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		Revision #	2.0
		Implementation Date:	02/01/2015
SOP Owner: Office of Sponsored Research Administration		**Last Reviewed/Update Date:**	03/01/2016
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Sponsor Pre-Funding "Just in Time" Requests
Standard Operating Procedure (SOP)

1.   Purpose

Many sponsors, including the National Institutes of Health (NIH) and Department of Defense (DOD), request additional information - known industry wide as Just-In-Time (JIT) – following internal peer review and scoring of a grant application. Requested additional information can vary from grant to grant and sponsor to sponsor. Examples include information on approval of the use of any human subjects (IRB approval), human subjects training certification, verification of approval of any proposed use of live vertebrate animals (IACUC approval), and updated other support pages for all key personnel.

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 a Sponsor. 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 should be used by PIs, Academic Departments and OSRA to respond to a JIT request.

3.   Prerequisites

- Grant application has been submitted and accepted by sponsor
- Sponsor is considering funding
- Sponsor provides a formal request for pre-funding JIT documents

4.   Related Documents

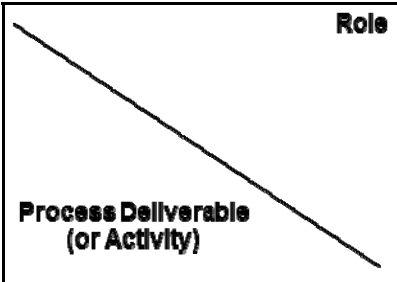Award Specific Conflicts Notification Standard Operating Procedure – SOP #JCTO0001

5. *Responsibilities*

- o **R**esponsibility = person or role responsible for ensuring that the item is completed
- o **A**ccountable = person or role responsible for actually doing or completing the item
- o **C**onsulted = person or role whose subject matter expertise is required in order to complete the item
- o **I**nformed = person or role that needs to be kept informed of the status of item completion

Responsibility Matrix

		Process Members				
Role **Process Deliverable (or Activity)**		**Principal Investigator**	**OSRA Specialist**	**Sponsor**	**Academic Department**	**OSRA Office**
Development/Maintenance of SOP		I	A		I	R/A
Submit formal JIT Request				R/A		I
Process the JIT inquiry and submit to departments			R/A			R
Prepare all JIT response information		R/A	C		A	
Review and approve JIT response		I/C	R/A		C	
Upload documents to eRA Commons (NIH)		R	I		A	I
Submit formal JIT Response		I	R/A	I	I	R/A
Manage process performance metrics		I	A			A

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6. Procedure

Step	Action	Method	Owner	Schedule
JIT Inquiry and Response procedures				
1.0	**Determine that additional information is required**		**Sponsor**	
2.0	**Submits a formal request to WCM**	**Email (OSRA listserv)**	**Sponsor**	
2.1	*For NIH a JIT link may automatically appear in the eRA Commons; however, only a formal request from the Grants Management Specialist constitutes an official notification*			
3.0	**Retrieve the inquiry**	**Manual**	**OSRA Specialist**	**Within 1 business day**
3.1	Determine the associated PI/Academic Department and OSRA staff assignment			
3.2	Reply to the listserv indicating assignment of request			
3.3	Review application ERF and Coeus record and determine if any personnel disclosed a potential financial conflict of interest related to the application; if a potential conflict was disclosed, notify the Conflicts Management Office *(see related SOP for more information #JCTO0001)*			

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4.0		**Review the JIT**	Manual	OSRA Specialist	**Within 2 business days of receipt**
	4.1	OSRA Specialist must review full request and identify JIT submission requirements			
	4.1.1	*While most requests are standard, requiring other support pages, IACUC and IRB approval (when applicable), in some instances sponsors will request additional information such as a revised budget, our F&A rate agreement, or other updated application components*			
5.0		**Prepare a request message for the PI and Academic Department**	Email	OSRA Specialist	**Within 2 business days of receipt**
	5.1	Email subject line should include grant number, Department, Sponsor, and "JIT- ACTION REQUIRED"			
	5.2	Email body should have a checkbox template for the Department to clearly understand what they need			
	5.2.1	*Email body template should also have a "response by" date*			
	5.3	Email should have settings set for return receipt upon recipient opening			
6.0		**PI and Academic Department review full request**		PI and Academic Department	**Within 2 business days of receipt from OSRA**
	6.1	PI and Department must thoroughly review JIT request and engage administrative offices as necessary			

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6.2	PI and Department will coordinate with the IRB Office to obtain project specific approval of human subjects research	310 form		If applicable, consult with IRB Office if human subjects are included in application – IRB@med.cornell.edu
6.2.1	*If a protocol has not been submitted to the IRB Office for review or a submitted protocol cannot be expedited, the PI must provide official attestation that no human subjects will be used until approval is provided*			
6.3	PI and Department will ensure all key personnel involved in human subjects research listed on the application (including external personnel) complete the CITI Course in the Protection of Human Research Subjects and will prepare a Human Subjects Education form			If applicable, consult with IRB Office if human subjects are included in application – IRB@med.cornell.edu
6.3.1	*WCMC faculty must complete the CITI Course every four years*			
6.3.2	*PI and Department will collect current training certification documentation from any external key personnel involved in human subjects research*			
6.4	PI and Department will coordinate with the IACUC Office to obtain project specific approval of animal use in research	Verification Letter		If applicable, consult with IACUC Office if animals are included in application – iacucadmin@med.cornell.edu

6.4.1	*If a protocol has not been submitted to the IACUCU Office for review or a submitted protocol cannot be expedited, the PI must provide official attestation that no animals will be used until approval is provided*			
6.5	PI and Department must prepare up to date Other Support pages for all application key personnel			If requested
6.5.1	*PI and Department are responsible for collecting other support pages from personnel in other departments and divisions in addition to any key personnel outside of WCM*			
6.5.2	*Should the pending application put any key personnel over 98% committed effort, personnel will need to note an effort management plan on their other support page and work with OSRA to make any necessary effort reductions (Complex matters will be referred to the Effort Management Office)*			
6.5.3	*Should PI add any additional key personnel at the time of JIT, up to date biosketches must accompany their other support page*			
6.6	PI and Department must prepare additional JIT documents as requested			If requested

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6.6.1	*Should a revised budget be requested, PI and Department must use current institutional base salaries in SAP (or a sponsor cap if applicable) and current fringe rates*			
7.0	**PI and Academic Department submits documentation to OSRA**	**Email**	**PI and Academic Department**	**As of the noted return by date**
7.1	Compile all of the necessary information and reply to the original JIT email from OSRA			
7.1.1	*Compile all other support pages into one PDF*			
7.1.2	*Check off on the body of the email that the information is complete and attached*			
7.1.3	*Reply to the email changing the action status on the subject from "JIT-ACTION REQUIRED" to "JIT-COMPLETED"*			
8.0	**OSRA review of JIT response**		**OSRA Specialist**	**Within two business days**
8.1	Review to ensure that all requested documentation has been received			
8.1.1	*If any documentation is missing, return the email noting omissions and change the status to "MISSING INFORMATION"*			
8.2	Obtain WCM authorized official signature on Human Subjects Education Form			

8.3	Review and approve other support pages			
8.3.1	*Log into Weill Business Gateway to Access BI Launch Pad and run an active effort report for all key personnel providing other support pages*			
8.3.2	*Compare each effort report to corresponding other support pages and note any discrepancies and/or issues*			
8.4	Work with PI and Department to adjust effort as needed, if necessary OSRA will work with PI and Department to request sponsor prior approval to reduce effort commitments			
9.0	**Confirm JIT Approval and Submit to Sponsor**	**Email**	**OSRA Specialist**	**Within 1 day of final approval**
9.1	For non-NIH requests email final approved JIT information to Sponsor, copying PI and Department			
9.2	Email the PI and Department with status change of "SUBMITTED" confirming submission is complete			
9.3	If NIH, email the PI and Department with status change of "APPROVED" and request upload into the eRA Commons			
10.0	**Upload JIT documents into the eRA Commons (NIH ONLY)**	**eRA Commons**	**PI or eRA Commons delegate**	**Within 1 day of approval**

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10.1	Log into eRA Commons and search on the Status page for the pending application for which JIT is requested – *see resources section below for instruction guides*			
10.2	Select the "JIT" link next to the relevant grant application record in the Action column			
10.3	On the JIT page, upload all other support pages as a single PDF document, listing the PI first and all additional key personnel in alphabetical order, in the "Other Support File" upload section			
10.4	If applicable, upload a revised budget in the "Budget Upload" section			
10.5	As applicable, upload a single combined PDF document including the IRB 310 form, a signed human subjects education form, IACUC verification letter, and any additional documents requested by the NIH in the JIT request in the "Other Upload" section			
10.6	If applicable, input the IRB approval date and select the Institutional Human Subjects Assurance Number FWA00000093 where requested on the JIT page			

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10.6.1	*The IRB approval date is the date the grant application received project specific approval as identified on the 310 form*			
10.6.2	*If IRB approval is pending leave section blank*			
10.7	If applicable, input the IACUC approval date where requested on the JIT page			
10.7.1	*The IACUC approval date is the date the grant application received project specific approval as identified on the verification letter*			
10.7.2	*If IACUC approval is pending leave section blank*			
10.8	Once all documents are uploaded, save JIT information in the eRA Commons and select "view" to generate a PDF preview of the full JIT submission and review for accuracy and legibility			
11.0	**Notify OSRA once JIT is ready for final OSRA review and submission (NIH ONLY)**	**Email**	**PI and Academic Department**	
11.1	Email OSRA with status change of "UPLOADED"			
12.0	**OSRA Specialist Final Review and Submission of JIT (NIH ONLY)**	**eRA Commons**		**Within 1 business day**
12.1	OSRA Specialist will log into the eRA Commons under the AOR account			

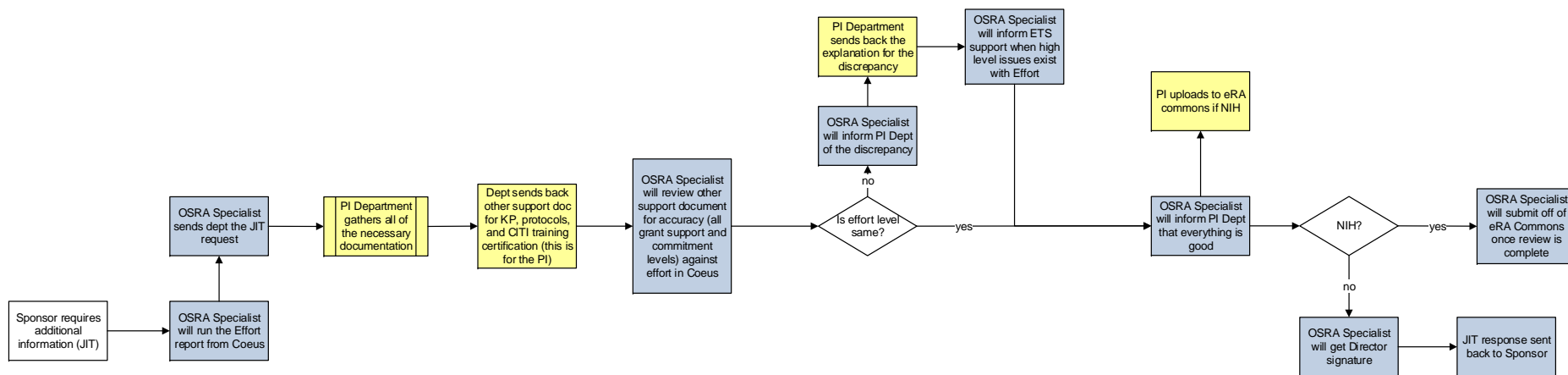| 12.2	OSRA Specialist will search for the grant application for which NIH has requested JIT on the Status page and select the "JIT" link next to the record in the Action column			
12.3	OSRA Specialist will select "view" on the JIT page and download a PDF version of the JIT submission			
12.4	OSRA Specialist will review the JIT document for accuracy, confirming all documents are final, legible, and meet the full request			
12.5	OSRA Specialist will select "submit" to send the JIT information to the NIH			
12.6	OSRA Specialist will forward the submission confirmation email from NIH to the PI and Academic Department			

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7.   Process Maps

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8. 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 2 business days of sponsor request
- PI and Academic Departments will provide a response to the OSRA JIT request message by the noted response date
- OSRA will review JIT documentation provided by the PI and Academic Department within 2 business days

9. References

NIH JIT guide: http://grants.nih.gov/grants/peer/jit.pdf

eRA Commons: https://public.era.nih.gov/commons/public/login

NIH Scoring System:
http://grants.nih.gov/grants/peer/guidelines_general/scoring_system_and_procedure.pdf

CITI Course www.citiprogram.org

OSRA forms page (human subjects education form):
http://osra.weill.cornell.edu/forms.html

10. Definitions

AOR – Authorized Organization Representative

eRA Commons – Electronic Research Administration website used by NIH

GMS- Grants Management Specialist from Sponsor

OSRA – Office of Sponsored Research Administration

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

11. Limitations/Exclusions

- Non-competing renewals and continuations are not subject to JIT inquiry and response