally be granted by OSP after all administrative and human subjects reviews have been completed successfully at HPHCI and all other institutions involved in the program.

Sponsored programs cannot be initiated until OSP has received a notice of award or issuance of a contract from the sponsor. When no external funds have been requested, or where an existing source of funds is to be used to support the proposed activities, the Principal Investigator may request approval

from OSP to initiate the program once the administrative and human studies reviews have been completed. In such cases, the project start- and end-dates will be agreed upon between the PI and OSP at the time that the approval is granted.

IV. PRINCIPAL INVESTIGATOR ROLES AND RESPONSIBILITIES

This section outlines the qualifications, roles, and responsibilities of a Principal Investigator (PI) leading a sponsored program at HPHCI. This section also provides information on administrative responsibilities and training requirements for investigators and summarizes key policies that affect the conduct of research.

HPHCI uses the definition of a Principal Investigator found in the National Institutes of Health (NIH) Grants Policy Statement of April 2024

The individual(s) designated by the applicant organization/recipient to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award. The applicant organization may designate multiple individuals as program directors/principal investigators (PD/PIs) who share the authority and responsibility for leading and directing the project, intellectually and logistically. When multiple PD/PIs are named, each is responsible and accountable to the official(s) at the applicant organization/recipient, or as appropriate, to a collaborating organization for the proper conduct of the project, program, or activity including the submission of all required reports. The presence of more than one PD/PI on an application or award diminishes neither the responsibility nor the accountability of any individual PD/PI. Who Can Serve as a Harvard Pilgrim Principal Investigator?

Every sponsored program at HPHC/I must have a local Principal Investigator who is an employee of HPHCI or a professional staff member of a Point32Health department or the Point32Health Foundation. An HPHCI PI must hold an HMS appointment at the rank of Instructor, or above. HPHCI staff with the role of Research Scientist may seek independent funding to lead projects or collaborate on external research projects for up to 10% of their effort; additional independent funding subject to approval of supervisor and Division Director. Exceptions to allow other investigators in addition to those listed to lead a sponsored program at HPHC/I may be made on a case-by-case basis by the DPM Chair, Director of Research, and the DOSP.

Covered activities include: (1) all sponsored or non-sponsored research programs conducted by investigators affiliated with HPHCI or Point32Health, involving contact with HPHC or Tufts members, providers, or staff, or using data derived from HPHC or Tufts information systems; (2) all sponsored teaching programs conducted by faculty affiliated with HPHCI; and (3) all sponsored service programs.

Investigators not affiliated with Point32Health or HPHCI must collaborate with a HPHCI investigator in order to work with HPHC or Tufts members, records or staff. The HPHCI collaborator will be listed as the internal PI on the HPHC Sponsored Program Application. The internal PI must have substantive involvement in the conduct of the sponsored program and be responsible for all duties of a PI within HPHCI.

A. Principal Investigator Responsibilities

The PI's responsibilities include, but are not limited to, the following:

- Being aware of and adhering to HPHCI's sponsored programs and other related policies, as referenced in this handbook and other referenced policy documents;
- Representing the study within HPHCI and serving as the principal programmatic contact for the study with external individuals and organizations;
- Obtaining all required internal and external approvals;
- Ensuring that a study is conducted as stated in the approved protocol and requesting approval from OSP and the IRB for any changes to the protocol in advance of their implementation;
- Assuring that all personnel involved in the sponsored program adhere to all relevant HPHCI policies, including those related to confidentiality, scientific integrity, conflict of interest, use of human subjects, and HIPAA privacy rule compliance;
- Assuring that all personnel involved in a sponsored program who have clinical contact with patients have appropriate licensure and malpractice insurance;
- Assuring that all data are used only for the purposes described in the approved protocol;
- Reporting any violations of HPHCI or Point32Health's confidentiality policy, HIPAA privacy policies, or any other applicable federal or state policies to OSP, the IRB, and/or to Point32Health Legal Department.

Principal Investigators must have expertise commensurate with the proposed sponsored activity. For research protocols, this determination is made the Director of Research. If necessary, a recommendation will be made through the DPM Chair to the Point32Health Chief Medical Officer, who has final authority to decide whether an individual can serve as a Principal Investigator. For teaching programs led by DPM faculty, this determination is made by the DPM Chair; for sponsored service programs led by HPHCI staff, the determination is made by the Director in the individual's department, the Point32Health Chief Medical Officer, or the President of the Point32Health Foundation, as appropriate.

B. Administrative Responsibilities of Principal Investigator

A Principal Investigator who wishes to lead a sponsored program at HPHCI has specific responsibilities with respect to proposal preparation and review and post-award program administration.

A PI's responsibilities include but are not limited to the following preparation and pre-award administrative activities:

- Identifying funding opportunities with government, foundation, or industrial sponsors consistent with HPHCI's mission;
- Informing the assigned Grants or Contract Manager in OSP of the plan to submit a proposal at least three weeks in advance of the sponsor's due date;
- Working with OSP on the Cayuse application process and proposal preparation guidelines from the sponsor;
- Submitting research-based disclosure (FCOI) for the proposal;
- Completing the study design and research plan consistent with HPHCI policies;
- Preparation of the administrative sections of the proposal and development of the proposed budget, in accordance with HPHCI and sponsor policies;

- Preparation of all additional application documents such as biographical sketches, other support pages, resources, documentation of education on the protection of human research participants, and consent forms;

Ensuring each application is final and ready for submission two business days prior to sponsor submission deadline. A PI's responsibilities include but are not limited to the following post-award administrative activities:

- Assigning a project manager who will assist the PI with the research and financial management of the sponsored project. This may include: review of monthly financial reports throughout the life cycle of the award, management of IRB submissions, and working with the PI to meet reporting and deliverable deadlines;
- Consulting in a timely way with the assigned OSP Grants or Contract Manager about sponsored program financial administration matters, including continuation applications for funding and submission of all financial reports to the sponsor;
- Stewardship of sponsored program funds in accordance with the approved budget and in accordance with HPHCI and sponsor policies;
- Communicating with the assigned OSP Grants or Contract Manager with respect to re-budgeting of award funds and obtaining prior written approval from the sponsor, as necessary;
- Adherence to guidelines regarding actions requiring prior written approval from the sponsor;
- Submission of timely and well-documented cost transfers;

C. Monthly submission/certification of accurate time and effort reporting. Required Training for Investigators

All HPHC/I employees, including the Institutional Official (IO), faculty, staff, fellows, contingent workers, students, and volunteers are required to complete specific training programs according to their assigned Learner Group. Learner Groups are outlined in the RIC Training Matrix. Training categories include but are not limited to onboarding orientation/s, grants management, IRB activities, and research compliance. Training may be provided on-line, in-person, annually, or span multiple years. Training requirements are subject to change to comply with federal, state, or institutional policies.

D. HPHCI Research Fellows

Fellows affiliated with HPHCI may participate in research or teaching projects and must complete all training required for investigators. Fellows must have their mentors or other appropriate faculty members act as the Principal Investigator for their projects. The named PIs will be responsible for the conduct and compliance of the research at HPHCI and must work with the Fellow to ensure successful completion of the project.

A Fellow, with the support of their mentor, may submit requests to the HPHCI Executive Committee to apply for K awards or for Individual NIH National Research Service Award (NRSA)Fellowships.

V. PRE-AWARD REVIEW AND POST AWARD ADMINISTRATION

A. Pre-award Proposal Review

HPHC/I requires full review of all proposals to conduct research, sponsored teaching, or sponsored service programs. Investigators wishing to conduct research, sponsored teaching, or sponsored service programs at HPHC/I should contact OSP to discuss potential proposals as early as possible in the development process.

The PI is responsible for completing the application through the Cayuse System. It is essential to initiate this process early to ensure all approvals are obtained prior to the submission deadline. Data or technical requirements for the proposal may necessitate review by Privacy and/or Security within the Cayuse System and will require additional time. Post-award Administration

All sponsored research is awarded to Harvard Pilgrim Health Care, Inc. and OSP has post-award administrative oversight for sponsored research and teaching programs, including all aspects of financial administration. Investigators are encouraged to consult with OSP, in advance, concerning sponsored program financial administration issues, continuation applications for funding, and the submission of all financial and technical reports to the sponsor. The post-award stewardship of federal funds is of great importance to HPHC as a grantee organization. If inappropriate financial transactions are identified during an audit, federal auditors may impose large financial penalties on the grantee organization. You must follow all Policy and Procedures, visit https://www.hphcinstituteosp.org/ for additional information, or consult your GM or CM.

VI. AGREEMENTS WITH OTHER ORGANIZATIONS

OSP recognized the need for HPHC/I PIs to enter into contractual arrangements with other organizations in order for HPHCI investigators to conduct sponsored research, teaching, and service activities. Examples of the types of activities may include consortium agreements, confidentiality agreements, or agreements with vendors, consultants or external organizations. Contact your OSP Grants or Contract Manager for information regarding contracts and agreements. OSP will work with Point32Health Legal to prepare the appropriate agreement for your activity.

VII. DATA USE GUIDELINES

A. Use of Data for Research

The use of individually identifiable data or Protected Health Information (PHI) for research purposes is subject to federal and state regulations and requires specific Institutional approvals. The following provisions apply to use of data for research:

- Regulatory requirements:
    - Only the minimum amount of amount of PHI reasonably necessary to conduct the research may be used in accordance with the HIPAA Privacy Rule and Point32Health's policy.
    - Data may be used only for the purposes stated in the protocol, approved by the Institutional Review Board (IRB) and described in any Data Agreement or Authorization. Secondary use of data (for another project) requires separate IRB and OSP approval.
    - IRB oversight is required as long as the Investigator remains engaged in human subjects research.
- Institutional Approvals:

    - Use of data containing PHI or individually identifiable information requires prior IRB and OSP approval. Data agreements may be necessary for use or disclosure.
- "Preparatory to research"
    - The HIPAA Privacy Rule permits a covered entity such as HPHC or Tufts to use data for preparatory to research purposes.
    - Prep to research data requests are submitted to the Research Support Data Center (RSDC) which will provide aggregated preliminary data to investigators. No individually identifiable data or PHI are disclosed. These requests do not require submission of a full study protocol or IRB approval. Refer to the Policy & Procedure *Prep-to-Research Reviews of PHI Prior to Conducting Research* for additional information.
- Data Sharing and Transmission:
    - Requires prior IRB and OSP approval. Data agreements may be necessary for use or disclosure.
    - HPHCI/Point32Health policy requires that all PHI, PI, and confidential information transmitted via a public network are encrypted. Use of software or systems for transferring data must have prior approval from Point32Health Security.

B. Data from Point32Health Information Systems

All research proposals requiring data from Point32Health information systems must have OSP and IRB approval. Investigators may only request data specifically stated in the approved study protocol.

- For access to data through the Research Services Data Center (RSDC), provision of the data will be the responsibility of the RSDC.
- Investigators and staff who require Point32Health data directly from a Point32Health department (not RSDC) must follow the data request instructions found on COMPASS. Contact your OSP GM or CM for more information.
- IRB approval for the specific research project is also required prior to data access.

C. Publication of Research Results

Research at HPHCI is to be conducted for the broadest possible audience, rather than for the benefit of individual sponsors. Therefore, it is expected that research reports will be shared with the public in an appropriate forum, subject to the appropriate internal HPHCI communications reviews.

Manuscripts submitted for publication must be reviewed by the DPM Chair and HPHCI Director of Communications at least seven working days prior to submission. For additional information, visit https://intranet.point32health.org/home/ls/community/harvard-pilgrim-health-care-institute-communications.

D. Publication of Research Results: Sponsor Rights and Responsibilities

A Sponsor does not have the right to approve either the content or timing of a HPHCI Investigator's dissemination of results from a sponsored program. However, sponsors may require that investigators allow prior review of reports for up to 30 days prior to submission for publication. Non-profit sponsors or consortia may require that collaborative research projects conform to the agreed-upon standards for

publication by the collaborating investigators. When the sponsor is a commercial organization, uses of collaborative data must be specifically approved by OSP.

Investigators may not provide analyzable datasets to a sponsor or other organization unless the analyses to be performed are clearly specified and there is a written agreement that no additional use will be made of the data without prior approval by OSP. In any event, all confidentiality provisions and HIPAA privacy rules must be maintained in accordance with applicable state and federal statutes and Point32Health and HPHCI policies.

Sponsors who receive unpublished reports or data may not publish or distribute them beyond their own organization without prior approval from OSP. Specific exceptions are considered on a case-by-case basis, for example, to support a claim for FDA action. Confidentiality provisions must be maintained in accordance with applicable state and federal statutes and Point32Health and HPHCI policies.

E. Disposal of PHI and Research Data

Research data must be disposed of in accordance with HPHC/I's policy and procedure Research Records Retention and Destruction. For additional information, visit https://www.hphcinstituteosp.org/osp-policies.

VIII. KEY RESEARCH POLICIES

This section provides guidance with respect to key policies that impact investigators in the conduct of research and sponsored programs. Policy areas covered in this section include:

A. Code of Conduct
B. Data Privacy and Security Agreements and Data Destruction Policy processes
C. Financial Conflicts of Interest of Researchers and Research Staff
D. HIPAA Privacy Rule for Research
E. Institutional Review Board (IRB) Policies
F. Post Approval Review Process
G. Intellectual Property Policy
H. Record Retention and Destruction
I. Research Misconduct

A. Code of Conduct

Point32Health's Code of Conduct is a compilation of the ethical and regulatory guidelines you are expected to follow in carrying out your professional duties. The Code is based on the ethical guidance provided by Point32Health's purpose, commitments, and values, and on the legal and regulatory expectations set by the external environment.

Point32Health's Code has been approved by the Board of Directors and applies to its Board of Directors, Officers, management, employees, and contingent workers (unless otherwise specified, hereinafter Point32Health employees and contingent workers are collectively referred to as "Colleagues"). Compliance with Point32Health's Code and all organizational policies and procedures is a condition of employment.

B. Data Privacy and Security Agreements and Data Destruction Policy Processes

Review and execution of all data agreements must be coordinated through OSP. . Once an agreement is fully executed, the PI/PM must complete a cover sheet for tracking purposes and the cover sheet and fully executed agreement are sent to the Manager of Administration.

C. Financial Conflicts of Interest of Researchers and Research Staff

HPHCI recognizes that a financial conflict of interest may arise due to the nature and scope of research activities. A financial conflict of interest may be actual, potential or perceived, and, if not properly identified and managed, could compromise the integrity of the research and reputation of HPHCI and its employees. HPHCI employees who are Harvard Medical School (HMS) Faculty must also comply with applicable HMS policies and requirements for reporting outside activities and conflicts of interest.

The purpose of the policy is to promote objectivity in research by establishing standards to ensure that the design, conduct, or reporting of research will not be biased by conflicting financial interests. The contents of the policy comply with the requirements established by the Public Health Service (PHS) and include processes to identify and manage any Financial Conflict(s) of Interest (FCOI); to manage and report any Significant Financial Interest(s) (SFIs)and FCOI; to provide training and compliance; and to publicly disclose FCOI related to PHS funded research.

For full details, please see HPHC/I's Financial Conflict of Interest in Research policy.

D. HIPAA Privacy Rule for Research

The HIPAA Privacy Rule describes the ways in which covered entities can use or disclose PHI (Protected Health Information), including for research purposes. Point32Health has implemented policies and procedures related to safeguarding of individuals' PHI and PI in accordance with federal and state laws and regulations. For more information, visit the Privacy section on Compass found here https://intranet.point32health.org/home/ls/content/6205461479030784/work/privacy.

E. Institutional Review Board (IRB) Policies

The Harvard Pilgrim Health Care's Institutional Review Board (IRB) is also called the Institutional Review Board. The IRB also serves as the Research Privacy Board for HPHC/Tufts under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

The IRB is an independent committee with the authority to review and approve research involving human subjects, which includes their individually identifiable health information. HPHC holds a Federal-Wide Assurance (FWA) with the United States Department of Health and Human Services (DHHS). HPHCI is listed as a component under HPHC's FWA. This FWA is the Institution's assurance of compliance with human subjects' regulations at 45 CFR 46 and the ethical principles of the Belmont Report. The HPHC FWA registration number is FWA00000100.

The IRB is responsible for ensuring that:

1. Risks to subjects are minimized.
2. Risks to subjects are reasonable in relation to anticipated benefits (if any).

3. Selection of subjects is equitable. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
4. Informed consent is obtained in accordance with the federal regulations
5. Informed consent is appropriately documented, in accordance with the federal regulations.
6. There are adequate provisions for monitoring data collected, when appropriate, to ensure the safety of subjects.
7. There are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data, when appropriate.
8. For purposes of conducting the limited IRB review required by 45 CFR 46.104(d)(7), (a) the IRB need not make the determinations at paragraphs (a)(1) through (a)(7) of this section, and shall make the following determinations: (i) broad consent shall not be used; and (ii) therefore, the requirement for broad consent documentation shall not apply; (iii) if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and (b) when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

All research proposals are submitted to the IRB in IRBNet. Research may not begin or funds (federal, foundation, private, corporate, internal or other) expended until the project has IRB approval or an exemption determination from the IRB. IRB Policies, forms and guidance documents are available in the IRBNet Library and at https://www.hphcinstituteosp.org/institutional-review-board.

F. Post Approval Review Process

The HPHC IRB and/or Research Integrity and Compliance (RIC) staff shall conduct post approval review (PAR) of currently approved research studies. RIC Quality Assurance/Quality Improvement (QA/QI) staff shall conduct a concurrent PAR of related IRBNet records concerning such studies. Both types of PARs shall be conducted to verify that ethical, technical and legal requirements are met and to improve the quality of research to ensure protection of human research subjects.

HPHC/I has established the Quality Assurance/Quality Improvement (QA/QI) component of the Research Integrity & Compliance Program to reflect its strong commitment to maintaining and improving the quality, integrity, efficiency and effectiveness of its HRPP intended to ensure the protections afforded to human research subjects.

For more information regarding Post Approval Reviews, visit: https://www.hphcinstituteosp.org/qa-qi-program.

G. Intellectual Property Policy

Intellectual Property is considered to be a valuable corporate asset of HPHC/I and Point32Health. HPHC Inc. owns all Intellectual Property conceived, created, made or discovered by Participants arising from or relating to their work with the Institute or with Point32Health, other than Academic Works.

The Harvard Pilgrim Health Care Institute Intellectual Property (IP) policy governs the ownership and disposition of intellectual property arising from or relating to research performed at the Institute. Please review the policy for additional information.

HPHC/HPHCI respects the valid legal rights of others to their ownership of intellectual property. Employees are prohibited from copying any copyrighted work, including copyrighted computer software, without the permission of the copyright owner or its authorized agent, as required by law.

H. Record Retention and Destruction

The purpose of this policy to set forth how long records created or used in the conduct of research, teaching or research administration activities in support of the charitable and educational mission of HPHC must be maintained and provide disposal guidelines for how such records should be destroyed.

See the records retention schedule in the OSP Records Retention and Destruction policy.

Complete copies of pertinent documents should be maintained in an orderly manner for the duration indicated in Table 1, in a location and manner appropriate to the nature of the material. Unless otherwise specified, retention does not require retaining both paper and electronic forms. If a document is signed, a paper or PDF of the signed version should be retained. If a document is an official document, such as a government license or certificate, the original should be maintained. If data are stored at an off-site repository, they must remain accessible and the repository must follow HPHC/HPHCI policies regarding data retention. As far as possible, off-site storage must be limited to data from closed studies. For research studies, data retention must be consistent with commitments made to subjects, IRB and the sponsor. All data must be retained such that it is accessible for investigations and government oversight.

I. Research Misconduct

The purpose of the policy is to describe the process to be followed at HPHC/I to report, respond to, and investigate any allegations of research misconduct. To report suspected research misconduct at HPHCI, contact the Director, Research Integrity & Compliance Officer.

The integrity of the research and teaching programs of HPHC/I requires that all HPHC/I personnel who are engaged in or support research activities follow the regulations set forth in 42 CFR 50 and 93 regarding responding to allegations of research misconduct and:

- give careful attention to any allegations of misconduct in research and carefully and equitably resolve any such allegations while providing maximum support to good faith whistleblowers; and
- be conscious of the following considerations:
    - the responsibility of HPHC/I to HPHC and Tufts members, HPHCI and Point32Health employees, affiliated institutions and to the community;
    - HPHCI responsibilities to the person making the allegations in good faith (Complainant) and the person who may be charged with research misconduct (Respondent);
    - obligations of HPHCI to research sponsors and to the Office of Research Integrity (ORI); and

- the importance of resolving allegations or suspicions of misconduct fairly, in a timely fashion, and with respect for all parties involved.

For more information see the complete Research Misconduct policy.