Sponsor Pre-Funding "Just in Time" Requests
Standard Operating Procedure (SOP)

1. Purpose

This standard operating procedure should be used by PIs, Academic Departments and OSRA to respond to a JIT request.

The National Institutes of Health (NIH) request additional information - known industry wide as Just-In-Time (JIT) – following internal peer review and scoring of a grant application. Requested information can vary from grant to grant. At a minimum, the request will include updated other support pages for all key personnel, date of approval of IRB protocol, human subjects training certification, date of approval of IACUC protocol, and Genome Data Sharing Certification when applicable to the proposed project.

In all cases, JIT information requires review, approval, and submission through the Office of Sponsored Research Administration (OSRA) via eRA Commons.

2. Scope

This standard operating procedure (SOP) should be used by PIs, Academic Departments and OSRA when responding to a JIT request for an application being considered for funding.

3. Prerequisites

Grant application has been submitted and accepted by sponsor.

Sponsor is considering funding the grant application.

Sponsor provides a formal request for pre-funding JIT documents.

4. Definitions

Just in Time (JIT) – process by which sponsors request additional application information following final funding determination.

OSRA – Office of Sponsored Research Administration

WRG – Weill Research Gateway

AOR – Authorized Organization Representative

eRA Commons – Electronic Research Administration website used by NIH

5. Policy

Once an application has been reviewed and is being considered for funding, the sponsor will request additional information via the JIT process. The request typically comes from the Grants Management Specialist to the AOR with copy to the Principal Investigator. **Any JIT requests sent directly to the PI should be forwarded to OSRA immediately.**

Recipients must not submit documents via JIT hyperlinks that appear automatically in eRA Commons without receiving an e-mail from the Grants Management Specialist. PI and Department must thoroughly review JIT request and engage collaborators and other administrative offices, as necessary.

PI and Department will coordinate with the regulatory compliance offices, as needed, for proposals that involve human and/or animal subjects' research. Protocol approvals must be in place before work can begin. NIH rarely releases Notices of Award when protocol approvals are pending.

PI and Department will ensure all key personnel involved in human subjects' research complete the CITI Course in the Protection of Human Research Subjects. Copies of current training certification documentation from any external key personnel must also be obtained. WCMC faculty are required to complete the CITI Course every four years.

PI and Department must obtain and prepare up to date Current and Pending (Other) Support Common Forms (CPOS) for all key personnel in line with the current NIH guidelines. All CPOS must be prepared in SciENcv and certified. The proposal under consideration must be listed as pending and the sum of all pending and active effort disclosed must not exceed 12 calendar months. Key personnel with active and pending effort above this threshold must include language in the "overlap" section of the CPOS to address any necessary effort adjustments.

The NIH has indicated that it does not verify specific award dates when reviewing effort overlap. Because awards may be extended, the safest approach -- when total active and pending effort exceeds 12 calendar months -- is to include a statement in the overlap section committing to resolve any potential overlap if it arises, even if no overlap is anticipated at the time of submission.

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. If they are not in English, translated copies must be provided.

6. Procedure for JIT Submissions – NIH and DOD

OSRA will forward JIT request and detailed instructions to the PI and their Department support upon receipt of the request, noting any specified deadlines.

PI and Department will coordinate for the preparation and upload of all required JIT materials in accordance with the NIH policy and prepare the JIT in Commons. Once the JIT is finalized, the OSRA Grants Specialist should be notified for prompt review and submission. JIT documents must be finalized for review **4 business days** before the sponsor's deadline to ensure sufficient time for review and to address any necessary revisions that may require the documents to be recertified.

JITs for multi-component applications and applications with more than 10 key personnel (including PIs) must be routed to OSRA **7 business days** before the deadline given the volume of information to review, and the likelihood that additional time and coordination with external sites will be needed should the documents need revision.

OSRA will review to ensure that all requested documentation has been received and is in line with NIH and WCM policies. If changes are required, OSRA will email the Department with all comments.

Once all documents have been reviewed and approved, OSRA will submit the materials to NIH via the eRA Commons portal. Upon submission, OSRA will download the final JIT pdf and email it to the PI and Department. A copy will also be uploaded to the Proposal Tracking record in WRG, and the record status will be updated to "JIT submitted".

7. Procedure for JIT Submissions – Other Sponsors

Other federal, state, city, and private sponsors may request updated documents and information prior to issuing of an award.

If OSRA receives such a request, the office will forward to the PI and their Department support upon receipt, including any specified deadlines.

The PI and Department will coordinate the preparation of all required JIT materials in accordance with sponsor guidance and return the documents to the OSRA Grants Specialist for review. Once approved, the PI and Department may submit the materials to the sponsor, unless submission by OSRA is required by the sponsor.

All documents must be provided to the OSRA Specialist for review **at least two (2) business days** prior to the sponsor deadline. Because the volume and complexity of requests can vary significantly by sponsor, Departments should confirm with the Specialist if additional time is needed for reviews involving substantial documentation.

8. Process Metrics

OSRA will provide PI and Academic Department with JIT request message within 1 business days of sponsor request.

PI and Academic Departments will provide all JIT materials to OSRA within 4 business days of NIH's deadline for standard applications and 7 business days for multi-component applications or applications with more than 10 key personnel.

OSRA will review JIT documentation provided by the PI and Academic Department within 2 business days of receipt.

Timelines will be adjusted accordingly for urgent JIT requests from the NIH that have a turnaround time of less than 10 business days.

9. Special JIT Considerations

IRB Approval – WCM IRB approval must be acquired for human subject's research funded through WCM regardless of where the research is performed. The PI/Department must submit a new protocol application or amendment to list the funding source to an existing protocol as soon as they know a proposal is likely to be funded to ensure the IRB office is able to review and approve the proposed work prior to JIT submission. Researchers should schedule a consult with the IRB during the grant review period to address any answers and increase the likelihood for a timely review once submitted.

When WCM is prime and all human subjects work is occurring at a US subsite, acknowledgement from WCM's IRB must still be obtained. If using a Non-WCM/external IRB, an acknowledgement letter from WCM IRB is needed before the study may be initiated at WCM. Determinations for who will be the Reviewing IRB should be made by the Reliance Team and discussed during grant submission. Once approved by the Reviewing IRB a submission must be made within 2 weeks for WCM acknowledgement. Please review IRB's Single IRB Reliance website for additional guidance on this process.

IACUC Approval – WCM IACUC approval must be acquired for animal research funded through WCM regardless of where the research is performed. The PI/Department must submit a new protocol or protocol amendment as soon as they know a proposal is likely to be funded to ensure the IACUC office is able to review and approve the proposed work prior to JIT submission. If the animal work proposed will all occur at a collaborating subsite, the PI/Department must complete the IACUC Collaboration Form and submit to the IACUC office. WCM IACUC concurrence is required on all proposed animal subjects work at a collaborating site.

Genomic Data Sharing (GDS) Certifications –Investigators working with large-scale human genomic data are required to submit a GDS Institutional Certification to NIH before an award can be issued. If WCM's IRB Office has already approved the proposed study, then the Institutional Certification form must be completed and routed to the IRB office for concurrence. Once approved, the form can be routed to OSRA for AOR signature and submission. Confirmation of IRB concurrence must be provided along with the form. If the proposed study is pending IRB approval, then the Provisional Certification form must be completed and routed to OSRA for AOR signature.

Projects reviewed by WCM IRB and determined to be non-human subjects research do not require a GDS certification to be submitted, unless it is requested by the agency.

Research Security Training (RST) – All key personnel involved in federally sponsored programs are required to obtain RST certification prior to proposal submission. If new key personnel are added at the JIT stage, they must complete the training before OSRA can submit the JIT through Commons.