Faculty Guide - Research Pod 2 NIH JUST-IN-TIME (JIT)

This Faculty Guide is meant to assist researchers and PIs with a quick overview of the NIH process of responding to NIH Just-in-Time (JIT) requests at GW with Pod 2.

The NIH uses <u>Just-in-Time</u> procedures for certain programs and award mechanisms. These procedures allow certain elements of an application to be submitted later in the application process, after review when the application is under consideration for funding. Standard components include other support information (<u>OS Form</u>) for senior/key personnel; certification of IRB approval of the project's proposed use of human subjects; verification of IACUC approval of the project's proposed use of live vertebrate animals; and evidence of compliance with the education in the protection of human research participants requirement (<u>CITI Training</u>). Other program-specific information may also be requested using this procedure. Applications in response to request for applications (RFAs) also may be subject to these procedures. The RFA will specify the timing and nature of required submissions.

NOTIFICATION

NIH will notify applicants and GW (osr@gwu.edu) by e-mail when JIT information is needed. Please note that this request is not a notice of award. Information must be submitted electronically using the Just-in-Time feature in the eRA Commons. In some circumstances the grants management officer (GMO) may ask for additional information if the application involves human embryonic stem cells (hesc) and the PI did not identify a hesc from the NIH Registry in the application.

REQUIREMENTS

Applicants are required to verify the accuracy and validity of all administrative, fiscal, and programmatic information submitted through the JIT process. Applicants are responsible for notifying NIH of any substantive changes to previously submitted JIT information up to the time of award such as OS changes that could lead to budgetary overlap, scientific overlap, or commitment of effort greater than 12 person-months for the PD/PIs or any Senior/Key Personnel. Or any changes in the use or approval of vertebrate animals or human subjects. Failure to address changes to JIT submissions prior to award does not diminish the applicant's responsibility to address changes post-award by submitting a JIT request to NIH in accord with Administrative Requirements-Changes in Project and Budget-NIH Standard Terms of Award.

GENERALLY REQUESTED DOCUMENTS

Other Support (OS): Information on other active and pending support will be requested as part of the JIT procedures. OS includes all resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. When a recipient organization discovers that a PI or other Senior/Key personnel person on an active NIH grant failed to disclose OS information outside of JIT or the RPPR, as applicable, the recipient must submit updated OS to the Grants Management Specialist named in the notice of award as soon as it becomes known.

<u>Certification of IRB Approval</u>: If the proposed project involves human subjects research, a certification to NIH that all non-exempt human subjects research has been reviewed and approved by an appropriate IRB must be submitted. Pending or expired approvals are not acceptable. See Public Policy <u>Requirements/Human Subjects</u> for additional information.

<u>Verification of IACUC Approval</u>: If the proposed project involves research with live vertebrate animals, verification of the date of IACUC approval of those sections of the application that involve use of vertebrate animals along with any IACUC-imposed changes must be submitted. Pending or out-of-date approvals are not acceptable. See <u>Public Policy Requirements/Animal Welfare for additional information</u>.

<u>Human Subjects Education Requirement</u>: If the proposed project involves human subjects research, certification that any person identified as senior/key personnel involved in human subjects research has completed an education program in the protection of human subjects must be submitted. <u>See Public Policy Requirements/Human Subjects/Education in the Protection of Human Research Participants for additional information.</u>

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<u>Human Embryonic Stem Cells (hESCs)</u>: If the proposed project involves hESCs and the applicant did not identify a hESC line from the NIH Human Embryonic Stem Cell Registry in the application, the line(s) should be included in the JIT submission.

<u>Genomic Data Sharing Institutional Certification</u>: If the proposed project involves a Genomic Data Sharing plan. The certification form and directions for completing it are available on the GDS Data Sharing website: https://osp.od.nih.gov/scientific-sharing/institutional-certifications/. This certification should be submitted as an "other Upload" in the eRA Commons JIT module.

SBIR Funding Agreement Certification: For SBIR applicants, provide only upon request the SBIR Funding Agreement Certification described in Section 2.18 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: https://grants.nih.gov/grants/forms/manage a small business award.htm. This should be submitted as an "Other Upload" in the eRA Commons JIT module.

STTR Funding Agreement Certification: For STTR applicants, provide only upon request the STTR Funding Agreement Certification described in Section 2.19 of the Supplemental Grant Application Instructions. The certification is available in fillable formats at: https://grants.nih.gov/grants.nih.gov/grants/forms/manage a small business award.htm. This should be submitted as an "Other Upload" in the eRA Commons JIT module.

My Bibliography Report of Publications: For renewal applicants to research training programs, a My Bibliography report of publications arising from work conducted by trainees while supported by the training grant will be requested as JIT information prior to award. This should be submitted as an "Other Upload" in the eRA Commons JIT module.

Other Information Requested by the Awarding IC: NIH IC's may also request additional JIT information on a case-by-case basis, such as revised budgets or changes to the human subjects or vertebrate animal sections of the application. These changes should be submitted as an "Other Upload" file in the eRA Commons Just-In-Time module.

PROCESS

<u>Step 1 - Notification:</u> Email notification from NIH to the PI and <u>osr@gwu.edu</u> regarding a JIT request. PI may notify their assigned Pod 2 SRA point of contact (POC). GW OSP will send notification via myResearch to Pod 2's organization email (<u>GWResearchPod2@gwu.edu</u>) communicating there is a JIT request for the applicant PI. Pod 2 management will add the Pod 2 SRA to myResearch and notify the assigned SRA that a JIT is available.

<u>Steps 2 through 4 - Preparation:</u> Pod SRA liaises with PI/Dept to review JIT request and specific NIH requirements. PI/Dept sends documentation needed to Pod SRA (e.g., Other Support, budget adjustments, Human Subjects Training Certifications, IRB letter, etc.). Pod SRA initiates assembly of any additional required documentation (e.g., F&A rate agreement, GW representations and certifications, etc.) for PI to upload into eRA Commons. PI/Dept respond to sponsor programmatic requests for information.

<u>Step 5 - Review/Approval Process</u>: PI uploads all documents to JIT module in eRA Commons. PI generates report and sends to Pod SRA for upload to myResearch. Once OSP reviewes and approve, OSP submits to NIH. Note: for JIT responses, the eRA Commons module does not allow delegates with the ASST role to upload and release JIT, see <u>roles and privileges</u>.

Steps 6 & 7 - Submission: Central OSP completes the submission to NIH. PI can monitor progress in eRA Commons.

RESOURCES

The following resources may help with JIT submission:

- 2.5.1 Just-in-Time Procedures
- NIH Other Support for format page
- Submit Just-in-Time eRA Commons

WORKFLOW

The following table, which is derived from the Roles & Responsibilities (R&R) Matrix of research administration, illustrates the NIH JIT workflow, step-by-step, and delineates who is involved in the process. Key: Sponsored Research Administrator (SRA), Sponsored Projects Administrator (SPA), Office of Sponsored Projects (OSP).

ACTION	PI/DEPT/ SCHOOL	POD		CENTRAL OSP
		SRA	OSP/SPA	
NIH JIT		1. Initiate		
(1) Pod 2 manager assigns JIT request to Pod SRA				
(2) PI is responsible for initiating JIT by sending required documentation to the Pod SRA (e.g. Other Support, budget adjustments, Human Subjects Training Certifications, IRB letter, etc.)	2. Initiate			
(3) Pod SRA initiates assembly of any additional required documentation and budget adjustments (e.g. F&A rate agreement, GW representations and certifications, etc.). PI/Dept develops the response to the sponsor pertaining to the programmatic request for information.	3. Initiate	3. Initiate/Review		
(4) PI to uploads JIT response information into eRA Commons. PI generates report and Pod SRA uploads report to myResearch	4. Initiate	4. Initiate		
(5) OSP/SPA reviews and approves JIT documentation			5. Review/Approve	
(6) Central OSP completes the submission to the sponsor				6. Submit
(7) PI monitors progress in eRA Commons	7. Monitor			
*Technical assistance with sponsor portals, contact sponsor technical support				