

NIH eSubmission Items of Interest - February 14, 2018

Valentine's Day Chocolate Heart of Truffles - \$75.00... A dozen roses in a red vase - \$82.99... Answers to nagging human subjects and clinical trials questions – PRICELESS!

We've been accepting applications using FORMS-E forms for a few weeks now. It will take us all a bit of time to adjust to a new normal, but we'll get there. The items below address the most common inquiries my Grants Information team has been fielding regarding human subjects, clinical trials and FORMS-E. Warning – this is a long one...there was just too much to say to be pithy.

Be a Lumper Not a Splitter



In many cases a single study record is all you need.

It is not uncommon for a single study record to cover multiple hypotheses, specific aims or processes. If you think multiple study records may be appropriate, look at the data fields collected in a study record and think about how much information would be virtually identical in each record. If you are proposing multiple, distinct protocols (for example, you know that multiple ClinicalTrial.gov report submissions will be needed down the line), then it may make sense to provide multiple study records at

time of application. But, when in doubt be a lumper not a splitter to the extent it makes sense for your research.

Bottom line: We will not turn away your application for the sole reason that we thought you should have split your information into multiple study records. As long as we have the information needed for review, we can adjust the structure of the information later, if needed.

Clinical Trial Questionnaire Questions Drive Data Collection for New Human Subjects Form



There are lots of resources on our [Clinical Trial Requirements for Grants and Contracts](#) page to help you determine if your application is a clinical trial including the [NIH's Definition of a Clinical Trial](#) page and a [clinical trial decision tool](#). It comes down to how you answer the 4 questions on the Clinical Trial Questionnaire.

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

If you answer Yes to all 4 questions, your application will be considered a clinical trial (or clinical trial research experience in the case of Fellowship or Career Development applications to Clinical Trial Not Allowed FOA). Answer No to any of the 4 questions and your application will not be considered a clinical trial.

Answering the 4 questions in the Clinical Trial Questionnaire of a study record (items 1.4.a-1.4.d) is key to providing the appropriate level of information for review of your application. Only clinical trial applications can provide information in study record sections 4 and 5. Misidentifying your application can lead to too much or too little information moving forward with your application. Reviewers can only evaluate what's in front of them.

Here is a bit of advice I find myself repeating often...

When answering the 4 questions, base your answers on the application in front of you. Suppose you're doing an ancillary study to an existing clinical trial. If your study adds an additional manipulation (prospectively assigned intervention) and all the elements of the NIH clinical trial definition are met then your application is likely a clinical trial.

If your study simply adds measures to an existing clinical trial and doesn't add a prospectively assigned intervention, then you'll have at least 1 No answer and your application is not (by itself) considered a clinical trial. Reviewers don't need to rehash the details of an existing study. They just need to know how your application fits in that bigger picture.

Done your homework and still confused?



If you've checked out the [on-line resources](#) and [clinical trial decision tool](#) and you're still confused as to whether your research meets the [NIH definition of a clinical trial](#), reach out to the Scientific/Research contacts listed in Section VII of your announcement. Sometimes you just need to talk scientist to scientist.

Do I Need to Create a Study For the Part of My Research that Uses Human Specimens?



No. When you answer No to the Human Subjects Involved question on the R&R Other Project Information form, we give you the opportunity on the PHS Human Subjects and Clinical Trials Information form to add an attachment to explain why the application does not involve human subjects research.

However, when a part of your research uses human specimens and other parts involve human subjects that attachment is no longer available to you. You will have at least one study record for the human subjects aspects of your application. You can simply add a blurb in the Protection of Human Subjects attachment (item 3.1) of the existing study record.

Working with Large Text Boxes in Application Forms



The PHS Human Subjects and Clinical Trials Information form includes several text box fields with large character count limits. We chose the text box format used by ClinicalTrials.gov, rather than attachments, to facilitate data exchange between eRA and ClinicalTrials.gov.

The cost of that data interoperability is the loss of rich formatting within the field. See our [Rules for Text Fields](#) (part of our [How to Apply – Application Guide](#) page) for more information

Where can I find the PHS Human Subjects and Clinical Trials Information Form?



Like all NIH application forms, the new PHS Human Subjects and Clinical trials Information form is accessed through the submission method you are using. ASSIST, Workspace and all system-to-system solutions provide a way to access and complete the forms.

- ASSIST allows you to complete the forms online within ASSIST or to download a study record form for offline completion and later upload the completed form into your ASSIST application.
- Workspace provides the ability to download and upload study record forms, but does not yet offer a webform for online data entry.
- Forms downloaded from ASSIST can NOT be uploaded to Workspace and vice versa. Forms downloaded directly from the Grants.gov website [form repository page](#) can NOT be uploaded to either ASSIST or Workspace applications for submission, but may work with your system-to-system solution (check with your provider).

Goodbye FORMS-D



If you are submitting an Administrative Supplement, Successor-in-Interest (Type 6) or Change of Institution (Type 7) to a FORMS-D Parent Announcement you have until February 25 to complete your submission using FORMS-D.

Otherwise, FORMS-D should be nothing but a fond memory. “Fond memory” may be a stretch, but “dead to you,” “closed,” “finished,” “done,” “kaput,” or “a thing of the past” might work – you pick.

- Getting this message – *“The Closing Date of the grant opportunity for which you have applied has already passed and the grantor agency is no longer accepting applications.”*
 1. Verify your funding opportunity announcement (FOA) is still open. Many FOAs expired early due to the form transition.
 2. Make sure you are using the correct application package (FORMS-E, not FORMS-D). This Grants.gov message can be misleading by indicating the “grant opportunity” is closed. It may just be the application package is closed, not the entire FOA.
 3. Still unsure – call the [eRA Service Desk](#) for assistance.
- Not sure which forms you’re using
 - [Do I Have The Right Forms For My Application?](#) explains what a Competition ID is (FORMS-D, FORMS-E) and where to find it in ASSIST, Workspace and submitted applications.

FORMS-E Parent Announcements



Most FORMS-E [parent announcements](#) are available. We hope to have the Fellowship parent FOAs posted by next week (a little behind our 60 day target, but ahead of the required 30 days).

Many activity codes now have two parent announcements – one designated as *Clinical Trial Not Allowed* and one designated as *Clinical Trial Required*. Don’t forget to double-check the participating organizations since institutes may not participate on both.

Navigating the Human Subjects Form Using Workspace



We’ve heard some chatter that folks have had some trouble entering their human subjects information using Workspace. Grants.gov is continuously updating the Workspace service and has some enhancements planned to make working with subforms (think subaward budgets and study records) more intuitive. In the meantime, I did a quick [video](#) to walk you through the process of completing your human subjects information using Workspace. Don’t judge – I was going for function over production - value. Whatever it takes to help you get your applications in. 😊

Don’t forget - if you download individual forms from Workspace for offline completion, you must use an [Adobe Reader compatible with the forms](#). I was recently reminded of this fact after my machine was updated to Windows 10 and I could no longer open forms (Microsoft 10 uses Edge for its default browser). After a colleague helped me change my settings to always open PDFs in Adobe Reader I had no more trouble.

What to Do When Systems Leave You Broken Hearted



If you encounter an issue with a Federal system that is beyond your control and impacts your ability to submit your application on time, follow our guidelines for [Dealing with System Issues](#).

We've run into a few minor FORMS-E bumps.

- Some system-to-system users encountered an unexpected message in section 5 of the study record in their application image (S2S solutions sending us unexpected information and us not handling it gracefully) – fix planned for late March.
- Some Workspace users received unexpected errors related to human embryonic stem cell information – shout out to the Grants.gov team who learned of the issue on February 5 and had a fix developed, tested and deployed in 4 days – wow!
- ASSIST is limiting the study titles for delayed onset studies to 25 characters, when 600 should be allowed – fix planned for late March.

Are these examples, frustrating, nerve-racking and annoying? Absolutely. But, thankfully, we've not encountered any showstoppers to application processing. Just reach out to the [eRA Service Desk](#) by the deadline and, if they confirm a system issue, we'll work with you to find a resolution.

Happy Valentine's Day!

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