

**Weill Cornell
Medicine**

OSRA Updates

RAPID 12.11.2017



**Weill Cornell
Medicine**

Weill Research Gateway Sponsored Programs



WRG-SP Phase II: Release 2.1

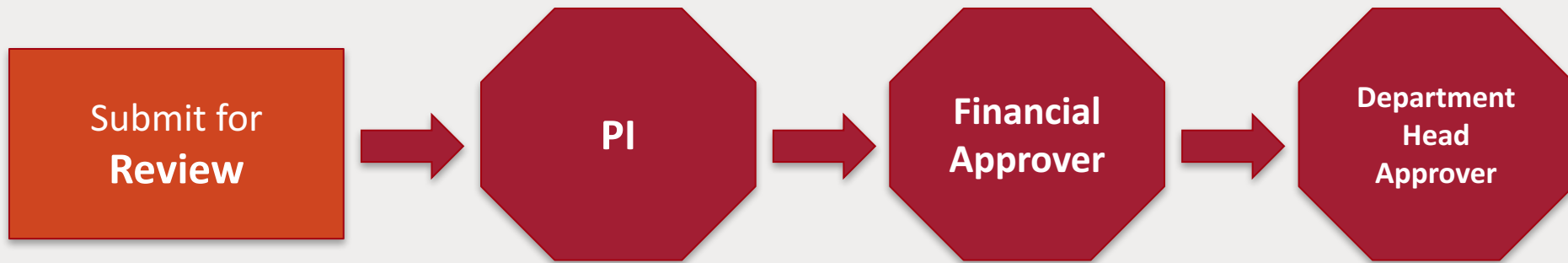
Major front facing enhancements:

- SF424 Forms E
- Single route for non-S2S Grants
- Reviewer Checklist
- Qatar UX
- EHS Interface
- Account Creation Notification



WRG-SP Phase II: Release 2.1

Single route for non-S2S Grants



- Eliminates dual routing for non-S2S proposals
- Maintains conditional notifications to collaborators and central offices

WRG-SP Phase II: Release 2.1

Reviewer Checklist

Reviewer Checklist

Instructions Complete

The Reviewer Checklist will be initiated by the Grants Specialist in OSRA once the proposal has been routed for review. OSRA will provide feedback in the OSRA Comments field. The department will respond in the Department Response fields as needed.

The checklist also lists the standard items OSRA is checking when reviewing a proposal. **The checklist is not all encompassing as every sponsor/program announcement is different. Be sure to continue to consult all applicable sponsor guidelines as they take precedence over this document.**

NIH/AHRQ Checklist

DOD Checklist

Other Sponsor Checklist

[Pre-Review Comments](#)
Reviewer Checklist Comments Table

Section	Subsection	OSRA Comments	Department Response

[Final Review Comments](#)

WRG-SP Phase II: Release 2.1

Reviewer Checklist

NIH/AHRQ Checklist

-PD/PI is eligible	<input type="text" value="Yes"/>	-Application package is correct	<input type="text"/>
-Application deadline is correct	<input type="text" value="See Comments"/>	-PHS Assignment Form included	<input type="text"/>
-Program is not a limited submission	<input type="text" value="Yes"/>	-Project dates follow sponsor guidelines	<input type="text"/>
-Related notices/institute specific guidelines reviewed	<input type="text" value="Yes"/>	-Institute participation confirmed	<input type="text"/>
-Cover letter includes approval to exceed \$500K DC	<input type="text" value="Not Applicable"/>	-Cover letter lists referees for F or Mentored K	<input type="text"/>
-Cover letter explains late submission	<input type="text"/>	-Cover letter confirms continuing submission	<input type="text"/>
-Project roles in line with sponsor guidelines	<input type="text"/>	-Biosketch is in the correct format	<input type="text"/>
-Other support is accurate	<input type="text"/>	-All costs are allowable per sponsor guideline	<input type="text"/>
-Budget falls within cap (including renewals)	<input type="text"/>	-Correct indirect cost rate is applied	<input type="text"/>
-MTDC/Indirect Cost Base is correct	<input type="text"/>	-All costs are justified in budget justification	<input type="text"/>
-Training grant costs follow NRSA & Institute guidelines	<input type="text"/>	-Facilities/Resources provided for all sites	<input type="text"/>
-All formatting guidelines have been followed	<input type="text"/>	-All page limitations have been followed	<input type="text"/>
-All required scientific attachments are included	<input type="text"/>	-System validations reviewed	<input type="text"/>
-Funding opportunity announcement accepts Clinical Trials	<input type="text"/>	-PHS Human Subjects & Clinical Trials Info Form completed as needed	<input type="text"/>

- Checklist organized by Sponsor Type
- Each item in checklist can be marked as Yes, See Comments, or Not applicable
- Comments table provides better format for more organized feedback

**Weill Cornell
Medicine**

SF424 Forms E



SF424 Forms E Program Announcements

Research (R) Announcements

Activity Code(s)	Title	Announcement Number	Issuing Organization	Release Date	Opening Date (SF424 Only) ?	Expiration Date
R01	NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)	PA-18-484	NIH	12/06/2017	01/05/2018	01/08/2021
R01	NIH Research Project Grant (Parent R01 Clinical Trial Required)	PA-18-345	NIH	11/03/2017	01/05/2018	01/08/2021
R01	NIH Research Project Grant (Parent R01)	PA-18-188	NIH	03/31/2018	03/03/2018	01/24/2018

Beginning January 25th, 2018 Forms E Packages are required

SF424 Forms E Program Announcements

Research (R) Announcements

Activity Code(s)	Title	Announcement Number	Issuing Organization	Release Date	Opening Date (SF424 Only) ?	Expiration Date
R01	NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)	PA-18-484		12/06/2017	01/05/2018	01/08/2021
R01	NIH Research Project Grant (Parent R01 Clinical Trial Required)	PA-18-345		11/03/2017	01/05/2018	01/08/2021
R01	NIH Research Project Grant (Parent R01)	PA-16-160	NIH	03/31/2016	05/05/2016	01/24/2018

Beginning January 25th, 2018 Forms E Packages are required

SF424 Forms E

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

Major Changes

- Removal of Human Subjects Sections from the Research Plan and other form pages
 - Protections
 - Data Safety Monitoring Plan
 - Inclusion/Enrollment
- Introduction of Human Subjects & Clinical Trials form

https://grants.nih.gov/grants/funding/Grant_Application_Form_Update-FORMS-E.pdf

SF424 Forms E

Weill Research Gateway

New Proposal Questionnaire Back

Step 0: *Confirm you intend for the PI of this proposal to be* Choi, Augustine M. K. [Change](#)

Step 1: *"New" or "Copy From Existing"?* [Create a New Proposal](#)

Step 1: *Continued* S2S [Search](#)

1 Records Found

Opportunity Number	CFDA Number	Competition ID	Competition Title	S2S	Open Date	Agency	Title	
PA-18-345 Select		FORMS-E	Use for due dates on or after January 25, 2018		05-Jan-2018	National Institutes of Health	NIH Research Project Grant (Parent R01 Clinical Trial Required)	SPIN

SF424 Forms E

Weill Research Gateway

Setup Questions

Universal
Questionnaire -
Grant

SF424 (R&R)

Other Project Info

Budget

Performance Sites

PHS 398 Research
Plan

Personnel

Pre-Review Route

Reviewer Checklist

PHS 398 Cover
Page Supplement


Human Subjects/CT

Finalize

 Support

 Show Help

SF424 (R&R)

Completed 

1. TYPE OF SUBMISSION: <input type="radio"/> Pre-application <input checked="" type="radio"/> Application <input type="radio"/> Changed/Corrected Application		2. DATE SUBMITTED <input type="text"/>	Application Identifier <input type="text" value="182181"/>																																								
		3. DATE RECEIVED BY STATE <input type="text"/>	State Application Identifier <input type="text"/>																																								
		4 a. Federal Identifier <input type="text"/>	b. Agency Routing Identifier <input type="text"/>																																								
		c. Previous Grants.gov Tracking ID <input type="text"/>																																									
5. APPLICANT INFORMATION Organizational DUNS: 0602175020000 Legal Name: Joan & Sanford I. Weill Medical College of Cornell University Department: <input type="text" value="WCM Executive Leadership"/> Division: <input type="text" value="None"/> Address (Street, city, state, zip/postal code) <input type="text" value="Weill Cornell Medical College"/> <input type="text" value="1300 York Avenue"/> <input type="text" value="New York NY 10085-4805"/> <input type="text" value="U.S.A."/> Province: <input type="text"/>																																											
Person to be contacted on matters involving this application <table border="0"> <tr> <td>Prefix:</td> <td>First Name:</td> <td>Middle Name:</td> <td>Last Name:</td> <td>Suffix:</td> </tr> <tr> <td><input type="text"/></td> <td><input type="text" value="Aleta"/></td> <td><input type="text" value="R."/></td> <td><input type="text" value="Gunsul"/></td> <td><input type="text"/></td> </tr> <tr> <td>Position/Title:</td> <td>Street1:</td> <td>Street2:</td> <td>City:</td> <td>County/Parish:</td> </tr> <tr> <td><input type="text" value="Director, Research Business Operations"/></td> <td><input type="text" value="1300 York Avenue"/></td> <td><input type="text" value="Box 89"/></td> <td><input type="text" value="New York"/></td> <td><input type="text" value="New York"/></td> </tr> <tr> <td>State:</td> <td>Province:</td> <td>Country:</td> <td colspan="2">Zip/Postal Code:</td> </tr> <tr> <td><input type="text" value="NY"/></td> <td><input type="text"/></td> <td><input type="text" value="U.S.A."/></td> <td colspan="2"><input type="text" value="10085-4805"/></td> </tr> <tr> <td colspan="2">Phone Number:</td> <td>Fax Number:</td> <td colspan="2">Email:</td> </tr> <tr> <td colspan="2"><input type="text" value="+1 846 982 8290"/></td> <td><input type="text"/></td> <td colspan="2"><input type="text" value="grantsandcontracts@med.cornell.edu"/></td> </tr> </table>				Prefix:	First Name:	Middle Name:	Last Name:	Suffix:	<input type="text"/>	<input type="text" value="Aleta"/>	<input type="text" value="R."/>	<input type="text" value="Gunsul"/>	<input type="text"/>	Position/Title:	Street1:	Street2:	City:	County/Parish:	<input type="text" value="Director, Research Business Operations"/>	<input type="text" value="1300 York Avenue"/>	<input type="text" value="Box 89"/>	<input type="text" value="New York"/>	<input type="text" value="New York"/>	State:	Province:	Country:	Zip/Postal Code:		<input type="text" value="NY"/>	<input type="text"/>	<input type="text" value="U.S.A."/>	<input type="text" value="10085-4805"/>		Phone Number:		Fax Number:	Email:		<input type="text" value="+1 846 982 8290"/>		<input type="text"/>	<input type="text" value="grantsandcontracts@med.cornell.edu"/>	
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6. EMPLOYER IDENTIFICATION NUMBER (EIN): <input type="text" value="13-1623978"/>		7. TYPE OF APPLICANT: <input type="radio"/> Private Institution of Higher Education																																									
8. TYPE OF APPLICATION: <input checked="" type="radio"/> New <input type="radio"/> Resubmission <input type="radio"/> Renewal		Other (Specify): <input type="text" value="Small Business Organization Type"/>																																									

SF424 Forms E

Weill Research Gateway

Setup Questions

Universal
Questionnaire -
Grant

SF424 (R&R)

Other Project Info

Budget

Performance Sites

PHS 398 Research
Plan

Personnel

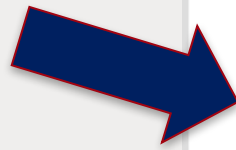
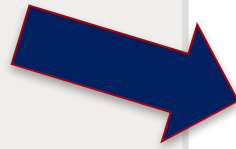
Pre-Review Route

Reviewer Checklist

PHS 398 Cover
Page Supplement

Human Subjects/CT

Finalize



SF424 Forms E

Weill Research Gateway

PHS 398 Research Plan Show Completed

[View Burden Statement](#)

Introduction

1. Introduction to Application
(for Resubmission and Revision applications)

Research Plan Section

2. Specific Aims Upload

3. *Research Strategy Upload

4. Progress Report Publication List Upload

Other Research Plan Section

5. Vertebrate Animals Upload

6. Select Agent Research Upload

7. Multiple PD/PI Leadership Plan Upload

8. Consortium/
Contractual Arrangements Upload

9. Letters of Support Upload

10. Resource Sharing Plan(s) Upload

11. Authentication of Key Biological and/or Chemical Resources Upload

Appendix

12. Appendix

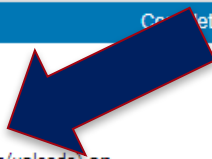
[Add New Document](#)

SF424 Forms E

Weill Research Gateway

Human Subjects/CT Completed

OMB Number: 0925-000
Expiration Date: 03/31/2020



* All mandatory data elements (fields/uploads) on **all screens** must be addressed in order to submit for NIH pre-submission validation.

Are Human Subjects Involved? Yes No (set on Setup Questions tab)

Is the Project Exempt from Federal regulations? Yes No (set on Other Project Information tab)

Exemption number:

1 2 3 4 5 6 7 8
(set on Other Project Information tab)

If No to Human Subjects

Does the proposed research involve human specimens and/or data? Yes No

If Yes, provide an explanation of why the application does not involve human subjects research.

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form

If Yes to Human Subjects

Add an appropriate record for each proposed Human Subject Study

"Add New Study"

Or

"Add New Delayed Onset Study"


Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies.

Attach file to **Other Requested Information** per funding announcement and/or agency-specific instructions.

SF424 Forms E

Human Subjects & Clinical Trials

Study Record(s) [Hide]			
Study Title			
Test title			Delete
Enter Study Title (each study title must be unique)		Add New Study	

Delayed Onset Study(ies) [Hide]			
			
Study Title	Anticipated Clinical Trial?	Justification	
		Original	PDF
No records to display.			
Enter Study Title (each study title must be unique)		Add New Delayed Onset Study	

SF424 Forms E

Human Subjects & Clinical Trials

Setup Questions

- Universal Questionnaire - Grant
- SF424 (R&R)
- Other Project Info
- Budget
- Performance Sites
- PHS 398 Research Plan
- Personnel
- Pre-Review Route
- Reviewer Checklist
- PHS 398 Cover Page Supplement
- Human Subjects/CT
 - Test title ←
 - Finalize

[Support](#)

[Show Help](#)

Study Record: PHS Human Subjects and Clinical Trials Information Completed

*** Always required field**

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)

1.2. * Is this Study Exempt from Federal Regulations? Yes No

1.3. Exemption Number 1 2 3 4 5 6 7 8

1.4. * Clinical Trial Questionnaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants? Yes No

1.4.b. Are the participants prospectively assigned to an intervention? Yes No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? Yes No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? Yes No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

2.2. Eligibility Criteria

2.3. Age Limits Minimum Age Maximum Age

2.4. Inclusion of Women, Minorities, and Children

SF424 Forms E

Human Subjects & Clinical Trials

Study Record Form

Section	Information	Example	HS Required?	CT Required?
1	Basic Information	Study Exemptions; Human Participants	Yes	Yes
2	Study Population	Study Focus; Inclusion Enrollment	Yes	Yes
3	Protection and Monitoring Plans	Protection of Subjects; DSMB	Partial	Yes
4	Protocol Synopsis	Narrative, Intervention Type	No	Yes
5	Other CT Attachments	Upload Link	No	Yes

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>

SF424 Forms E

Human Subjects & Clinical Trials Resources

Forms E

Faculty and Research Administrator Town Hall

Tuesday January 16th

5:15pm – 6:00pm

1300 York Avenue – Room A250