

**Weill Cornell
Medicine**

OSRA Updates

RAPID 2.12.2018



Account Creation Notification



**Weill Cornell
Medicine**

575 Lexington Ave, 9th Floor
New York, NY 10022

WBS 5250000101 has been successfully created via the WRG/SAP interface

Award Details

PI NAME:	Doe, John	Budget Period Valid From:	01/01/2018
Fund Center:	1000000000	Budget Period Valid To:	12/31/2018
Date of Creation:	01/01/2018	Project Period Valid From:	01/01/2018
WRG Record:	11111	Project Period Valid To:	12/31/2023
Award Type:	New		
Originating Sponsor	National Institute of Mental Health		
Sponsor	National Institute of Mental Health		
Award No	1 R01 CA12345-01		
Project Title	New Proposal Created		

SAP Information

SAP Grant Number	52500000		
SAP WBS Element Number	5250000101	Single Use-	YES

Access Details:

Please, note that access to the newly created WBS Element is provisioned based on the org structure under the fund center that is used. A GRC request will need to be submitted by the Department Administrator to add anyone not listed below.

Responsibility Type	CWID	Employee Name
PI Principal Investigator	JDOE1212	John Doe
AP Approver	MOM2029	Mohammad Mansour
DA View Access	MOM2029	Mohammad Mansour
BI BI Report Admin	MOM2029	Mohammad Mansour

Health & Human Services Salary Cap Increase

- Executive Level II Salary increase from \$187,000 to \$189,600
- Effective immediately all submissions to PHS agencies should employ the new cap
 - » Includes NIH, AHRQ, CDC and HRSA
- The Weill Research Gateway will automatically populate the cap where applicable

Health & Human Services Salary Cap Increase

Applications

All PHS/NIH grant applications will now employ this new cost cap for all personnel with a base salary at or over \$189,600

Awards

All PHS/NIH awards and subawards received with a start date on or after January 8th should employ this new cost cap for all personnel with a base salary at or over \$189,600

For awards with active periods both before and after January 8th (i.e. 11/1/17 – 10/31/2018) it is highly recommended that departments prorate salary, employing the \$187,000 cap prior to January 8th and \$189,600 cap after

SF424 Forms E

Faculty Town Hall

- Forms E Major Updates
- Human Subjects and Clinical Trials form walk through
- Available resources for investigators

Recording available on the OSRA Home Page

osra.weill.cornell.edu

SF424 Forms E

Faculty Town Hall

Major Items Covered:

- Identifying HS and CT research
- WRG Updates to Accommodate Forms E
- Exemptions and Advance Discussions
- Delayed Onset
- Study Records
- Recruitment and Retention Resources
- Data Safety and Monitoring
- sIRB

SF424 Forms E

Lessons Learned – 20 Days Later

- Grey Areas – NIH is responsive to inquiries
- sIRB – contact IRB and OSRA in advance
- NIH Adobe CT/HS form – strategize completion timeline
- Text boxes and allowable characters
- Copy and Paste – Note Pad
- Sections 4 and 5 – CT only
- Start Early/Faculty Education

Am I doing Human Subjects Research?

Infopath Questionnaire

OEP has developed a quick decision tool that should assist you with determining if your research involves human subjects, may be considered exempt from the Federal regulations or is not considered human subjects research. This tool should not be used as the sole determination of exemption. This tool should be used in conjunction with the [instructions](#) for preparing the Protection of Human Subjects section with your NIH application or proposal.

Start Now!

✓ Question One

Please check which best describes your research:

- For the purpose of this study, at some point there will be an intervention or interaction with subjects for the collection of specimens or biological material or data (including health or clinical data, surveys, focus groups or observation of behavior).
- This study will involve *only* the use of secondary analysis of biological material/tissue/specimens or data not collected specifically for this study.
- This study will involve materials/specimens or data from deceased individuals *only*.
- My study does not fit any of these categories.

Next

 <https://humansubjects.nih.gov/questionnaire> 

Is my submission a Clinical Trial?

Does your human subjects research study meet the NIH Definition of a clinical trial?

The NIH definition of a clinical trial is very broad. Some investigators conducting human subjects research may not be aware that NIH considers their study to be a clinical trial. Use this tool to help determine if your research meets the NIH definition of a clinical trial.

For application due dates on/after January 25, 2018, identifying whether your study is a clinical trial will be important for:

- picking the right NIH **funding opportunity**
- ensuring your application includes all the **information required for peer review**
- complying with the appropriate **policies and regulations**

1. Does the study involve human participants?

Unsure how to respond? Our [case studies](#) and [FAQs](#) may help you decide.



<https://grants.nih.gov/ct-decision/index.htm>

SF424 Forms E

Human Subjects & Clinical Trials Resources

Walkthrough Video

<https://www.youtube.com/watch?v=nz9NWFhYOG8>

SF424 Application Guide

<https://grants.nih.gov/grants/how-to-apply-application-guide.html>

NIH Annotated Forms E

[https://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_Genera
I_FORMS-E.pdf](https://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_Genera
I_FORMS-E.pdf)

NIH e-Protocol Template

<https://e-protocol.od.nih.gov/#/home>

NIH Definition of Clinical Trial Case Studies

<https://grants.nih.gov/policy/clinical-trials/case-studies.htm>

Weill Cornell Resources

IRB

http://researchintegrity.weill.cornell.edu/institutional_review_board/

DSMB

<http://researchintegrity.weill.cornell.edu/dsmb/>

Joint Clinical Trials Office Standardized Protocol Template

https://jcto.weill.cornell.edu/sites/default/files/downloads/iit_protocol_template_-_wcm_-_version_2.0.doc

Joint Clinical Trials Office Subject Recruitment and Activation

<https://jcto.weill.cornell.edu/investigators/study-activation-and-conduct/researchers-toolbox>

Clinical & Translational Science Center

http://weill.cornell.edu/ctsc/services_and_resources/

Weill Research Gateway Guides

<https://its.weill.cornell.edu/guides/wrg-sponsored-programs-guides>

Contact Information

Office of Sponsored Research Administration

<https://research.weill.cornell.edu/about-us/leadership-directory/osra-directory>

IRB/Office of Human Research Protections & DSMB

http://researchintegrity.weill.cornell.edu/ORI_staff/index.html

Joint Clinical Trials Office

<https://jcto.weill.cornell.edu/>

Study Recruitment

jctosrc@med.cornell.edu