# 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. Automatic, system notifications are sent to applicants whose overall impact score is 30 or less, even though that threshold is usually higher than most NIH Institutes/Centers. NIH sends this email promptly after peer review.

Requested additional information can vary from grant to grant. At a minimum, the request will include updated other support pages for all key personnel, IRB protocol approval letter, human subjects training certification, and IACUC protocol approval letter, when applicable to the proposed project.

In all cases JIT information requires review, approval, and submission through the Office of Sponsored Research Administration (OSRA). PIs should not attempt to submit JIT directly to the NIH because NIH Grants Management Specialists are not allowed to accept JIT information without approval from the institution's Authorized Organization Representative. It is essential for Weill Cornell Medicine (WCM) to provide an appropriate and timely response to the request to ensure the highest probability of funding.

### 2. Scope

This standard operating procedure (SOP) should be used by PIs, Academic Departments and OSRA when responding to a JIT request from a sponsor, 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

**OSRA –** Office of Sponsored Research Administration

**WRG –** Weill Research Gateway

**AOR** – Authorized Organization Representative

**eRA Commons** – Electronic Research Administration website used by NIH

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

## *5. Policy*

Once an application has been reviewed and is within or near published paylines, the sponsor will request additional information via the JIT process. The request typically comes from the Grants Management Special to the AOR, who will review and forward to the Principal Investigator and their team. Any JIT requests sent directly to the PI should be forwarded to OSRA immediately.

NIH advises recipients to not respond to automated messages sent by eRA commons or to JIT hyperlinks that appear automatically in eRA Commons without receiving an e-mail from the Grants Management Specialist. However, if the PI's application is within a fundable range and an automated JIT request is received, the PI should begin the protocol/amendment process if their proposal involves human and/or animal subjects research, to help ensure protocol approvals are in place by the time a formal JIT request is received.

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 and will prepare a Human Subjects Education form for WCM personnel. 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 Other Support pages for all application key personnel in line with the current NIH Other Support guidelines. All Other Support pages must include the investigator's electronic e-certified signature in compliance with NIH requirements. The proposal under consideration must be listed as pending and the sum of effort committed under active awards and this pending award must not exceed 11.76 calendar months for WCM key personnel and 12 calendar months for external key personnel. Key personnel with active and pending effort above this threshold must briefly outline a plan to adjust the effort on their other support document, under the section "effort overlap" and work with OSRA to make any necessary effort reductions.

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.

PI and Department must prepare additional JIT documents as requested (i.e., revised budget, genomic data sharing certifications).

## 6. Procedure for JIT Submissions

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 obtain and prepare all JIT materials in accordance with the policy and forward to OSRA for review. All JIT documents must be submitted to OSRA four business days before the sponsor's deadline to ensure sufficient time for review and approval, and for any necessary revisions that may require the documents to be recertified by the respective faculty. JITs for Multi-component applications and applications with many key personnel should be routed to OSRA seven business days before the deadline given the volume of information to review.

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 PI and Department with all comments.

Once all documents have been reviewed and approved, OSRA will confirm approval to upload and 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.

## 7. Process Metrics

Unless otherwise instructed, JIT materials must be submitted to sponsor at least 60 days before the proposed project start date.

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 many 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.*

## 8. Special JIT Considerations

**IRB Approval** – WCM IRB approval must be acquired for human subjects research funded through WCM regardless of where the research is performed. The PI/Department must submit a new protocol application or add 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. If WCM is prime and all human subjects work is occurring at a US subsite, acknowledgement from WCM's IRB must still be obtained. If WCM is the prime and all human subjects work is occurring at a non-US site, the WCM IRN must still review and approve the work. 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.