

Just In Time

Concepts & Review

Office of Sponsored Research & Sponsored Programs Office

August 10th, 2018

Kim Jones and Jim Kenny

Sponsored Programs Office

<https://www.med.unc.edu/spo/>

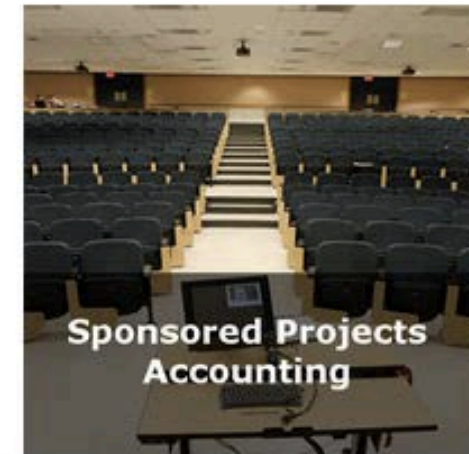
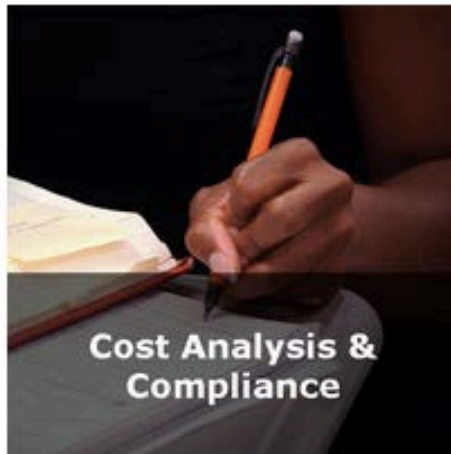
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Office of Sponsored Research

- ▶ ResAdminOSR@unc.edu
- ▶ <https://research.unc.edu/sponsored-research/about/business-units/>
 - ▶ Contact RESEARCH ADMINISTRATION

OSR BUSINESS UNITS



Receiving a Just In Time (JIT)

- ▶ JIT procedures are used for certain award mechanisms and programs to request information after proposal submittal and automatically sent for an impact score of 40 or less.
- ▶ The Funding Opportunity Announcement will indicate the use of JITs and specific guidance related to that application.
- ▶ The PI/PD will be notified, typically by email, that JIT information is needed. This request needs to be sent to your OSR or SPO contact.
- ▶ Upon receipt of the JIT request, the JIT email request will be uploaded to the attachments section in RAMSES. As appropriate, OSR/SPO will update the status in RAMSES to JIT Request Received. (For projects that include animal research, OACU will receive notification that the congruency review needs to be initiated once the status is updated.)
- ▶ JIT Information is subject to the same accuracy and validity requirements as all other submitted information.

Just-in-Time (JIT) Request Overview

- ▶ Certain elements of an application are to be submitted later in the application process, after the review when the application is under consideration for funding.
- ▶ Score of 40 or less = automatic notification from NIH
 - ▶ JIT hyperlink in eRA Commons action column is added
 - ▶ JIT Request email sent to PI and UNC (OSR / SPO)
 - ▶ This JIT Request is **NOT** a guarantee of funding or intent to fund
- ▶ Grants Management Specialist (GMS) involvement = funding likely
 - ▶ OSR / SPO will submit **your** response via eRA Commons or email
 - ▶ GMS may request additional and follow up information

Central Review Process

- ▶ Review of other support including confirming effort on project, project period, and annual direct costs.
- ▶ Confirm IACUC congruency review is completed and approved for the project.
- ▶ Confirm that IRB has been approved for the project.
- ▶ Confirm human subjects education certificate is included for all individuals involved in human subjects research on the project.
- ▶ Confirm all other information that may be requested is correct.

Possible Requested Information

- ▶ Other Support (active, pending, and an overlap statement)
- ▶ IRB Approval - Date
- ▶ IACUC Approval - Date
- ▶ Human Subjects Education
- ▶ Human Embryonic Stem Cells (hESC)
- ▶ Institutional Certification for Human Genomic Data Sharing
- ▶ SBIR Funding Agreement
- ▶ STTR Funding Agreement
- ▶ *Other Information Requested by Awarding IC*

JIT submitted in eRA Commons

- ▶ Department will prepare the information for the JIT response.
 - ▶ JIT hyperlink used to access JIT input page
 - ▶ *Sometimes* NIH Grants Management Specialist (GMS) requests additional follow up information via email
- ▶ OSR / SPO will review and will submit the JIT response.
- ▶ eRA Commons “Signing Official” (SO) role needed to submit JIT
- ▶ JIT can be requested and submitted multiple times

Application/Award ID	Grants.gov Tracking #	Proposal Title	PD/PI Name	Application Status	Budget Start Date	FFATA	Show All Prior Errors	Action
1R61AI142686-01	GRANT12593173	Innovative 3D Printed Intravaginal Rings: Reengineering Multipurpose Intravaginal Rings for Prevention of HIV and Unintended Pregnancy	BENHABBOUR, SOUMYA RAHIMA	Council review completed	12/01/2018	Yes	Show All Prior Errors	JIT Transmittal Sheet Human Subjects
1R01MH117758-01 (MPI)	GRANT12518426	Transgenerational Patterns of Altered Neural Processing Associated with PTSD in Rwanda	TELZER, EVA HAIMO	Council review completed	09/20/2018	Yes	Show All Prior Errors	JIT Transmittal Sheet Human Subjects
1R01AI141333-01 (MPI)	GRANT12551939	Micro-Particle Delivery of a Potent Intracellular Adjuvant for a Universal Flu Vaccine	TING, JENNY P	Council review completed	12/03/2018	Yes	Show All Prior Errors	JIT Transmittal Sheet
1R25GM129832-01	GRANT12522883	"Authentic Biomedical Maker Experiences: Leveraging makersp concepts	BOYETTE	Council review completed			All Prior Errors	JIT Transmittal Sheet Human Subjects
1U24NS107202-01	GRANT12486471	The UNC-Duke NeuroNEXT Collaboration	HOANG, DAVID YU-YIAO	Council review completed	09/01/2018	Yes	Show All Prior Errors	JIT Transmittal Sheet Human Subjects
1R01CA224539-01A1	GRANT12499134	Affective mechanisms of sustained physical activity for cancer prevention	FREDRICKSON, BARBARA LEE	Council review completed	09/01/2018	Yes	Show All Prior Errors	JIT Transmittal Sheet Human Subjects
1R01AI135049-01A1	GRANT12583748	Understanding alpha-gal red meat allergy	COMMINS, SCOTT PALMER	Council review completed	09/01/2018	Yes	Show All Prior Errors	JIT Transmittal Sheet Human Subjects
1R01AI143381-01	GRANT12621585	Regulation of HIV Latency by Host Cell Transcriptional and Epigenetic Networks	BROWNE, EDWARD P	Council review completed	09/01/2018	Yes	Show All Prior Errors	JIT Transmittal Sheet
1DP5OD026419-01	GRANT12484962	Tumor heterogeneity		Council review completed	09/01/2018	Yes	Show All Prior Errors	JIT Times Revised (1) Transmittal Sheet
1K08AI141689-01	GRANT12564434	Genomic analysis of African pfhrp2/3-deleted Plasmodium falciparum	PARR, JONATHAN BOYD	Council review completed	09/01/2018	Yes	Show All Prior Errors	JIT Transmittal Sheet Human Subjects
1R01AI135188-01A1	GRANT12583637	Positive Rewards: A Pay-for-Performance Strategy to Improve Syphilis Detection	SMITH, M KUMI	Council review completed	09/01/2018	Yes	Show All Prior Errors	JIT Transmittal Sheet Human Subjects
1R01AI143432-01	GRANT12622628	Polycomb Repressive Complexes as Key Regulators of HIV Latency and Targets for Latency Reversal	JAMES, LINDSEY INGERMAN	Council review completed	09/01/2018	Yes	Show All Prior Errors	JIT Transmittal Sheet Human Subjects
1RF1MH117053-01	GRANT12502696	Mechanisms of BOLD in		Council review completed	09/01/2018	Yes	Show All Prior Errors	JIT Times Revised (2) Transmittal Sheet

JIT Hyperlink found in the Action column

Note "Times Revised (1)"

Note "Times Revised (2)"

Application Information

Award Number: 1R01AI134042-01
PI Name: ANDERSON, R. R.
Proposal Title: The NEXT Great Thing

Please provide active and pending support for all key personnel. **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 awards, cooperative agreements, contracts, and/or institutional awards.** Training awards, prizes, or gifts do not need to be included.

To provide the NIH Other Support, follow the suggested format available at <http://grants1.nih.gov/grants/funding/phs398/othersupport.doc> and upload the document using the Import button provided below.

Files	File Name	Date Created	Status	Number of Submissions
Other Support File:			NOT UPLOADED	<input type="button" value="Import"/>
Budget Upload:			NOT UPLOADED	<input type="button" value="Import"/>
Other Upload:			NOT UPLOADED	<input type="button" value="Import"/>

IACUC Date in MM/DD/YYYY format: (MM/DD/YYYY) **Number of Submissions**

The institution must verify approval by the Institutional Animal Care and Use Committee (IACUC) of those components of the application related to the care and use of animals. By specifying a date and saving this form you confirm that IACUC approval of this application was awarded on that date. If the IACUC required any modifications in the care or use of animals as described in the Research Plan, those changes must be submitted to the appropriate NIH Awards Management office. The OLAW Assurance Number listed for your Institution is **A3410-01**.

IRB Date in MM/DD/YYYY format: (MM/DD/YYYY) **Number of Submissions**

Your Institution must certify to NIH that the research described in this application has received Institutional Review Board (IRB) approval by an IRB registered at OHRP under your Human Subjects Assurance Number. If the required IRB approval has been obtained, enter the IRB approval date. By specifying a Date and saving this form, you certify that you have IRB approval for this research. Please select the correct OHRP Human Subjects Assurance Number from the list of numbers associated with your Institution:

Human Subject Education. This document is required for key personnel (all individuals responsible for the design and conduct of the study) that are involved in human subject research. Please upload a PDF file that includes the following: the names of the key personnel who are responsible for the design and conduct of the study; the title of the education program completed by each named person plus a brief description of the program. Note: If research meeting the criteria for Exemption 4 is proposed, documentation is recommended, but not required.

Files	File Name	Date Created	Status	Number of Submissions
Human Subject Education:			NOT UPLOADED	<input type="button" value="Import"/>

Genome Data Sharing Certification. An Institutional Certification is expected prior to funding award for all research generating large-scale human genomic data under the NIH Genomic Data Sharing Policy (<http://gds.nih.gov/03policy2.html>). The Institutional Certification is a document from the authorized Institutional Signing Official of the institution submitting the data, and assures that the data submission and sharing is appropriate (see http://gds.nih.gov/Institutional_certifications.html for templates). If a final Institutional Certification is not available at Just-In-Time, you may submit a provisional Institutional Certification along with other Just-In-Time documents. A final version of the Institutional Certification may be uploaded in the "Additional Information" section of your award folder at a later date. You should keep Program Staff of the funding IC informed of the expected date of submission of the final Institutional Certification.

Files	File Name	Date Created	Status	Number of Submissions
Genome Data Sharing Certification:			NOT UPLOADED	<input type="button" value="Import"/>

Other Support

- ▶ Other Support requested at JIT should include Active, Pending grants, and an Overlap statement.

ANDERSON, R.R.

ACTIVE

2 R01 HL 00000-13 (Anderson) NIH/NHLBI Chloride and Sodium Transport in Airway Epithelial Cells	3/1/2017 – 2/28/2022 \$186,529	3.60 calendar
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The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

5 R01 HL 00000-07 (Baker) NIH/NHLBI Ion Transport in Lungs	4/1/2014 – 3/31/2018 \$122,717	7.8 calendar
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Remove award from "Active"
or adjust date range

The major goal of this project is to define the biochemistry of ion transport in normal and diseased lungs.

R000 (Anderson) Cystic Fibrosis Foundation Gene Transfer	9/1/2017 – 8/31/2020 \$43,123	1.20 calendar
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Effort for the three awards total more than 12CM. Something is not right, try again = 12.6 calendar

The major goal of this project is to define the biochemistry of ion transport in airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

PENDING

DCB 950000 (Anderson) National Science Foundation Liposome Membrane Composition and Function	12/1/2017 – 11/30/2019 \$82,163	2.40 calendar
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The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

OVERLAP

There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

Other Support

- ▶ Sufficient levels of effort are committed to the project
- ▶ There is no scientific, budgetary, or commitment overlap.
 - ▶ Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more application or awards, regardless of the funding sources
 - ▶ Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source.
 - ▶ Commitment overlap occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application.
 - ▶ Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the IC with the applicant and the PD/PI at the time of award.

Human Subjects Education

- ▶ To generate a certificate for the UNC research team, go to the Human Research Ethics Training Database.
- ▶ Non-UNC Personnel must provide you with their certificate.
- ▶ Link to training database can be found at:

https://acap.research.unc.edu/research_training/?event=administration.certificates.pgCertSelectTraining

Certificate Generator

This interface allows you to generate an official certificate for documenting training.

To build a certificate:

1. Select a Training Type from the drop down below.
2. To add a person to the certificate list, use the search box below and enter a person's information in the appropriate search field and click on the corresponding search button. Clicking on a person from the results list will add them to the certificate list.
3. Once all the people are selected, click on the "generate certificate" button to produce a PDF file that you may then save or print.

To start over, use the "clear certificate" button to remove all the names from the certificate list, or you can remove individual names by clicking the "REMOVE" link to the right of a name on the certificate list.

>> Select the Training Type to generate a certificate on:

Human Subjects Protection Training ▼

>> Select the Trainees for Human Subjects Protection Training

🏠 Search for an Investigator

First Name:

Last Name:

PID:

🏠 Certificate Trainees

Name	Email	Phone	PID	
Jim Kenny	jim.kenny@unc.edu	(919) 966-7760	714338400	REMOVE

Human Embryonic Stem Cells (hESCs):

- ▶ 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

- ▶ NIH information on Institutional Certifications

<https://osp.od.nih.gov/scientific-sharing/institutional-certifications/>

- ▶ UNC information on Institutional Certifications

- ▶ Office of Human Research Ethics

- ▶ John Roberts, Reliance Compliance Manager

- ▶ jtr@unc.edu (919) 966-2748

- ▶ <https://research.unc.edu/human-research-ethics/>

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.
- ▶ What "Other" information have you been asked for ?

Questions?

References

- ▶ https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5_completing_the_pre-award_process.htm#Just-in-
- ▶ <https://research.unc.edu/human-research-ethics/>
- ▶ <https://research.unc.edu/iacuc/>
- ▶ <https://research.unc.edu/sponsored-research/operating-standards/#300.10>
- ▶ https://era.nih.gov/applicants/submit_jit.cfm
- ▶ <https://osp.od.nih.gov/scientific-sharing/institutional-certifications/>
- ▶ https://grants.nih.gov/stem_cells/registry/current.htm