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.
**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.
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:

<table>
<thead>
<tr>
<th>If your due date is....</th>
<th>You must use......</th>
</tr>
</thead>
<tbody>
<tr>
<td>On or before January 24, 2018, including:</td>
<td></td>
</tr>
<tr>
<td>• Applications submitted for due dates on or before January 24, 2018</td>
<td></td>
</tr>
<tr>
<td>• Applications submitted under NIH Late Policy 2-week window of consideration for intended due dates on or before January 24, 2018</td>
<td></td>
</tr>
<tr>
<td>• Applications submitted by February 7, 2018 under NIH Continuous Submission Policy for January 7, 2018 AIDS intended due date</td>
<td></td>
</tr>
<tr>
<td>You must use......</td>
<td></td>
</tr>
<tr>
<td>FORMS-D application package</td>
<td></td>
</tr>
</tbody>
</table>

| 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 |
| You must use...... |
| 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.
NIH Updates – Clinical Trial Applications

Resources

NIH Clinical Trials Resource Page
https://grants.nih.gov/policy/clinical-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

Related Announcements
NOT-OD-17-062
NOT-OD-17-043
NOT-OD-16-147
Weill Research Gateway
Sponsored Programs
We Are Here:

Kick Off, Project Plan & Stakeholder Meetings
Jan 16 – May 16

Focus Groups & User Testing
June 16 – Dec 16

Alpha Launch
March 17

Beta Launch
April 17

Go Live
July 17

Change Management
Summer/Fall 17

Upgrades and Release II
Winter 18
Documented Issues

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

WRG Support Analyst

InfoEd/Vendor

WRG Business Analyst

OSRA

WRG Support Analyst

ITS Helpdesk
X64878 – Press “4”
Wrg-support@med.cornell.edu
## WRG-SP Bulletin Board

### Known Issue

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

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### Known Issue

- Resolution Progress
- Alternative Solution
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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

**Requirements Gathering**
- Meetings with Qatar and EHS
- Anticipate changes due to Forms E
- Single route non-S2S change analysis

**Development**
- eForm updates; updating non-S2S route
- Take Forms E patches
- Creation of Dean’s Letter BI report
- Unit testing

**Regression Testing**
- Functional and performance testing in QA

**Training Updates**
- Separate contracts submission training
- Updating existing trainings to reflect Release 1.0 changes

**Timeline**
- **Sept 5**
  - 1.5 months
- **Oct 15**
  - 1 month
- **Nov 15**
  - 2 weeks
- **Dec 1**
  - 2 weeks

- **Oct 30**: Forms E patches available
- **Dec 15**: Prod Go-Live

**Additional Information**
- 1.5 months
- 1 month
- 2 weeks

**Weill Cornell Medicine**