Proposal Development and Submission

Writing an NIH Data Management and Sharing Plan (DMS Plan).

With the NIH Data Management & Sharing Policy effective Jan. 25th, 2023, PIs are required to submit Data Management & Sharing (DMS) Plans for most NIH-funded mechanisms. The policy requires the submission of a DMS Plan that outlines how Scientific Data and any accompanying metadata will be managed and shared, taking into account any potential restrictions or limitations in the six plan components (researchers should refer to the MGB policy on Limitations and Restrictions for Data Sharing).

The NIH does not require any particular tool to be used to write a DMS Plan, however, MGB has drafted a template with required language that is strongly recommended.

Additional information on writing a plan, NIH and MGB plan templates, and information on choosing a repository is available at the following link: 2023 NIH Data Management & Sharing Policy (sharepoint.com).

Just-in-Time (JIT)

Investigators submitting a funding proposal to the NIH may receive a notification from the funding agency that their grant proposal is likely to be funded and that more information is required to secure the funding – a JIT notice. If there are human subject activities included in the funding proposal, one of the JIT requirements will be to provide documentation of IRB approval. Investigators should follow the procedures below during the JIT process:

- **Robo JITs - Do NOT submit an IRB protocol in Insight at this stage.:** NIH may first send an automatic notification (a Robo JIT) requesting JIT information. This occurs after peer review, for applications under consideration for funding based on overall impact scores.
- **Real JITs - Submit the IRB protocol in Insight at this stage:** After the automatic notification, for proposals most likely to be funded, a more formal and detailed request is sent to the investigator by the grantor agency's Grants Management Specialist (the Real JIT).

See examples of Robo and Real JIT requests in Appendix A below.

PIs should not submit an Initial Review application or an Amendment with new funding to the IRB until they have received a notification from an NIH grants specialist (Real JIT), as this ensures the application will be funded. The application will be returned to the PI if the submission does not include a notification from a grants specialist (i.e., a Real JIT request).

What to Submit to the IRB for Approval

- The JIT documentation must be included in the IRB submission.
- The IRB will prioritize Real JIT submissions.
- For existing studies, the Real JIT documentation should be included with an amendment submission.

JIT and Clinicaltrials.gov Registration

For protocols which are required to be registered on ClinicalTrials.gov per NIH and/or FDA criteria, initial IRB approval is contingent upon completion of registration on ClinicalTrials.gov (receipt of National Clinical Trials number or NCT). The review of new Clinical Trials.gov registrations can take 2-4 weeks. It is not uncommon for the ClinicalTrials.gov reviewers to issue queries or comments that must be resolved before the registration is approved and the NCT number is assigned. If the timelines for completing registration on ClinicalTrials.gov, receiving IRB approval, and release of NIH funds are not compatible with each other, please email the HRA Compliance and Education Office at QIProgramCTgovTeam@partners.org to discuss your circumstances.

JIT and NIH Data Management and Sharing Policy

- NIH DMS plans are reviewed by NIH program officers who may request changes or modifications to the plan at JIT. At JIT, PIs will receive an email deliverable from Insight to verify information regarding their research.
- Based on those responses, an additional ancillary review of the plan by the Mass General Brigham Joint Committee may be triggered.
    - When triggered, the Joint Committee will review the DMS plan and determine if the proposal is in compliance with MGB institutional policy.
    - If not, they will work with the PI on revisions to the plan to meet policy.
    - Review and approval of DMS Plans by the Joint Committee will not hold up the submission of JIT materials.
    - Revised DMS Plans may be submitted via JIT or NIH's Prior Approval mechanism through MGB Research Management.

When the Funding Proposal Does Not Describe a Specific Research Study, But Intends to Use Human Subjects (Research Protocol To Be Developed During the Project Period)

Under the Common Rule (45 CFR 46.118) certain types of applications for grants are submitted with the knowledge that participants may be involved, but definite plans may not be described in the funding application or proposal. These include:

- Institutional-type grants when the selection of specific projects is the institution's responsibility;
- research training grants in which the activities involving subjects remain to be selected; and,
- projects in which human subjects' involvement will depend upon the completion of instruments, prior animal studies, or purification of compounds.

In these cases, Federal agencies may still require investigators to obtain a determination from the IRB before an award is granted or before use of funding is allowed.

In order to meet federal agency requirements, the IRB will issue a "118 determination" letter for projects that meet the above definition, where the human research component is yet to be developed. To request a "118 determination," submit the following to the IRB via email (partnersirb@partners.org):

- Description of the study
- Description of the human research components that need to be developed
- Name of the federal agency and notification from the funder requesting IRB review
- A copy of the grant

After the human research components are developed, the investigators must submit an application to the IRB and obtain IRB approval prior to enrolling participants.

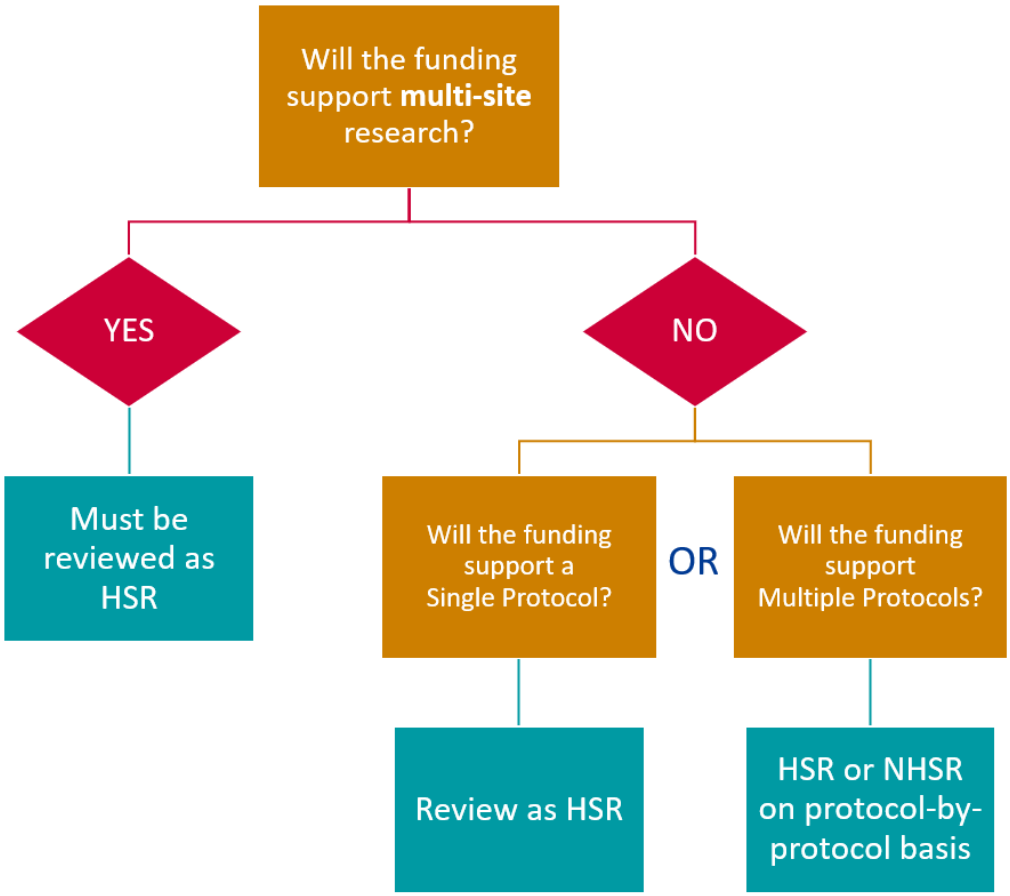
When Mass General Brigham Site is Prime Awardee of Federal Funding that Supports BOTH Human Subjects (HSR) and Not Human Subject Research (NHSR)

If Mass General Brigham is the primary awardee of federal funding, and if the funding supports both human subject research (HSR) and not human subject research (NHSR) aims or activities, the Mass General Brigham IRB ("IRB") will consider the funded research as follows:

- If the funding in its entirety is used to support a single protocol, the protocol will be reviewed as HSR.

- When MGB is the only participating site, and the funding will support multiple protocols:
  - Protocols that meet HSR criteria may be reviewed as HSR.
  - Protocols that meet NHSR criteria may be reviewed as NHSR.

- Research involving multiple sites:



- Example: If the funding supports a multi-site protocol and the role of Mass General Brigham investigators is only to receive de-identified data or materials from other sub-award institutions or organizations that are conducting the HSR portions of the grant, Mass General Brigham's role then is considered NHSR. However, since this grant supports HSR activities and NHSR activities, the grant is considered to be HSR overall. Similarly, if the funding supports multisite research, the same principle applies. The IRB, by regulation, cannot make a NHSR determination based only on Mass General Brigham's role since we are the prime awardee, therefore we consider the research to be HSR. We must make a determination based on all activities conducted at all sites. This is the case regardless of whether Mass General Brigham serves as the single IRB or cedes review to another IRB.

Note: When Mass General Brigham is the primary awardee of federal funding that supports human subject research and animal research, investigators should consult with the Institutional Animal Care and Use Committee (IACUC) at their site to obtain a determination for animal research.

Sub-awards

If Mass General Brigham receives a sub-award and is engaged in NHSR activities, the IRB will review such applications as NHSR if it does not meet the regulatory definition of human subject research. . Investigators can obtain a NHSR determination from the IRB by submitting an NHSR application via REDCap.

Completing the Insight Application

It is not necessary for the grant title to match the title of the IRB application as one grant may cover many different types of applications, which may need to be submitted separately to the IRB. The IRB is also not responsible for ensuring that grantees are listed as study staff.

Grants with Multiple Aims

If a grant supports several different aims, and if each aim builds on the results of previous aims, investigators should submit separate protocols for each aim. If all aims are submitted under one protocol, the IRB will likely not have all the information necessary for all aims in order to grant approval. Hence, the IRB will require that each aim be submitted as its own protocol application.

Having each aim as its own IRB protocol application will also facilitate registration and results reporting on ClinicalTrials.gov. For aims which do not meet the regulatory criteria for ClinicalTrials.gov registration, it will be the responsibility of the PI to determine whether they wish to register them voluntarily for publication or other reasons.

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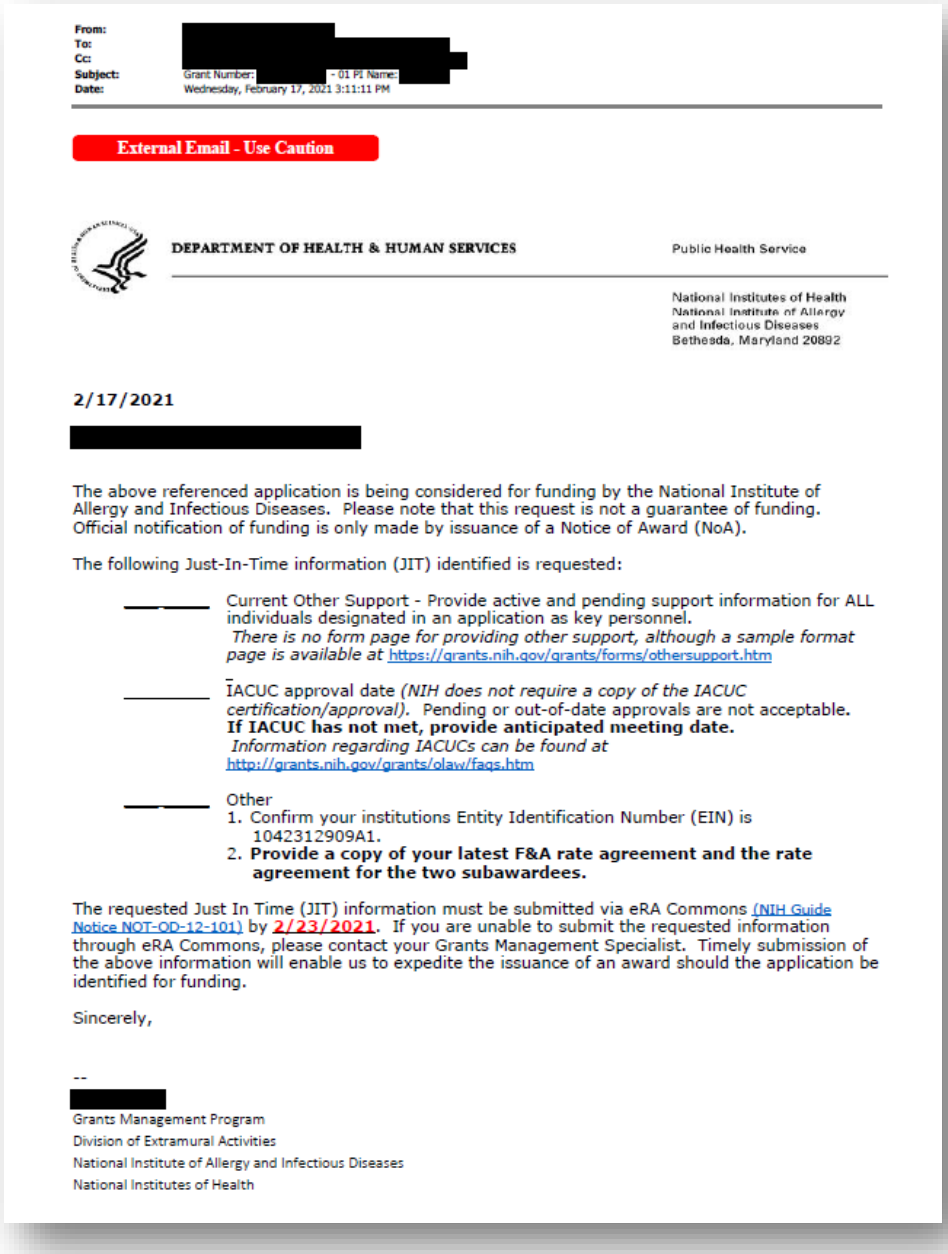
Appendix A

Real JIT Example:



From: [redacted]
To:
Cc:
Subject: Grant Number: [redacted] - 01 PI Name: [redacted]
Date: Wednesday, February 17, 2021 3:11:11 PM

External Email - Use Caution

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Bethesda, Maryland 20892

2/17/2021

[redacted]

The above referenced application is being considered for funding by the National Institute of Allergy and Infectious Diseases. Please note that this request is not a guarantee of funding. Official notification of funding is only made by issuance of a Notice of Award (NoA).

The following Just-In-Time information (JIT) identified is requested:

_____ Current Other Support - Provide active and pending support information for ALL individuals designated in an application as key personnel.
There is no form page for providing other support, although a sample format page is available at https://grants.nih.gov/grants/forms/othersupport.htm

_____ IACUC approval date *(NIH does not require a copy of the IACUC certification/approval).* Pending or out-of-date approvals are not acceptable.
If IACUC has not met, provide anticipated meeting date.
Information regarding IACUCs can be found at
http://grants.nih.gov/grants/olaw/faqs.htm

_____ Other
1. Confirm your institutions Entity Identification Number (EIN) is 1042312909A1.
2. **Provide a copy of your latest F&A rate agreement and the rate agreement for the two subawardees.**

The requested Just In Time (JIT) information must be submitted via eRA Commons (NIH Guide Notice NOT-OD-12-101) by **2/23/2021**. If you are unable to submit the requested information through eRA Commons, please contact your Grants Management Specialist. Timely submission of the above information will enable us to expedite the issuance of an award should the application be identified for funding.

Sincerely,

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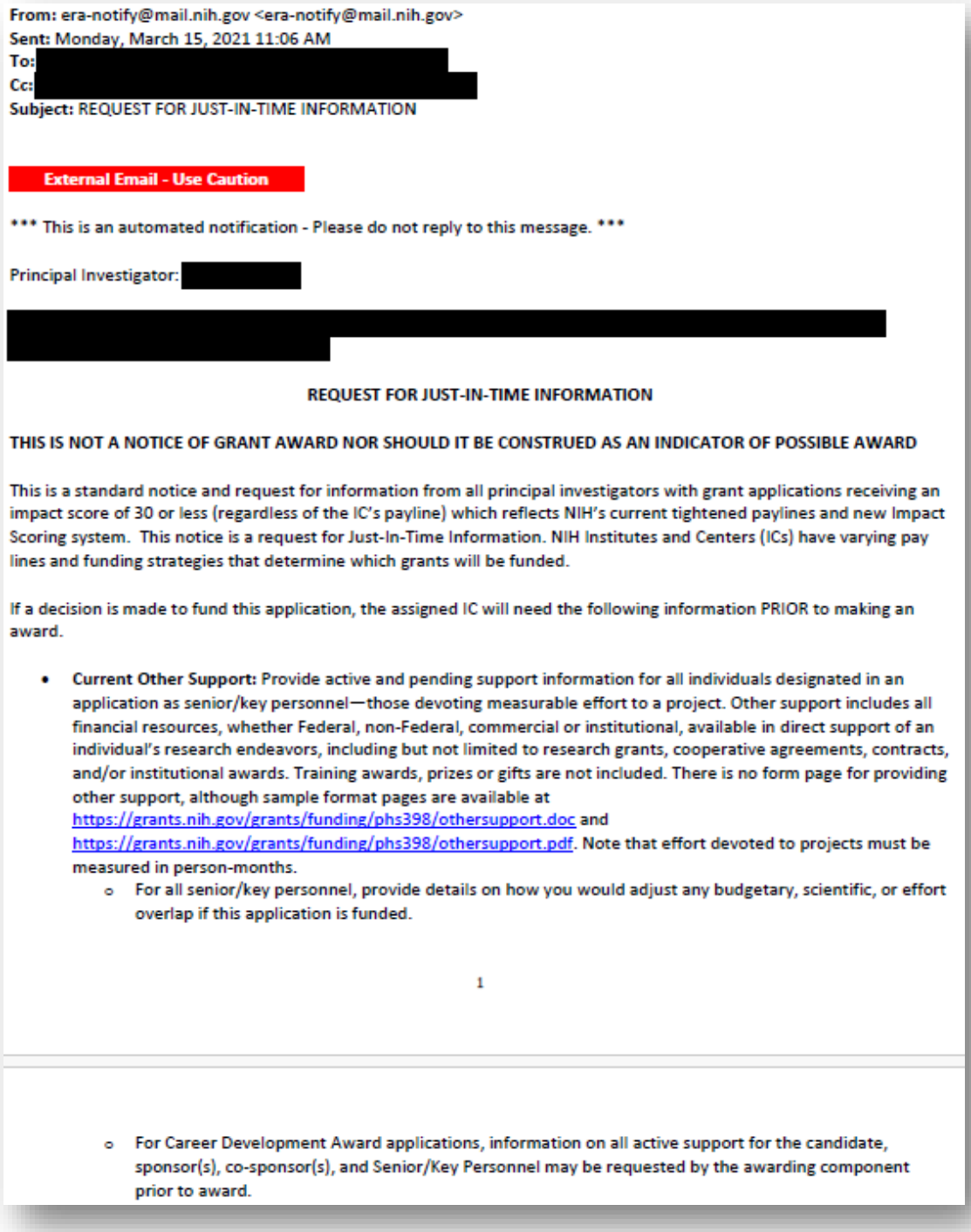
[redacted]
Grants Management Program
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
National Institutes of Health

Robo JIT Example:



From: era-notify@mail.nih.gov <era-notify@mail.nih.gov>
Sent: Monday, March 15, 2021 11:06 AM
To: [redacted]
Cc: [redacted]
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: [redacted]

[redacted]

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.
    - For all senior/key personnel, provide details on how you would adjust any budgetary, scientific, or effort overlap if this application is funded.

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- For Career Development Award applications, information on all active support for the candidate, sponsor(s), co-sponsor(s), and Senior/Key Personnel may be requested by the awarding component prior to award.

- **Certifications:**
  - **IRB Approval**: If the proposed project involves human subjects research, the certification date of IRB review and approval must be submitted. Pending or out-of-date approvals are not acceptable.
  - **IACUC Approval:** If the proposed project involves research with live vertebrate animals, the 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.
  - **Human Subjects Education:** 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.
  - **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
  - **Institutional Certification for Human Genomic Data Sharing:** If the proposed project involves a genomic data sharing plan for the generation of human genomic data, investigators must submit an Institutional Certification, or, in some cases, a Provisional Institutional Certification. Institutional certification forms and directions for completing them are available on the NIH GDS: https://osp.od.nih.gov/scientific-sharing/institutional-certifications/. This certification should be submitted as a "Genome Data Sharing Certification" in the eRA Commons Just-in-Time module.
  - **SBIR Funding Agreement:** 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 Just-in-Time module.
  - **STTR Funding Agreement:** 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/forms/manage_a_small_business_award.htm https://grants.nih.gov/grants/forms.htm#sbir. This should be submitted as an "Other Upload" in the eRA Commons Just-in-Time module.

- **Other Information Requested by the Awarding IC:** NIH IC's may also request additional Just-in-Time 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.

Applicants must submit their information at least 60 days before the proposed project period start date. However, you should contact the IC for specific guidance. We understand that obtaining IRB and/or IACUC approval may take more than two weeks. Therefore, you may submit these approvals at the earliest date they are available.

All of the information must be submitted electronically using the Just-In-Time feature of the eRA Commons found in the Commons **Status** section. Department and Division assignments may be changed or added by the organization's Signing Official (SO) via the eRA Commons found in the Commons Status section, under Re-Assign Award. For information on the Commons see: https://public.era.nih.gov/commons/index.jsp.

Timely submission of the requested information will enable NIH staff to expedite an award should an application be identified for funding. Institute staff will contact you if they have not received the requested information or if additional information is required. If you have any additional questions, please contact the assigned Grants Management Specialist. Contact information for these individuals can be found in Commons Status.

Please be reminded that this notice and request for information applies only to principal investigators with grant applications receiving an impact score of 40 or less (regardless of the IC's payline). For additional information on the Just-in-Time procedures, see section 2.5.1 of the NIH Grants Policy Statement.