

Harvard Pilgrim Health Care, Inc.  
 Harvard Pilgrim Health Care Institute  
 Office of Sponsored Programs

Glossary of Terms and FAQs

Term	Definition
<b>AIS</b> Account Information Sheet	OSP Generated form that relays award information to the PI/PD, PM and other interested parties. Revised and distributed when an award is initiated and updated.
<b>AHRQ</b> Agency for Healthcare Research and Quality	Federal agency whose mission is to improve safety and quality of United States health care system.
Atrius formerly known as Harvard Vanguard Medical Associates (HVMA)	A medical institution with which HPHCI has a research relationship.
<b>AO or SO</b> Authorized Official or Signatory Official	Designated person authorized to sign financial documents for the institution on behalf of HPHC. The AO or SO is the Director, Office of Sponsored Programs.
Award	The provision of funds by the Sponsor, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.
Budget	The financial expenditure plan for the grant-supported project or activity, including revisions approved by the sponsor as well as permissible revisions made by the grantee. The budget is typically shown in detailed budget categories and prepared in a spreadsheet form (398 budget file).

<b>BA Business Associate</b>	<p>A “business associate” is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information (PHI) on behalf of, or provides services to, a covered entity. A member of the covered entity’s workforce is not a business associate. A covered health care provider, health plan, or health care clearinghouse can be a business associate of another covered entity. The types of functions or activities that may make a person or entity a business associate include payment or health care operations activities, as well as other functions or activities regulated by the Administrative Simplification Rules.</p> <p>Business associate functions and activities include: claims processing or administration; data analysis, processing or administration; utilization review; quality assurance; billing; benefit management; practice management; and repricing.</p> <p>Business associate services are: legal; actuarial; accounting; consulting; data aggregation; management; administrative; accreditation; and financial. See the definition of “business associate” at 45 CFR 160.103.</p> <p><a href="http://www.hhs.gov/ocr/privacy/index.html">http://www.hhs.gov/ocr/privacy/index.html</a></p>
Budget Justification	Detailed narrative description of all the lines of the budget.
<b>CDC Centers for Disease Control and Prevention</b>	Federal agency that is part of the United States Department of Health and Human Services (DHHS) and is considered the nation’s health protection agency.
Closeout	The process by which a grant is “closed” at the end of its budget period. This process includes the submission of a final financial report (or invoice); final invention statement (NIH); final scientific report and disposition of any left-over funds. IRB closeout is often many years later.
Collaborator	A professional, usually at another institution, who works with the prime grantee to develop and conduct a research project.

Committed Effort	Amount or percentage of time an individual has communicated to the sponsor that he/she will work on a specific sponsored project over a specified period of time. Commitments are made in the award proposal and may be documented by the sponsor in award documents. Changes to reduce committed effort may require sponsor approval.
Contract	An award instrument establishing a binding legal procurement relationship between a sponsor and a recipient obligating the latter to furnish a product or service defined in detail by sponsor and binding the sponsor to pay for it.
Consultant	An individual providing professional advice or services on the basis of a written agreement for a fee. These individuals are not normally employees of the organization receiving the services. Consultants also include firms providing professional advice or services. Consultants provide a specific expertise to the grant and is not involved in the actual conduct of the research.
Cost Principals	Rules set by sponsor (usually federal) for regulating expenses incurred on grants or contracts.
Cost Reimbursement	Mechanism for repayment of expenses on awards in which the grantee incurs a cost and invoices the sponsor at the end of a pre-specified period, such as monthly or quarterly.
Cost Sharing	Any project costs that are not borne by the sponsor. Cost sharing of effort is the provision of faculty and/or staff time and related fringe benefits that were committed and provided in support of a project but are paid for by other sources of funding. Cost-shared effort in excess of the commitment made in the proposal must be identified and certified.

<p><b>DUA Data Use Agreement</b></p>	<p>An agreement entered into by both the covered entity and the researcher, pursuant to which the covered entity may disclose a limited data set to the researcher for research, public health, or health care operations. See 45 CFR 164.514(e). A limited data set excludes specified direct identifiers of the individual or of relatives, employers, or household members of the individual. The data use agreement must:</p> <p>Establish the permitted uses and disclosures of the limited data set by the recipient, consistent with the purposes of the research, and which may not include any use or disclosure that would violate the Rule if done by the covered entity;</p> <p>Limit who can use or receive the data; and</p> <p>Require the recipient to agree to the following:</p> <p>Not to use or disclose the information other than as permitted by the data use agreement or as otherwise required by law;</p> <p>Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the data use agreement;</p> <p>Report to the covered entity any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware;</p> <p>Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient with respect to the limited data set; and</p> <p>Not to identify the information or contact the individual.</p>
<p><b>DPM Department of Population Medicine</b></p>	<p>A research department that resides within the Harvard Pilgrim Health Care Institute, and is an appointing department of Harvard Medical School.</p>

Effort Reporting	The mechanism used to provide assurance to federal or other external sponsors that salaries charged or cost shared to sponsored awards are reasonable in relation to the work performed. Effort reports are also referred to as “certifications” or “statements.” See “Time & Effort Certification”.
Faculty	Professional members of an academic institution.
<b>IBS</b> Faculty Institutional Base Salary	Annual compensation paid by HPHC/I for an employee’s appointment, whether that individual’s time is spent on research, teaching, or other activities. IBS does not include bonuses, one-time payments, or incentive pay. Additionally, IBS does not include payments from other organizations or income that individuals are permitted to earn outside of their HPHC/I responsibilities, such as consulting. IBS must be used as the base salary on all grant proposals.
<b>FDA</b> Food and Drug Administration	A federal agency under the of the Department of Health and Human Services that regulates foods, drugs and medical devices. .
<b>FCOI</b> Financial Conflict of Interest	A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.
<b>FFR</b> Financial Status Report	A high level or detailed explanation of the expenses incurred by the grantee during a specified period, usually annually.
Fringe Benefits	An amount established by an institution (usually approved by Federal government) and charged against an employees’ salary to cover various benefits, such as subsidized life or health insurance, paid holidays, a pension, etc., received by an employee in addition to regular pay.

<b>Grant</b>	Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used when the sponsor anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities. A grant is more likely to be used than a contract in instances where the PI needs and is allowed great flexibility in the conduct of the research in investigator-initiated research.
<b>GA Grant Accountant</b>	An OSP staff member who coordinates financial reporting and tracking activities for active grants and contracts.
<b>GM Grant Manager</b>	An OSP staff member who oversees the business and other non-programmatic pre- and post-award aspects of one or more grants and contracts.
<b>GMS Grants Management System</b>	The module within the official HPHC financial system of record (Oracle) that records expenditures and invoices of awarded grants, contracts and departmental (DPM) accounts.
<b>HPHC Harvard Pilgrim Health Care, Inc.</b>	A large health insurance company with diverse enrollees across New England and the parent company of the Institute.
<b>HPHCI Harvard Pilgrim Health Care Institute, LLC</b>	A collaboration between Harvard Pilgrim and Harvard Medical School to help answer important questions in the medical, health insurance, and public health worlds.
<b>HIPAA Health Insurance Portability and Accountability Act of 1996</b>	HIPAA establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” See 45 CFR 164.501. A covered entity may always use or disclose for research purposes health information which has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions below. <a href="http://www.hhs.gov/ocr/privacy/index.html">http://www.hhs.gov/ocr/privacy/index.html</a>
<b>HSC Human Studies Committee</b>	See Institutional Review Board..

<p><b>IDC</b> Indirect Costs /aka Facilities &amp; Administration (F&amp;A)</p>	<p>The IDC rate is awarded by the cognizant agency to cover costs that are incurred by a grantee for common or joint objectives that cannot be identified specifically with a particular project or program.</p> <p>HPHC 's rate is based on "Modified Direct Costs" (MTDC) and is charged on the first \$25,000 of each subcontract and all other costs, except equipment over \$5,000.</p> <p>How to calculate:  Yr 1: \$5,000 salary &amp; fringe; \$5,000 supplies, travel, etc. = \$10,000 x 64% = \$6400 = \$16,400 total Yr 1.  Yr 2: \$5,000 salary &amp; fringe; \$5,000 supplies, travel, etc., sub to BWH \$30,000 = \$40,000  10,000 x 64% = \$6400; \$25,000 (first \$25K of sub) x 64% = \$16,000 = \$ 22,400 IDC =\$62,400 total Yr 2.</p>
<p><b>IC</b> Informed Consent</p>	<p>A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the Investigator, the sponsor, the entity or agents thereof from liability for negligence.</p>
<p><b>IP</b> Intellectual Property</p>	<p>A work or invention that is the result of creativity, such as a manuscript or a design, to which one has rights and for which one may apply for a patent, copyright, trademark, etc. Title to such work usually rests with institution to which the grant was awarded. (See HPHCI Intellectual Property Policy).</p>
<p>Investigator</p>	<p>The principal investigator, key personnel, and any other person, regardless of their title or position, who is responsible for the design, conduct, or reporting of research.</p>
<p><b>IRB</b> Institutional Review Board</p>	<p>A committee that performs ethical review of proposed research in order to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.</p>

<b>IAA IRB Authorization Agreement</b>	An agreement that allows institutions engaged in research projects involving more than one institution to enter into joint reviewing arrangements or rely on the review of one of the institutions' IRBs.
<b>IRBNet</b>	Online site where all IRB documentation is kept including submissions, communications with the IRB, and IRB determinations.
<b>JIT Just In Time requests</b>	A request by sponsors to submit additional information usually signifying a significant score during the grant review process.
<b>LD Labor Distribution</b>	A "core" module within the Oracle Financials system that allows users to distribute the effort of employees to the appropriate projects.
<b>LOI Letter of Intent</b>	Official form or agreement by which the subcontracting institution commits itself to participate in a research project.
<b>LDS Limited Data Set</b>	Data set that includes dates or geographic information except street address that does not require authorization or waiver.
<b>MTDC Modified Total Direct Costs</b>	See Indirect Costs
<b>Milestone</b>	A pre-determined event or date during the life of a contract upon which payment is based.
<b>NIH National Institutes of Health</b>	The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the primary Federal agency for conducting and supporting medical research.
<b>NOA Notice of Award aka NGA Notice of Grant Award</b>	The legally binding document that notifies the grantee and others that an award has been made; contains or reference all terms and conditions of the award; documents the obligation of Federal funds; may be in letter format and may be issued electronically.
<b>OMB Office of Management &amp; Budget</b>	Executive Branch office assisting the U.S. president in preparing the Federal budget, evaluating agency programs and policies, and setting funding priorities. In setting policy, OMB issues Government-wide policy directives, called circulars that apply to grants. OMB also approves the forms used by our funding agencies.

<b>OSP Office of Sponsored Programs</b>	A department within Harvard Pilgrim Health Care Institute, LLC that oversees the appropriate stewardship of sponsored research, teaching, and service activities at Harvard Pilgrim Health Care, Inc. and serves faculty and student investigators in all aspects of pre and post-award administration.
<b>Preparatory (prep) to Research</b>	<p>Covered entity may allow access to a small (minimum necessary) amount of data only to prepare a research protocol or other limited purposes:</p> <ol style="list-style-type: none"> <li>1) Preparing a grant submission;</li> <li>2) Preparing a research protocol; and</li> <li>3) Aiding in research recruitment.</li> </ol> <p>Data cannot leave the covered entity.</p> <p>See 45 CFR 164.512(i)(1)(ii).</p>
<b>Prime</b>	The institution that is granted the award.
<b>PD Program or Project Director</b>	See definition for PI.
<b>PI Principal Investigator/Program or Project Director</b>	An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and the sponsor for the proper conduct of the project or activity.
<b>PM Project Manager</b>	A person within the project that manages time, staff, reports, and other duties to ensure the project stays on track.
<b>PHI Protected Health Information</b>	Under HIPAA, individually identifiable health information about the member that is transmitted or maintained by electronic media or in any other form or medium. PHI includes demographic information that is created or received by a health care provider, health plan, employer, or health care clearinghouse. PHI relates to the past, present, or future physical or mental health or condition of the member; the provision of health care to the member; or the past, present, or future payment for the provision of health care to the member; and identifies the member, or can reasonably be used as a basis to identify the member.

The 18 elements of PHI:

1. Names
2. Geographic subdivisions smaller than a state (e.g., street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code, if according to the currently available data from the Bureau of the Census, the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people. If such geographic units contain 20,000 people or less, then the initial three digits of the zip codes must be changed to 000 and thus treat them as a single geographic area
3. All elements of dates, except year, directly related to an individual including birth date, admission date, discharge date, date of death; and for all ages over 89, all elements of date (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4. Telephone numbers
5. Fax numbers
6. Electronic-mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web universal resource locators (URLs)
15. Internet protocol (IP) address numbers
16. Biometric identifiers including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code

<b>PHS</b> Public Health Service	Umbrella organization in the U.S. Federal Government consisting of eight <u>HHS</u> health Agencies, the Office of Public Health and Science, and the Commissioned Corps (a uniformed service of more than 6,000 health professionals). The NIH is the largest Agency within the PHS.
<b>RFP</b> Request for Proposal	Announcements that a sponsor would like to award a contract to meet a specific need.
<b>RSDC</b> Research Support Data Center	HPHC Research data service center. .
<b>SAE</b> Serious Adverse Events	Event/s that: <ul style="list-style-type: none"> <li>• Results in death</li> <li>• Is life threatening</li> <li>• Requires hospitalization</li> <li>• Results in persistent or significant disability/incapacity</li> <li>• Any other adverse event that may jeopardize the subjects health</li> </ul>

<p>Significant Financial Interest</p>	<p>Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include:</p> <ul style="list-style-type: none"> <li>(1) Salary, royalties, or other remuneration from the applicant institution;</li> <li>(2) Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;</li> <li>(3) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;</li> <li>(4) Income from service on advisory committees or review panels for public or nonprofit entities;</li> <li>(5) An equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: Does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity; or</li> <li>(6) Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.</li> </ul>
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<p><b>SPA HPHC Sponsored Programs Application</b></p>	<p>Required form which collects information regarding the project. Used for grants management and IRB reviews.</p> <p>The first 3 sections of the SPA is typically required 5 weeks prior to sponsor submission date along with the RFP, RFA, PA, and instructions.</p>
<p><b>SOW Statement of Work</b></p>	<p>Description of work to be conducted.</p>
<p><b>Subcontract/Subaward</b></p>	<p>Agreement with another institution to collaborate on the grant or contract. Spells out and/or passes through terms and conditions of the award.</p>
<p><b>Subcontractor</b></p>	<p>The institution collaborating on the grant or contract with the prime grantee.</p> <p>Generally, the following documents are required</p> <ul style="list-style-type: none"> <li>Letter of Intent</li> <li>Scope of Work</li> <li>Budget and Justification</li> <li>Biosketch of all key personnel</li> </ul>
<p><b>Subrecipient</b></p>	<p>See Subcontractor. Generally the term is only used for grant awards (not contracts).</p>
<p><b>Time &amp; Effort Certification</b></p>	<p>After-the-fact certification of actual activity performed on federally sponsored programs and each report must account for THE TOTAL ACTIVITY for which employees are compensated and which is required in fulfillment of their obligations to the organization.</p> <p>All effort must be charged appropriately, regardless of funding source. Faculty clinical effort is funded by clinical revenues generated by the clinical work (not by departmental funds). Faculty with regular clinical duties must charge the appropriate effort to their clinical account.</p>

<p><b>UP Unanticipated Problems</b></p>	<p>Any incident, experience, or outcome that meets all of the following criteria:</p> <p>(1) Events are not expected given (a) the nature of the research procedures and (b) the characteristics of the subject population being studied;</p> <p>(2) Related or possibly related to a subject’s participation in the research; and</p> <p>(3) Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.</p>
<p><b>Vendor</b></p>	<p>A person or company that performs a service only (no analysis or discretionary judgment) such as lab testing, reporting printing, etc. that are part of regular business operations and are available to many different purchasers or customers.</p>

URLS:

HIPAA: <http://www.hhs.gov/ocr/privacy/index.html>