

ORA Office Hours: Just In Time Process

School of Medicine
Office of Research Administration

February 8, 2024
11:00 AM



JOHNS HOPKINS
M E D I C I N E

Office Hours Overview

- I. Welcome
- II. Just In Time (JIT) process
- III. Different Types of JIT Files
- IV. JIT Submission
- V. Open Q & A with panel of ORA Staff

Defining Just In Time (JIT)

- NIH policy allows the submission of certain elements of a competing application to be deferred until later in the application process, after review when the application is under consideration for funding
- The requirement for applicants to verify the accuracy and validity of all administrative, fiscal, and programmatic information extends to information submitted through JIT process
- Applicants are responsible for promptly notifying NIH of any substantive changes
- In eRA Commons within the Status module, users will find a feature to submit JIT information when requested by the NIH
- Institutions can electronically submit the JIT information that is requested after the review, but before award

Defining Just In Time (JIT)

- The JIT feature lets you electronically submit additional grant application information after the completion of peer review, and prior to funding
- The program director/principal investigator (PD/PI) and the signing official (SO) work together to complete and submit information requests directly to the funding agency
- JITs are requested for grant mechanisms: R, F, T, K, U, and P

JIT Roles

- JIT capabilities cannot be delegated
- If you have the PI role, you may upload and save JIT information; however, you must be an SO to submit it to the funding agency
- Personally identifiable information and Protected Health Information should be redacted from all documents you are uploading via JIT
- It is VERY important to submit by the JIT deadline, but your GA and PI may request an extension if necessary from the GMS

JIT Feature

- The JIT feature is available for applications meeting established business criteria
- This feature becomes available for applications that fall within a certain percentile or priority score range, based on NIH Institute
- Applicants should not submit any JIT information unless specifically requested via email directly from the awarding agency's GMS
- PIs should notify the Department/Division GCA immediately after receiving the formal JIT request
- ORA does **NOT** respond to automated JIT request emails

JIT Requests – Automated Request Email

From: era-notify@mail.nih.gov <era-notify@mail.nih.gov>

To: PI Name

Cc: JHU Awards <eawards@jhu.edu>

Subject: REQUEST FOR JUST-IN-TIME INFORMATION

External Email - Use Caution

*** This is an automated notification - Please do not reply to this message. ***

Principal Investigator: PI NAME

Application 1R01XX123456-01A1 entitled PROJECT TITLE has completed the first phase of peer review.

REQUEST FOR JUST-IN-TIME INFORMATION

THIS IS NOT A NOTICE OF GRANT AWARD NOR SHOULD IT BE CONSTRUED AS AN INDICATOR OF POSSIBLE AWARD

This is a standard notice and request for information from all principal investigators with grant applications receiving an impact score of 30 or less (regardless of the IC's payline) which reflects NIH's current tightened paylines and new Impact Scoring system. This notice is a request for Just-In-Time Information. NIH Institutes and Centers (ICs) have varying pay lines and funding strategies that determine which grants will be funded.

If a decision is made to fund this application, the assigned IC will need the following information PRIOR to making an award.

- **Current Other Support:** Provide active and pending support information for all individuals designated in an application as senior/key personnel—those devoting measurable effort to a project. Other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes or gifts are not included. There is no form page for providing other support, although sample format pages are available at <https://grants.nih.gov/grants/funding/phs398/othersupport.doc> and <https://grants.nih.gov/grants/funding/phs398/othersupport.pdf>. Note that effort devoted to projects must be measured in person-months.

Automated JIT emails have several identifying factors:

- From: eRA Commons email address
- Subject: Request for JIT Information (no reference to PI or grant #)
- First line: "Automated Notification"
- Generic language: "This is a standard notice and request for information from all principal investigators with grant applications receiving an impact score of 30 or less."

JIT Requests – Formal Request Email

From: NIH Institute Grants Management Specialist Name NIH@nih.gov
To: PI Name ; ORA Grants Associate
Cc: NIH Program Officer Name
Subject: JIT REQUEST -Grant Number: 1R21XX123456 - 01A1 PI Name: Last Name, First Name

External Email - Use Caution

Dear Principal Investigator & Signing Official/Authorized Organizational Representative (AOR):

Your application is being considered for possible funding by the National Institute of Mental Health (NIMH) with available end of year funds. At this time, we are requesting additional information, which was not required as part of the original application. Receipt of this information is required before finalizing funding decisions. I have checked our files—including the NIH Commons—and this information is still pending at this time.

This request does not constitute a commitment of funding: funding decisions require Council concurrence, Program selection, and Institute approval; however, in the event this grant is chosen for funding, in order to consider paying it before the end of the fiscal year (September 30) we request this information within three (3) business days of this email. To be funded in FY2023 we need clear communication if this deadline cannot be met: we understand that IRBs and/or IACUCs may be pending. If the grant were not funded in FY2023, we would expect to award the grant within the first quarter of FY2024. If you have questions about the timing of this email, please contact [NIH CONTACT] (name@nih.gov).

Please provide the following items:

- **Authorizing Signature:** We recommend that you submit your Just-in-Time information using the Just-In-Time feature of the NIH Commons (further described below). If you do not use the Commons, a cover letter containing the signature of the Authorized Organizational Representative (AOR) must be attached and submitted with the document(s) designated below.
- **Updated "Other Support" Information:** List all active and pending other support (Federal, non-Federal, commercial, or institutional) for the principal investigator and all key personnel,

Formal JIT emails have other identifying factors:

- From: The name of the NIH Grants Management Specialist
- Subject: JIT Request + specific grant number and PI name
- First line: Dear PI and Signing Official/AOR
- Detailed list of documents requested + may have additional request for clarification
- Typically includes a JIT submission deadline (either in date form or “within X business days of this email”)

Required JIT Format

- All JIT attachments must be submitted in PDF format with a maximum size of 6MB
- Each upload area can accept only a single PDF, and if you re-upload a file, it replaces the previous file
- All elements on the JIT form can be submitted multiple times and will be appended to the JIT report, with the latest version at the top of the report
- PDF uploads for all sections are required to be a flattened PDF, one that does not have fillable forms or other layers, such as movable images

Different JIT Files

1. Other Support File
2. Budget File
3. Other File
4. Animals Research
5. Human Subjects Research
6. Human Subjects Education Certificates
7. Genomic Data Sharing

JIT in eRA Commons (OS, Budget, Other Files)



Application Information

Award Number: R01 [REDACTED]-01

Principal Investigator Name: [REDACTED]

Proposal Title: [REDACTED]

Total Submissions: 0

Primary Research Site: JOHNS HOPKINS UNIVERSITY

Please provide "active and pending" support for all senior/key personnel. Other Support includes all resources (i.e., domestic and foreign) 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. Other Support does not include training awards, prizes, or gifts.

For more information on Other Support and suggested formats, please review [OtherSupport](#) . Upload the document using the Upload button provided below. Alternatively, you can drag and drop a file into the respective panel. Please note that when you upload a document it is automatically attached to your application.

Other Support File

Last Uploaded File Name:

[OS pages.pdf](#)

Date Created:

02/05/2024

Number of Submissions:

0

Delete

Upload

Budget File

Last Uploaded File Name:

[budget just.pdf](#)

Date Created:

02/05/2024

Number of Submissions:

0

Delete

Upload

Other File

Last Uploaded File Name:

[DMSP.pdf](#)

Date Created:

02/05/2024

Number of Submissions:

0

Delete

Upload

Other Support File

- NIH requests that active and pending support for all senior/key personnel be provided
- 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. This includes, but is not limited to:

Other Support includes

- Resources and/or financial support from all foreign and domestic entities that are available to the researcher. This includes, but is not limited to, financial support for laboratory personnel and provision of high-value materials that are not freely available
- Consulting agreements, when the PD/PI or other senior/key personnel will be conducting research as part of the consulting activities and the activities fall outside of their appointment at the applicant or recipient institution
 - *Many divisions, including the School of Medicine, do not permit faculty to conduct research under a private consulting agreement*
- In-kind contributions, e.g. office/laboratory space, equipment, supplies, or employees or students supported by an outside source

Other Support continued

- For Other Support submissions that include **foreign activities and resources**, recipients are required to submit copies of contracts, grants, or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution as supporting documentation, translated in English
- Institutional resources, such as core facilities or shared equipment that is made broadly available, should **not** be included but rather listed under Facilities and Other Resources
- Training awards, prizes, or gifts do NOT need to be included

Other Support Tips for Departments/Divisions

- Active effort + pending JIT grant effort cannot exceed **12 calendar months**
- Dept/Division GCA should verify effort proposed in the application and ensure it is correct on the OS prior to sending to GA for upload
- GCA reviews and confirms all active and pending awards do match what's reflected in the Fibi BIRT report system
- Ensure Overlap and In-Kind sections are correct
- Confirm that the PI has reviewed, verified, and signed their OS page via DocuSign
- ORA requests the Department/Division GCA combine PDF uploads into 1 flattened PDF for GAs to upload to JIT
- NIH OS sample: <https://grants.nih.gov/sites/default/files/other-support-sample-7-20-2021.docx>

Budget File

- This upload may be requested by GMS for budget revisions to the application on a case by case basis
- May include revised Budget and/or Justification

Other File

- This upload *may* be requested by NIH for something specific that is not related to Other Support or Budget on a case by case basis
- Examples: F&A rate agreement; Resource Sharing Plan, Data Management Sharing Plan, Equipment quote, Biohazards explanation, etc.




JIT eRA Commons: Human Subjects

Human Subjects Information

Please Note: If you have not received an IRB Date from the Internal Review Board, you are not required to enter the IRB Date or OHRP Human Subjects Assurance Number prior to submitting JIT Documents

IRB Date:

 Number of Submissions: 0

Your Institution must certify to Agency that the research described in this application has received Institutional Review Board (IRB) approval by an IRB registered at OHRP under your Human Subjects Assurance Number. If the required IRB approval has been obtained, enter the IRB approval date. By specifying a Date and saving this form, you certify that you have IRB approval for this research. Please select the correct OHRP Human Subjects Assurance Number from the list of numbers associated with your Institution:

Human Subject Education. This document is required for key personnel (all individuals responsible for the design and conduct of the study) that are involved in human subject research. Please upload a PDF file that includes the following:

- The names of the key personnel who are responsible for the design and conduct of the study
- The title of the education program completed by each named person plus a brief description of the program

Note: If research meeting the criteria for Exemption 4 is proposed, documentation is recommended, but not required.

Human Subjects Education

Last Uploaded File Name:

None

Date Created:

None

Number of Submissions:

1

 Delete

 Upload

Human Subjects Research

- IRB protocol approval date is valid for 1 year; must be renewed on an annual basis
- GA selects the JHUSOM assurance number from drop down box in JIT
- GAs need approved IRB protocol numbers ASAP to provide the IRB enough time to process the grant vs. protocol review which confirms congruency with project aims (via Grant vs. Protocol Word doc)
- If PD/PI does not have an approved IRB protocol number yet, GAs can submit JIT with IRB as pending and send an email to NIH GMS

Human Subjects Education Certificates

- Human subjects education certificates (HSEC) are valid for 3 years in duration
- “Basic Human Subjects Research” training module can be found in JHU myLearning [JHM Human Subjects Research Training \(hopkinsmedicine.org\)](https://hopkinsmedicine.org/jhm-human-subjects-research-training)
- Department/Division GCA must provide HSEC training certs for all senior/key personnel involved in human subjects research in 1 flattened PDF document for GAs to upload

JIT eRA Commons: Animals Research

Animal Subjects Information

IACUC DATE:

01/08/2024



Number of Submissions: 0

The institution must verify approval by the Institutional Animal Care and Use Committee (IACUC) of those components of the application related to the care and use of animals. By specifying a date and saving this form you confirm that IACUC approval of this application was awarded on that date. If the IACUC required any modifications in the care or use of animals as described in the Research Plan, those changes must be submitted to the appropriate NIH Awards Management office. The OLAW Assurance Number listed for your Institution is D16-00173

Animals Research

- IACUC protocol approval date is valid for 3 years; must be renewed every 3 years
- GAs need approved IACUC protocol numbers ASAP to provide IACUC enough time to process the grant vs. protocol review which confirms congruency with project aims
- If PD/PI does not have an approved IACUC protocol number yet, GAs can submit JIT with IACUC as pending and send an email to NIH GMS
- GAs will not provide IACUC approval letters to NIH due to PETA restriction

JIT eRA Commons: Genomic Data Sharing

Genome Data Sharing Certification

Genome Data Sharing Certification. An Institutional Certification is expected prior to funding award for all research generating large-scale human genomic data under the Agency Genomic Data Sharing Policy (<https://osp.od.nih.gov/scientific-sharing/institutional-certifications/>). The Institutional Certification is a document from the authorized Institutional Signing Official of the institution submitting the data, and assures that the data submission and sharing is appropriate (see <https://osp.od.nih.gov/scientific-sharing/institutional-certifications/> for templates). If a final Institutional Certification is not available at Just-In-Time, you may submit a provisional Institutional Certification along with other Just-In-Time documents. A final version of the Institutional Certification may be uploaded in the "Additional Information" section of your award folder at a later date. You should keep Program Staff of the funding IC informed of the expected date of submission of the final Institutional Certification.

Genome Data Sharing Certification

Last Uploaded File Name:

None


Date Created:

None

Number of Submissions:

0

 Delete  Upload

 Back to Search

 View Just In Time Report

Save

Submit

Genomic Data Sharing

- In rare cases, GDS policy applies to all NIH-funded research that generates large-scale human or non-human genomic data and the use of the data for subsequent research, regardless of funding level
- GDS applies to a broader range of research so will use a wide array of data repositories
- Investigators working with large-scale human genomic data are required to submit an Institutional Certification to NIH
- GDS certificate is provided by IRB

JIT Submission

- GAs should upload and submit JIT in eRA Commons by the due date and after reviewing files from Department/Division
- Only those with the SO role in eRA Commons can submit JITs, **not** the PI
- Please don't send multiple files of the same type to your GA
 - *For example: send 1 PDF document for all OS and 1 PDF document for all HS Education Certificates*
- eRA Commons performs validations upon saving or submitting and if required information is missing or invalid, error messages appear

Viewing the JIT Report

- If you are an SO or a PI, you can view the JIT report directly from the JIT screen prior to submission
- If the JIT information has already been submitted to the awarding agency, the JIT report can be viewed from a web link within Status Information in eRA Commons
- You can submit as many JIT requests as necessary prior to the grant being awarded

JIT Resources From NIH

- [Just in Time \(JIT\) \(nih.gov\)](https://www.nih.gov/just-in-time)
- [2.5.1 Just-in-Time Procedures \(nih.gov\)](https://www.nih.gov/just-in-time-procedures)

Q & A Panel

ORA Panelists:

- Ashley Evans, Assistant Director (Grants)
- Laurel Peck, Grants Associate (Grants)
- Michelle Swift, Grants Associate (Grants)
- Mike Harmon, Assistant Director (Contracts)
- Brett Mortenson, Contracts Associate (Contracts)
- Adam Young, Sponsored Projects Associate (Contract Specialists)
- Megan Lemieux, Subawards Associate (Outgoing Subawards)