Just-in-time (JIT) Checklist

JIT information is only required when the PI receives an email from the sponsor requesting information. To see what information is required, click on the JIT link next to the application (in the "Action" column of the grant on eRA Commons).

When you prepare a JIT response, you should follow two processes simultaneously:

1. Create a single PDF for each section in eRA Commons. You may upload only one document for each section. For guidance, click on the link for details https://era.nih.gov/applicants/submit-jit.htm.

2. Create a single PDF of the information (all sections combined into one document) uploaded on to eRA Commons, and upload this PDF into Cayuse SP. Notify OGS (email).

NOTE: DO NOT SUBMIT THE JIT INFORMATION TO NIH UNTIL APPROVED BY OGS. Please upload and email OGS at least a day before the deadline to inform OGS that your documents are ready for review and submission. You should allow the OGS personnel additional time for review and approval if the due date falls on a major NIH deadline or requires budgetary review.

The JIT request will require the PI to provide one or more of the following:

a) OTHER SUPPORT
b) BUDGET UPDATE OR REVISION
c) OTHER ITEMS, INFORMATION OR EXPLANATION
d) CERTIFICATION OF IRB APPROVAL AND HUMAN SUBJECT EDUCATION REQUIREMENT
    1. IRB APPROVAL DATE
    2. HUMAN SUBJECTS ASSURANCE NUMBER OR FEDERAL WIDE ASSURANCE NUMBER (FWA)
    3. HUMAN SUBJECTS EDUCATION
e) VERIFICATION OF IACUC APPROVAL (i.e. IACUC APPROVAL DATE
f) HUMAN EMBRYONIC STEM CELLS
g) GENOMIC DATA SHARING PLAN/CERTIFICATION OR OTHER DATA SHARING AGREEMENTS
h) TRAINING GRANT APPLICATION INFORMATION

Additional required items may be requested in eRA Commons depending on whether the proposal has human or animal subjects or other components.

A. OTHER SUPPORT

NOTE: NIH has issued a new Other Support page. We encourage you to use this new Other Support Page. Please see new format/sample here
https://grants.nih.gov/grants/forms/othersupport.htm.

1. Almost all JITs require updating the Other Support pages of all individuals listed as key-personnel. Please ensure that any research support, consultancy, board appointment(s) and academic appointment(s) outside Einstein-Montefiore (including foreign) are included on the Other Support page (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-114.html). Review Other Support pages for:
   a. accurate listing of all completed (last three years), active and pending support
   b. accurate effort in Calendar Months (for active grants) and committed effort (for pending grants).

   NOTE: Total Support should not exceed 95%. If active and pending support exceed 95%, include a statement that the investigator will reduce effort (indicate on which grant).

2. Review Other Support to ensure that an overlap statement for scientific, budgetary, and effort overlap is included. If none, state "None."

3. Effective January 25, 2022:
   a. NIH will require that financial COI be addressed: PIs must include supportive documentation (copies of agreements or contracts) related to each and every disclosure – including foreign relationships.
   b. PIs must sign the Other Support page.

B. BUDGET UPDATE OR REVISION

Provide a revised budget *if* requested from the awarding NIH Institute or Center. Upload into the *Budget File* in eRA Commons. If you have any questions, contact Gerard.mcmorrow@einsteinmed.org for guidance.

C. OTHER ITEMS, INFORMATION OR EXPLANATION

If the awarding NIH Institute or Center requests other items (such as revised bio-sketch, IACUC approval letter, clarification on the use of special biologics), provide a letter addressing the issue. Upload into *Other File* in the eRA Commons. If you have additional questions, contact Dhanonjoy.saha@einsteinmed.org for guidance.

D. CERTIFICATION OF IRB APPROVAL (HUMAN SUBJECTS) AND HUMAN SUBJECTS EDUCATION REQUIREMENT

If your study involves human subjects, NIH and Einstein require the following:

1. Verification of a recent IRB Approval Date and the IRB Protocol #.

   NOTE: Initial approval of the protocol should be within the past 2 calendar years. (OGS does not need the approval letter unless it is specifically mentioned in the JIT request). If you urgently require a new IRB approval for a JIT notification, please email IRB@einsteinmed.org with "NIH JIT" in the subject line.

   Ensure that the following elements on both the approved protocol and grant are identical. If the three elements are not identical, contact IRB@einsteinmed.org
   a. PI Name
   b. Title of the Study
   c. Initial IRB approval is no more than two years old

2. Human Subjects Assurance Number i.e., the Federal Wide Assurance Number (FWA), must be populated from the eRA Commons JIT page dropdown list (FWA for Einstein is 00023382).

3. CITI completion certificate for the PI and all key personnel must be uploaded into the *Human Subjects Education* in the eRA Commons. Instructions for obtaining CITI certificates are here: https://einsteinmed.org/administration/human-research-affairs/education/education-documentation.aspx

   NOTE: *If* this application includes human subjects with a collaborating institution (subcontract), approval of the external IRB may be required.

   NOTE: *If* you are unsure whether your application is subject to human research regulations (including human specimens or data), use this tool (click on the link below): https://einsteinmed.co1.qualtrics.com/jfe/form/SV_9oxZb6K6zzQ6FA9. For questions or guidance, contact IRB@einsteinmed.org

E. VERIFICATION OF IACUC APPROVAL (VERTEBRATE ANIMALS)
If vertebrate animals are used, contact IACUC (Sunder.shrestha@einsteinmed.org). Include "JIT IACUC" in the subject line and provide the following information in the body of your email:
- Grant Proposal # from Cayuse
- PI Name
- PI Department name
- Administrator's name
- Project Title
- Project Number
- Proposal Project Period
- Funding Agency
- Award Start Date and End Date

- Animal Research Protocol #
- Protocol Number
- Protocol Title

1. Once received, the IACUC will initiate a congruent analysis process and may request additional documentation from the PI. Please allow three to seven business days for this process to be completed.

2. Once approved, the PI is required to provide the following to OGS:
   a. the most recent IACUC approval date.
   b. the animal care training certificates, if requested by NIH.

3. *If* this application includes a collaboration with another institution (subcontract), approval of the external IACUC may be required.

F. HUMAN EMBRYONIC STEM CELLS (HESCS)

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.

1. Upload into *Other File* in the eRA Commons. If you have additional questions, contact Dhanonjoy.saha@einsteinmed.org for guidance.

2. All use of hESCs must be submitted to the Office of Human Research Affairs (OHRA) in compliance with this policy. If you have questions about the submission process, contact escro@einsteinmed.org .

G. GENOMIC DATA SHARING PLAN/CERTIFICATION OR OTHER DATA SHARING AGREEMENTS

If the project involves a Genomic Data Sharing plan, NIH requires the following:

1. Genomic Data Sharing Certification Form can be found here https://osp.od.nih.gov/wp-content/uploads/GDS_Extramural_Certification.pdf. This form is submitted to the Office of Human Research Affairs in the Research Agreement Request Portal: https://einsteinmed.co1.qualtrics.com/jfe/form/SV_8fgVaus0Bpcpeux . If you have questions about the form, contact irb@einsteinmed.org. OHRA staff will route the form for signature by the Institutional Signing Official.

2. If you have a prospective study where the IRB has not completed its review of the protocol and therefore the institution cannot attest to all of the elements of the formal Institutional Certification, you can submit a Provisional Institutional Certification. Please click on the link here for the forms/process - Provisional Institutional Certification. This

form is submitted to the Office of Human Research Affairs in the Research Agreement Request Portal: https://einsteinmed.co1.qualtrics.com/jfe/form/SV_8fgVaus0Bpcpeux . If you have questions about the form, contact irb@einsteinmed.org. OHRA staff will route the form for signature by the Institutional Signing Official.

H. TRAINING GRANT RENEWALS REQUIRE "MY BIBLIOGRAPHY" REPORT OF PUBLICATIONS:

1. As applicable, provide "My Bibliography" report of publications arising from work conducted by trainees while supported by the training grant.

2. This should be submitted into *Other File* in the eRA Commons.   If you have additional questions, contact Nancy.glassman@einsteinmed.org for guidance.

STEP 2 – CAYUSE SP

After all documentation is complete:

1. Log into Cayuse SP (Sponsored Projects)
2. Select the applicable Proposal Number
   a. ***If this is an application submitted prior to January 2021*** – (considered a legacy application):
      i. a new proposal must be created.
      ii. from the proposal type dropdown menu select: "JIT/OPAS"
      iii. copy the Cayuse S2S (formerly Cayuse 424) application and upload as an attachment
3. ***If this is a new application***, navigate to the Proposal Attachment section (attachment icon is on top bar)
4. Select document type "JIT" from the dropdown menu and upload all applicable documents. Name each document using the following nomenclature: Other Support Page, Bio-sketch, IACUC Approval, IRB approval, etc.
5. Email Office of Grant Support (OGS) with the subject "JIT – 21 – XXXX [proposal number] and the due date".
   a. If at JIT there is a Budget related question, email Gerard.mcmorrow@einsteinmed.org
   b. All other JIT related questions (except budget) should be addressed to regina.janicki@einsteinmed.org
6. Once OGS receives the JIT email, OGS will change the status in Cayuse to JIT Received.
7. Once OGS approves the JIT submission document, OGS will change the status to JIT Approved.
   a. **NOTE:** If OGS has an issue approving the JIT, the status in OGS will remain JIT Received. OGS will email you with the details of what needs to be revised or added. As an Administrator/PI, please reply to the OGS email once completed.

NOTE: The JIT request may include a specific due date. Please ensure that the information is uploaded into Cayuse SP and reach OGS at least a day before the deadline. You should allow OGS additional time for review if the response due date falls on a major NIH deadline.

Frequently Asked Questions

Q. Sometimes, I receive emails from NIH that the JIT information can be emailed to NIH. Do I still need the information to be uploaded into Cayuse SP?
A. Yes, the information must be reviewed by OGS and approved before it can be sent to NIH. Please prepare the information, upload it to Cayuse SP and send an email to OGS (preaward@einsteinmed.org) that the information is uploaded into Cayuse. The OGS will review the information and send to NIH.

Q. What if NIH calls to request JIT information and I did not get an e-mail?
A. The PI should send a follow-up e-mail to the Program Officer (PO) and Grants Management Specialist (GMS) at NIH and CC OGS (preaward@einsteinmed.org)

Q. How do I know who is my GMS?
A. His or her name and contact information should be listed on the NIH eRA Commons under the grant in question. It can also be found at the end of the NOA.

Q. Will I be able to submit JIT information to eRA Commons through Cayuse SP?
A. JIT will be developed concurrently in eRA Commons and Cayuse SP. OGS will review the information provided in Cayuse SP and approve for submission into eRA Commons. The PI is allowed to submit it on eRA Commons for institutional approval once it is approved by OGS (see the process below). You submit the information into eRA Commons, it comes to OGS, and OGS submit it to NIH. Please note that eRA Commons notification to OGS is not automatic and you need to inform the person at OGS to submit it to NIH.

Q. I need to know more about preparing the OS page. Where can I find it?
A Research support indicated on bio-sketches are different than the information required on OS pages. The PHS 398 instructions contain valuable information regarding Other Support. See Part III, Sections G and H and the Other Support Format Page Example found on the following website: http://grants1.nih.gov/grants/funding/phs398/phs398.html

Q. Is there any additional information required for Research Career Development Awards (K Series)?
A. Yes. JIT response documents will include a detailed, categorical budget and narrative justification pages (Form Page 4 and Page 5). Additionally, Other Support may be requested for the sponsor(s) and co-sponsor(s) (mentors or co-mentors) in addition to the PI and other Key Personnel.

Q. Should I submit Other Support pages for individuals classified as "Other Significant Contributors (OSC)?"
A. No. Other Support is not required for those individuals who are considered OSC.

Q. Should I provide NIH with copies of my protocol approval letters from the IRB and/or IACUC?
A. No, unless they specifically ask for these.

Q. I do not have the IACUC or IRB information and the NOA is awaiting for these information. What do I do?
A. If it is critical that the grant starts soon, write a letter explaining the situation (or the reason for the delay in obtaining the approval), and send it to OGS. OGS will concur and send the communication to NIH. NIH may issue the NOA with restrictions. It may also be possible to have one of the preliminary, less complex, minimal risk Aims of the study (e.g. a preliminary test of a survey tool, a retrospective chart review to fine-tune a power analysis) be approved by the IRB by expedited review to satisfy the JIT requirement for IRB approval. Contact irb@einsteinmed.org for guidance with "NIH JIT" in the subject line of the email.

Q. How do I know if OGS has an issue approving the JIT?
A. The status in OGS will remain JIT Received. OGS will email you with the details of what needs to be revised or added. As an Administrator/PI, please reply to the OGS email once completed.

Q. Does the IPF need to route in SP?
A. No.

Q. Does the PI have to certify in SP?
A. No.

Q. Starting January 25, 2022, does the PI have to sign the Other Support page?
A. Yes, NIH encourages it now, but the new form page and the signature would be mandatory starting January 25, 2022.

Q. I have a PI who has an outside financial COI (consultant or other activities). Do I need to report this in the JIT?
A. Yes, you need to report on the other support page. PI will need to sign the page effective January 25, 2022. In addition, we must attach a copy of the agreement or contract with the outside entity. NIH encourages investigators to start using the new form and format now.

Guidelines for Just-In-Time (JIT) Procedure
Cayuse SP. Revised 01/14/2021

Administrator takes the following action:
1) Log into Cayuse Sponsored Projects (SP).
2) Select the applicable Proposal Number. If the proposal is not in SP, see steps below for Legacy JIT.
3) Navigate to the Proposal Attachment section of the proposal (Click on the attachment Icon on top bar).
4) Select the document type "JIT" from the dropdown list on the new page and upload all applicable documents. Please name the documents appropriately such as Other Support Page, Bio-sketch, IACUC approval etc.
5) Email OGS (either Gerard or Regina) with the subject "JIT – 21-XXXX [proposal number] and the due date".

OGS takes the following action:
6) Change the proposal status type to "JIT Request Received."
7) OGS will email IRB and IACUC to verify that the protocol numbers and dates provided are correct for <u>this specific project.</u> **NOTE: Administrators should continue his/her normal procedures. This is a new step for OGS, it's a double check.**
8) Once IRB/IACUC approves, then OGS will change proposal status type to "JIT Request Approved."
9) In the compliance tab, OGS will:
   -enter the IRB/ IACUC protocol number
   -enter the IRB/ IACUC approval date
   -check the verified button(s)
10) OGS will respond to the email letting the Administrator know the JIT is approved.
11) If any signatures are required or any edits, then OGS will upload the final document in to Cayuse SP.

Submission to the sponsor:
12) Administrator will upload, submit and or route the JIT to the sponsor using the sponsor's portal (following sponsors' requirements and notify the OGS of such processes), unless the sponsor requires the Authorized Organizational Representative (AOR), in which case, OGS will submit the JIT to the sponsor, and CC the PI and the administrator(s).

Legacy JIT:
13) Follow steps 1 – 10 with a modified step #2.
Step #2 has a modification, if there is not an SP record, a new proposal must be created with the proposal type. Selects Legacy JIT/OPAS from the dropdown list. Then the administrator copies the Proposals 424 application and uploads it in the attachment section of the Legacy JIT/OPAS as an attachment.