Account Creation Notification

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**Weill Cornell Medicine**

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**WBS 8250000101 has been successfully created via the WRG/SAP interface**

**Award Details**

- **PI NAME:** Doe, John
- **Fund Center:** 1000000000
- **Date of Creation:** 01/01/2018
- **WRG Record:** 11111
- **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
- **Budget Period Valid From:** 01/01/2018
- **Budget Period Valid To:** 12/31/2018
- **Project Period Valid From:** 01/01/2018
- **Project Period Valid To:** 12/31/2023

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**SAP Information**

- **SAP Grant Number:** 52500000
- **SAP WBS Element Number:** 525000101
- **Single Use:** YES

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**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.

<table>
<thead>
<tr>
<th>Responsibility Type</th>
<th>CWID</th>
<th>Employee Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI Principal Investigator</td>
<td>JDOE1212</td>
<td>John Doe</td>
</tr>
<tr>
<td>AP Approver</td>
<td>MOM2029</td>
<td>Mohammad Mansour</td>
</tr>
<tr>
<td>DA View Access</td>
<td>MOM2029</td>
<td>Mohammad Mansour</td>
</tr>
<tr>
<td>BI BI Report Admin</td>
<td>MOM2029</td>
<td>Mohammad Mansour</td>
</tr>
</tbody>
</table>
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
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.

SF424 Forms E
Human Subjects & Clinical Trials Resources

Walkthrough Video
https://www.youtube.com/watch?v=nz9NWFhYOG8

SF424 Application Guide

NIH Annotated Forms E

NIH e-Protocol Template
https://e-protocol.od.nih.gov/#/home

NIH Definition of Clinical Trial Case Studies
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