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OSRA Updates

RAPID September 11th 2017

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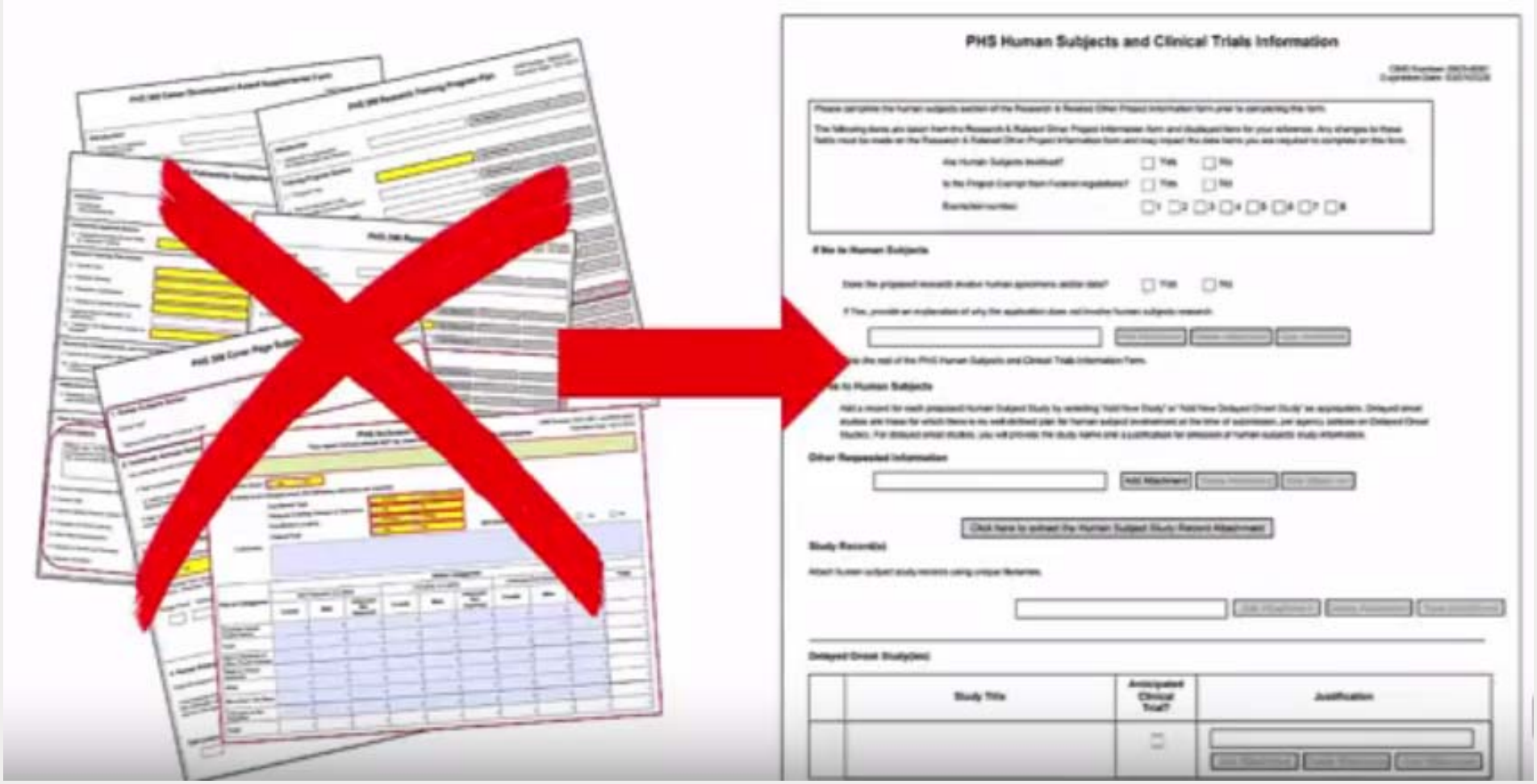
NIH Forms E

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**



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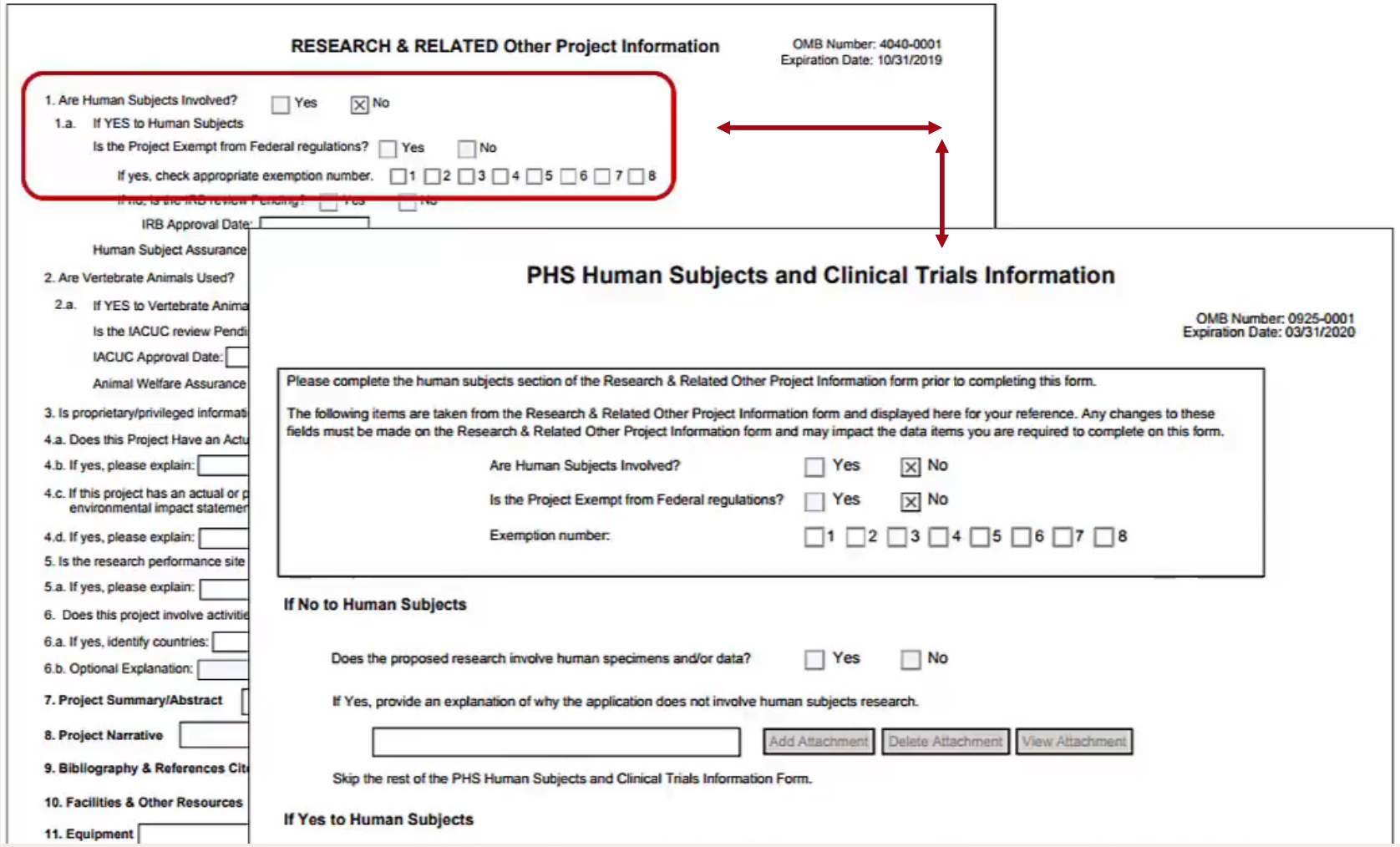
FORMS E – What is Changing?

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
IRB Approval Date:
Human Subject Assurance
2. Are Vertebrate Animals Used?
2.a. If YES to Vertebrate Anima
Is the IACUC review Pendi
IACUC Approval Date:
Animal Welfare Assurance
3. Is proprietary/privileged informati
4.a. Does this Project Have an Actu
4.b. If yes, please explain:
4.c. If this project has an actual or p
environmental impact statemer
4.d. If yes, please explain:
5. Is the research performance site
5.a. If yes, please explain:
6. Does this project involve activitie
6.a. If yes, identify countries:
6.b. Optional Explanation:
7. Project Summary/Abstract
8. Project Narrative
9. Bibliography & References Cit
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**

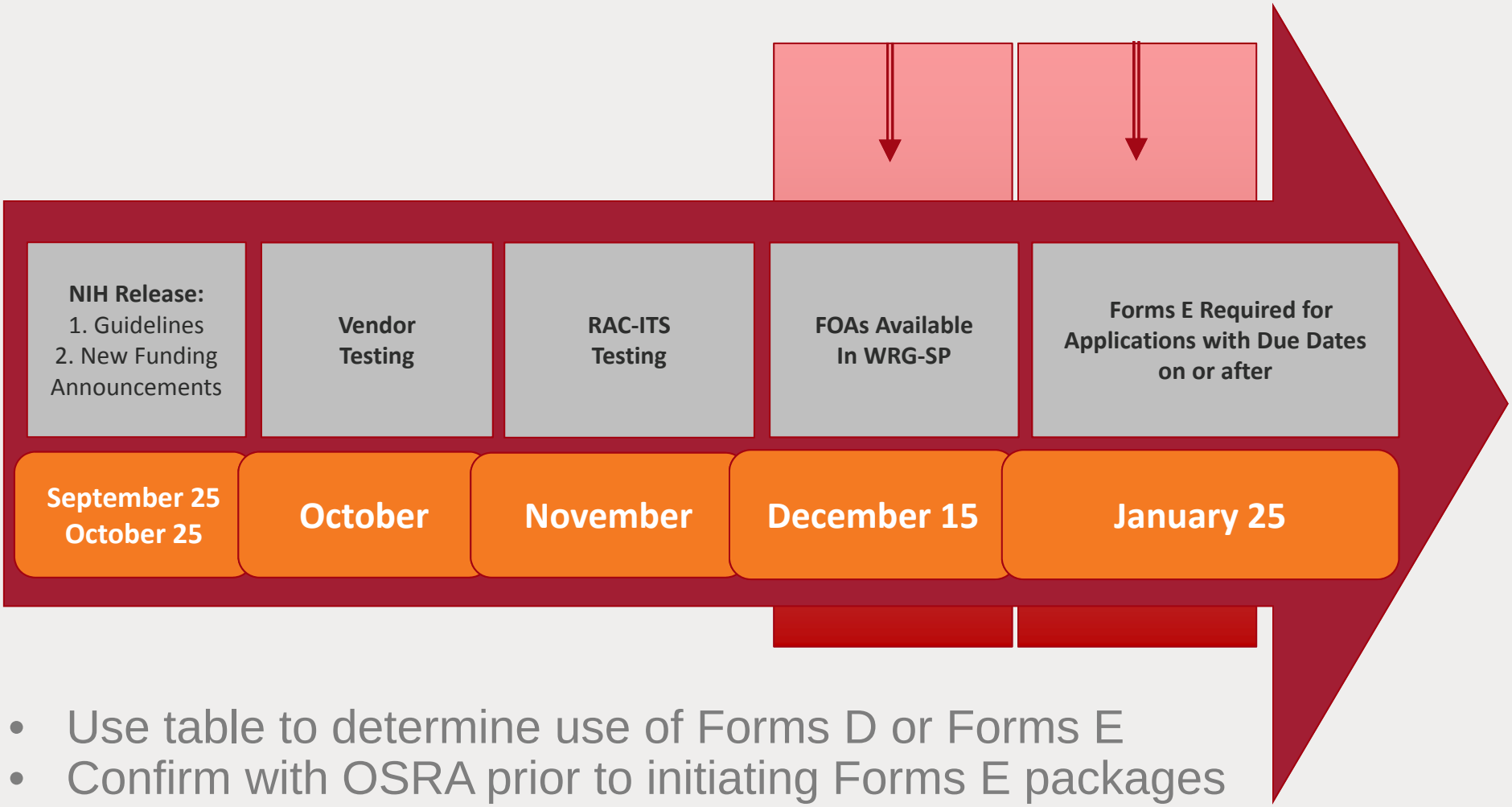
- Clinical trial applications must be submitted to specifically designated FOAs
  - **Allowability of clinical trials will be noted in *Section II - Award Information***
  - **N*ew* FOAs will specify allowability of clinical trials in FOA title**
- FOAs that accept clinical trials will incorporate specific 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 dues 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

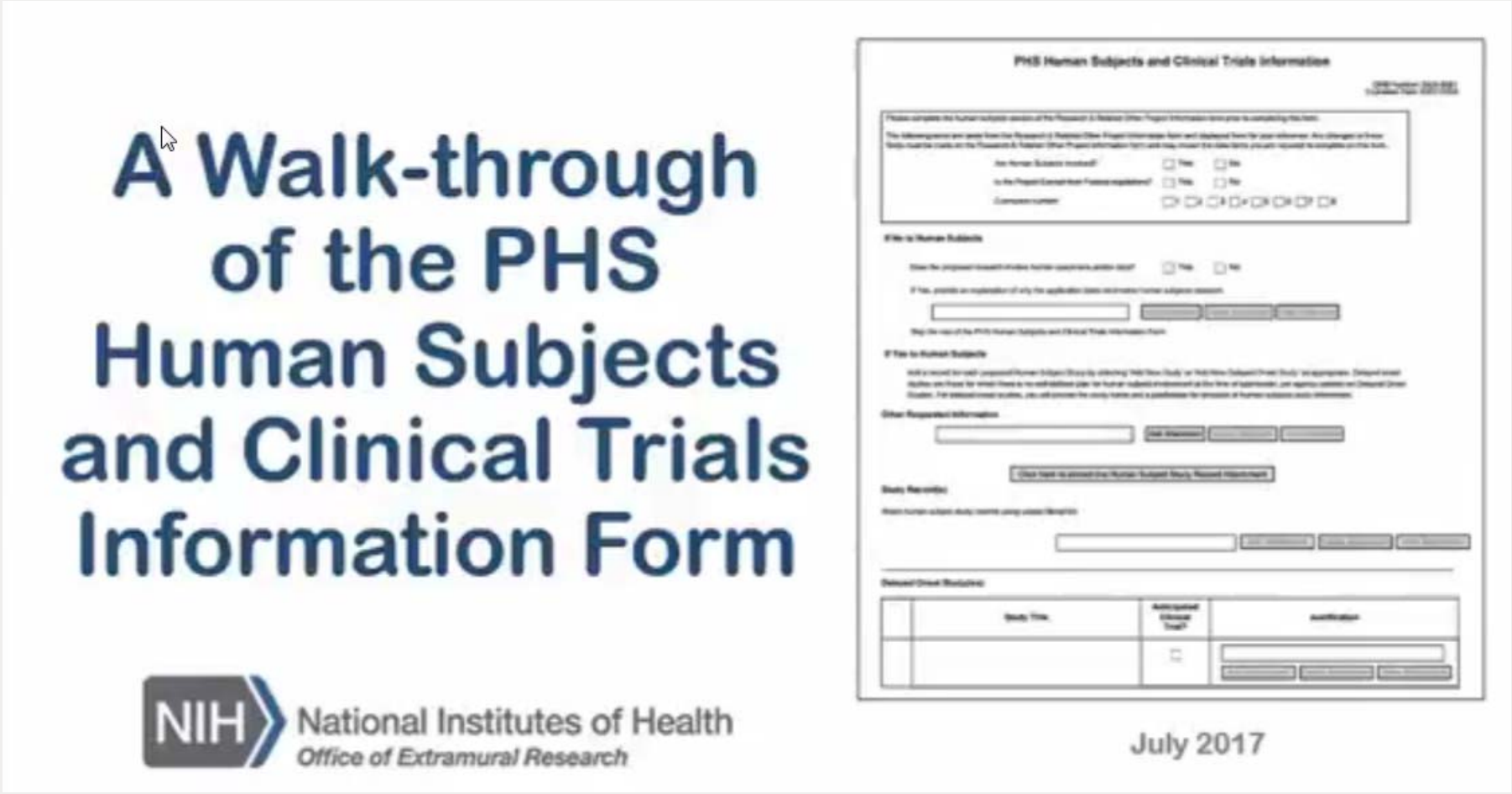
FORMS E – Benefits

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



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NIH Updates – Clinical Trial Applications

Resources

NIH Clinical Trials Resource Page
https://grants.nih.gov/policy/clnical-trails.htm

NIH Human Subjects & Clinical Trails Form Overview
https://www.youtube.com/watch?v=nz9NWFhYOG8&list=PLOEUwSnjvqBJeHcb4yai7_fDnFZFPEmQK&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

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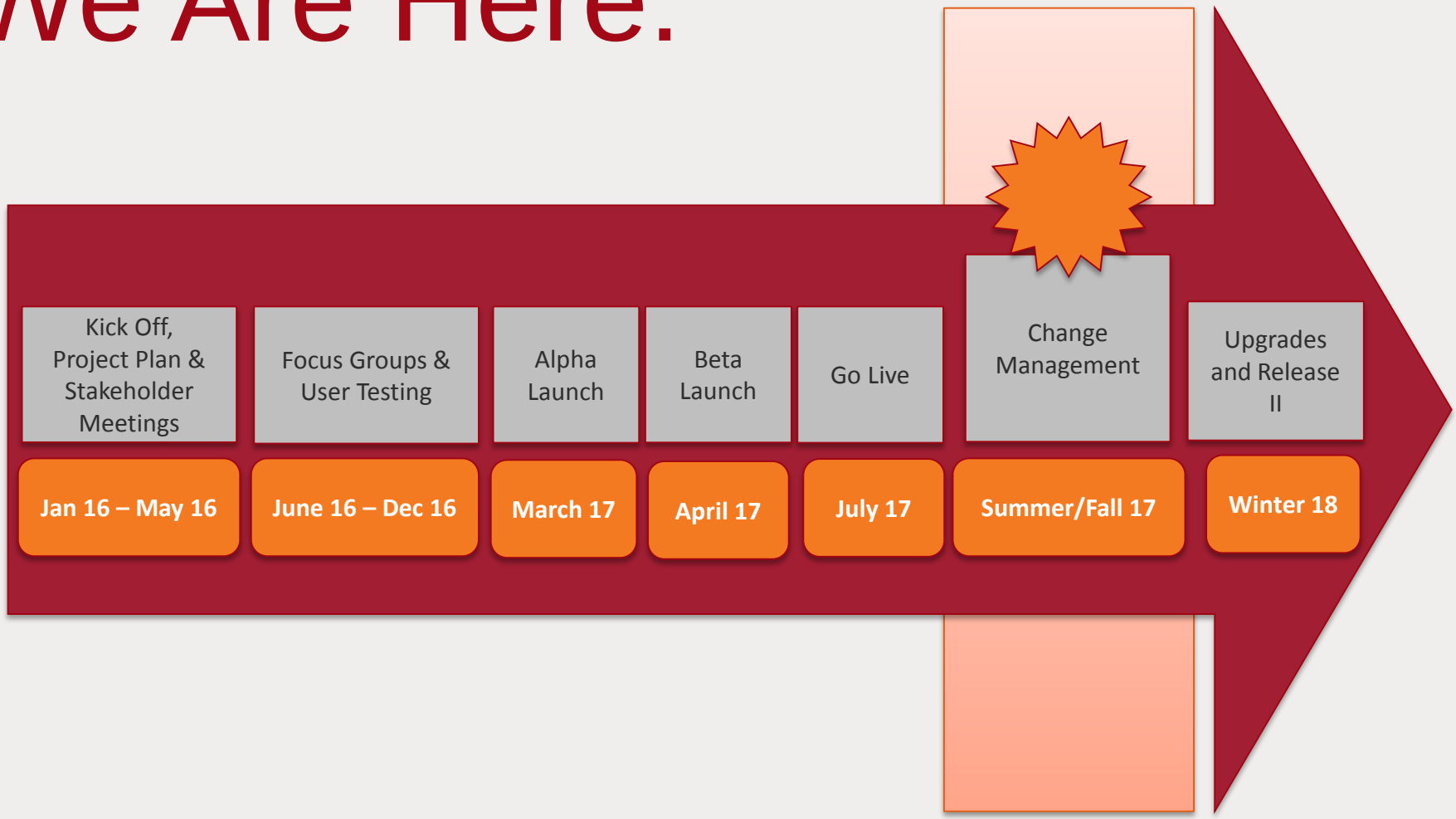
Weill Research Gateway
Sponsored Programs

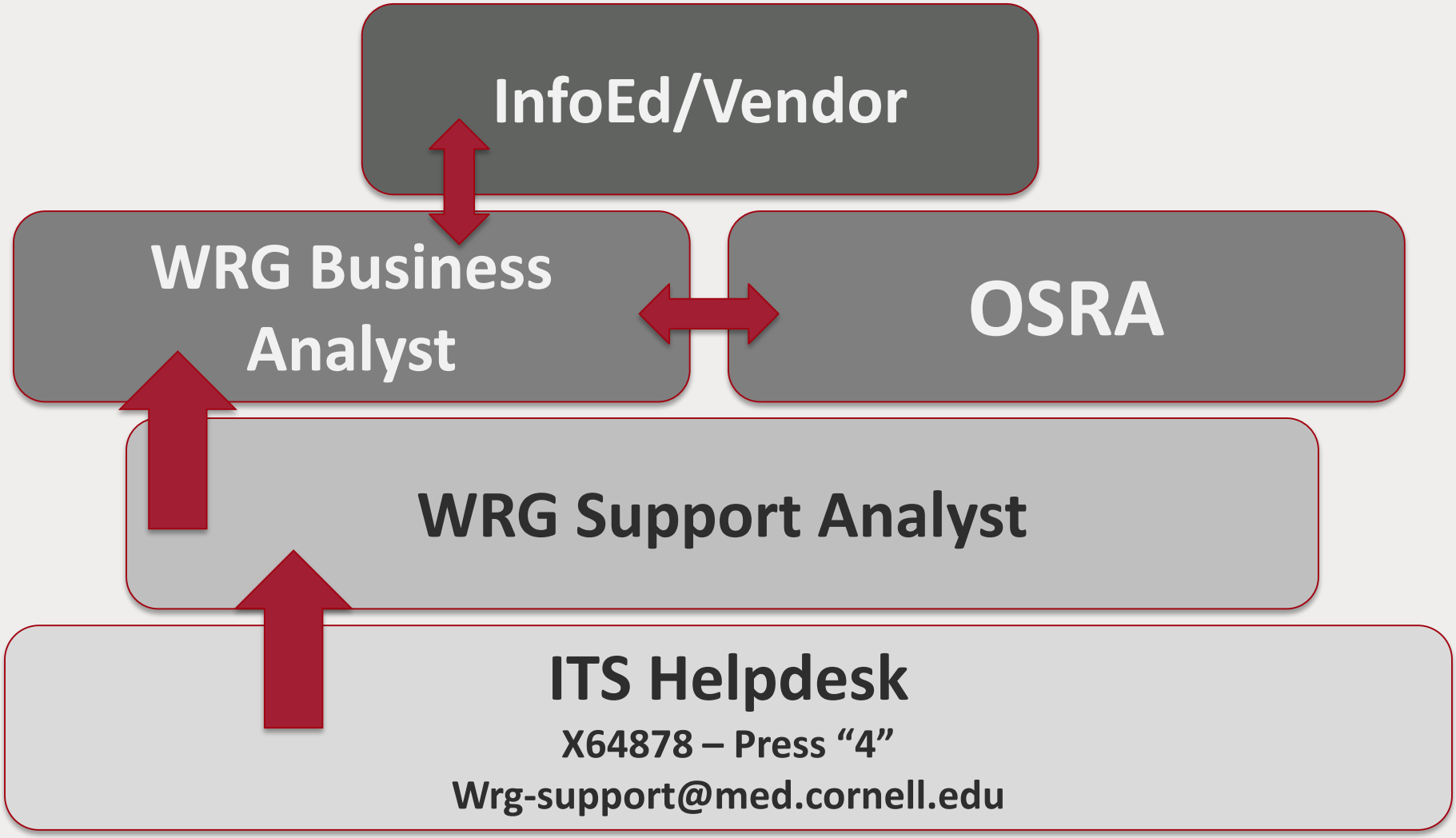
We Are Here:


Kick Off, Project Plan & Stakeholder Meetings
Focus Groups & User Testing
Alpha Launch
Beta Launch
Go Live
Change Management
Upgrades and Release II
Jan 16 – May 16
June 16 – Dec 16
March 17
April 17
July 17
Summer/Fall 17
Winter 18

Documented Issues

- Budget
- Notifications & Routing
- Training Materials
- S2S Integration
- User Experience

Support


InfoEd/Vendor
WRG Business Analyst
OSRA
WRG Support Analyst
ITS Helpdesk
X64878 – Press “4”
Wrg-support@med.cornell.edu

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

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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