

**Weill Cornell
Medicine**

OSRA Updates

RAPID September 11th 2017



**Weill Cornell
Medicine**

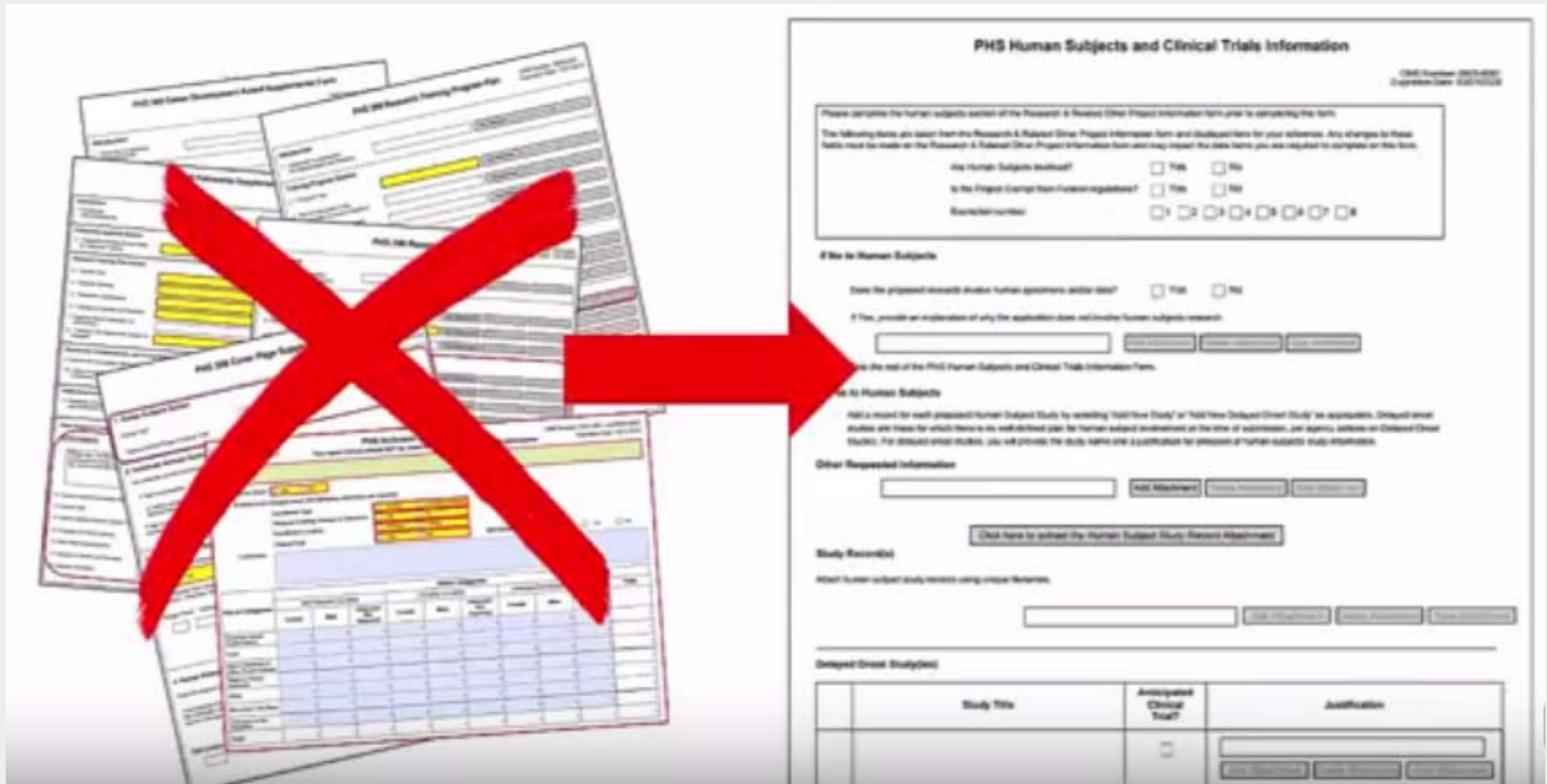
NIH Forms E

COMING SOON



FORMS E – What is Changing?

Human subjects, inclusion enrollment and clinical trials information will be collected on a single **PHS Human Subjects and Clinical Trials Information** form



PHS Human Subjects and Clinical Trials Information

OMB Number: 0935-0047
Update Date: 03/15/2018

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.
The following items are taken from the Research & Related Other Project Information form and should be used for your reference. Any changes to these items must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? ☐ Yes ☐ No
Is the Project Exempt from Federal Regulations? ☐ Yes ☐ No
Exemption Number: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

If Not Human Subjects

Does the proposed research involve human subjects or their data? ☐ Yes ☐ No
If Yes, provide an explanation of why the application does not involve human subjects research.

This is the end of the PHS Human Subjects and Clinical Trials Information Form.

If Human Subjects

Add a record for each proposed human subject study by selecting "Add New Study" or "Add New Subject/Event Study" as appropriate. Only add new studies and events for which there is no well-defined plan for human subject involvement at the time of submission per agency policies on Orphan Drug Studies. For Orphan Drug Studies, you will provide the study name and a justification for provision of human subjects study information.

Other Requested Information

Study Record(s)
Attach human subject study records using unique identifiers.

Orphan Drug Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
		☐	 Add Attachment Delete Attachment Clear Attachment

FORMS E – What is Changing?

The **Research & Related Other Project Information** form will populate the top section of the **PHS Human Subjects and Clinical Trials Information** form

RESEARCH & RELATED Other Project Information OMB Number: 4040-0001
Expiration Date: 10/31/2019

1. Are Human Subjects Involved? ☐ Yes ☒ No

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

If yes, check appropriate exemption number. ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

If no, is the IRB review Pending? ☐ Yes ☐ No

IRB Approval Date: _____

Human Subject Assurance _____

2. Are Vertebrate Animals Used?

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date: _____

Animal Welfare Assurance _____

3. Is proprietary/privileged information involved?

4.a. Does this Project Have an Actual or Potential Environmental Impact Statement?

4.b. If yes, please explain: _____

4.c. If this project has an actual or potential environmental impact statement

4.d. If yes, please explain: _____

5. Is the research performance site outside the United States?

5.a. If yes, please explain: _____

6. Does this project involve activities in foreign countries?

6.a. If yes, identify countries: _____

6.b. Optional Explanation: _____

7. Project Summary/Abstract _____

8. Project Narrative _____

9. Bibliography & References Cited _____

10. Facilities & Other Resources _____

11. Equipment _____

PHS Human Subjects and Clinical Trials Information OMB Number: 0925-0001
Expiration Date: 03/31/2020

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? ☐ Yes ☒ No

Is the Project Exempt from Federal regulations? ☐ Yes ☒ No

Exemption number: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

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.

[Add Attachment](#) [Delete Attachment](#) [View Attachment](#)

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

If Yes to Human Subjects

FORMS E – Effective Date & Other Changes

Effective for application due dates on **January 25, 2018**

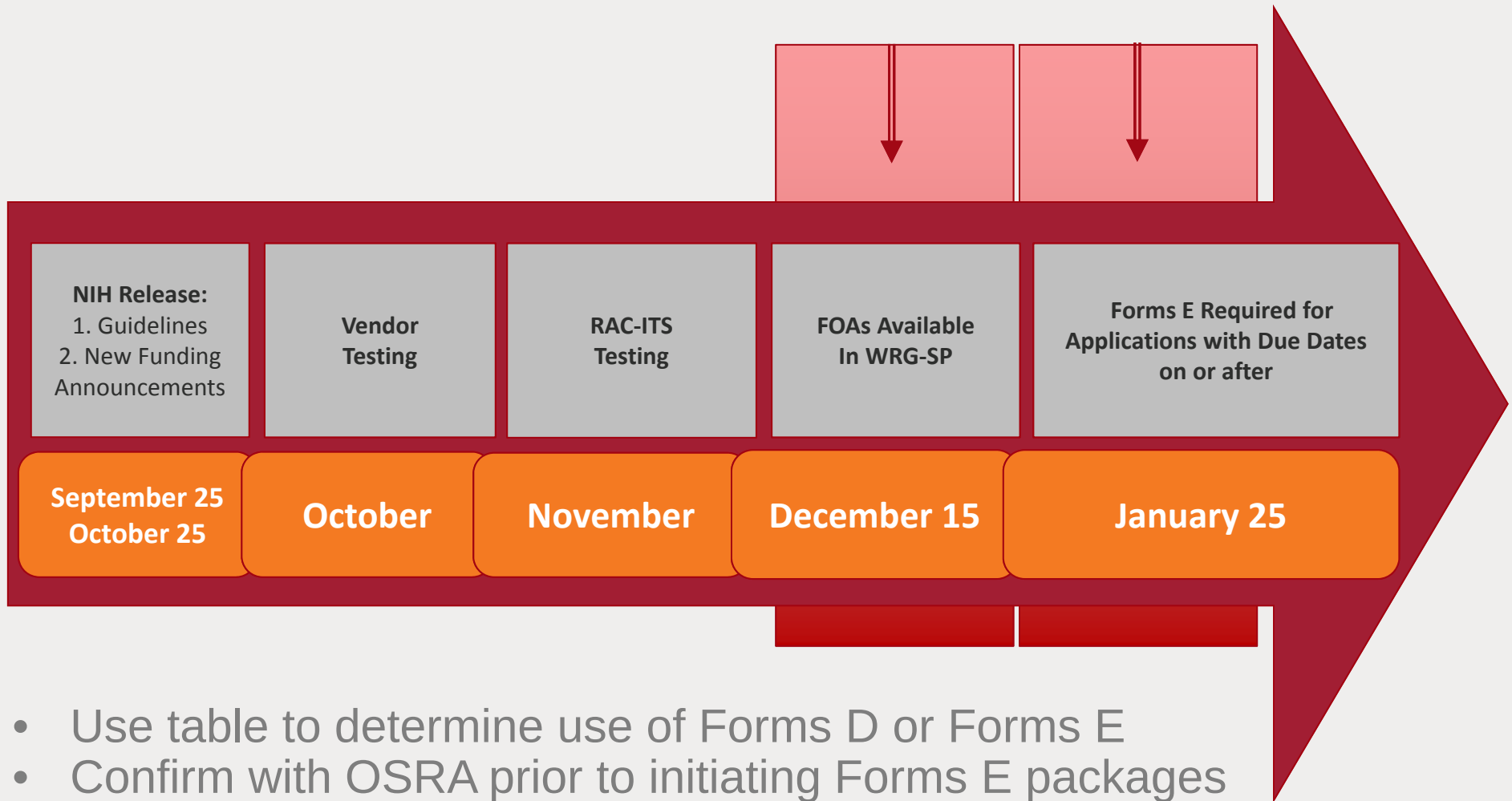
- Clinical trial applications must be submitted to specifically designated FOAs
 - **Allowability of clinical trials will be noted in *Section II - Award Information***
 - **New FOAs will specify allowability of clinical trials in FOA title**
- FOAs that accept clinical trials will incorporate specific review criteria to ensure reviewers appropriately consider clinical trial-related information
- Clinical trial data collection will be expanded to ensure appropriate level of information for review and to improve oversight

NIH will publish new application guidelines on September 25th

FORMS D vs. FORMS E:

If your due date is....	You must use.....
On or before January 24, 2018, including: • Applications submitted for due dates on or before January 24, 2018 • Applications submitted under NIH Late Policy 2-week window of consideration for intended due dates on or before January 24, 2018 • Applications submitted by February 7, 2018 under NIH Continuous Submission Policy for January 7, 2018 AIDS intended due date	FORMS-D application package
On or after January 25, 2018, including: • Applications submitted for due dates on or after January 25, 2018 • All application types (New, Resubmission, Renewal, Revision) • Applications submitted early for intended due dates on or after January 25, 2018	FORMS-E application package

FORMS E - Timeline



- Use table to determine use of Forms D or Forms E
- Confirm with OSRA prior to initiating Forms E packages
 - **Avoid using Forms E packages prematurely or erroneously**
- Use FOAs specifically designated for Clinical Trials

FORMS E – Benefits

The new PHS Human Subjects and Clinical Trials Information form

- ✓ Consolidates human subjects information currently scattered across multiple agency forms
- ✓ Uses structured data fields to lead user through key requirements
- ✓ Aligns with ClinicalTrials.gov and positions the NIH for future data exchange between systems
- ✓ Provides a consistent format for reviewers and staff to quickly find key information
- ✓ Expands clinical trial data collection to provide the appropriate level of information to improve oversight

FORMS E – A Video Walk-through

A 9 minute walk-through of the **PHS Human Subjects and Clinical Trials Information Form** is available - the URL is included on our resources slide

A Walk-through of the PHS Human Subjects and Clinical Trials Information Form

A screenshot of the PHS Human Subjects and Clinical Trials Information Form. The form is titled "PHS Human Subjects and Clinical Trials Information" and includes a version number "PHS Form 398-001" and a date "October 2017". The form contains several sections with checkboxes and text boxes. The first section is titled "Please complete the Human Subjects portion of the Research & Related Other Topics Information form prior to completing this form." and includes checkboxes for "Are Human Subjects involved?", "Is the Project Exempt from Federal regulations?", and "Consent number". The second section is titled "If Yes to Human Subjects" and includes checkboxes for "Does the proposed research involve human participants under 18?" and "If Yes, provide an explanation of why the application does not involve human subjects research." The third section is titled "If Yes to Human Subjects" and includes a text box for "Study description" and a button for "Click here to access the Human Subject Study Record Worksheet." The fourth section is titled "Other Research Information" and includes a text box for "Other Research Information" and a button for "Click here to access the Human Subject Study Record Worksheet." The fifth section is titled "Study description" and includes a text box for "Study description" and a button for "Click here to access the Human Subject Study Record Worksheet." The sixth section is titled "Research Clinical Worksheet" and includes a table with columns for "Study Title", "Anticipated Research Topic", and "Justification".

July 2017

NIH Updates – Clinical Trial Applications

Resources

NIH Clinical Trials Resource Page

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

NIH Human Subjects & Clinical Trials Form Overview

https://www.youtube.com/watch?v=nz9NWFhYOG8&list=PLOEUwSnjvqBJeHcb4yai7_fDnFZFP_EmQK&index=1

Forms E Major Changes

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

Annotated Form Set for NIH Grant Applications

https://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_General_FORMS-E.pdf

Related Announcements

[NOT-OD-17-062](#)

[NOT-OD-17-043](#)

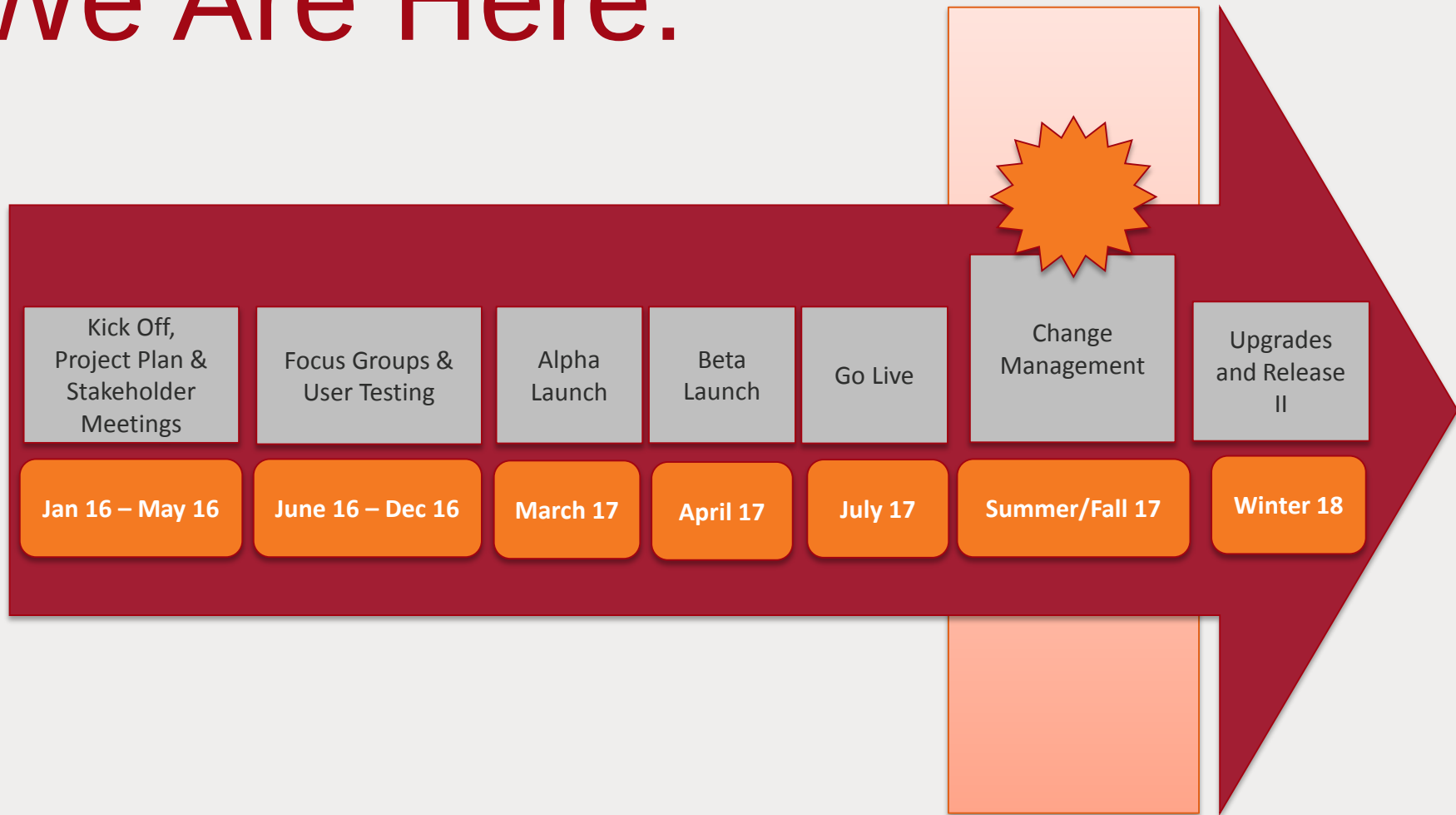
[NOT-OD-16-147](#)

**Weill Cornell
Medicine**

Weill Research Gateway Sponsored Programs



We Are Here:



Documented Issues

Budget

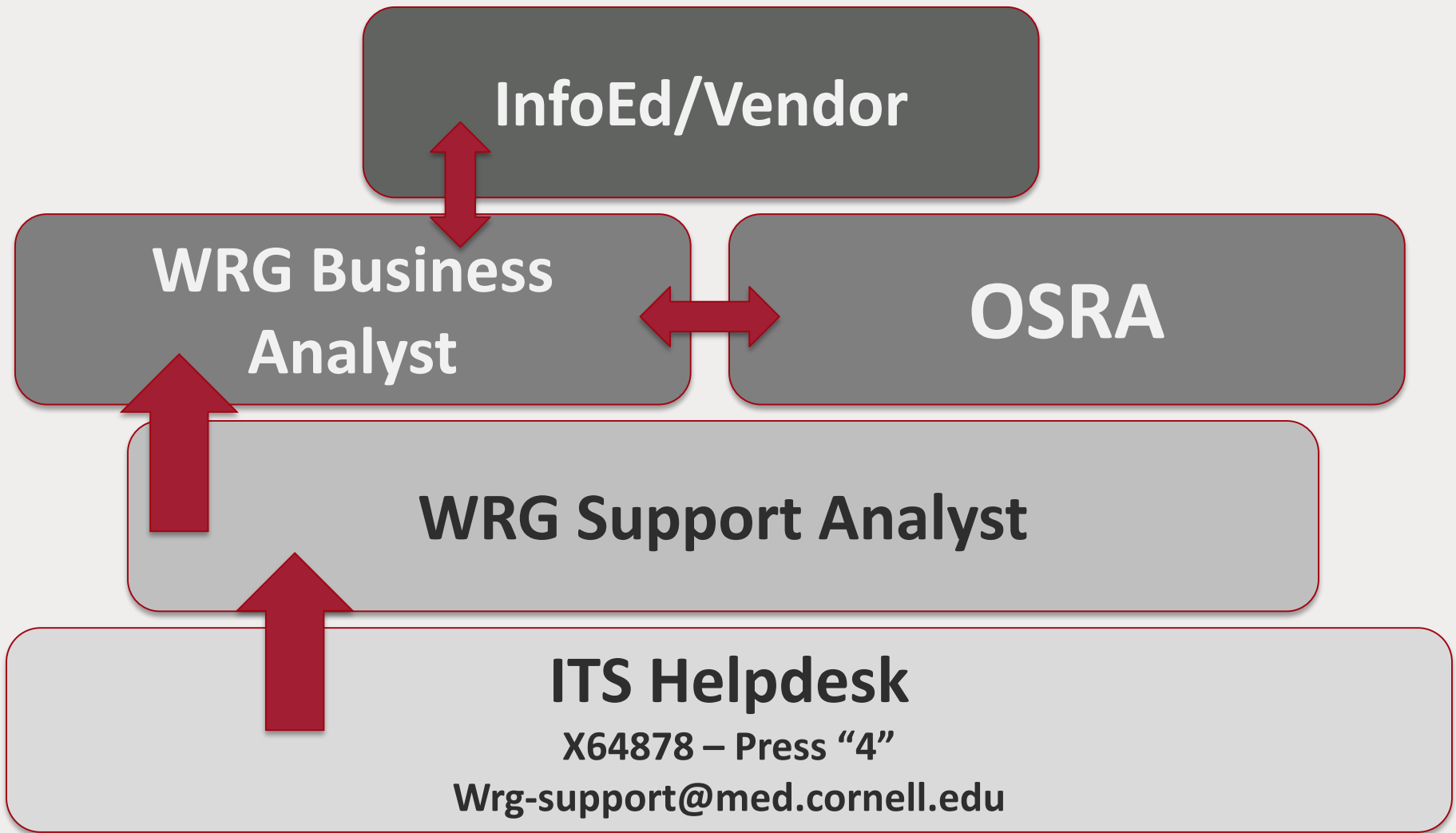
Notifications & Routing

Training Materials

S2S Integration

User Experience

Support



WRG-SP Bulletin Board

WRG-SP Wiki Page

Known Issue

- Resolution Progress
- Alternative Solution
- Tips & Tricks
- Community Solutions

Known Issue

- Resolution Progress
- Alternative Solution
- Tips & Tricks
- Community Solutions

Sponsored Programs

Phase II

High-Level Project Plans



We Are Here

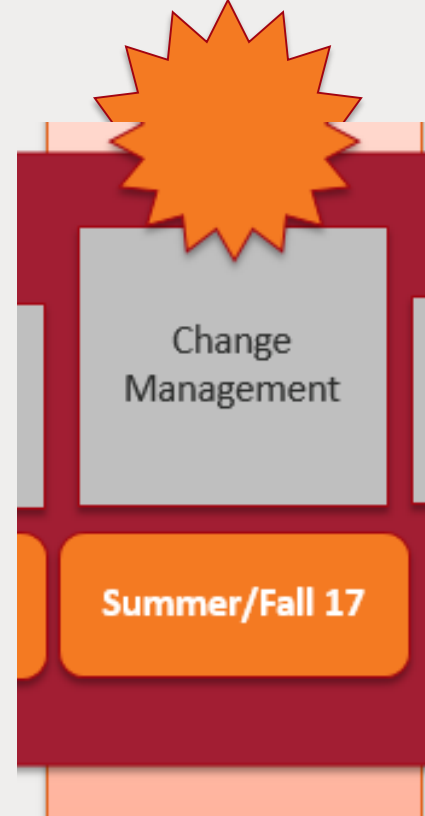


Release I (Current phase)

- Integration and Fine-tuning
- Identify, track and resolve known issues
- Collect user input for Release II
- Complete training materials

Release II (Winter)

- Single Route for non-S2S Grants
- EHS & Qatar
- Proposal Tracking
- Reporting
- User Requests



WRG-SP Phase II: Release 2.1

