University of Pittsburgh

FINANCIAL GUIDELINE

Subject: Fee-For-Service Activities in Academic Units

I. Guiding Principles

The University of Pittsburgh's mission is to "advance learning through the extension of the frontiers of knowledge and creative endeavor" and to "cooperate with industrial and government institutions to transfer knowledge in science, technology, and health care."¹ The University regularly performs client-initiated work under fee-for-service arrangements that help increase the impact of the University's three-fold mission of instruction, research, and public service. This work can be provided to external for-profit as well as not-for-profit clients and represent an extension of the University's "core competencies" for the benefit of the private and public sectors.

Client-initiated work at the University must adhere to the following principles

- **No subsidization**. Fee-for-service activities should neither displace nor be subsidized by the University's core research and teaching missions. All resources must be included in the analysis when determining the cost to the University of providing the fee-for-service activity.
- **Fair and reasonable pricing**. Fee-for-service clients cannot be charged a price lower than the price charged to Federal awards for comparable services performed.
- **No unfair competition**. Inappropriate outside use of facilities could give rise to legal risk arising from unfair pricing in relation to service providers in the business community. Fee-for-service clients cannot be charged a price lower than the prevailing market price for comparable services.
- **Prudent Risk Management**. Fee-for-service activities are to be executed within the same compliance context as that of similarly situated research or educational activities carried out by the University Member. Particular attention needs to be paid to conflict of interest, foreign engagements, export controls compliance, and that consent has been obtained by clients for client-supplied human subject data or biospecimens. Furthermore, fee-for-service activities should not place the tax-exempt status of the University or the status of any tax-exempt bonds at risk.
- **Stability**. Fee-for-service activities should be highly routinized with respect to the use of templated contracts ("build once, use many") by the unit providing the activity. An excessive administrative burden is placed on the University, and the Office of Sponsored Programs in particular, if each engagement requires contract negotiation.

¹ See http://ir.pitt.edu/factbook/fbweb02/general/MISSION.PDF.

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The Office of the Senior Vice Chancellor for Research is responsible for overseeing the implementation of this Guideline and its associated procedures.

II. Definitions

- *Human Anatomical Material* includes human cadavers, cadaveric tissue and decedent medical records falling within the responsibility of the Committee for Oversight of Research and Clinical Training Involving Decedents (CORID).
- *Human Biological Material* include, but are not limited to, tissue, organs, blood, plasma, serum, DNA, RNA, proteins, cells, urine and other body fluids. (Note: this definition does not include immortalized cell lines).
- **Scope of Work document** outlines a description of all services to be provided, any acceptance criteria, all key personnel, any client-supplied equipment or materials, the effective date of services to be performed, and the detail of any deadline/milestone requirements. Any requirement for the University to protect the client's confidential information should be disclosed.
- **University Member** refers to faculty, staff, students, fellows, trainees, and interns employed by the University.

III. Scope of Fee-for-Service Work

The Fee-for-Service contract is appropriate where the deliverable requested by the client is generated by University Members using practical applications of generally-accepted procedures, established theories, well-understood methods, or standard experiments, subject to the following limitations:

- **Creative Works**. Fee-for-service is not appropriate for investigator-initiated work. Neither is fee-for-service appropriate for cases where the deliverable requested by the client requires novel, original contributions on the part of University Members. Examples include the discovery and interpretation of facts, revision of accepted theories in light of new facts, development of new analytical and experimental protocols, or practical applications of such new theories, analysis, data gathering and experiments. The pathway to discovery and the creativity of new ideas is in the hands of a principal investigator and other University employees and usually starts as a proposal outlining a promising area of inquiry. Work of this type is classified as sponsored research.
- Human Anatomical Material. Fee-for-service is not appropriate for work involving human anatomical material held in the Pitt Biorepository or obtained by Pitt through the Humanity Gifts Registry. All such requests should be directed to the Office for Oversight of Anatomic Specimens at <u>http://ooas.pitt.edu/</u>.

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- Commercialization. Fee-for-service is not appropriate for cases where the client wants to commercialize Pitt technology, intellectual property (whether existing or created during the fee-for-service work), or copyrighted material. Requests to license or spin out Pitt technology should be directed to the Innovation Institute at https://www.innovation.pitt.edu/.
- **Public Sector Clients**. Fee-for-service is not the appropriate mechanism contracting with the Federal government or other public sector clients.

The scope of Fee-for-Service work, which may be revised based on discussions with University Members, is generally initiated by clients rather than the result of responses on the part of University investigators to widely-circulated requests for proposals. Four major categories of fee-for-service work are defined below. Proposed work falling outside these categories will be evaluated on a case-by-case basis.

A.) Services

University Members provide a service in response to a scope of work initiated and defined by the external client. Examples include, but are not limited to, the physical, chemical, molecular, or functional analysis of client-supplied samples (laboratory services); advanced product testing, which excludes clinical trials; printing (2D or 3D) or other fabrication of a client-supplied design; or specialized equipment repair. In all cases, University Members do not participate in the creation of the idea or concept on which the fee-for-service work is based.

- University Members seeking approval of agreements involving the incoming receipt of human biological materials should consult with the IRB Office for assistance in ensuring that the client sending the samples has the appropriate subject consents and originating-institution IRB approvals in place to cover the draft scope of work. The IRB Office consultations may be initiated via email (<u>askirb@pitt.edu</u>) or phone (412-383-1480).
- Any incoming Material Transfer Agreements (MTA), when required by the client, must be routed to the Office of Sponsored Programs (OSP) for review and signature. Once signed, they must be included as an attachment to the Fee-for-Service contract.
- Fee-for-service work that will rely upon Pitt-developed and Pitt-hosted software applications may require an End User License Agreement (EULA) as the contractual vehicle with the individual users of that application. A copy of the EULA should be included in the fee-for-service package for work requiring a user-facing software application.
- Fee-for-service work is not appropriate for engagements that require substantial collaboration between the client and University Members in the



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design and performance of creative new works or discoveries. These types of activities are sponsored research.

B.) Use of Equipment or Labs

University Members provide access to equipment, laboratory space or both to a client who will use those assets on a non-exclusive basis, subject to the supervision of a university employee where the University Member is not participating in the enhancement or advancement of the client's idea. Examples include, but are not limited to, charging clients an hourly rate to use analytical, experimental or fabrication equipment in a University lab or core facility.

- University Members are responsible for ensuring that their external users register with the <u>University's Visitor Liaison</u>, complete a <u>Lab Use</u>
 <u>Addendum</u>, and complete all applicable Employee Health and Safety (EH&S) training.² The Office of Risk Management, Insurance & Workers' Compensation requires external users who will be physically utilizing the University's facilities to formally acknowledge Pitt's non-liability in case of any accident while they are working on campus.
- Fee-for-service agreements proposing use of the animal care facilities under the control of the Division of Laboratory Animal Resources will not be approved.
- Fee-for-service agreements are not appropriate for renting or licensing use of Pitt real estate to spin out companies or other external parties, although a real estate license may contain an fee-for-service addendum defining agreed upon fee-for-service arrangements.

C.) Product

University Members provide a copy of information, documents, technology, deliverables, work product, or other materials produced through Pitt's prior research activity for the client's non-commercial, non-research use.

- Fee-for-service agreements must be consistent with any requirements or limitations imposed by the agency or organization that funded the original sponsored research activity at Pitt.
- Fee-for-service agreements are not appropriate for the provision of a first-ofa-kind or early prototype of a technology or other work product which still involves substantial creative design work that generates intellectual property on the part of University Members. These types of activities are sponsored research.
- Fee-for-service agreements are not appropriate for the transfer of tangible research materials such as research reagents, cell lines, chemical

² <u>http://www.ehs.pitt.edu/workplace/training.html</u>



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compounds, physical hardware or other material to the external client *when the recipient intends to use it for their own research purposes*. Outgoing MTAs should be used with academic, government, non-profit, or industry partners to ensure the University's rights and any legal obligations to third parties for the material are preserved, including rights in any progeny or derivatives of the transferred materials.

- Fee-for-service agreements are not appropriate for the outgoing transfer of live research animals or human biological materials, regardless of the recipient's use case. Those transfers must use an MTA and may require other documentation.
- Fee-for-service agreements are not appropriate for use with an industry partner seeking the right to commercialize (use, develop, market and sell) existing Pitt technology or copyrighted materials in the marketplace. The Innovation Institute will negotiate licensing agreements for Pitt-owned IP, including Pitt-owned software.

D.) Evaluation, Assessment, and Training

University Members provide evaluation, assessment, training or other organized, unit-based consulting services. Clients will receive a license to use any customized information products derived from Pitt's existing copyrighted materials for their internal use. Clients may also receive a license permitting broad, non-commercial dissemination of any such materials. All such materials should be clearly marked with a University of Pittsburgh copyright and the sponsorship of the client acknowledged.

- Fee-for-service agreements are not appropriate for an individual faculty member's independent consulting engagements, unless the revenue will accrue to the benefit of the University.
- University Members within the Health Sciences Division should consult with the Associate Vice Chancellor for Industry Relations and Continuing Education, Health Sciences to determine whether the proposed activities should be offered through the joint Pitt/UPMC Center for Continuing Education in the Health Sciences (<u>CCEHS</u>).
- Surgical training: For all surgical training activities that involve live vertebrate animals, a signed IACUC approval letter must be furnished to OSP prior to approval and commencement of work.
 - Fee-for-service surgical trainings may not involve non-human primates or companion animals.
 - All visitors who enter animal research facilities must abide by the Visitors to Animal Research Facilities Standard Operating Procedure (ES&H 05-025):



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https://www.ehs.pitt.edu/section-v-biosafety

IV. Governance

The Senior Vice Chancellor for Research may appoint, at his or her discretion, a committee to conduct this review these Guidelines. Any substantive changes to these Guidelines recommended by the committee must be presented to the Senior Vice Chancellor for Research for approval.

V. Contact Information/Public Accessibility

These Guidelines are posted on the following website: <u>http://www.cfo.pitt.edu</u>

University Members are encouraged to contact OSP for assistance with understanding their obligations related to compliance with this Guideline.

VI. Appendix – Related Authorities and Policies

- Outside Employment 02-06-01 (<u>http://www.cfo.pitt.edu/policies/policy/02/02-06-01.html</u>).
- Conflict of Interest for Designated Administrators and Staff 07-05-02 (<u>http://www.cfo.pitt.edu/policies/policy/07/07-05-02.html</u>).
- Conflict of Interest for University of Pittsburgh Employees 07-05-03 (<u>http://www.cfo.pitt.edu/policies/policy/07/07-05-03.html</u>).
- Responsibilities of Sponsored Research Investigators 11-01-02 (<u>http://www.cfo.pitt.edu/policies/policy/11/11-01-02.html</u>).
- Conflict of Interest Policy for Research 11-01-03 (<u>https://www.policy.pitt.edu/conflict-interest-policy-research-11-01-03</u>).
- Organization Conflict of Interest 11-01-08 (<u>http://cfo.pitt.edu/policies/documents/policy11-01-08web.pdf</u>).
- Academic Visitors: For Visitors (<u>https://visitor.pitt.edu/for-visitors/</u>).
- Industry Relationships Policy ("Policy on Conflicts of Interest and Interactions between Representatives of Certain Industries and Faculty, Staff and Students of the School of the Health Sciences and Personnel Employed by UPMC at all Domestic Locations") (<u>https://www.coi.pitt.edu/sites/default/files/documents/regulations-policies/Industry-Relationships-Policy-Pitt.pdf</u>).
- Guidelines on Sponsored Projects and Gifts University's Financial Guideline (<u>https://www.cfo.pitt.edu/policies/guideline/sponsored_projects_vs_gifts.pdf</u>).

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- University of Pittsburgh Faculty Handbook (<u>https://provost.pitt.edu/faculty-handbook</u>).
- University of Pittsburgh Staff Handbook (<u>http://www.hr.pitt.edu/handbook</u>).