OFFICE OF SPONSORED PROGRAMS

Harvard Pilgrim Health Care | Harvard Pilgrim Health Care Institute

Harvard Pilgrim Health Care Institute Investigator Handbook

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I. INTRODUCTION

Harvard Pilgrim Health Care Institute LLC (HPHCI) was created to support the charitable and educational mission of Harvard Pilgrim Health Care, Inc. (HPHC) by conducting research and teaching to improve individual and population health through research and advance the health of populations through clinical care, delivery system and health policy leadership.

This Investigator's Handbook describes the policies and procedures related to the conduct of sponsored programs at Harvard Pilgrim Health Care Institute, LLC (HPHCI), which apply to faculty and staff of HPHCI, other Harvard Pilgrim Health Care, Inc. (HPHC) staff conducting sponsored s research, and external investigators conducting sponsored research involving HPHC members or data. This Handbook covers important topics and provides links to information that investigators and staff must understand as they carry out a sponsored program project, including but not limited to:

- The missions of sponsored research teaching and service programs at HPHC and the HPHCI Office of Sponsored Programs (OSP);
- The roles and responsibilities of investigators in managing sponsored projects;
- 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 conflicts of interest; and
- Policies and procedures for the protection of human subjects involved in sponsored programs 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 sponsored programs at HPHC are carried out effectively, efficiently, and in accordance with all applicable government, sponsor, and institutional guidelines.

The mission of the OSP is to ensure the appropriate stewardship of sponsored research and teaching activities at HPHC. Serving HPHC investigators and HPHCI faculty and student investigators in all aspects of pre- and post-award administration, OSP's mission is:

- To ensure 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 HPHC

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. If the Director and the Principal Investigator are unable to agree on the status of the activity, they will present their considerations through the HPHCI Executive Director to the HPHC Chief Medical Officer, who will make the final determination on the status of the activity.

Visit our website for additional information and resources: **hphcinstituteosp.org**

2. Department of Population Medicine (DPM)

Formerly the Department of Ambulatory Care & Prevention, this appointing Department of Harvard Medical School is housed at HPHCI. Created in 1992, it conducts research and teaching to improve health care delivery, enhance prevention, and evaluate and inform health care policy. All of DPM's research and teaching programs are administered by OSP.

Contact information for staff primarily responsible for grant and administration policies and procedures can be accessed through the **Administrative Specialist Handbook - Grants and Administrative Contact List**.

B. Investigators Outside of DPM

1. Investigators from Other HPHC Departments

A variety of staff in other HPHC departments 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 make a determination if the project needs to be managed in OSP.

2. Investigators from Outside Institutions

Under certain circumstances, investigators located at an institution outside HPHC/I may be allowed to conduct research at HPHC. However, an HPHC/I co-investigator is required to be included on the research team for such projects. Research by outside investigators will also be subject to the policies described in the Handbook, as appropriate

II. SPONSORED PROGRAMS ADMINISTRATION

A. Office of Sponsored Programs

The OSP works with investigators and staff members involved in sponsored research, teaching, and service programs to ensure the appropriate stewardship of sponsored activities. OSP provides comprehensive services in the pre-award and post-award administration of all sponsored programs. In order to protect the interests of HPHC, 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
- Preparing and negotiating Harvard Pilgrim's F&A (indirect cost) rate with the Department of Health and Human Services (DHHS)
- Coordinating financial audits of sponsored research activity, including the federal A-133 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

2. Pre-award administration

- Providing guidance in the preparation of the administrative sections of a proposal
- Managing internal review processes, including Human Studies review, for all proposed projects
- Endorsing and submitting all applications for external funding
- Negotiating terms and conditions of awards with sponsors

3. **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 Sponsored Program Applications, 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**.

4. Research Integrity & Compliance

- The Research Integrity & Compliance team is part of the OSP. It consists of the Research Integrity & Compliance Officer, IRB staff and a Quality Assurance/Quality Improvement Specialist.
- The Research Integrity & Compliance team provides staffing for the IRB, regulatory oversight over the conduct of research at HPHCI, review of conflict of interest disclosures of researchers, IRB, and the organization and its key leaders, accreditation activities for AAHRPP accreditation, export controls and foreign collaboration reviews.

B. Institutional Review Board IRB

The Institutional Review Board (IRB) at Harvard Pilgrim Health Care 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 Harvard Pilgrim 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. The IRB staff assists 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 covered by the policies in this Investigator's Handbook 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.

Research studies involving Harvard Pilgrim members <u>do not require HPHC cognizance or approval</u>, if ALL the following conditions are met:

- The study was approved by a federally accredited Institutional Review Board;
- The investigator does not represent the study as being approved or endorsed by Harvard Pilgrim Health Care;
- The investigator does not require data from Harvard Pilgrim information systems;
- The study will not induce clinical encounters, tests, or other forms of health care that would be delivered or paid for by Harvard Pilgrim;
- Data collection will not take place on Harvard Pilgrim premises;
- No Harvard Pilgrim employee serves as an investigator for the study, unless that employee is functioning in some capacity other than as a Harvard Pilgrim employee;
- The study will not be represented in publications or otherwise as emanating from Harvard Pilgrim.

An example of such research would be a clinical study involving Harvard Pilgrim members that does not use Harvard Pilgrim data nor induce additional health care utilization.

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 HPHC staff members without external sponsorship are not subject to the policies in this Handbook.

C. Sponsored Service Programs

Some service programs conducted by operational staff at Harvard Pilgrim 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 HPHC 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 the Principal Investigator has received a letter from OSP stating that the program is certified for conduct. 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 Harvard Pilgrim 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 HPHC. This section also provides information on administrative responsibilities and training requirements for investigators and summarizes key policies that affect the conduct of research.

HPHC uses the definition of a Principal Investigator found in the National Institutes of Health (NIH) Grants Policy Statement of December 2019.

An individual designated by the grantee to direct the project or activity supported by the grant. He or she is responsible and accountable to the grantee and NIH for the proper conduct of the project or activity.

A. Who Can Serve as a Harvard Pilgrim Principal Investigator?

Every sponsored program at Harvard Pilgrim must have a local Principal Investigator who is an employee of the Harvard Pilgrim Institute or a professional staff member of a Harvard Pilgrim department or the Harvard Pilgrim 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 his/her effort; additional independent funding subject to approval of supervisor and Group Director. Qualifications of HPHC professional staff to serve as PI are subject to review by the Director of Research and the Director of OSP. Exceptions to allow other investigators in additional to those listed to lead a sponsored program at Harvard Pilgrim may be made on a case by case basis by the DPM Chair, Director of Research, and Director of OSP.

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

Investigators not affiliated with HPHC or HPHCI must collaborate with an HPHC or HPHCI investigator in order to work with Harvard Pilgrim members, records or staff. The HPHC/HPHCI collaborator will be listed as the internal PI on the Harvard Pilgrim 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 Harvard Pilgrim.

B. Principal Investigator Responsibilities

The PI's responsibilities include:

- Being aware of and adhering to HPHC's sponsored programs and other related policies, as described in the Investigator's Handbook and other referenced policy documents;
- Representing the study within HPHC 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 for any changes to the protocol in advance of their implementation;
- Assuring that all personnel involved in the sponsored program adhere to all relevant Harvard Pilgrim 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, except as granted in advance by written approval from OSP;
- Reporting any breaches of Harvard Pilgrim's confidentiality policy, HIPAA privacy policies, or any other applicable federal or state policies to OSP and/or to Harvard Pilgrim's Privacy Officer.

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 HPHC Medical Director, 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 HPHC staff, the determination is made by the Director in the individual's department, the HPHC Medical Director, or the Executive Director of the HPHC Foundation, as appropriate.

C. Administrative Responsibilities of Principal Investigators

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

A PI is responsible for the following preparation and pre-award administrative activities:

- Identifying funding opportunities with government, foundation, or industrial sponsors consistent with HPHC's mission;
- Informing the assigned Grants 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 application process, including obtaining application materials and proposal preparation guidelines from the sponsor;
- Completing the study design and research plan consistent with HPHC policies;
- Preparation of the administrative sections of the proposal and development of the proposed budget, in accordance with HPHC 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;
- Completion of the HPHC Sponsored Programs Application (SPA): **hphcinstituteosp.org/spa-form**. Obtaining, in a timely manner, the necessary reviews and approvals for all matters related to compliance or conflict of interest.

Please see Sponsored Programs Administration, Pre-Award Administration in Section II of this Handbook for further information.

A PI is responsible for the following post-award administrative activities:

- Assigning a project manager who will review financial data as the sponsored program is implemented, manage initial and continuing reviews of the sponsored program with the Harvard Pilgrim IRB, and inform the PI in a timely way about requirements for deadlines and deliverables;

- Consulting in a timely way with the assigned OSP Grants 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 HPHC and sponsor policies;
- Consulting with the assigned OSP Grants Manager with respect to re-budgeting of award funds and obtaining prior written approval from the sponsor, as necessary;
- Cognizance of guidelines regarding actions requiring prior written approval from the sponsor;
- Timely and well-documented cost transfers;
- Timely and accurate time and effort reporting and certification.

Please also see **Sponsored Program Administration, Post-Award Administration, in Section II** of this Handbook for further information.

D. 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. OSP Learner Groups are outlined in the **OSP 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.

E. HPHCI Research Fellows

Fellows affiliated with HPHCI may participate in research or teaching projects and submit for Individual NRSA's. However, Fellows must have their mentors or other appropriate faculty members act as the internal Principal Investigator for their research projects; these individuals will be responsible for the conduct of the research at HPHC. Fellows have the same research responsibilities as other faculty investigators and they must complete all training required for investigators except time and effort reporting. A Fellow, with the support of their mentor, may submit requests to the HPHCI Executive Committee to apply for K awards.

F. Student Research Projects

Harvard Pilgrim Health Care supports student research projects and understands their value to an educational program. The following conditions are applied to student research activities:

- A student must obtain an HPHCI faculty mentor to serve as the HPHC Principal Investigator. A student may be listed on an application as the overall PI of the project or as co-investigator. If needed, the Director of Research will help to determine an appropriate mentor. The mentor will serve as the guarantor of the scientific value of the student project.
- The student research project must be demonstrated to have no financial burden to HPHC, or if resources are required, the proposal must indicate the source of these funds.
- The student must complete the HPHC CITI, HIPAA, and Research Misconduct training prior to commencing the project.

If these conditions are met, the student may submit a reduced Sponsored Programs Application (SPA) that includes the following elements: face page, executive summary, study protocol, instruments, and the relevant sections of the SPA describing contact with human subjects.

A student proposal will undergo a review process consisting of the following components:

- The faculty mentor will provide the scientific and statistical review.
- The IRB Coordinator will determine if the student project can qualify for a human studies exemption, typically if there is no patient contact or access to records with PHI. If the project is not exempt, the proposal will be submitted to the IRB for review. In its review, the IRB will consider time and cost issues facing student projects.
- The HPHC senior management will review student research proposals as part of the normal review process.

V. PRE-AWARD REVIEW AND POST AWARD ADMINISTRATION

A. Pre-award Proposal Review

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

The PI is responsible for obtaining a current copy of the Sponsored Programs Application (SPA) and for obtaining the approval HPHCI Executive Director before submitting the SPA to the appropriate OSP Grants Manager. The OSP Grants Manager will help PIs to identify key individuals who may need to be involved in proposal review. In order to ensure that approvals are in place prior to proposal submission date, the PI PIs should initiate discussions with key HPHC/HPHCI/Atrius administrators at the beginning of the pre-award process

The SPA may be downloaded from the OSP website at:
hphcinstituteosp.org/spa-form

The time required to review and approve a proposal to conduct research or sponsored teaching depends on the complexity of the proposal and the relationships to human subjects' protection. OSP first obtains input from HPHCI/HPHC management if the proposal involves patients or record systems of Harvard Vanguard Medical Associates (HVMA) and/or Atrius, the proposal will also be reviewed by the Atrius Health Department of Research and Clinical Program Evaluation's Medical Director. The Atrius Health Department of Research and Clinical Program Evaluation requires a minimum of five business days to review any submission prior to sign off. This material must be submitted to the OSP Grants Manager at least three weeks prior to a planned submission to an external sponsor. Request for Applications (RFA) or Request for Proposals (RFP) format instructions and/or sponsor guidelines should also be provided to OSP at this time.

The following table details the components of the review process for proposed sponsored research programs at Harvard Pilgrim as well as the areas of responsibility for obtaining necessary approvals.

Approval Component	Purpose	Responsibility for Approval
Consistency with HPHC mission & policies All proposals	Assesses relevance to HPHC mission, impact on HPHCI or HPHC, and relationship to existing or planned activities.	HPHCI and HPHC senior management
Scientific merit All research proposals	Determination that research can yield valid information and will not conflict with existing activities.	Initial screen by HPHCI Executive Director and Director of Research, and HPHC department director, if indicated. Independent peer review by recognized process, or by reviewer approved by the HPHCI Director of Research, OSP will manage process, as necessary
Impact on administrative departments If program involves an HPHC, HVMA or Atrius clinical or administrative department	Determines whether proposed activity can be accommodated by staff and facilities. Assures that sponsored program will provide resources to offset costs in these areas.	Manager with responsibility for affected departments. PI is responsible for obtaining sign-off.
Pharmacy review If research program involves pharmacy or drug administration	Assesses programmatic relevance and operational impact of studies involving drugs.	HPHC Director of Pharmacy or P&T Committee. PI is responsible for obtaining sign-off.
Data and computing needs If research program requires HPHC data or computing services HPHC/I member/employee data from an HPHC department	Determines need and budget for data and/or programming support	HPHCI Manager of Administrative Services. PI is responsible for obtaining sign-off. HPHC VET
Human Subjects Programs that involve access to human subjects or, medical records, or other protected data	Assesses protection of human subjects from risks and the PI's plan to protect confidentiality and privacy of all information about human subjects.	OSP and IRB staff provide preliminary review. IRB provides full review according to federal regulations. IRB staff will contact PI with concerns and/or modifications
OSP Review All proposals	Review all aspects of the proposal, and approve or negotiate terms and conditions of sponsored awards	OSP staff. OSP will contact PI with issues or concerns

B. Post-award Administration

All sponsored research is awarded to HPHC and OSP has post-award administrative oversight for all 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.

This section describes the following areas of post-award financial administration:

1. Direct Costs
2. Cost Sharing
3. F&A (Indirect) Costs
4. Changes Requiring Sponsor Approval
5. Cost Transfers
6. Advance Account Requests
7. Invoice Preparation and Monitoring of Contractual Agreements
8. Time and Effort Reporting and Certification
9. Project Close Out

1. Direct Costs

A sponsored program budget is composed of separate line items for direct and F&A (indirect) costs, which are identified in the proposal budget. When the activity is funded, these costs are formalized into a discrete sponsored program account by OSP. For an expense to be considered an allowable cost against a sponsored program activity, it must meet certain standards, as described below.

All direct costs for a sponsored program, including, but not limited to, personnel, administrative costs, data processing, statistical analysis, and other direct services must be allocated and allocable to an external funding source or some other identified source of funding. Policies with respect to budgets and expenditures are governed by federal, HPHC, and sponsor policies. Allowable cost principles for non-profit institutions such as HPHC are governed by ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl.

For an expense to be considered an allowable direct cost against a sponsored program activity, it must be:

- Reasonable for the conduct of the project
- Consistent with policies and procedures that apply to other non-grant funded activities of the institution
- Adequately documented in accordance with generally accepted accounting principles
- Allocable to the project
- Consistent with all other federal, HPHC, and sponsor policies

OSP will assist investigators in determining the reasonableness of direct cost budget items and expenditures. If costs charged to a sponsored program are later deemed to be not allowed or allocable to the sponsored program, that cost must be transferred to non-sponsored account.

2. Cost Sharing

Faculty applying for Ks or other awards that cap salary support at a level below the faculty member's actual salary should, at the time the application is submitted, work with their mentors to identify funding sources to cover the associated salary gaps. Potential sources can include non-federal research grants, and discretionary funds. Departmental funds might also be available on a case-by-case basis with the Chair's approval. Each application's SPA package should include the form *Section IV Cost Sharing* describing the plan to cover salary gaps over the life of the grant.

3. F&A (Indirect) Costs

It is the policy of Harvard Pilgrim Health Care to charge Facilities and Administrative costs (also known as F&A, indirect costs, or overhead) on all sponsored programs. The F&A rate is negotiated with the Department of Health and Human Services (DHHS), Division of Cost Allocation, New York Office. Information on current F&A rates is available on the HPHC website: **hphcinstituteosp.org/grants-management-resources**
HPHC has negotiated two F&A rates with DHHS. The on-site rate is applied to all sponsored programs for which the activities are to be conducted at HPHCI/HPHC. The off-site rate can be applied to some HPHC research programs for which the work is primarily based outside of HPHC. When it is uncertain which rate should be applied, the Director of OSP will make the final determination.

As of the 2008 rate agreement, F&A will be charged on the first $25,000 of each subcontract for awards which carry the full F&A rate.

All proposals for industry-sponsored programs must be budgeted using the full on-site F&A rate, except under the following condition. An industry contract may use a lower F&A rate if the budget also includes earmarked direct costs for items typically covered under F&A such that the total of earmarked direct costs plus F&A recovery at the lower rate is equivalent to the amount that would have been recovered if the full F&A rate had been used. Earmarked direct costs can include charges for items such as: space, utilities or personnel whose salary is entirely paid by an HPHC or HPHCI department. This arrangement must be approved in advance by the Director of OSP.

Some foundations, international organizations, and other non-profit sponsors have institutional policies that limit the F&A costs they will pay to less than the full HPHC F&A rate. If these institutional policies are written and clearly documented, proposals from these sponsors can be budgeted using these lower rates if approved in advance by the HPHC Director of Research or the Director of OSP.

When an F&A rate lower than the negotiated off-site rate is used, efforts should be made to include in the budget earmarked direct costs recoverable by OSP or that can offset some of the foregone F&A recovery. At a minimum, space costs should be budgeted based on the budgeted total FTE for personnel at a cost per FTE that will be determined each year by DPM administration or the HPHC Real Estate Office, as appropriate. Other direct costs earmarked in this way can include utilities, IRB services, OSP staff, or personnel whose salary is entirely paid by an HPHC or HPHCI department.

All grants under the HPHCI Faculty Grants Program will be budgeted using a 10% F&A rate.

4. Changes Requiring Sponsor Approval

Many sponsors require prior approval for re-budgeting, changes in scope, changes in PI, or other changes that materially affect the conduct of a sponsored program. All such changes should be discussed in advance with the assigned OSP Grants Manager who will determine whether the proposed changes require sponsor approval and who communicate with sponsors to obtain approval. All changes to human subjects research must also be approved by the IRB prior to initiating those changes.

5. Cost Transfers

A cost transfer is necessary to correct an error in the allocation of charges caused by clerical error, changes in grant numbers or funding cycles, or a variety of other reasons. There is a potential for an audit disallowance of cost transfers that are poorly documented and/or not completed in a timely manner. An internal or external auditor may disallow a cost transfer for the following reasons:

- The transfer is not supported by documentation that appropriately supports why the transfer is being made
- The Principal Investigator, designee, or other responsible individual of the grantee organization does not sign the request for cost transfer
- The cost transfer is not done in a timely manner after the original charge has been recorded

When requesting a cost transfer, all documentation must be submitted through OSP for review and approval. The documentation submitted to OSP must be signed by the PI or approved designee and include the reason for transfer and the account originally charged. In addition, to mirror the standard federal requirements, all transfers that are requested after 90 days must be supported by a strong written justification for the lateness of the transfer. Requests to transfer costs after 90 days will require the approval of the HPHC Controller.

6. Advance Account Requests

Harvard Pilgrim Health Care recognizes that on rare occasions it may be necessary to initiate sponsored program activities in advance of the receipt of the actual award document from the sponsor. In such cases, the PI assumes all risks and burdens in the event that the award is not forthcoming, or an impasse is reached in contractual negotiations precluding HPHC from agreeing to specific terms and conditions in the proposed agreement.

Situations where OSP may approve special pre-award spending include federal programs under PHS Expanded Authorities; letters or other documentation from the sponsor indicating the intent to fund the activity; and other sponsor documentation as may be offered in support of the request to initiate spending.

If the sponsor does not make an award, if the award is not accepted by HPHC, or if certain pre-expenditures are not unallowable, the PI is responsible to cover all advance and/or unallowable spending from a discretionary source of funds.

To open an advance account, PIs should contact the assigned OSP Grants Manager. A request form indicating the discretionary source of funds to be used to cover disallowed charges must be completed and signed by the Principal Investigator and department administrator and submitted to OSP for approval.

7. Invoice Preparation and Monitoring of Contractual Agreements

All contracts and subcontracts, and the subsequent invoices these generate, must be reviewed, approved, and tracked by the Office of Sponsored Programs. When HPHC is the subcontractor on a prime grant or contract, OSP is responsible for initiating invoices to the prime contractor, in accordance with the payment terms of the specific contract, and then tracking the receipt of invoice payments.

The payment terms of an award are either cost-reimbursable or milestone/deliverable. Payments for cost-reimbursable awards require that costs are incurred first at HPHC and OSP invoices the sponsor/prime contractor based on actual costs incurred. The payment schedule for milestone/deliverable awards is set at the time of contract negotiation. Invoices for set payments are sent based on HPHC having met the specific milestone/deliverable.

OSP is also responsible for initiating and renewing subcontract agreements with collaborating institutions. OSP initiates purchase orders for subcontracts in order to encumber the necessary funds. OSP monitors, pays, and tracks payments for invoices received from subcontractors, and monitors, bills, and tracks payments for projects in which HPHC is a subcontractor.

8. Time and Effort Reporting and Certification

As a recipient of federal funds, Harvard Pilgrim Health Care is required to provide regular, monthly, after-the-fact certification of all actual activity performed on sponsored programs (federal and non-federal). This is inclusive of research, teaching, clinical, and/or administrative activities. The report certifying this activity must be signed by the individual employee or a responsible supervisory official who has first-hand knowledge of the actual activities performed by the employee.

The certification must represent a reasonable estimate of the actual work performed by the individual during the period covered by the report. The report indicates the current salary splits (if the salary is charged to more than one project), adjustments if applicable, and the total percent of effort 100%).

These reports are generated from the Grants Management System (GMS) by OSP on a monthly basis and distributed to every employee whose salary is paid from a sponsored program. The forms should be reviewed and signed within 30 days of the receipt date and returned to OSP. If the report for an investigator or staff member is not returned, reminder emails will go out on days 31 and 45, after which the individual will be suspended from all research activities until the report is returned to OSP. Questions about time and effort reports should be directed to the assigned OSP Grant Manager.

9. Project Close-out

Closeout includes timely submission of all required reports; disposition of real property, equipment, and supplies; adjustments for amounts due the grantee; and adjustments for amounts due the sponsor. Most reports from grantees are due within ninety (90) days of the end of the grant. HPHC expects the PI's full cooperation in meeting this deadline.

Closeout of a grant does not affect the requirements for equipment accountability, record retention, or human studies (IRB) requirements. Funds may not be expensed from projects with closed human subjects (IRB) status.

C. Special Faculty Funds

In addition to the administration of sponsored programs funding, HPHC has fiscal oversight for certain discretionary funds, general purpose funds, and gift funds. These are administered as described below.

1. Discretionary Funds

At HPHC, discretionary funds are defined as funds remaining from an award that do not have to be returned to the sponsor at the formal close of the sponsored activity. These awards are usually for work completed under a fixed price or milestone/deliverable contract for industry or another sponsor. The PI may use remaining direct dollar funds for any allowable future expense, as defined below.

F&A (indirect) dollars remaining in a grant or contract at the point of conversion to a discretionary account will be captured by HPHC at the rate awarded on the original award. HPHC will remove the remaining indirect funds prior to moving approved funds to the PI's general-purpose account under a separate project

number. Thus, the discretionary project will contain only the direct dollars remaining, thereby providing the PI with an accurate accounting of available funds.

The OSP administers all discretionary funds at HPHCI. The following steps are needed to move funds to a discretionary project.

- The PI must submit the form "Request for Disposition of Left-Over Funds" to the assigned OSP Grants Manager requesting the unexpended project balance be transferred to a discretionary fund
- OSP must verify that the amount is appropriate and that all terms and conditions of the sponsor have been met
- The Director of OSP, Director of HPHCI Administration, and HPHC Controller must approve the request

2. General Purpose Funds

At HPHCI, general purpose funds are defined as miscellaneous faculty/PI and departmental income, which may include book royalties, honoraria for speaking engagements, teaching compensation, and other miscellaneous revenues. These funds are unrestricted and may be used for any allowable future expense, as defined below. The relevant Department at HPHC/HPHCI administers all general funds. No F&A will be charged to expenditures from General Purpose Accounts.

To deposit funds in general purpose accounts, checks must be made payable to Harvard Pilgrim Health Care Institute. Documentation from the payor is required to establish the source of the funds and any restrictions on their use.

3. Use of Discretionary and General-Purpose Funds

DPM has the responsibility for managing general purpose funds for HPHCI faculty. Other departments at HPHC that conduct research infrequently may petition OSP to act on their behalf. DPM or OSP will establish a cost center for the funds for the investigator's general-purpose accounts and specify any spending restrictions.

A single award will be established per investigator. General purpose funds from multiple sources will also be contained in one project under the award Discretionary funds from more than one grant or contract will be contained in one project under the GP award after all remaining F&A funds have been stripped from the fund. Monthly accounting reports will be provided to the PI, if requested.

Expenditures incurred on discretionary and general-purpose accounts may be made by the investigator for any research, educational, or service program consistent with any stated restrictions on the use of the funds, as applicable. Examples of allowable expenses include salaries, office and medical supplies, laboratory tests, pharmacy costs, patient recruitment costs, parking and travel costs, computers, software, business travel, and general research and educational expenses. Documentation for and compliance with personnel, travel reimbursement, purchasing, and other standard business procedures are required. These funds may not be used for salary supplements for investigators or other staff, except as consistent with standard HPHC/HPHCI Human Resources policies.

4. HPHCI Gift Funds

From time to time, a non-federal sponsor or an individual donor may elect to provide funds in the form of a gift in support of research and teaching programs to the HPHCI and/or to an individual investigator. These funds will be classified as gift accounts in support of research or education, either restricted or unrestricted. With a restricted gift, the donor stipulates that the funds must be spent for a specific purpose or during a specific time period. With an unrestricted gift, the donor does not stipulate the purposes for which the funds may be used or impose a time limit before which the funds must be spent. If the sponsor/donor requires specific deliverables the funds will be classified as a contract or grant and will be awarded to HPHC rather than as a gift.

Gifts may be accepted only after HPHCI management and the Director of OSP determine that there is no conflict of interest in the acceptance and use of the funds. The account will be closed when all funds have been expended or as specified in the gift documentation.

Restricted gift funds are administered by OSP unless otherwise required by the sponsor or donor. Checks/payments must be made payable to HPHCI. The sponsor or donor must send a letter stating: the intention to make a gift; the amount of funds to be gifted; whether there are restrictions or time limits on the use of the funds; any expected deliverables related to their use, and any requirements to document how the funds were used. Receipt or use of a gift cannot be contingent on a specific deliverable or the gift will be considered a contract or grant and administered as an HPHC sponsored program.

5. Use of Gift Funds

The investigator may expend funds from a gift account for any research or educational purpose consistent with any stated restrictions on the use of the funds. OSP will exercise discretionary control over expenditures. Examples of allowable charges on gift funds include salaries, office/medical supplies, laboratory tests, pharmacy costs, patient recruitment costs, parking or travel costs, computers, software, business travel, and general research and educational expenses. Documentation for and compliance with personnel, travel reimbursement, purchasing and other standard business procedures must be provided. Gift funds may not be used for salary supplements for investigators or other staff, except as consistent with standard HPHCI human resources policies.

6. Disposition of Special Faculty Funds on Departure

If a Principal Investigator leaves HPHCI/HPHC under ordinary circumstances, residual discretionary, general purpose, and gift funds will remain at HPHC for such purposes as may be deemed appropriate by HPHCI management and consistent with any stated restrictions on the funds.

VI. AGREEMENTS WITH OTHER ORGANIZATIONS

HPHC enters contractual arrangements with other organizations in order for HPHCI and HPHC investigators to conduct sponsored research, teaching, and service activities. These relationships are described below.

A. Consortium Agreements

In consortium grants, a subcontract is a written agreement between the two institutions, one that holds a grant directly from a sponsor (the "prime grantee"), and another that agrees to provide the prime institution with part of the programmatic work outlined in the prime grant (the "subcontractor").

1. Harvard Pilgrim Health Care as Prime Contractor

When HPHC is the prime grantee, it is the responsibility of the Principal Investigator to request that the other institution(s) prepare and submit a subcontract packet consisting of, at a minimum: a letter of intent, if applicable, cover page, detailed budget and budget justification, checklist, and proof of human subjects training for all individuals identified as key personnel in their proposal and FCOI approvals. Both the PI and an authorized financial officer from the other institution(s) must sign the letter of intent and the cover page. The entire, signed subcontract budget packet from the other institution(s) must be included in the overall budget that the investigator provides for review by OSP prior to the submission of the proposal to the funding agency. When the award is granted to HPHC, OSP issues a subcontract to the other institution(s) once all contractual issues are resolved.

2. Harvard Pilgrim Health Care as Subcontractor

At the time of proposal submission, OSP prepares a Statement of Intent to Establish a Consortium Agreement, which is signed by the Principal Investigator and the Director of OSP.

When HPHC serves as a subcontractor to another institution, the HPHC Principal Investigator should prepare a subcontract administrative packet consisting of: a letter of intent prepared by OSP, cover page, detailed budget and budget justification, biographical sketches, resources and environment page, checklist, FCOI attestation and/or any other specific information required by the prime grantee. When the source

of funding originates with the NIH, a face page must be included in the administrative packet. The entire subcontract administrative packet should be submitted to OSP for review and approval. After OSP reviews the cover page and letter of intent are returned to the PI for his/her signature. After the PI signs, the cover page and letter of intent should be returned to OSP, where an authorized HPHC official will sign-off. The fully executed cover sheet and other materials are then returned to the PI for transmittal to the collaborating investigator at the prime institution.

B. Industry-Sponsored Research

1. Principles Guiding Participation in Industry-funded Research

HPHC uses the following principles to guide its participation with industry-sponsored research.

- Value: There must also be clear value of the research to HPHC. At HPHC, research serves a public purpose, and is conducted for the broadest possible audience.
- Strategic Importance: Collaborative research with industry must be consistent with HPHC's goals and objectives. These include many research topics that are generally perceived to be in the public interest.
- Scientific merit: A study must be designed to allow the full range of relevant and likely results to be observed. A study's aims and methods must be clearly stated in advance. Protocols must have adequate statistical power to provide an informative answer to the questions being posed. Situations in which the design may be modified should be stated in advance. All protocols must pass independent peer review.
- Expectations about intellectual participation: A Principal Investigator is expected to take an active role in the development, implementation, and reporting of research. Participation by HPHC does not imply endorsement of a sponsor's product.
- Rights to present and publish results: HPHC investigators must retain the right to present and publish any findings. An industrial sponsor may not retain right of approval of the content or timing of publication or presentation, except to protect proprietary information.
- Sharing of data: HPHC investigators ordinarily do not provide analyzable datasets to a sponsor. When they do, the analyses to be performed must be clearly specified, with a written agreement that no additional use will be made of the data without OSP approval. Confidentiality and the HIPAA Privacy Rule also apply to these

datasets. Sponsors or other parties who receive unpublished reports or data may not publish or distribute them beyond their own organizations without specific approval from OSP. In multi-center studies and registries, investigators may require that institutional identities be kept confidential in any reports. Each investigator must agree in advance to central data collection processes. HPHC retains control over the uses of data developed in this way.

Intellectual property is considered to be a valuable corporate asset of HPHC. Intellectual property rights are derived primarily from laws granting patent, copyright and trademark protection. Harvard Pilgrim owns all intellectual property conceived, created, made or discovered by HPHCI and HPHC employees while employed on research funds awarded to Harvard Pilgrim. See the section on Intellectual Property below for further information.

2. Steps to Initiate Industry-Sponsored Projects

A Principal Investigator considering the initiation of a program funded by an industrial sponsor should alert the OSP at the earliest opportunity. All proposals for industry-sponsored programs must be accompanied by a detailed budget and must carry full F&A costs or their equivalent (as described above in the section on F&A Costs).

Because of the potential for conflicts of interest, proposed sponsored programs to be supported by industry come under special scrutiny by OSP, the IRB, and the HPHC corporate leadership. Industry-sponsored programs will be approved as long as mutual expectations and the language of the contractual agreement are consistent with the HPHC mission and with all corporate policies. In addition, review by legal counsel will likely be necessary.

C. Consultants

Harvard Pilgrim Health Care may use consultants on sponsored research, teaching, or service activities in order to accomplish the goals of the project. A consultant is an individual or a company hired to provide professional advice or services for a fee. Contact your OSP Grants Manager to review the need to hire an IC. HPHC must review and approve your choice of a consultant (Independent Contractor). As an independent contractor (IC), the consultant is not an employee, is not eligible for employee benefits, and does not have taxes withheld from fees paid. Therefore, HPHC/HPHCI employees cannot be consultants on HPHC grants. Private companies

hired as consultants are not required to the above review. Consulting agreement must be on file in OSP for all consultants on sponsored programs.

D. Confidentiality Agreements

To protect member confidentiality, vendors who perform work on behalf of HPHC that require the use or disclosure of PHI are required to execute confidentiality agreements. Examples in the context of research might include firms engaged to conduct mailings, to carry out research interviews, or to contact patients to try to enroll them in a research protocol. The type of agreement required depends on the nature of the vendor and the services to be performed on behalf of HPHC.

E. Agreements with Vendors and Other External Organizations

HPHCI may disclose PHI to a collaborator and may allow a business associate to create or receive PHI on its behalf. Each vendor needs to execute only one BAA with HPHC.

- A Non-Disclosure Confidentiality Agreement (NDCA) is required for any vendor or consultant who is not considered a business associate, but who performs a service and may have incidental exposure to PHI during the conduct of their service.

- A Data Use Agreement (DUA) is required when releasing HPHC Limited Data Sets or PHI to other covered entities.

- A signed Data Confidentiality Agreement (D-CA) is required from individuals or entities to which Harvard Pilgrim transmits ePHI prior to the transmission of ePHI. Electronic transmission methods include file transfers, internet, email, diskette and CD.

OSP Grants Manager will assist in identifying which agreements are required. If at any point during the course of a research project, an external vendor or consultant is to be engaged to carry out activities involving use, receipt or creation of any PHI, the Principal Investigator should notify the Grants Manager at OSP. An agreement must be executed before the vendor can be contracted to carry out the work.

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 **Harvard Pilgrim's Minimum Necessary 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 necessary for use or disclosure.
- "Preparatory to research"
    - The HIPAA Privacy Ryle permits a covered entity such as HPHC 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. Requests submitted to RSDC should contain a brief description of the data required and the reason.
    - Use of the DPM Query Tool may be used directly by Investigators to obtain aggregate counts for use preparatory to research. IRB approval is not required.

- Data Sharing and Transmission:
    - Requires prior IRB and OSP approval. Data agreements may necessary for use or disclosure.
    - HPHC 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 HPHC Information Technology (IT) documented in the SPA.
    - Proposals for data to be collected/transmitted/analyzed via an internet application or cloud service must have prior IT review and approval before submission to the IRB. IT approval is documented in the SPA. Contact OSP Grants Manager for further information.

B. Data from Harvard Pilgrim Information Systems

All research proposals requiring PHI from Harvard Pilgrim 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), including requests for Atrius full-text electronic medical records, provision of the data (or designation of an employee or department to provide the data) will be the responsibility of the RSDC.
- Investigators and staff who may have direct access to Harvard Pilgrim information systems may not access the system for research purposes without prior HPHC Virtual Extract Team (VET) review and approval. VET will approve access to data services by submitting an email notification of approval, and having the business sponsor sign SPA Section V. IRB approval for the specific research project is also required prior to data access.
- The IRB has the final authority to review the protocol and either accept or reject the access to data from Harvard Pilgrim information systems. Investigator submits an IRB application in IRBNet for the research for review.
- Optum Data: Access to Optum data is subject to prior approval for use by the DPM Manager of Administration. Contact DPM Manager of Administration for access requirements and business rules. Prior IRB approval is required.

C. Publication of Research Results

Research at Harvard Pilgrim Health Care Institute 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 HPHC corporate reviews. HPHC may allow sponsors up to a 30-day review prior to submitting a report for publication.

Research manuscripts do not require review by OSP. However, at least 7 days before submission for publication, an Institute Principal Investigator must submit the report for review to the DPM Chair and Director of Institute Administration, or for Harvard Pilgrim Investigators, to the corporate officer who supervises his or her department at Harvard Pilgrim.

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 Harvard Pilgrim 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 the Harvard Pilgrim OSP. In any event, all confidentiality provisions and HIPAA privacy rules must be maintained in accordance with applicable state and federal statutes and Harvard Pilgrim corporate policies, as described elsewhere in this Handbook.

Sponsors who receive unpublished reports or data may not publish or distribute them beyond their own organization without prior approval from the Harvard Pilgrim 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 Harvard Pilgrim corporate policy.

E. Storage of Research Data

- Electronic Information: Data containing PHI should be stored only on a secure, password-protected Harvard Pilgrim server behind a firewall. Restricted folders are created for any new project storing PHI. Access is limited to those individuals listed on the approved IRB application. Contact the Institute's IT Coordinator for assistance in creating a restricted folder for any new project.

  HPHC encrypts the hard drives on all personal computers, both desktops and laptops, as well as portable devices such as memory sticks.

- Paper based Information: Research data containing PHI must be stored in a secure location with appropriate access controls approved by the IRB. Research data requiring archive storage may be arranged with Harvard Pilgrim's confidential archive storage contractor at the investigator's expense. Please contact DPM Operations Coordinator for current contractor information.

- Additional related Harvard Pilgrim Health Care policies: Shredding Confidential Media, Computer Media Disposal, and Safeguarding Electronic PHI.

F. Disposal of PHI and Research Data

Research data must be disposed of in accordance with Harvard Pilgrim and the Institute's data destruction policies and procedures. **Records Retention and Destruction.**

IRB Policy requirements: Research records shall be maintained for a minimum of six years after study closure at Harvard Pilgrim.

- Research data containing PHI in paper form that are not needed for record retention purposes, must be destroyed, in accordance with Harvard Pilgrim Data Destruction policies, once study closure has been approved by the IRB and OSP termination of the project.

- Electronic data with PHI is maintained in a restricted access directory by the Institute's Privacy Manager with a scheduled destruction date consistent with Institute policies, unless otherwise specifically approved by the IRB. Principal Investigators are responsible for transferring data files to the Privacy Manager for storage in this directory within 30 days of closing the project in IRBNet.
- Paper based data containing PHI that are located on the premises of Harvard Pilgrim must be disposed of in confidential waste bins or shredded so that the

data are unrecoverable. Hard copy data containing PHI that are located off-site must be returned to Harvard Pilgrim for confidential disposal, or the investigator should show sufficient proof of confidential disposal capabilities such as possession of a shredder, hospital medical record disposal site, or contract with an approved HPHC vendor.

VIII. KEY RESEARCH POLICIES

This section provides guidance with respect to key policies that impact investigators in the conduct of 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 Conflict of Interest in Research
D. HIPAA Privacy Rule for Research
E. Intellectual Property
F. Institutional Review Board (IRB)
G. Post Approval Review
H. Record Retention Guidelines
I. Research Misconduct

A. Code of Conduct

Harvard Pilgrim Health Care Institute's (Institute's) Code of Conduct is a compilation of the ethical and legal guidelines which Institute employees are expected to use in carrying out their professional duties. In some instances, more specific Institute policies will apply.

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

Data agreements (Limited Data Sets, Research Confidentiality Agreements, etc.) are coordinated by the OSP Grants Manager and the Principal Investigator/Project Manager. Once the agreement is fully executed, the Grants Manager sends a copy to the privacy manager, and the required elements are entered into the HPHCI tracking database.

C. Financial Conflict of Interest in Research

The purpose of this 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 this 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.

The Institute recognizes that the potential for conflict of interest arises due to the nature and scope of research activities conducted at the Institute and that conflicts may occur in the normal conduct of activities. It is essential, however, that any significant conflicts of interest be appropriately reported, reviewed and managed.

This policy applies to Investigators and research personnel responsible for the design, conduct, or reporting of research. This includes, but is not limited to, Faculty, Fellows, Project Managers, and any other individual who has a substantive role in the research. Substantive roles include those in which individuals have decision making authority or provide advice to those who have decision making authority with respect to the design of the research; the conduct of the work or the reporting of results.

For full details, please see Harvard Pilgrim's **Financial Conflict of Interest in Research policy.** Key aspects of the policy are outlined below:

1. Definition of significant financial interest

A financial interest of the Investigator and/or Family that reasonably appears to be related to the Investigator's institutional responsibilities, that meets one or more of the following criteria established by the PHS:

i. Financial Income: Payments or anything of monetary value from a single entity that when aggregated for the Investigator and immediate family member(s) for the past 12 months or expected over the next 12 months exceeds $5,000. This includes salary and other payments (e.g. consulting fees, honoraria, paid authorship, etc.).

ii. Equity Interest: For a *publicly traded* business, an equity interest (e.g., stock, stock options, or other ownership interest) that when aggregated for Investigator and immediate family member(s) exceeds $5,000. For a *Non-publicly traded* business, *any* equity interest in such business, regardless of the amount, even if the value of the equity is unknown.

iii. Intellectual Property Interest: Any income (regardless of amount) related to intellectual property rights and interests (patents, copyrights, etc.).

iv. Travel: Any reimbursed or sponsored travel, related to institutional responsibilities, which was paid on Investigator's behalf, even if the exact value of the travel is unknown.

Exclusions:

i. Salary, royalties, or other remuneration paid to you by the Institute, including Intellectual property rights assigned to the Institute and agreements to share in royalties related to such rights.

ii. Equity and related income from investment vehicles such as mutual funds and retirement accounts over which the Investigator exercises no control.

iii. Income from seminars, lectures, or teaching engagements sponsored by government agencies, institutions of higher education and research institutes affiliated with them, academic medical centers, and teaching hospitals.

iv. Income from a private organization acting as a contractor to a state, local, or federal government agency.

v. Travel reimbursed by a government agency, an institution of higher education, an academic teaching hospital, medical center, or research institute affiliated with an institution of higher education.

2. Applicability

This policy applies to Investigators and research personnel responsible for the design, conduct, or reporting of research. This includes, but is not limited to, Faculty, Fellows, Project Managers, and any other individual who has a substantive role in the research. Substantive roles include those in which individuals have decision making authority or provide advice to those who have decision making authority with respect to the design of the research; the conduct of the work or the reporting of results. For certain research activities, this may apply to all study staff listed on an IRB research protocol.

The policy also applies to sub-recipients, subcontractors or collaborators of Harvard Pilgrim or the Institute involved in PHS research activities unless the home institution of the sub-recipient, sub-contractor, or collaborator has its own written policy on conflict of interest that is in accordance with 42 CFR 50, Subpart F.
Investigators who are involved with HPHC under formal subrecipient agreements do not need to complete HPHC COIDF. The Director of OSP shall take reasonable steps to ensure that Investigators working for subrecipients on HPHC prime awards have adequate COI policies and procedures in place.

3. Procedure

Researchers and research staff including any Investigator, or any other person regardless of title or role, responsible for the design, conduct or reporting of research are required to report their external commitments and financial interests annually and on an event-required basis for themselves and their immediate family member(s).

Event based reporting is required:

(1) when external commitments and financial interests materially change;

(2) prior to submission of new application for federal funding;

(3) when submitting an application for grant renewal or IRB approval;

(4) prior to expenditure of funds under federal award or initial IRB approval;

(5) upon appointment or employment;

(6) when newly assigned to a research personnel role;

(7) when initiating licensing activity; and

(8) when otherwise required.

Annual Disclosure Reporting:
Researchers and research staff are required to disclose external commitments and financial interests annually. HPHCI's Financial Disclosure form and instructions can be found in Click Commerce at: **esupport.hms.harvard.edu/COI**. Annual reports must be submitted even where researchers and research staff do not have any SFI to disclose. Researchers who have HMS faculty appointments through the Department of Population Medicine are also required to disclose financial interests to HMS in accordance with HMS policy. The Institute's Financial Disclosure form and instructions can be found in Click Commerce at: **esupport.hms.harvard.edu/COI.**

4. Identification and management of conflicts

Disclosures of Financial Interests will initially be reviewed by the Research Integrity and Compliance Officer in the Office of Sponsored Programs. Significant Financial Interests related to research activities will be referred to and reviewed by the Conflict of Interest Management Committee (COIMC) for a determination. If a Financial Conflict of Interest exists, the COIMC will take action to eliminate, reduce, or manage the conflict, as appropriate. Management Plans may include:

- Disclosure in publications and presentations;
- Monitoring of research by independent reviewers;
- Modification of the research plan;
- Disqualification from participation in all or a portion of the funded research;
- Divestiture of significant financial interests;
- Severance of relationships that create actual or potential conflicts; or
  Other actions the COIMC deems appropriate.

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. Harvard Pilgrim has implemented policies and procedures related to safeguarding of individuals' PHI and PI in accordance with federal and state laws and regulations. (**HPHC Privacy & Security Resource Center)**

In general, the Rule allows covered entities to use and disclose PHI for research:

- With written authorization from the subject;
- With a waiver of Authorization from Harvard Pilgrim's Institutional Review Board (IRB) acting as a Privacy Board, under certain circumstances. Application for a waiver or authorization is submitted for IRB review through IRBNet.
- In a limited data set with a Data Use Agreement. As limited data sets contain identifiable information, they are PHI.
- There are also separate provisions for how PHI can be used or disclosed for activities preparatory to research and for research on decedents' information. The complete text of the rule may be found at: **45 CFR §164.530(c)**.

Training: Institute workforce members, including DPM faculty, staff, students and consultants must complete HIPAA privacy Rule training appropriate to their roles and functions within the organization. Specifically, Harvard Pilgrim Level 1 and Level 2 on-line HIPAA training must be completed within thirty days of employment. Faculty, staff, students and consultants who will be involved in research projects must also complete Level 3 HIPAA research-specific training.

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 serves as the Research Privacy Board for HPHC 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. Harvard Pilgrim holds a Federal-Wide Assurance (FWA) with the United States Department of Health and Human Services (DHHS). 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 require are submitted to OSP and 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 **hphcinstituteosp.org/institutional-review-board**.

F. Post Approval Review Process

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.

Objectives include:

- overseeing, monitoring and improving the HRPP;
- evaluating regulatory compliance and legal conduct;
- identifying and preventing non-compliance and unethical or illegal conduct;
- formulating and utilizing internal controls to promote ethical, regulatory, and procedural compliance;

creating an environment that encourages personnel to report potential problems without fear of retaliation.

All research, including those determined to be exempt by the IRB, are subject to quality monitoring. However, greater emphasis will be given to studies that:

- present greater than minimal risk to subjects;
- involve vulnerable populations;
- are initiated by the investigator;
- involve or may involve a conflict of interest;
- have known compliance problems;
- or involve the testing of a drug or device for which the investigator holds an IND or IDE.

Policy and Procedures for Post Approval Review are located at:
hphcinstituteosp.org/qa-qi-program.

G. Intellectual Property Policy

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.

The policy establishes the rights and obligations of researchers relating to the reporting of inventions, release of inventions by Harvard Pilgrim to inventors, revenue sharing, copyright, and trademark and applies to all full time and part time faculty, staff and employees, students, pot-doctoral fellows and non-employees (visiting faculty, consultants, Business Associates, etc.) who use HPHC/I funds, facilities or resources, or participate in HPHC/I administered research.

The Bayh Dole Act (37 CFR 40.14) requires that institutions receiving federal research funding have an IP policy and obtain Research Agreements from its employees acknowledging ownership rights to Institution arising from research. Rights under this policy are subject to terms and conditions in grants and contracts.

Key Issues of IP Policy:

1. Academic Works are not subject to the IP Policy
   Academic works are not considered Intellectual Property under this policy and are defined as works of an academic or scholarly nature that are authored in the course of customary research, clinical and educational activities. This includes articles published in scientific journals, textbooks, course and curriculum materials and presentations. As such, you are permitted to assign copyright to publishers for your academic work. The policy does not include software, databases, and courseware.

2. Invention Reporting and Review
   Inventions are reported by using the HPHC/I Invention Disclosure form available on the **Forms page** of the OSP website and submitting it to the Director of Research Integrity in the OSP.

   Harvard Pilgrim's Intellectual Property Committee provides initial review of reported inventions for consideration of commercialization by HPHC and makes recommendations to Harvard Pilgrim's Chief Operating Officer. The timeframe for the final ownership determination, in most instances, will be within 20 business days of the IP Committee's receipt of an Intellectual Property disclosure form.

If HPHC determines not to pursue patent, license or copyright, it shall release the work back to the creator.

3. Obligations to Third Parties under Grants and Contracts
   In many cases, Intellectual Property created at the Institute or by Participants is subject to the terms and conditions of grants, contracts and other agreements entered into by Harvard Pilgrim or the Institute and third parties, such as federal agencies and/or other research sponsors. These agreements include sponsored research, clinical trial and material transfer agreements, license agreements, federal grants and contracts, etc. Any rights in IP are subject to any applicable conditions and rights granted to third parties under grants and agreements undertaken by Harvard Pilgrim and/or the Institute.

4. Research Participation Agreement
   Participants are required to execute a Research Participation Agreement at the time of employment, research appointment, or prior to commencement of work involving Harvard Pilgrim or Institute resources or participation in research administered by Harvard Pilgrim or the Institute. The Research Participation form is available on the **Forms page** of the OSP website and should be submitted to the Director of Research Integrity in OSP.

5. Other Agreements
   Participants are not authorized to sign and should not sign confidentiality agreements, material transfer agreements, research agreements or any other agreements that may restrict, commit or affect Harvard Pilgrim's rights in Intellectual Property. Contact your Grants Manager if you have questions about research related agreements or documents.

6. Royalty Sharing
   Generally, under Harvard Pilgrim's Royalty Sharing Formula, net royalties are calculated as gross receipts less HPHC out of pocket costs and fees from patenting and licensing expenses and distribution costs. For more specific information about the royalty distribution formula please see the **IP policy**.

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

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.

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I. Research Misconduct

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:
  o the responsibility of HPHC/I to HPHC members, HPHC/I employees, affiliated institutions and to the community;
  o HPHC/I responsibilities to the person making the allegations in good faith (Complainant) and the person who may be charged with research misconduct (Respondent);
  o obligations of HPHC/I 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 our complete **Research Misconduct policy**.