InfoEd Adobe Forms E Update

In response to the change in government and NIH requirements, InfoEd has been updated to support the new Adobe Forms E. Users can now submit all funding opportunities utilizing the new Other Project Info Form v1.4 system-to-system through InfoEd. More information is available in this NIH Guide Notice.

Detailed changes to InfoEd

1. The Project Narrative, Project Summary, References Cited, Resources and Other Attachments tabs will all be combined into one tab called Other Project Info which populates the new Other Project Info form v1.4. The new Other Project Info form is mandatory even if there are no Human Subjects.
2. The update will consolidate Human Subject, Inclusion Enrollment, and Clinical Trial sections and create a new Human Subject / Clinical Trial form.
3. The Human Subject section will be removed from the PHS 398_Research Plan tab.
4. If Human Subjects are indicated on the setup questions, InfoEd will push the relevant requirements to the new Human Subject / Clinical Trial form and validate that at least one study exists.
5. Due to the structure of the validation web-service, proposals with human subjects or clinical trials must pass the InfoEd XML validation before the NIH web-service validation will work.

RO1 Tabs Before

- Setup Questions
  - SF424 (R&R)
  - Other Project Info
  - Performance Sites
  - Project Summary
  - Project Narrative
  - References Cited
  - Resources
  - Other Attachments
  - Personnel
  - Budget
  - PHS398_Research Plan
  - Approvals
  - Internal Documents
  - PHS398_CoverPage Supplement
  - NU Project Summary
  - Finalize

RO1 Tabs After

- Setup Questions
  - SF424 (R&R)
  - Performance Sites
  - Other Project Info
  - Personnel
  - Budget
  - PHS398_Research Plan
  - Approvals
  - Internal Documents
  - PHS398_CoverPage Supplement
  - NU Project Summary
  - Human Subjects/CT
  - Finalize
**NIH Due Dates**

Using the new Adobe Forms E will be required for all NIH proposals with a **due date** on or after January 25, 2018. Now that InfoEd supports the new forms, a proposal can be created in InfoEd for a new Forms E funding opportunity as soon as they are available. Proposals using the new Forms E with a due date after January 25th can be submitted at any time prior to the cutover date.

**Details Regarding NIH FOA Postings:**

NIH staff have begun posting/updating funding opportunity announcements (FOAs) reflecting the Forms E update.

As part of the Forms E update, NIH is:

1. Replacing parent FOAs with entirely new FOAs (so, the parent R01 will change from PA-16-160).
2. Posting new FOAs for any opportunity that can support a clinical trial (optional or required).
3. Updating existing FOAs for opportunities that do not support clinical trials to reflect new requirements, however they are not editing the titles to demonstrate that clinical trials are not allowed.
4. All new opportunities for which FOAs are posted (parent packages, opportunities allowing clinical trials, and any new opportunities), will state whether clinical trials are required, optional, or not allowed in the opportunity title.
5. FOAs that do not support clinical trials and have deadlines both before and after the January 25, 2018 Forms E implementation date will have two packages posted.

**NIH Exemptions:**

NIH is not implementing the Common Rule update with respect to exemptions. This includes not supporting the new exemption numbers 7 and 8 on the updated Other Project Information form and not transitioning to the new definitions of the exemptions. This does not affect your InfoEd PD proposals, other than that for NIH applications, the new exemption numbers 7 and 8 are not allowed. There are Commons validation rules to preclude their acceptance.

**Inclusion Enrollment Form**

The new navigation to the **Inclusion Enrollment Report** is from the left hand navigation bar after clicking the **Add Inclusion Enrollment Report** button from an individual study.
Forms D to Forms E Conversion

A proposal record started as Forms D can be converted to Forms E. Data content and attachments will be retained according to the chart below. Northwestern is recommending that users carefully choose their funding opportunities to avoid issues with conversion.

<table>
<thead>
<tr>
<th>Form</th>
<th>Content</th>
<th>Attachments</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF424</td>
<td>✓</td>
<td>✓</td>
<td>Form version does not change between D and E.</td>
</tr>
<tr>
<td>Performance Sites</td>
<td>✓</td>
<td>N/A</td>
<td>Form version does not change between D and E.</td>
</tr>
<tr>
<td>Personnel</td>
<td>✓</td>
<td>✓</td>
<td>Form version does not change between D and E.</td>
</tr>
<tr>
<td>Budget</td>
<td>✓</td>
<td>✓</td>
<td>Form version DOES change between D and E; Budget is a &quot;tool.&quot; Populates multiple budget forms/versions</td>
</tr>
<tr>
<td>Modular Budget</td>
<td>✓</td>
<td>✓</td>
<td>Form version does not change between D and E.</td>
</tr>
<tr>
<td>Other Project Info</td>
<td>✓</td>
<td>☎</td>
<td>Form version changes between D and E. Data model change storing attachments between versions.</td>
</tr>
<tr>
<td>Human Subjects/CT</td>
<td>☎</td>
<td>☎</td>
<td>New Form</td>
</tr>
<tr>
<td>Research Plan</td>
<td>N/A</td>
<td>✓</td>
<td>Form version changes between D and E; Data Model does not, allowing for retention of documents on persisting fields</td>
</tr>
<tr>
<td>Career Development Award</td>
<td>☎</td>
<td>☎</td>
<td>Form version changes between D and E. S2S forms do not retain content/attachments.</td>
</tr>
<tr>
<td>Supplemental</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training Program Plan</td>
<td>N/A</td>
<td>☎</td>
<td>Form version changes between D and E. S2S forms do not retain content/attachments.</td>
</tr>
<tr>
<td>Training Budget</td>
<td>✓</td>
<td>✓</td>
<td>Form version does not change between D and E.</td>
</tr>
<tr>
<td>Training Subaward Budget</td>
<td>✓</td>
<td>✓</td>
<td>Form version does not change between D and E.</td>
</tr>
<tr>
<td>Fellowship Supplement</td>
<td>☎</td>
<td>☎</td>
<td>Form version changes between D and E. S2S forms do not retain content/attachments.</td>
</tr>
<tr>
<td>Cover Page Supplement</td>
<td>✓</td>
<td>N/A</td>
<td>Form version changes between D and E; Data Model does not, allowing for retention of content on persisting fields</td>
</tr>
<tr>
<td>Assignment Request Form</td>
<td>☎</td>
<td>N/A</td>
<td>Form version changes between D and E. S2S forms do not retain content/attachments.</td>
</tr>
</tbody>
</table>