OGC Team Talks

Thursday, August 29, 2019

- Funding Opportunity Announcements
  - Ryan Holland – Director of PreAward and Contracting Services
- InfoEd Upgrade
  - Grant Garceau – Financial Services Business Analyst
  - Kavitha Jakkula – Reporting Analyst Team Lead
- NIH Human Fetal Tissue Research
  - Ryan Holland – Director of PreAward and Contracting Services

Funding Opportunity Announcements

Ryan Holland
Director- PreAward and Contracting Services
August 29, 2019

What is a Funding Opportunity Announcement

- Publicly available document that contains all the official information (e.g., goals, deadline, eligibility, reporting) about federal or nonfederal extramural funding
- Also referred to as a Request for Proposals, Program Announcement, Request for Application, Funding Opportunity, etc.
- Main point of reference for proposal development in the department and proposal review in OGC

Key Elements of an FOA

- Program Purpose, Goals, and Measurement
- Type of Award
- Sponsor's Participating Components
- Sponsor's Activity Code
- Award Information
- Eligibility Information
- Proposal Preparation Instructions
- Submission Instructions
- Registration Requirements
- Due Dates
- Sponsor Review Dates and Criteria
- Reporting Requirements
- Applicable Terms and Conditions
- Agency Contacts
- Other Applicable Information

Program Purpose, Goals, and Measurement

- Summary of the type of sponsored research the sponsor is seeking to fund
- Must align with the mission of the PI, Department and University of Colorado Denver|AMC
- Some sponsors will provide a summary for how their reviewers will consider the provided review criteria to determine the scientific and technical merit of the proposed project

Type of Award

- Discretionary Grant
  - » Sponsor selects the awardee based on merit and eligibility
- Cooperative Agreement
  - » Collaborative and technical assistance funding. Award recipient will work closely with skilled staff from the sponsor on the project
- Contract
  - » Sponsor is acquiring goods and services from the University of Colorado Denver|AMC

Participating Components of a Sponsor

- Some sponsors have different components or affiliates within their organization that participate in specific funding opportunities
  - NIH
  - NSF
  - AHA

Sponsor Activity Code

- Some sponsors utilize a specific character code to identify specific research programs within their organization
  - Fellowship
  - Career Development
  - Independent Research
  - Training
  - Multi Project
  - Construction
  - Other

Award Information

- Funding Mechanism (Contract, Grant & Cooperative Agreements)
- Application types allowed
  - New, Renewal, Resubmission, Supplement, etc
- Total number and amount of anticipated awards
- Award budget and project period
  - Allowable expenses
  - Total direct cost amount
  - Allowable indirect cost recovery

Eligibility Information

- Eligible organizations
- Eligible programs within an organization (ie. Nursing, Public Health, etc.)
- Eligible individuals
- Limited submission opportunities
  - Sponsor limits the number of applicants by organization or per organization program
  - Sign up for Academic Announcements listserv for opportunities and internal selection procedures
  - Contact ryan.Holland@cuanschutz.edu for opportunities yet to be announced to the institution

Proposal Preparation Instructions

- Identify all the sponsor and institution required materials for submission
  - » Each document or form required by the sponsor will have corresponding instructions
    - Required forms and requested information
    - Page limits
    - Attachment templates
    - Attachment filename and location requirements
    - Required Protocols

Submission Instructions

- Where to submit the application
- Who is required to submit the application
  - PI submission
  - AOR submission
- Required and optional steps of submission
  - Submitting by a specific date and time
  - Verifying sponsor receipt of the application
  - Verifying the contents of the submitted application

Registration Requirements

- Organizational Registrations
  - **Grants.gov**
  - **SAM**
    - **CAGE code is included with SAM registration**
  - **DUNS**

- Organizational & Individual Registrations
  - eRA Commons
  - FastLane/Research.gov
  - AHA
  - JDRF
  - NMSS
  - Proposal Central
  - eBRAP/DOD

Due Dates

- Specific date and time an application is due
- Standard due dates for sponsors that run repetitive review cycles
  - » Refer to the FOA to double check for accurate due date information
- Federal due dates that fall on weekends or Federal holidays typically move to the next Federal Business day

Sponsor Review Dates and Criteria

- Sponsor will list dates for their review and decision schedule

- Review Criteria
  - Scientific significance
  - PI and Co-Investigator qualifications
  - Innovation
  - Approach
  - Resources
  - Institutional Support
  - Applicable Protocol Approvals

Reporting Requirements

- Required interval for required reports (quarterly, semi-annual or annual)
  - Financial Reports
  - Progress Reports
  - Invention Reports
  - Other Reports

Applicable Terms and Conditions

- Required to agree to certain terms and conditions at proposal
  - » Exception letter process
- Sample terms and conditions in FOA
  - » Determine the degree of difficulty at the contract negotiation stage
- Refer to specific terms and conditions that apply to specific funding types

Agency Contacts

- Technical Support
  - Portal
  - E-Forms
  - Submission
- Scientific Review Officer (SRO)
  - Facilitates the scientific review process
  - Answer scientific questions at application stage
- Grants Management Specialist (GMS)
  - Oversees the business and other non-programmatic aspects awarded
  - Evaluates grant applications for administrative content and compliance with statutes, regulations, and guidelines;
  - Negotiates grants;
  - Provides consultation and technical assistance to grantees
  - Administers grants after award.
- Program Officer (PO)
  - Responsible for the programmatic, scientific, and/or technical aspects of a grant

Other Applicable Information

- Special announcements
- Specific attachment instructions
- If possible sign up for the update option on each FOA
  - Monitor FOA related notices
  - Sponsor will send notification any time a change is made to an applicable FOA
    - Examples of commons changes are due dates, project start dates, eligibility, forms, budget information, proposal preparation instructions, etc.

Questions?

NIH Requirements Regarding Proposed Human Fetal Tissue Research

NOT-OD-19-128

Release Date: July 26, 2019

Human Fetal Tissue (HFT) Research

- Research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions and includes the following:
  - Human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor
  - Animal models incorporating HFT from elective abortions, including obtaining such models from a vendor
  - Derivative products from elective abortion tissues or cells such as protein or nucleic acid extracts
  - Any human extra-embryonic cells and tissue, such as umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi, if obtained from the process of elective abortion

Note: This definition implements the statute (42 U.S.C. Chapter 6A, Subchapter III, Part H, Sec. 289) and is consistent with the NIH Grants Policy Statement (4.1.14).

Human Fetal Tissue Research

- The definition of research involving HFT does not include the following:
  - Human fetal primary or secondary cell cultures, if cells were not derived from an elective abortion
  - Already-established (as of June 5, 2019) human fetal cell lines (e.g. induced pluripotent stem cell lines from human fetal tissue, immortalized cell lines, differentiated cell lines)
  - Derivative products from human fetal tissue or cells (e.g. DNA, RNA, protein) if not derived from elective abortion
  - Human extra-embryonic cells and tissue, including, but not limited to, umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi if not derived from elective abortion
  - Human fetal cells present in maternal blood or other maternal sources
  - Embryonic stem cells or embryonic cell lines
  - Research on transplantation of HFT for therapeutic purposes (because of the statutory provision(s) addressing such research)

Applicability

- Applies to competitive applications for grants and cooperative agreements submitted for due dates on or after September 25, 2019 and R&D contract proposals submitted to solicitations issued after September 25, 2019
- Does not address any changes to Research Performance Progress Reports (RPPR) for currently active grant awards or annual progress reports for ongoing contract awards with respect to research including HFT
- The addition of research involving HFT to a funded NIH grant project is considered an indicator of a change in scope and, due to the additional information required, such changes will require the submission of a competing revision application. Competing revision applications must include all required information, as described below
- For R&D contracts, a modification request to include research involving HFT must undergo technical evaluation and must include all information regarding use and procurement of the tissues.
- Administrative supplements to add HFT research will not be allowed.
- Complex grant mechanisms that include centers/cores with discretionary funds will not be allowed to expand existing HFT funding or to add HFT funded activities, including pilot projects
- Training awards and individual fellowships may not propose research using HFT

Specific Changes to Competing Application Instructions

- Page limits will not be increased to accommodate revised requirements

- 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

- Section 21. Cover Letter Attachment, Sub-Section Content Item 9

- Include a statement in the cover letter if the proposed study involves HFT
  - » Required regardless of whether or not HS is involved

  - » Required if there are no cost associated with the HFT

G.300 - 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
  - HFT costs must be included as a specific line item under Section F. Other Direct Costs, lines 8-10, whether or not cost are incurred for HFT
    - The line item must be labeled “Human Fetal Tissue Costs”
    - If no cost will be incurred, enter “0” in the “Funds Requested” column
  - HFT justification must be included in the required budget justification attachment whether or not costs are incurred to obtain HFT
    - Include a detailed justification including the quantity, type(s), and source(s) of the HFT, including the stage of fetal development

G.320 - 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

- 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
- Specific instructions will be located within 'Research Strategy' – subsection 3: Approach
  - » 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

G.400 - PHS 398 Research Plan Form Cont.

- Justification Requirements
  - 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

G.400 - PHS 398 Research Plan Form Cont.

- Description of planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained
  - 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
  - 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
  - To be signed by both the woman and the person who obtains the informed consent. Include an assurance letter

G.400 - PHS 398 Research Plan Form Cont.

- Description of planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained
  - 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
  - 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
  - To be signed by both the woman and the person who obtains the informed consent. Include an assurance letter

G.400 - PHS 398 Research Plan Form Cont.

- Recipient organization must provide assurances in letter format specific to HFT
  - » Name the PDF formatted letter ‘HFTComplianceAssurance.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

'HFTComplianceAssurance.pdf'

- Countersigned by the Institutional AOR and Project PD/PI
- Must provide assurance for the following:
  - 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, 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)
  - 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.

Note: These assurances will be added to the terms and conditions for all grants and cooperative agreements

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
  - Scientific appropriateness/justification of the use of HFT will be allowed to affect individual criterion scores for the Approach criterion
  - Will affect overall merit and impact score during initial peer review
  - Applicants will receive comments about the appropriateness/justification of HFT
  - Alternative models will be evaluated
- 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
  - Committee will assess compliance with HFT policy requirements
  - Committee will review and verify core ethical principals and procedures for obtaining written voluntary informed consent
  - Committed will consider if NIH Should fund the project

Questions?