

OSP News & Updates

Office of Sponsored Projects

9/19/2019

2019 Volume 3, Issue 6

The [OSP News & Updates](#), published by the Office of Sponsored Projects, is a bi-weekly subscription-based newsletter that provides OSP and sponsor updates and reminders, quick facts, guidance and training in all aspects of sponsored projects administration. [Subscribe to OSP News & Updates](#)ⁱ

Table of Contents

1. [Action Requested - Let us know what questions you have about PSCAs](#)
2. [At-Risk Account Request Form 1304 FR.01](#)
3. [OSP Training](#)
 - 3.1. [Brown Bag Meeting](#)
 - 3.2. [Upcoming OSP Classes](#)
4. [NOT-OD-19-128: Changes to NIH Requirements Regarding Proposed Human Fetal Tissue Research](#)
5. [OSP Staff Updates](#)
 - 5.1. [Award Management](#)

1 ACTION REQUESTED - LET US KNOW WHAT QUESTIONS YOU HAVE ABOUT PSCAs

We have received requests for a presentation on Professional Services and Consulting Agreements (PSCAs) and are in the process of preparing a presentation for the next Brown Bag. What PSCA questions you would like answered? Is there a specific area you would like to learn more about?

Please email any PSCA questions or topics to osp.trainings@yale.edu – and be as specific as possible.

2 AT-RISK ACCOUNT REQUEST FORM 1304 FR.01

The [At-Risk Request Form \(1304 FR.01\)](#) has been updated and is available on the [OSP Resources page](#). It includes two new fields that will capture information (cost center, award name) that allows account setup without further documentation (i.e. webform).

3 OSP TRAINING

3.1 BROWN BAG MEETING FOR RESEARCH ADMINISTRATORS

Join us for the October 9th Brown Bag session. [Visit the TMS Brown Bag webpage](#) to register and view the

OSP News & Updates

Office of Sponsored Projects

9/19/2019

2019 Volume 3, Issue 6

event details. Topics for next month's meeting are still in the planning phase and will be posted in TMS once confirmed.

3.2 UPCOMING OSP TRAINING CLASSES

OSP classes are designed for Research Administrators and those in DBOs (department business offices) who manage sponsored projects. Attend a class to learn more about the issues you deal with in your office or take a refresher to stay up-to-date. [Register to attend](#) an OSP training class.

Introduction to Sponsored Projects Administration: This course is designed to be an overview of the sponsored projects process from pre-award to post award and closeout and relevant for those who manage some part of the award process. Attendees include those new to research administration or those who would like a refresher or an overview of the entire life-cycle of an award. Topics covered include:

- Award basics and terminology
- Preparation, submission, negotiation and acceptance
- Award setup and managing an award
- Reporting obligations, award closeout and audits

Effort Reporting Principles: This module provides administrators with a comprehensive understanding of the principles of effort reporting and documenting activities as it relates to sponsored awards including:

- Key terms, policies, procedures and regulations
- Effort management activities from proposal through closeout
- Key roles and responsibilities
- Understanding the effort reporting lifecycle, with case studies, e.g., appointing faculty and staff, proposing effort, charging salaries...
- Key roles and responsibilities
- An overview of the effort certification process in Workday

Direct Charging of F&A Type Costs on Sponsored Awards: This module is designed expand participants' understanding of the direct charging of administrative costs to sponsored awards including:

- An awareness of Yale's research policies and procedures
- An understanding of acceptable exceptions
- How to appropriately document exceptions

OSP News & Updates

Office of Sponsored Projects

9/19/2019

2019 Volume 3, Issue 6

4 NOT-OD-19-128: CHANGES TO NIH REQUIREMENTS REGARDING PROPOSED HUMAN FETAL TISSUE RESEARCH

The following information was excerpted from the [NIH Notice NOT-OD-19-128](#) that was issued

“to inform the extramural research community of upcoming [HHS requirements](#) and review considerations regarding research that is supported by the NIH and involves the proposed use of human fetal tissue obtained from elective abortions (HFT) in extramural applications for grants, cooperative agreements and R&D contracts. These requirements are in addition to the existing requirements as detailed in the NIH Grants Policy Statement (4.1.14). In addition, NIH reminds the community of expectations to obtain informed consent from the donor for any NIH-funded research using HFT ([NOT-OD-16-033](#)).

Overview of Application and R&D Contract Proposal Instructions

For competing grant applications submitted for due dates on or after September 25, 2019 and R&D contract solicitations published on or after September 25, 2019, NIH will require applicants/contract offerors to address HFT requirements by providing a justification of the use of HFT, details regarding procurement and costs, and information about how the applicant/contract offeror will use HFT. These additional requirements must be met within existing applicable page limits.

Applications that do not address all the required information, including the detailed budget as instructed below, will be administratively withdrawn and not reviewed.

Application and Contract Proposal Research Plan Changes

In the Approach section of the Research Strategy, applicants/contract offerors must justify the need for use of HFT for the research proposed. The description must include a heading “Human Fetal Tissue Justification” and should be sufficiently detailed to permit meaningful evaluation by NIH. The applicants/contract offerors must:

- Indicate why the research goals cannot be accomplished using an alternative to HFT (including, but not limited to, induced pluripotent cells not developed from HFT, organoids not developed from HFT, neonatal human tissue, human tissue obtained from adults, human fetal tissue not derived from elective abortion, animal models, and *in vitro* models that are not developed from HFT, and computational models)
- Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments)

OSP News & Updates

Office of Sponsored Projects

9/19/2019

2019 Volume 3, Issue 6

- Conduct and describe results from a literature review used to provide justifications
- Describe plans for treatment of HFT and the disposal of HFT when research is complete
- Describe planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained. Include a sample of the IRB-approved informed consent form with the application or during the Just-in-Time (JIT) process. The informed consent for donation of HFT for use in research requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and to be signed by both the woman and the person who obtains the informed consent.

Application/Proposal Budget Changes

NIH will not accept modular budgets for applications for research involving HFT. This applies whether HFT costs are proposed on the grant application or whether HFT is donated at no cost to the project. NIH will require all applicants for research involving HFT to use the R&R Budget Form to provide the detailed budgets for the cost of acquisition of HFT, and sufficiently describe and document in the budget justification the quantity, type, and source of the HFT, as well as a certification that valuable consideration has not been provided for the acquisition of HFT. If researchers are using donated or existing HFT, the line item costs should be indicated as a value of \$0.00. In the case of complex grant applications that involved an overall budget and multiple project/core budgets, HFT should be included in both the overall budget form/justification and each project/core budget in which HFT use is occurring (even if there is no HFT cost).

For R&D contract proposals, the offeror must sufficiently describe and document in the budget justification section of the proposal, the quantity, type, and source of the HFT. The offer must provide a line item budget cost for acquisition of HFT or indicate the cost is \$0.00 if using donated or existing HFT.

NIH reminds the research community that the acquisition of HFT is subject to the prohibition in section 498B of the Public Health Service Act, 42 U.S.C. § 289g-2, that it is unlawful to knowingly acquire, receive, or otherwise transfer any HFT for “valuable consideration,” as that term is defined in that section; if the applicant is not proposing to use existing HFT, the applicant is expected to document how he/she will assure that the acquisition of such tissue complies with these legal requirements.

Peer Review and Technical Evaluation

Applications involving HFT will be evaluated using the review criteria presented in the Funding Opportunity Announcement as a significant aspect of the experimental design. For grants, evaluation of the scientific appropriateness/justification of the use of HFT will be allowed to affect individual criterion

OSP News & Updates

Office of Sponsored Projects

9/19/2019

2019 Volume 3, Issue 6

scores for the Approach criterion, and therefore assessments of overall merit and overall impact scores during initial peer review. For R&D contracts, this evaluation may affect scores for technical approach, and cost, as examples, and overall technical score during the technical evaluation of proposals. Comments about the appropriateness/justification of HFT will be included under the Approach review criterion for grants, and under Technical Approach for R&D contracts.

Applications and proposals involving HFT that fall within a fundable scoring range will be assessed for policy compliance by an [ethics advisory board](#) comprised of scientists, bio-ethicists and others as specified in section 492A of the Public Health Service Act. This committee will assess, among other things, compliance with the policy requirements described in this Notice, including additional consideration of the scientific justification for the use and quantity of HFT requirements proposed, as well as the consideration of alternative models. The committee will review and verify the core ethical principles and procedures used in the process for obtaining written voluntary informed consent for the donation of the tissue and recommend whether, in light of the ethical considerations, NIH should fund the research project.

Administrative Requirements and Terms and Conditions of Award

The following terms and conditions will be added to all grants and cooperative agreements awarded with HFT or that add HFT, on or after September 25, 2019. Additional terms may be added as needed and on a case by case basis.

The recipient institution including AOR and PD/PI(s) assures:

- The PD/PI is complying with all applicable laws and HHS/NIH policies specific to HFT.
- Funding for research involving HFT, or continued use of HFT, as defined above, will require justification for the ongoing scientific necessity for the use of HFT in the annual RPPR.
- Informed consents for use of HFT in research, containing certain statements/representations that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and the informed consent will be signed by both the woman and the person who obtains the informed consent.
- NIH award recipient has documentation from the HFT donating organization assuring adherence to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration. The NIH awardee will acquire this assurance for each year of the award HFT research is conducted for the life of the award and maintain this documentation in accordance with the NIH Record Retention and Access policy (NIH GPS 8.4.2),

OSP News & Updates

Office of Sponsored Projects

9/19/2019

2019 Volume 3, Issue 6

- HFT was not obtained or acquired for valuable consideration, as such term is defined in 42 USC § 289g-2.
- The treatment of HFT, and the disposal of HFT when research is complete, should be consistent with the plans outlined in the HFT application justification.

Specific Changes to Competing Application Instructions

This Notice implements the following changes to the application instructions. Page limits will not be increased to accommodate these requirements. For applications proposing research involving HFT, please follow the instructions below. These changes capture the required information noted above.

For multi-project applications, the information should be provided in the component where the research involving HFT is conducted.

- G.200 – SF 424 (R&R) Form
 - Added language under section “21. Cover Letter Attachment,” sub-section Content (item 9): Include a statement in the cover letter if the proposed studies involve HFT, regardless of whether or not Human Subjects are involved and/or there are costs associated with the HFT. For further information on HFT policy, refer to the NIH Guide Notice NOT-OD-19-128.
- G.300 – R&R Budget Form
 - Added language under “Who should use the R&R Budget Form?”: If HFT as defined in NOT-OD-19-128) are included in the proposed application, you must use the R&R Budget Form and cannot use the PHS Modular Budget Form. Whether or not you incur costs to obtain HFT, you will need to include a Budget Justification attachment (L).
 - Added language under section “F.1. Materials and Supplies”: If HFT costs (as defined in NOT-OD-19-128) are included in the proposed budget, they must **not** be included here but listed as a specific line item under *Section F.8-10 Other*.
 - HFT costs must be included only as a specific line item under Section F. 8-10 Other if these costs are included in the proposed budget. The line item must be labeled HFT. Do not include HFT costs in this F1 Materials and Supplies section. Regardless of whether you will incur a cost for HFT, you will still need to include a justification in “L Justification” if you are proposing to use HFT. For more information on the HFT definition, see NOT-OD-19-128.
 - Added language under section “F.8-10.” Other: If HFT (as defined in NOT-OD-19-128) are included in the proposed application, regardless of whether costs will be incurred, it must be noted as a line item here. The line item **must** be titled Human Fetal Tissue Costs. If no

OSP News & Updates

Office of Sponsored Projects

9/19/2019

2019 Volume 3, Issue 6

- cost will be incurred, enter “0” in the “Funds Requested” column. Details regarding HFT should be specified in the Budget Justification, pursuant to the instructions.
- Added language under section “L. Budget Justification”: If HFT is included in the proposed application, include a detailed justification including the quantity, type(s), and source(s) of the HFT, including the stage of fetal development. This information should be included if costs for the HFT are assigned to the grant or if HFT is acquired under the grant at no cost.
 - G.320 – PHS Modular Budget Form
 - Added language under “Who should use the PHS 398 Modular Budget Form?”: If HFT (as defined in NOT-OD-19-128) are included in the proposed application (regardless of whether you will incur a cost for HFT), you cannot use the PHS Modular Budget Form and must use the R&R Budget Form.
 - G.400 – PHS 398 Research Plan Form
 - Under the introductory part of ‘3. Research Strategy’ section: New section titled *Note for Applications Proposing the Use of Human Fetal Tissue*: If HFT use is proposed, you will include specific information in the Research Strategy attachment. This information should be provided regardless of whether Human Subjects research is proposed or not. HFT is defined per NOT-OD-19-128. See specific instructions below in Section 3. Approach.
 - Within ‘3. Research Strategy’ - subsection 3: Approach – added a new bullet point for this information:
 - Use the specific heading: Human Fetal Tissue Research Approach
 - Describe the proposed characteristics, procurement, and procedures for the research use of HFT. The description should be sufficiently detailed to permit meaningful evaluation by NIH.
 - Justify the use of HFT in the proposed research by indicating the following:
 - Why the research goals cannot be accomplished using an alternative to HFT?
 - What methods were used (e.g. literature review, preliminary data) to determine that alternatives could not be used?
 - Results from a literature review used to provide justifications
 - Plans for the treatment of HFT and the disposal of HFT when research is complete
 - Description of planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained. Include a sample of the IRB approved consent form with the application or during the JIT process. The informed consent for use of HFT from elective abortion requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not

OSP News & Updates

Office of Sponsored Projects

9/19/2019

2019 Volume 3, Issue 6

affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and to be signed by both the woman and the person who obtains the informed consent. Include an assurance letter

- Information must be submitted by the applicant Institution in a letter assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration. Name the PDF formatted letter 'HFTComplianceArssurance.pdf' and attach it in the Other Attachments section of the Research & Related Other Project Information form. Applications proposing HFT research that do not include this assurance will be administratively withdrawn and not reviewed.

For R&D contracts, please refer to specific solicitations published on or after September 25, 2019 for proposal instructions regarding the use of HFT.”

5 OSP STAFF UPDATES

5.1 AWARD MANAGEMENT

We are pleased to announce that **Lindsey Bosak** joined the Award Management group as Award Manager on September 9. Lindsey is new to Yale. Prior to coming to Yale, Lindsey worked in sponsored research at Arizona State University. We are so excited to have her join the team.

ⁱ Thank you to all who have contributed to this newsletter. Please direct questions or suggestions regarding newsletter content to Tracy Coston at osp.communications@yale.edu or tracy.coston@yale.edu. Use the following link to [unsubscribe to OSP News & Updates](#). For archived issues, visit [OSP News & Updates archives](#).