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:

- <u>Authorizing Signature:</u> 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, excluding consultants. NOTE: Key personnel include all individuals responsible for the design and conduct of the study. NIH expects applicants and recipients to use the updated other support format as outlined in NOT-OD-21-073 for applications, Just-in-Time (JIT) Reports, and Research Performance Progress Reports (RPPRs) as of May 25, 2021.

As of January 25, 2022, NIH requires an electronic signature on all Other Support submissions.

NIMH is requesting that the Authorized Organization Representative provide confirmation that the signatures on the Other Support submission are electronic and meet the requirements outlined in NOT-OD-21-073. For example:

- Are all Other Support documents for principal investigators and other senior/key personnel electronically signed prior to its submission to NIH?
- Is the PDF flattened for all Other Support submissions after all signatures are obtained (see <u>Format Attachments</u> for more details)? Recipients and applicants may use the electronic signature software of their choice, and in alignment with their institutional practices. A typed name is not an electronic signature and is not acceptable.

 If Applicable: Are copies of any foreign contract/agreement included for any key personnel who are employed/have appointments at foreign institutions? You can review this helpful FAQ if you are unsure what to submit.

Applicants and recipients must maintain supporting documentation to reasonably authenticate that the appropriate individual signed the form. Recipients must and make the documentation available upon request in accordance with 45 CFR Part 75.364.

• Human Subjects Research

- Certification of IRB Approval: If Human Subjects are involved in the project, provide verification of IRB approval date (valid within 12 months) and any IRB-imposed changes. If necessary, please alert the Grants Management Specialist (GMS) identified below of the scheduled IRB review date.
- Human Subjects Education Certification: For grants involving Human Subjects, NIH requires certification that all key personnel have completed an educational program in the protection of human subjects. (See http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html). Training is available online at https://phrp.nihtraining.com/users/login.php.
- Tri-yearly Milestone Recruitment: NIMH has a policy to monitor the recruitment of participants in NIMH-sponsored clinical research studies proposing to enroll 150 or more subjects per study, and all clinical trials, regardless of size. Please refer to the automated Recruitment Milestone Reporting (RMR) system provided at: http://www.nimh.nih.gov/rmr. Contact your Program Officer if you have questions regarding this policy.
- <u>Data Sharing:</u> If a data sharing plan is applicable per the relevant NIH Guide Notice (NOT-MH-19-033 or NOT-OD-14-124) and was not included in the original application, please provide a plan meeting the guidelines outlined in the Notice.
- <u>Summary Statement Concerns:</u> If the Summary Statement for your application raised scientific concerns, those concerns will need to be addressed in writing with your Program Officer. Justification or explanation of any scientific concerns raised in your application's Summary Statement should be handled directly with your Program Officer. Depending on the nature of your application and its review, you may receive an additional request for scientific information directly from your program officer.

You are strongly encouraged to submit your Just-in-Time information using the Just-In-Time feature of the NIH Commons found in the Commons Status section. If you are not familiar with this feature, speak with your Sponsored Research office or visit: https://commons.era.nih.gov/commons/index. If you do submit JIT materials via the Commons, it will be extremely helpful if you let me know this by email, so that I retrieve the information in a timely manner. Alternatively, you may submit the information to me either by email. Delays in submitting this information will delay any eventual award.

Thank you for your prompt attention to this request. Please let me know if you have any questions.

Sincerely,

NAME
Grants Management Specialist
National Institute of XXXXXXXXX
Address
Contact information