NIH-funded Human Subjects Research/Clinical Trials and the Transition to Forms E

How Do Changing NIH Policies Impact Me?

LCOM Informational Sessions

Nov. 14, 16 2017

Jeralyn Haraldsen, PhD

Grant Proposal Manager

Office of the Vice President for Research

Introductions:

Research Protections Office	
Donna Silver, CIP	Director
Office of Clinical Trials Research	
Kimberly Luebbers, MSHS, RN, BSN, OCN	Director Assistant Dean for Clinical Research
Sponsored Projects Administration	
Julie Macy	Team Lead Proposal Submission & Award Administration
Karin Bourassa	Research Administrator
Joshua Tyack	Research Administrator
Gretchen Argraves	Research Administrator
Cathy Ruley Condon	Business Systems and InfoEd Analyst
Office of the Vice President for Research	
Jeralyn Haraldsen, PhD	Grant Proposal Manager

Goal for Today's Session:

- **Overview** of NIH changes regarding Human Subjects Research and Clinical Trials
- New Human Subjects and Clinical Trials Information form
- **Resources**

Why Are We Here?

High-level Overview: Reforms & Initiatives

To enhance the stewardship of research involving human subjects, NIH is implementing the following:

All Research Involving Human Participants

- ✓ New forms to collect human subjects information
- ✓ Use of a single Institutional Review Board (IRB) for multi-site studies
- ✓ Certificates of confidentiality for all research that uses "identifiable, sensitive information"

Research that Meets the NIH Definition of a Clinical Trial

- ✓ Training in Good Clinical Practice (GCP)
- ✓ Clinical trial-specific Funding Opportunity Announcements (FOAs)
- ✓ New review criteria
- ✓ Expanded registration and results reporting in ClinicalTrials.gov

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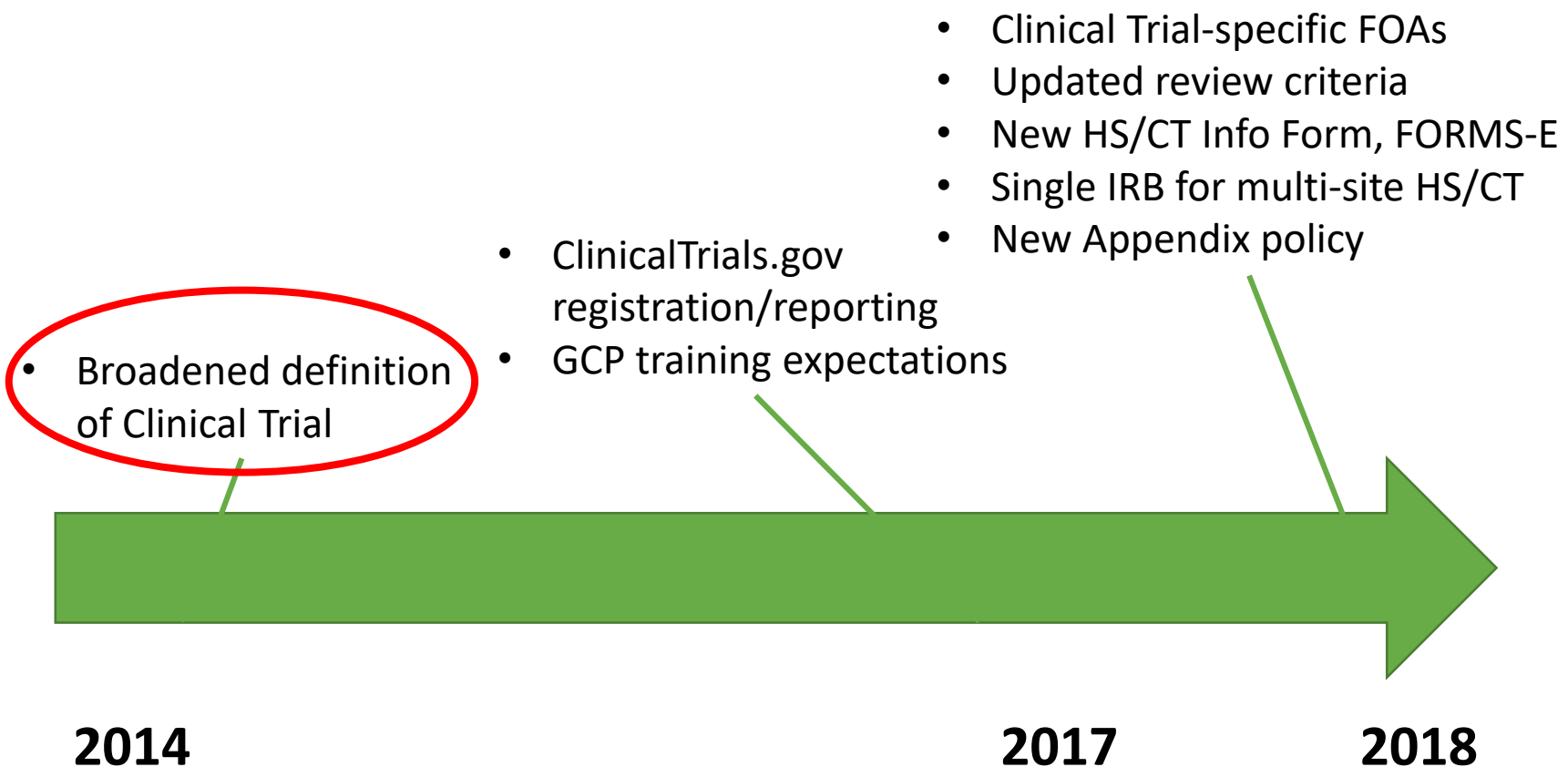
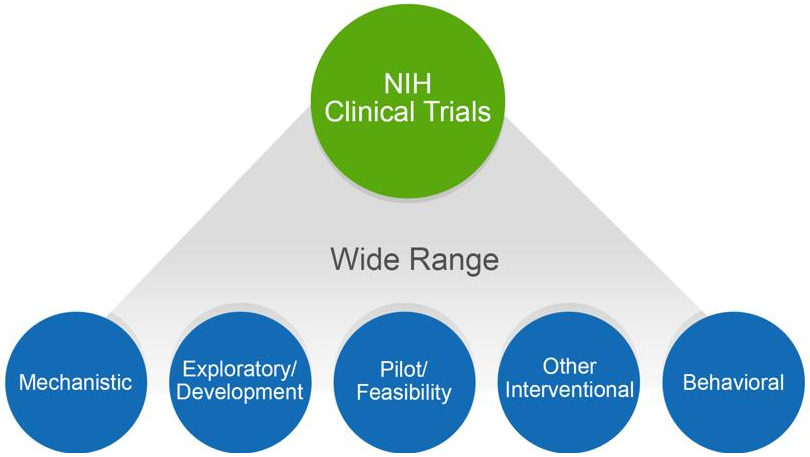
Changes to NIH Human Subjects Research and Clinical Trials Policies



NIH Might Consider Your Human Subjects Research to be a Clinical Trial

Does your study…

- ✓ Involve one or more **human subjects**?
- ✓ **Prospectively assign** human subject(s) to intervention(s)?
- ✓ Evaluate the **effect of intervention(s)** on the human subject(s)?
- ✓ Have a **health-related biomedical or behavioral outcome?**



If "yes" to ALL of these questions, your study is considered a clinical trial

Unsure how to answer the questions? We have a tool that can help! https://grants.nih.gov/ct-decision/

Additional Information & Resources

Refer to the following resources for help determining if your study is a clinical trial:

- ✓ Decision Tool
- ✓ Case Studies
- ✓ FAQs
- ✓ Decision Tree
- ✓ When in doubt, contact your Program Official

UVM

- ✓ Office of Clinical Trials Research
- ✓ Research Protections Office

Learn more at: https://grants.nih.gov/policy/clinical-trials/definition.htm

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Changes to NIH Human Subjects Research and Clinical Trials Policies

Registering & Reporting Requirements for ClinicalTrials.gov

Effective for applications due on/after January 18, 2017 – All clinical trial applications requesting support for a trial that will be initiated on/after January 18, 2017 must **register** and **report** the results in ClinicalTrials.gov

In order to comply with the NIH Policy on Clinical Trial Dissemination, awardees must:

- ✓ Submit a plan in the application that outlines compliance with the expectations of the policy
- ✓ Register the clinical trial no later than **21 days** after enrolling the first participant
- ✓ Submit summary results no later than **one year** after primary completion date

Learn more at https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

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More Information on Registering & Reporting in ClinicalTrials.gov

- ✓ Decision tree for ensuring compliance
- ✓ FAQs

Learn more at https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

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Good Clinical Practice Training Requirement: Expectations

Effective January 1, 2017 – All NIH-funded clinical investigators and clinical trial staff involved in the design, conduct, oversight, or management of clinical trials are required to be trained in Good Clinical Practice (GCP)

- GCP training can be achieved through:
  - ✓class or course
  - ✓academic training program
  - ✓certification from a recognized clinical research professional organization

- Training should be refreshed every 3 years
- Retain documentation of GCP training and make it available to NIH upon request

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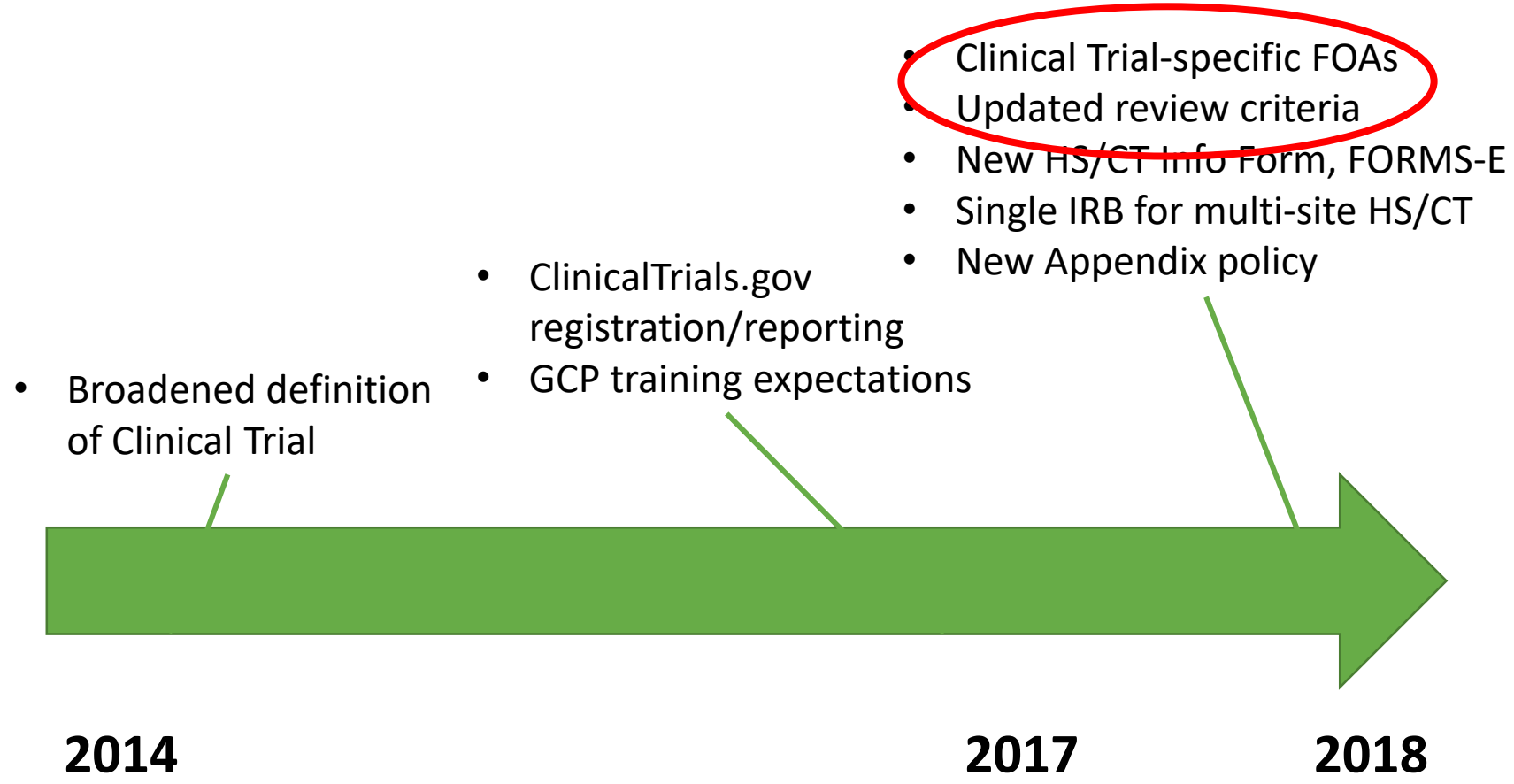
Changes to NIH Human Subjects Research and Clinical Trials Policies



Specific Funding Opportunity Announcements (FOAs) for Clinical Trials

Effective for due dates on/after January 25, 2018 – All grant applications & contract proposals involving one or more clinical trials must be submitted through an FOA or Request for Proposal (RFP) *specifically designated for clinical trials*

Clinical Trial-specific FOAs allow NIH to:

- ✓identify proposed clinical trials
- ✓ensure that key pieces of clinical trial-specific information are submitted with each application
- ✓uniformly apply clinical trial-specific review criteria

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Clinical Trial Designations for FOAs

Effective for due dates on/after January 25, 2018 – all FOAs will be designated as one of the following in Section II of the FOA:

- ✓Clinical Trial Required
- ✓Clinical Trial Not Allowed
- ✓Clinical Trial Optional
- ✓No Independent Clinical Trials: *only for Career Development (K) & Fellowship (F)

Tip: Contact your Program Official or the Scientific/Research contact listed in Section VII of the FOA to ensure you are submitting to the correct announcement

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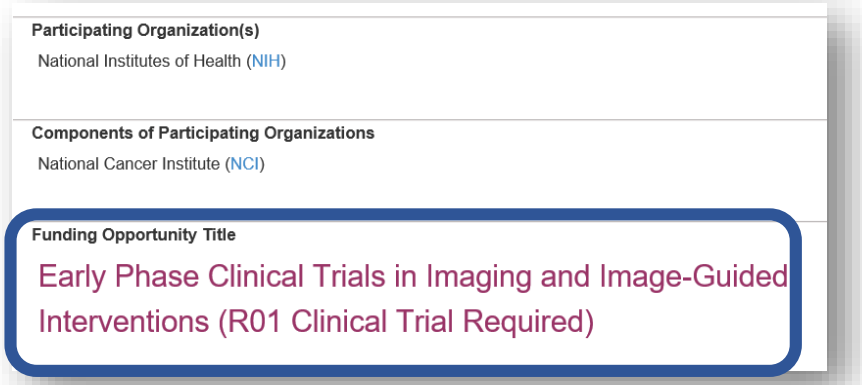
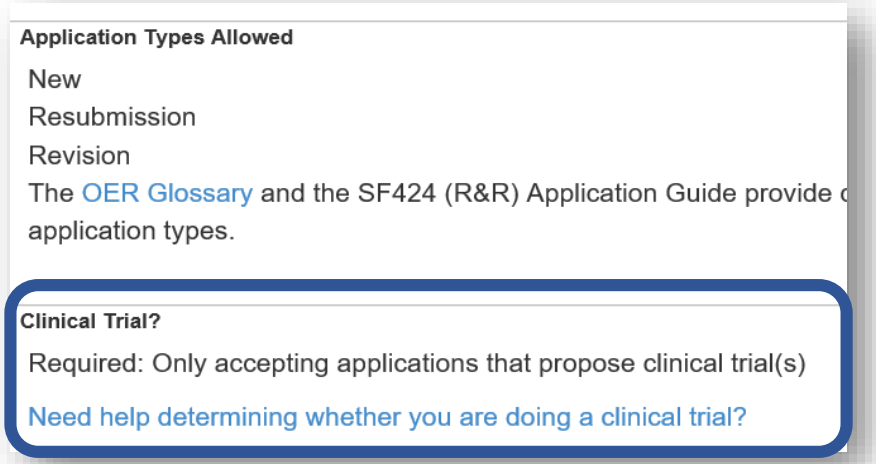
How to Determine if an FOA Accepts Clinical Trials?

FOA Title (new FOAs only)



FOA Section II. Award Information



Tip: Check your FOA at least 30 days before the due date for any updates

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Plans for Publishing Clinical Trials-specific Parent Announcements

- NIH has published Clinical Trial **Parent** announcements:
  - **R01** (PA-18-345)
  - **R21** (PA-18-344)
- Look carefully at participating ICs – some ICs issuing independent solicitations
- Some ICs will only accept **mechanistic** trials in response to the Parent announcements

See: NOT-OD-18-010

Special Considerations for Training, Fellowship, and Career Development FOAs

Training (T) awards: Institutional Training awards do **NOT** support clinical trials (with the exception of some D43 and K12 awards)

Fellowship (F) awards: The NIH encourages fellows to receive training in clinical research; however, NIH supported fellows are **NOT** permitted to conduct a clinical trial independently

Career Development (K) awards: Career Development awards may support either independent clinical trials or a mentored research training experience, **depending on the FOA**

Learn more at https://grants.nih.gov/policy/clinical-trials/specific-funding-opportunities.htm

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Review Criteria for Clinical Trials

FOAs that accept clinical trials will include new review criteria:

Scored Review Criteria

- ✓ Significance
- ✓ Investigator
- ✓ Innovation
- ✓ Approach
- ✓ Environment

Additional Review Criteria

- ✓ Study Timeline & Milestones

Tip: Read the FOA carefully and be sure your application addresses the review criteria appropriately

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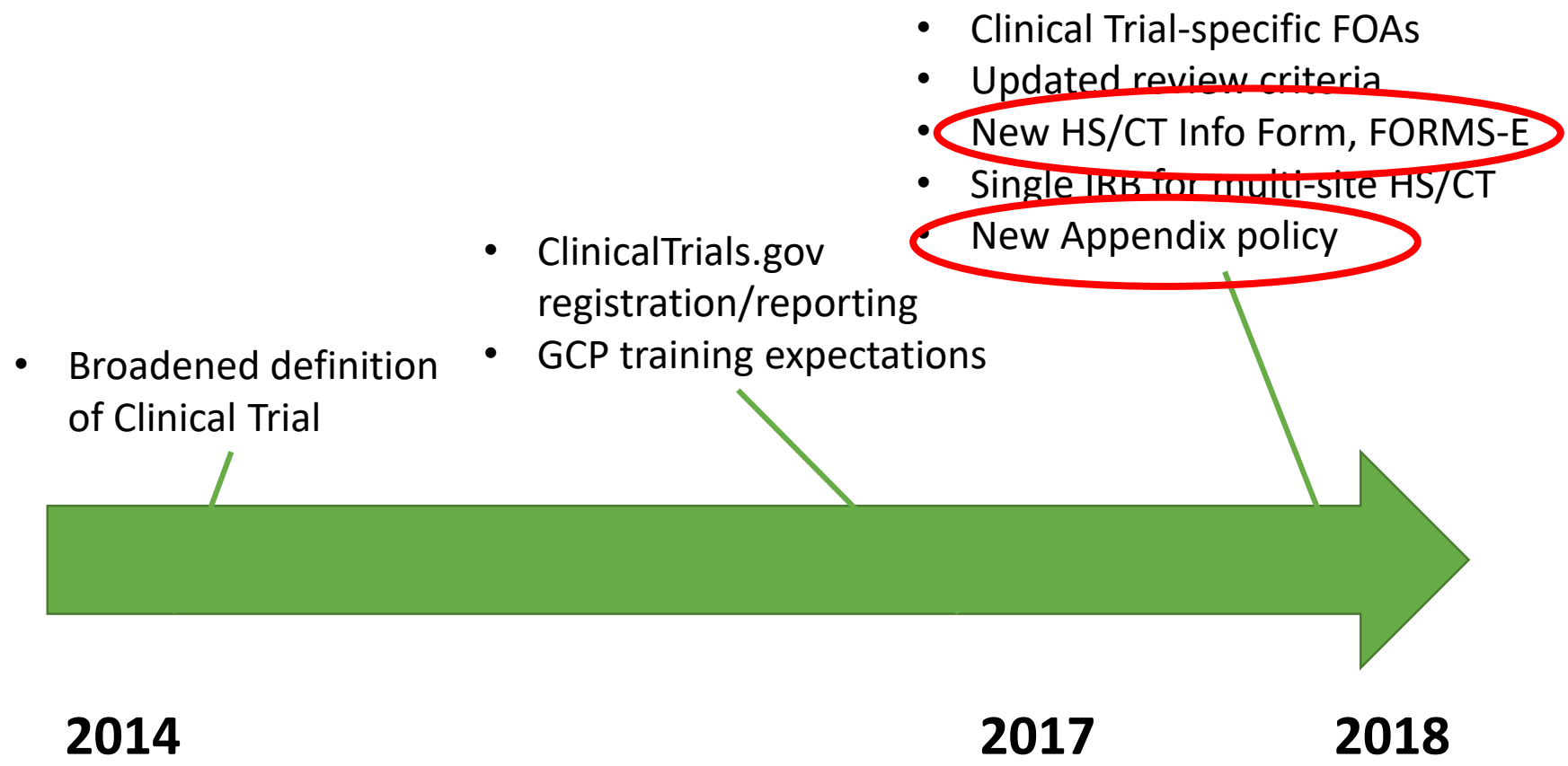
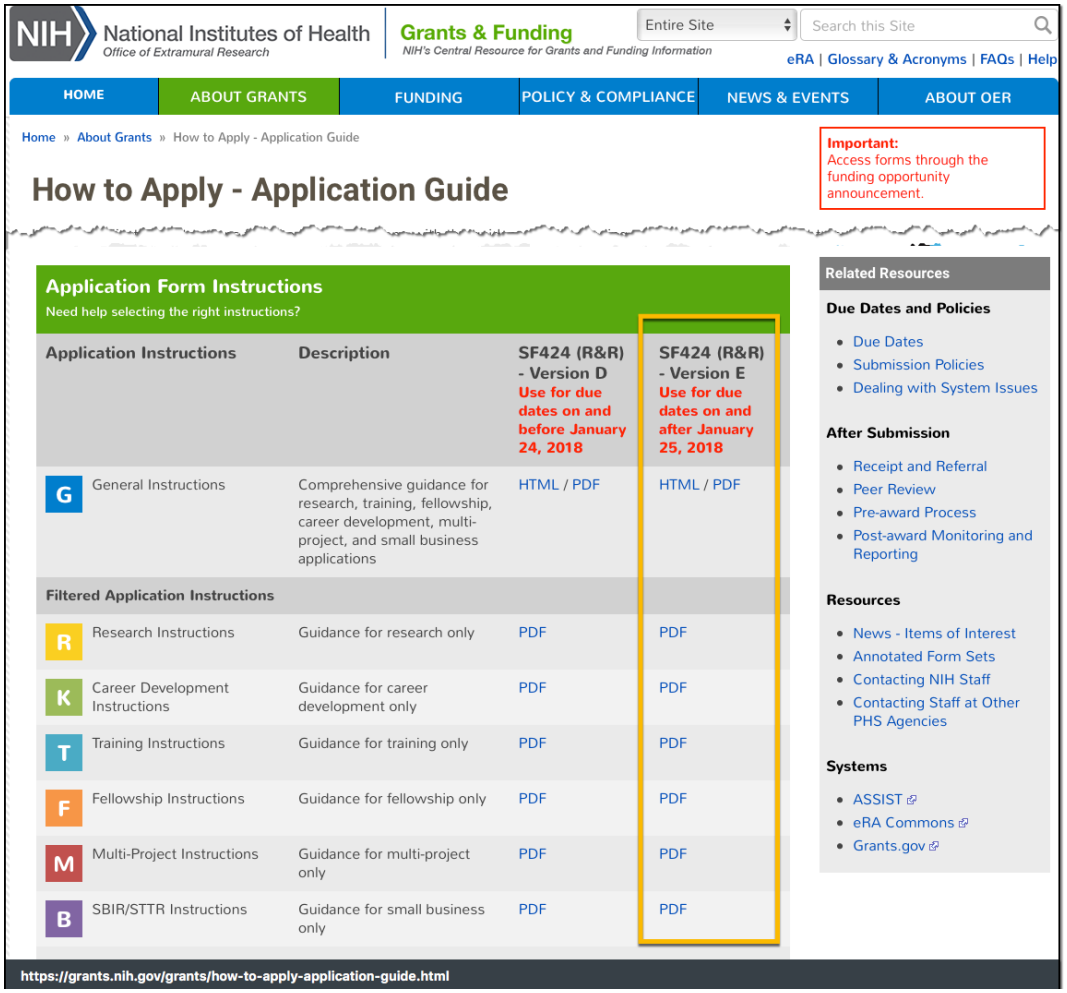
Changes to NIH Human Subjects Research and Clinical Trials Policies



New FORMS E Instructions are Available Now



NIH – Forms E Application Guide

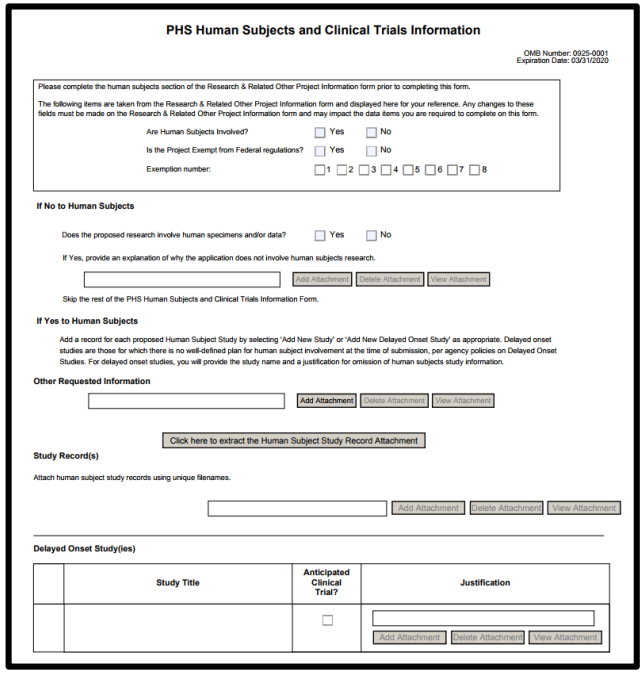
- https://grants.nih.gov/grants/how-to-apply-application-guide.html
- The PDF is a local download, but using the HTML version ensures you are always looking at the latest version in case there are updates.

New Human Subjects & Clinical Trials Information Form

REQUIRED: Due Dates on or after January 25, 2018

A primary component of NIH's clinical trial reform is the creation of a new application form that:

- ✓ **Consolidates** human subjects, inclusion enrollment, and clinical trial information into one form
- ✓ Collects information at the **study-level**
- ✓ Uses **discrete form fields** to capture clinical trial information and provide the level of detail needed for peer review
- ✓ Presents key information to reviewers and staff in a **consistent format**
- ✓ **Aligns** with ClinicalTrials.gov (where possible) for future data exchange with ClinicalTrials.gov



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

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Add Attachment | Delete Attachment | View Attachment

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

Add Attachment | Delete Attachment | View Attachment

Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
		☐	Add Attachment | Delete Attachment | View Attachment

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How Does the Human Subjects & Clinical Trials Information Form Impact Applicants?

New form collects information previously included in the Research Strategy

Applicants will now be instructed to:

- ✓Use the PHS Human Subjects and Clinical Trials Information form to capture detailed study information
- ✓Use the Research Strategy section to discuss the overall strategy, methodology, and analyses of proposed research, but *do not duplicate* information collected in the PHS Human Subjects and Clinical Trials Information form

Tip: Applicants should familiarize themselves with the new Human Subjects and Clinical Trial Information form to ensure information is captured appropriately in the application

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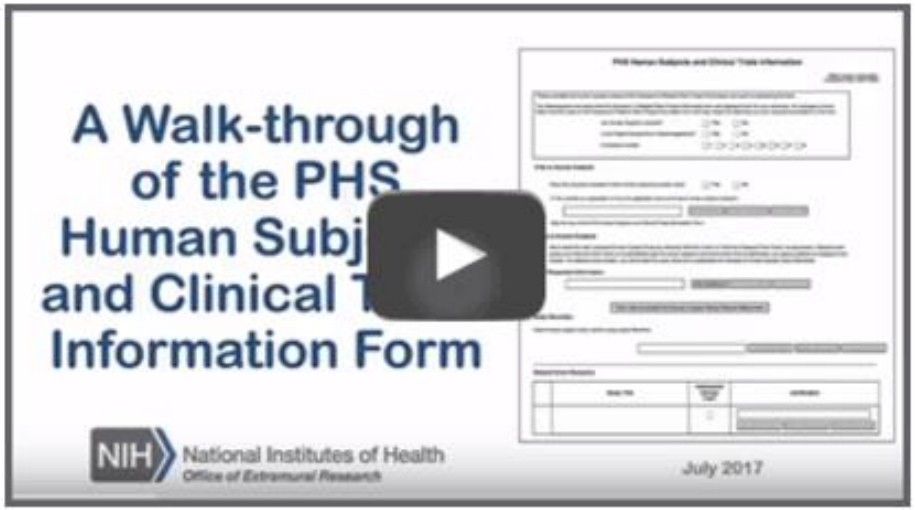
Resources for the Human Subjects & Clinical Trials Information Form

- ✓Explore the new Annotated Form Set for FORMS-E
- ✓Take a video tour of the new Human Subjects and Clinical Trial Information form



YouTube https://www.youtube.com/watch?v=nz9NWFhYOG8

Learn more at https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

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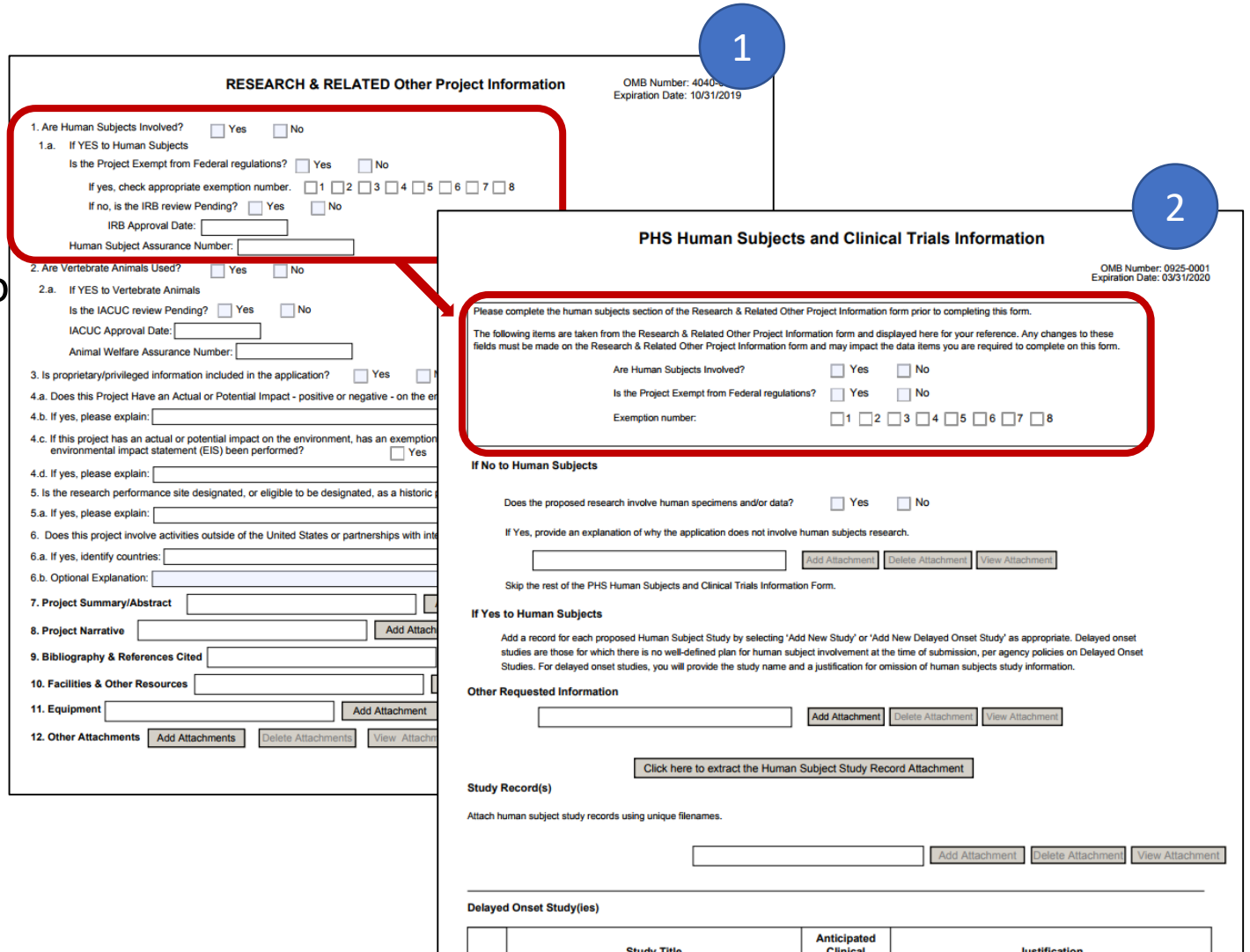
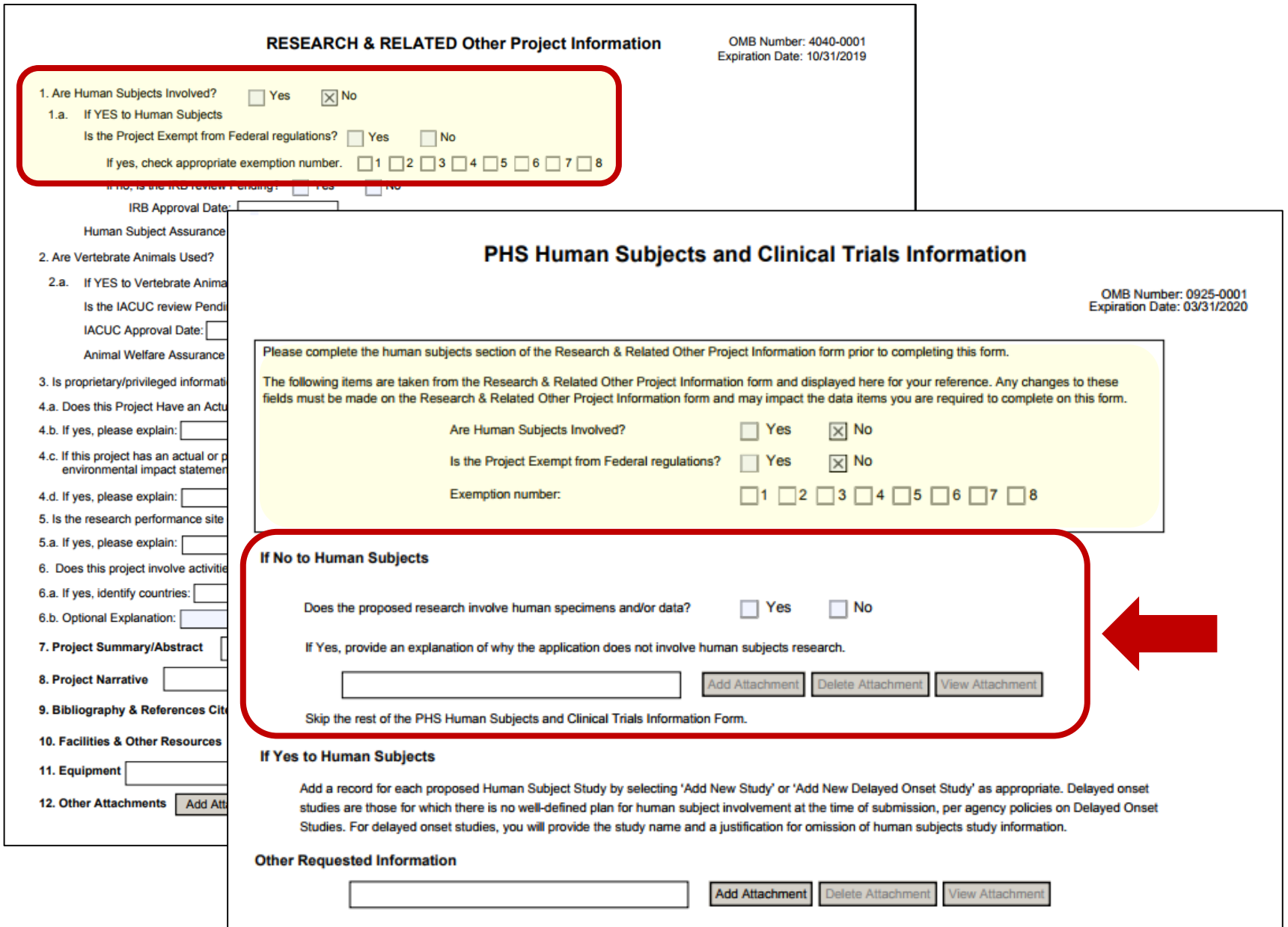
Relationship between forms

- Human Subjects data on R&R Other Project Info form drives behavior on new form



When Human Subjects = **NO**



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
12. Other Attachments Add Att

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

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Add Attachment | Delete Attachment | View Attachment

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Other Requested Information

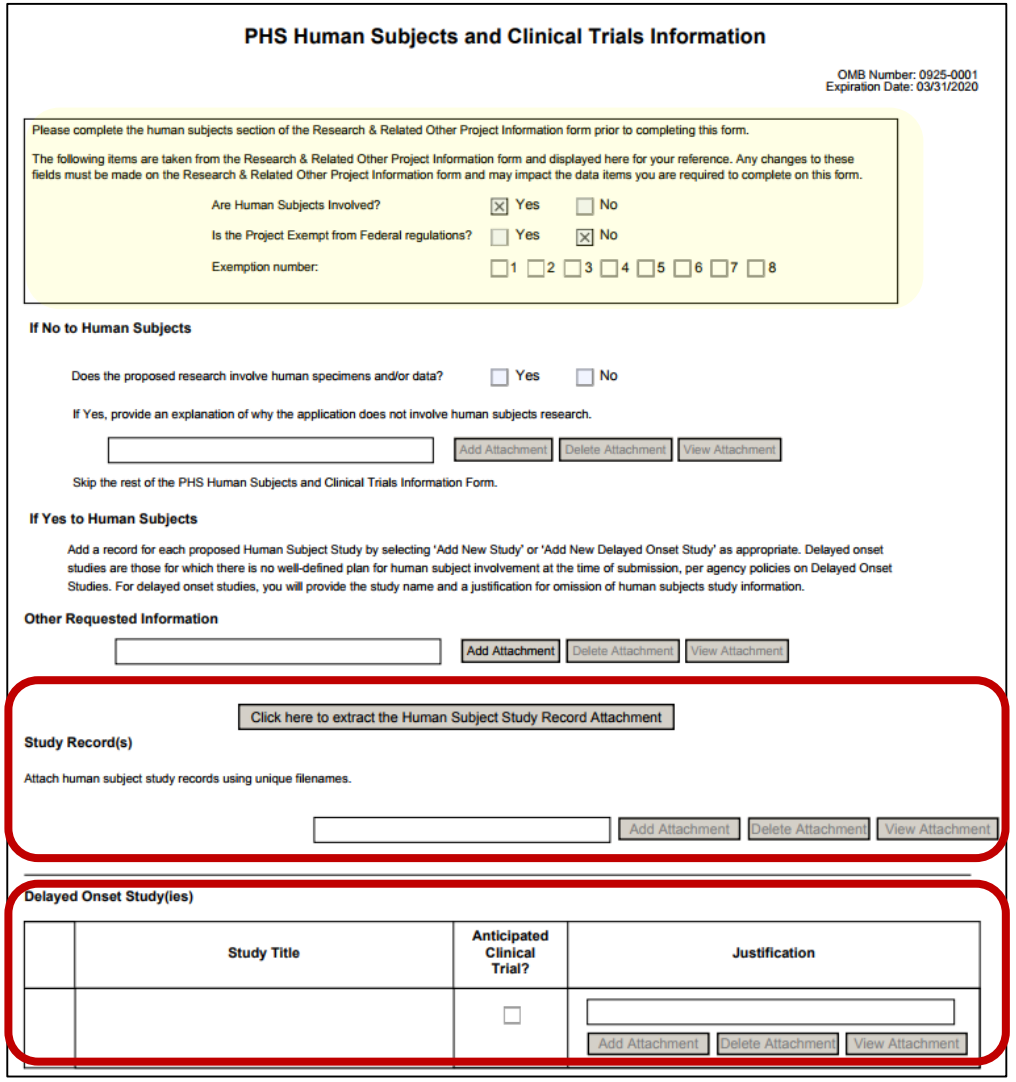
Add Attachment | Delete Attachment | View Attachment

When Human Subjects = **YES**

…must include at least one full or delayed onset study record.

Full Study Record

Delayed Onset Study



PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
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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

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Other Requested Information

Add Attachment | Delete Attachment | View Attachment

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

Add Attachment | Delete Attachment | View Attachment

Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
		☐	Add Attachment | Delete Attachment | View Attachment

Delayed Onset Studies

Glossary of NIH Terms

Delayed Onset Human Subject Study

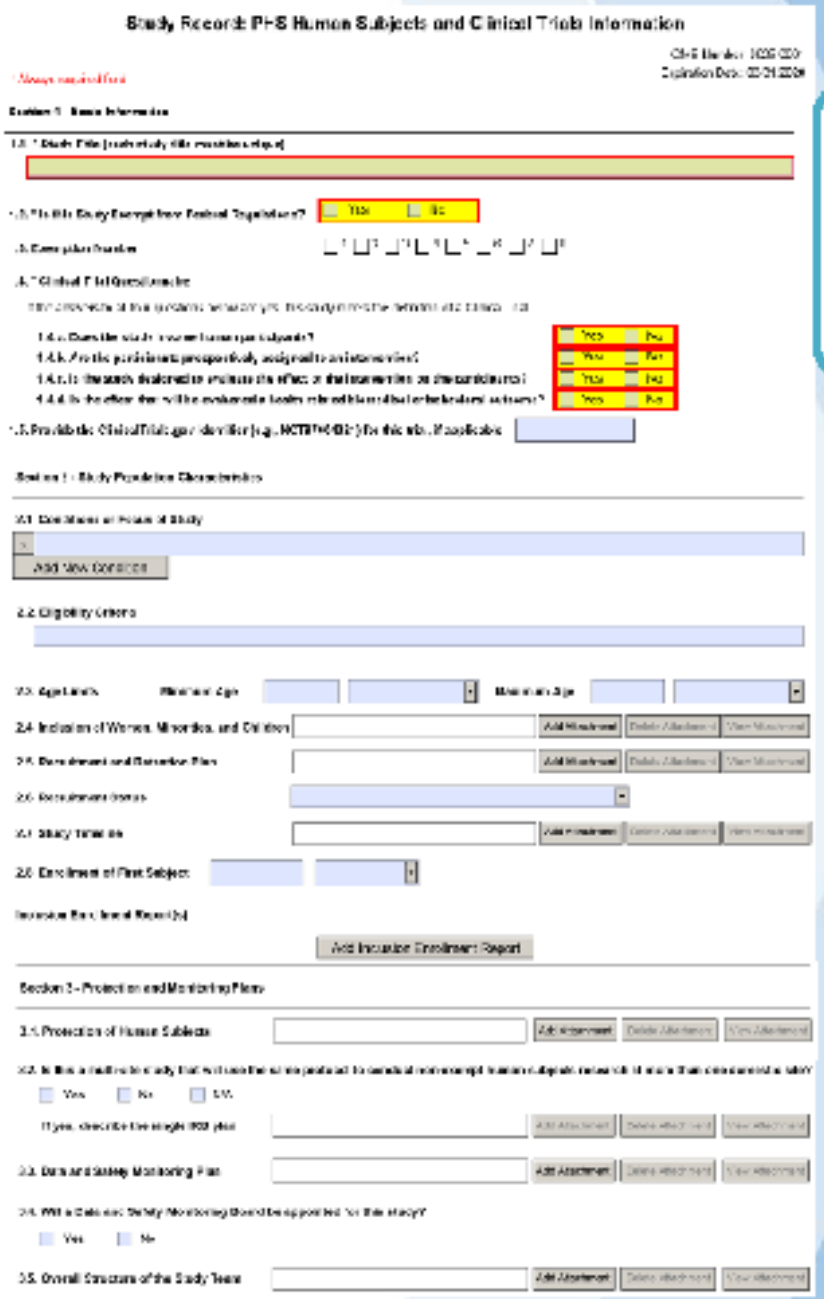
Human subjects research is anticipated within the period of award but definite plans for this involvement cannot be described in the application.

Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
		☐	Add Attachment / Delete Attachment / View Attachment

STUDY RECORD

- 5 sections
- All human subjects research
  - Some Clinical Trials specific
- Individual study records; one/protocol; up to 150
- Structured data
  - Some information shuffled a bit
- Aligns with ClinicalTrials.gov information



Section 1 – Basic information

All HS

Has 4 CT questions

Section 2 – Population

All HS; except E4

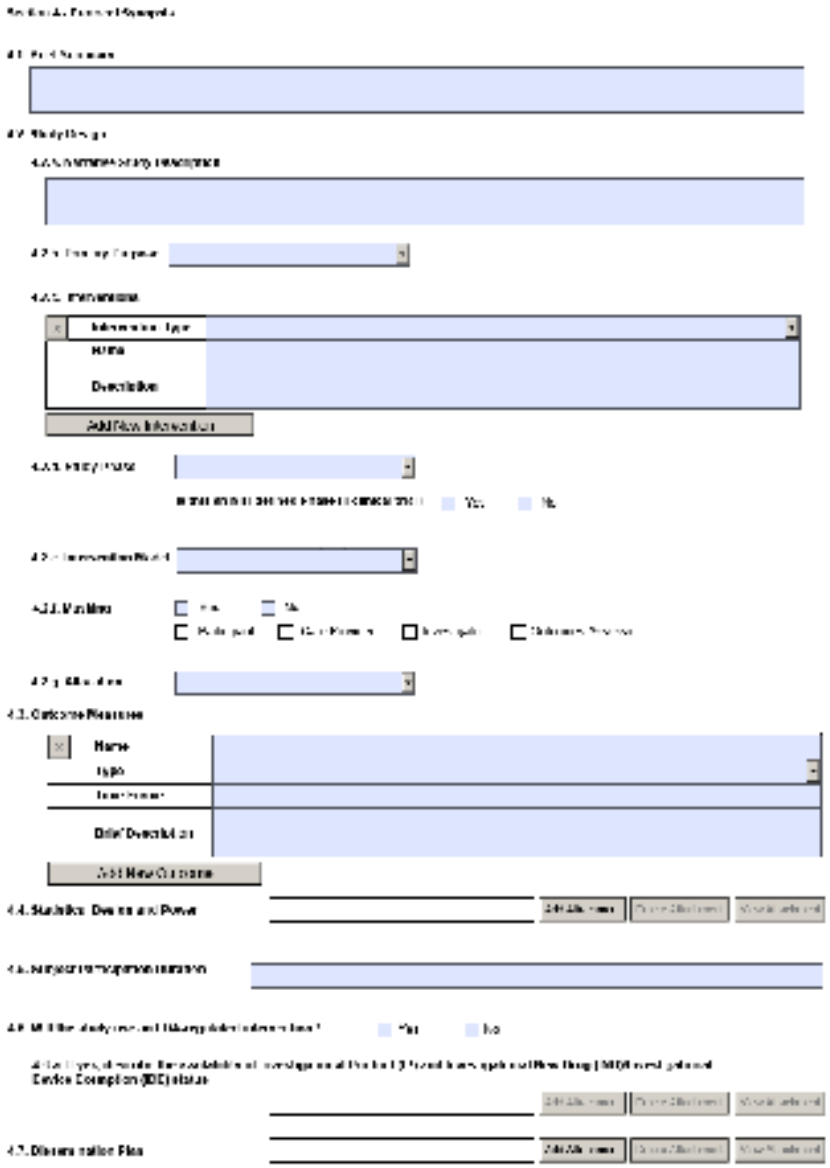
Inclusion information

Section 3 – Protection

Protection of Human Subjects and DSMP

Single IRB question

SECTION 4 – PROTOCOL SYNOPSIS



Sections 4 & 5

- Clinical Trial specific
- Should align with info from CT.gov
- Section 5 is FOA specific attachments

Tip: Become familiar with the PHS Human Subjects and Clinical Trial Forms at: https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

Study Record: Section 1 Basic Information

HS Required for Human Subjects studies
CT Required for Clinical Trial studies

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-000
Expiration Date: 03/31/202

* Always required field

Section 1 - Basic Information

CT HS **1.1. * Study Title (each study title must be unique)**

CT HS **1.2. * Is this Study Exempt from Federal Regulations?** ☐ Yes ☐ No

CT HS **1.3. Exemption Number** ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

CT HS **1.4. * Clinical Trial Questionnaire**

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

CT HS **1.4.a. Does the study involve human participants?** ☐ Yes ☐ No

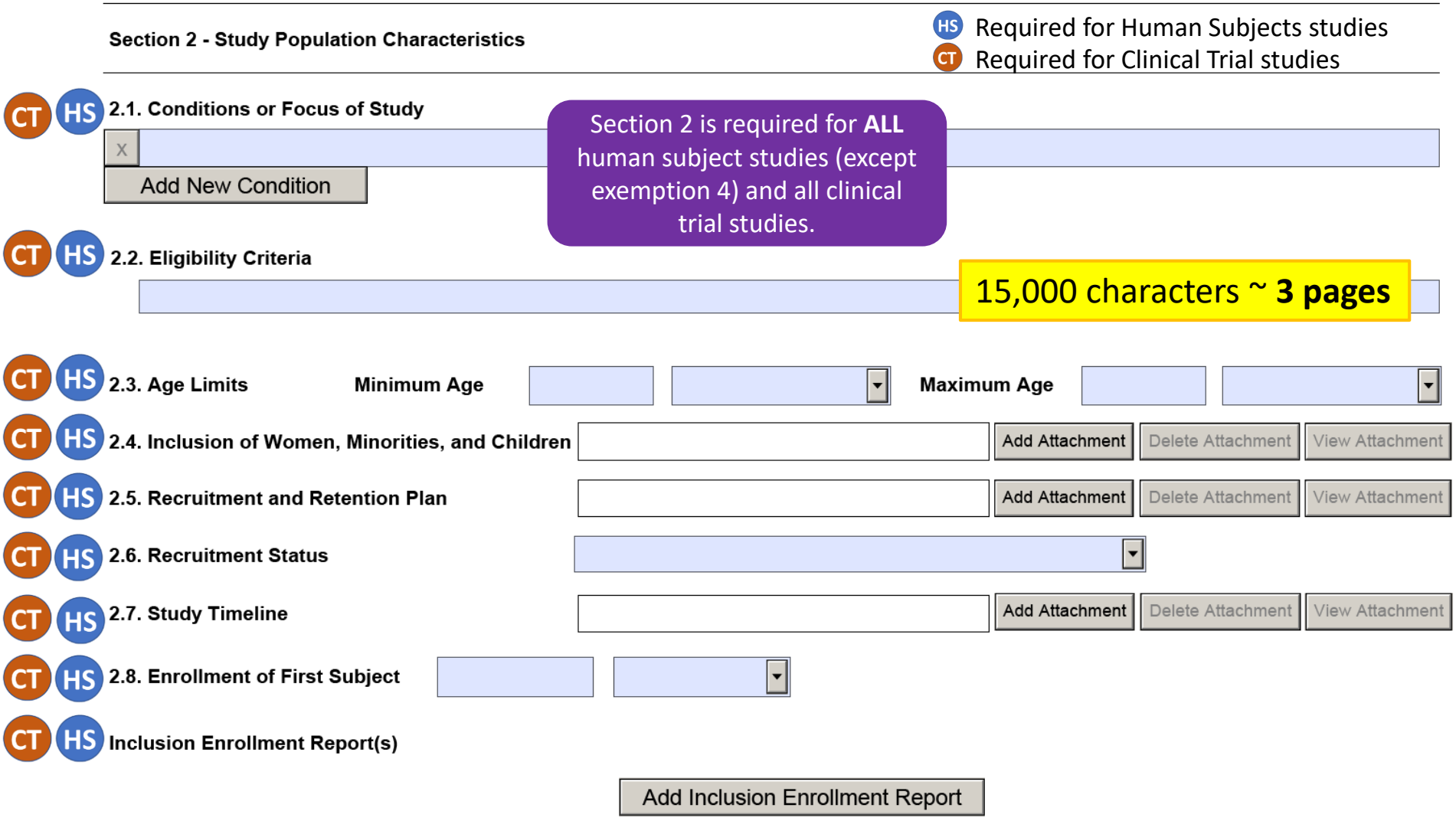
CT HS **1.4.b. Are the participants prospectively assigned to an intervention?** ☐ Yes ☐ No

CT HS **1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?** ☐ Yes ☐ No

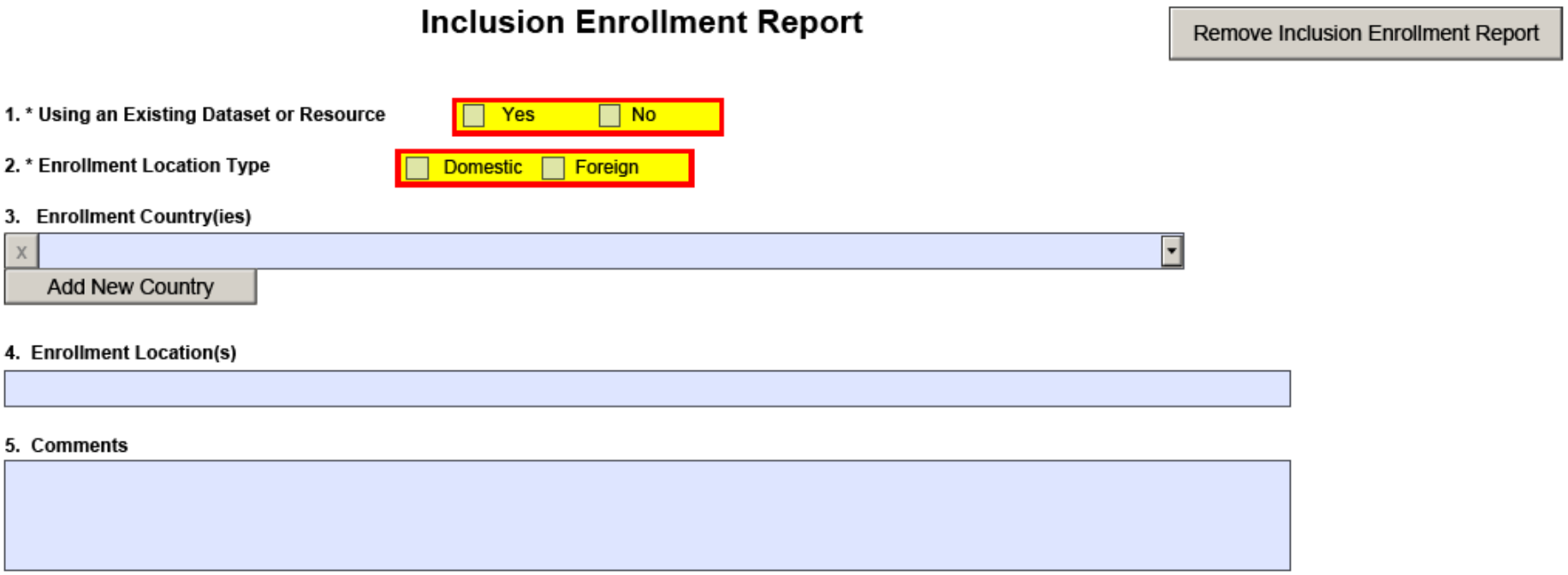
CT HS **1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?** ☐ Yes ☐ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Study Record: Section 2
Study Population Characteristics



Inclusion Enrollment Report



Planned vs Cumulative Enrollment Report

Planned enrollment required when “Using an Existing Dataset or Resource” = No.

Planned

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian					
Native Hawaiian or Other Pacific Islander					
Black or African American					
White					
More than One Race					
Total					

Cumulative enrollment required when “Using an Existing Dataset or Resource” = Yes.

Cumulative (Actual)

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

< Previous Report | Report 1 of 1 | Next Report >

|<< First Report | Delete Report | Last Report >>|

Study Record: Section 3 Protection and Monitoring Plans

3.1 and 3.2 are required for human subject studies (3.3-3.5 are optional).

All fields in Section 3 are required for clinical trial studies.

HS Required for Human Subjects studies
CT Required for Clinical Trial studies

Section 3 - Protection and Monitoring Plans

CT HS **3.1. Protection of Human Subjects** | Add Attachment | Delete Attachment | View Attachment

CT HS **3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?**

☐ Yes ☐ No ☐ N/A

If yes, describe the single IRB plan | Add Attachment | Delete Attachment | View Attachment

CT **3.3. Data and Safety Monitoring Plan** | Add Attachment | Delete Attachment | View Attachment

CT **3.4. Will a Data and Safety Monitoring Board be appointed for this study?**

☐ Yes ☐ No

CT **3.5. Overall Structure of the Study Team** | Add Attachment | Delete Attachment | View Attachment

Study Record: Section 4 Protocol Synopsis

CT Required for Clinical Trial studies

Section 4 - Protocol Synopsis

4.1. Brief Summary

CT

5,000 characters ~ **1 page**

4.2. Study Design

CT **4.2.a. Narrative Study Description**

CT

32,000 characters ~ **6.5 pages**

4.2.b. Primary Purpose

CT

4.2.c. Interventions

CT

X	**Intervention Type**	
	Name	
	Description	

Add New Intervention

CT **4.2.d. Study Phase**

Is this an NIH-defined Phase III clinical trial? ☐ Yes ☐ No

CT **4.2.e. Intervention Model**

CT **4.2.f. Masking** ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

CT **4.2.g. Allocation**

Study Record: Section 4 (cont.)

CT Required for Clinical Trial studies

CT **4.3. Outcome Measures**

X Name	
Type	
Time Frame	
Brief Description	

Add New Outcome

CT **4.4. Statistical Design and Power** Add Attachment Delete Attachment View Attachment

CT **4.5. Subject Participation Duration**

CT **4.6. Will the study use an FDA-regulated intervention?** ☐ Yes ☐ No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

Add Attachment Delete Attachment View Attachment

CT **4.7. Dissemination Plan** Add Attachment Delete Attachment View Attachment

Study Record: Section 5

CT Required for Clinical Trial studies

CT **Section 5 - Other Clinical Trial-related Attachments**

5.1. Other Clinical Trial-related Attachments | Add Attachments | Delete Attachments | View Attachments

Only use when specifically requested by FOA

Examples from recently published FOAs:

- Clinical Trial Research Experience
- Project Management Plan
- Milestone Plan
- Single Site Justification Plan

Changes to the Appendix Policy

Due Dates on or after January 25, 2018

Since the new Human Subjects and Clinical Trials Information form collects key elements from the protocol, the **optional protocol submission will be removed from the Appendix Policy.**

Parent FOAs

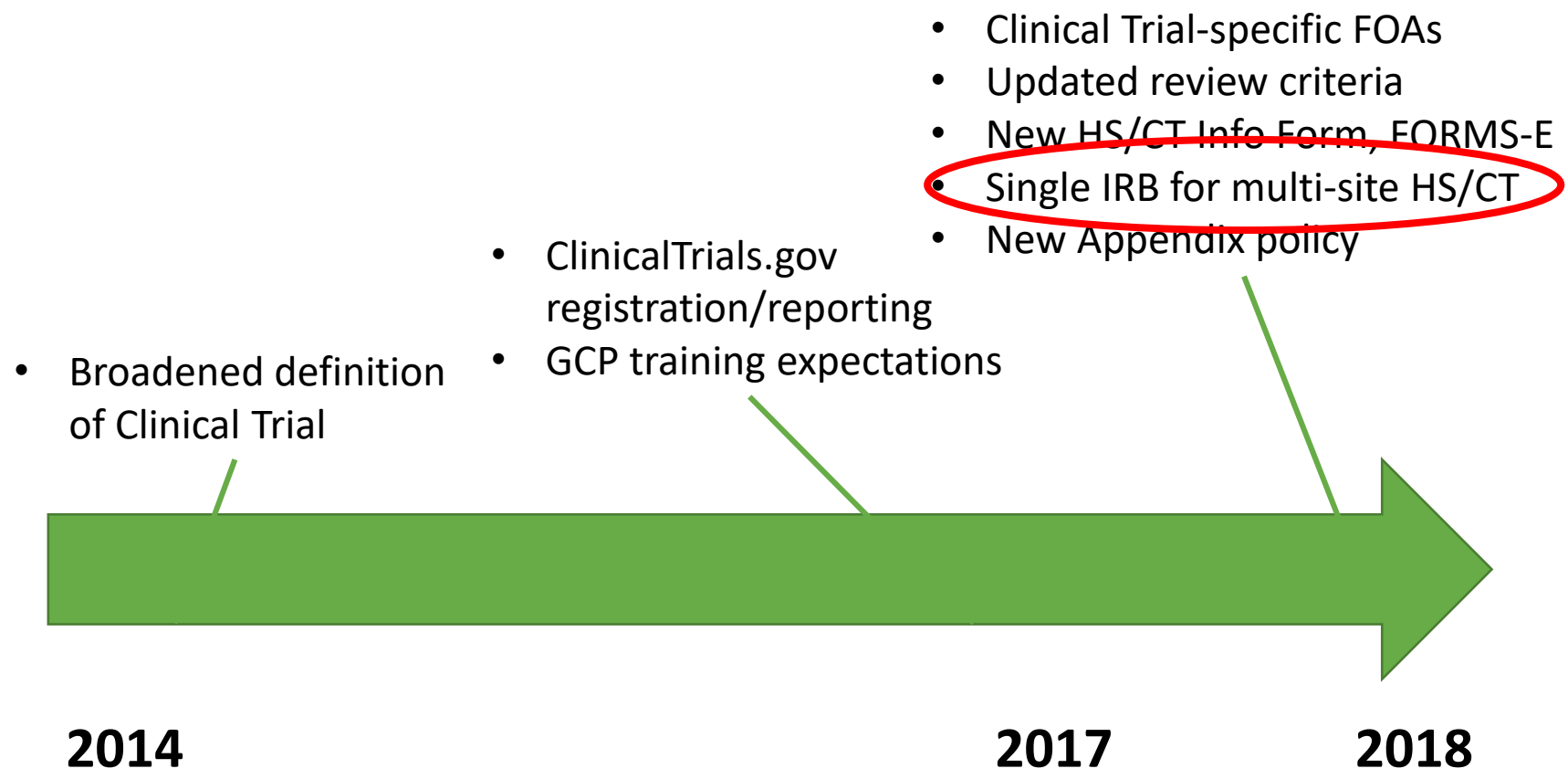
- ✓ Will **NEVER** allow inclusion of the protocol in the application
- ✓ If the protocol is included, the application will be sent back

IC issued FOAs

- ✓ Protocols and other materials allowed only when specified as required in the FOA

See NIH Guide Notice: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-098.html

Changes to NIH Human Subjects Research and Clinical Trials Policies



Single Institutional Review Board (sIRB) Policy for Multi-site Research

Effective for due dates on/after January 25, 2018 – NIH expects that all multi-site studies, which involve non-exempt human subjects research funded by the NIH, will use a *single Institutional Review Board (sIRB)* to conduct the ethical review required for the protection of human subjects

sIRB policy aims to:

- ✓ Streamline IRB review process to enhance research efficiency
- ✓ Reduce unnecessary administrative burdens and inefficiencies

Learn more at https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

NIH National Institutes of Health

What Does the sIRB Policy Apply To?

- Domestic sites of NIH-funded multi-site studies where each site will conduct the **same** protocol involving non-exempt human subjects research
- Includes research supported through:
  - ✓ Grants
  - ✓ Cooperative agreements
  - ✓ Contracts
  - ✓ NIH Intramural Research Program

- sIRB policy does NOT apply to
  - career development, research training, or fellowship awards
  - Foreign sites

Key Dates

Grants: Applications **due** on or after January 25, 2018

Contracts: Solicitations **published** starting January 25, 2018

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sIRB Plan for Applicants/Offerors

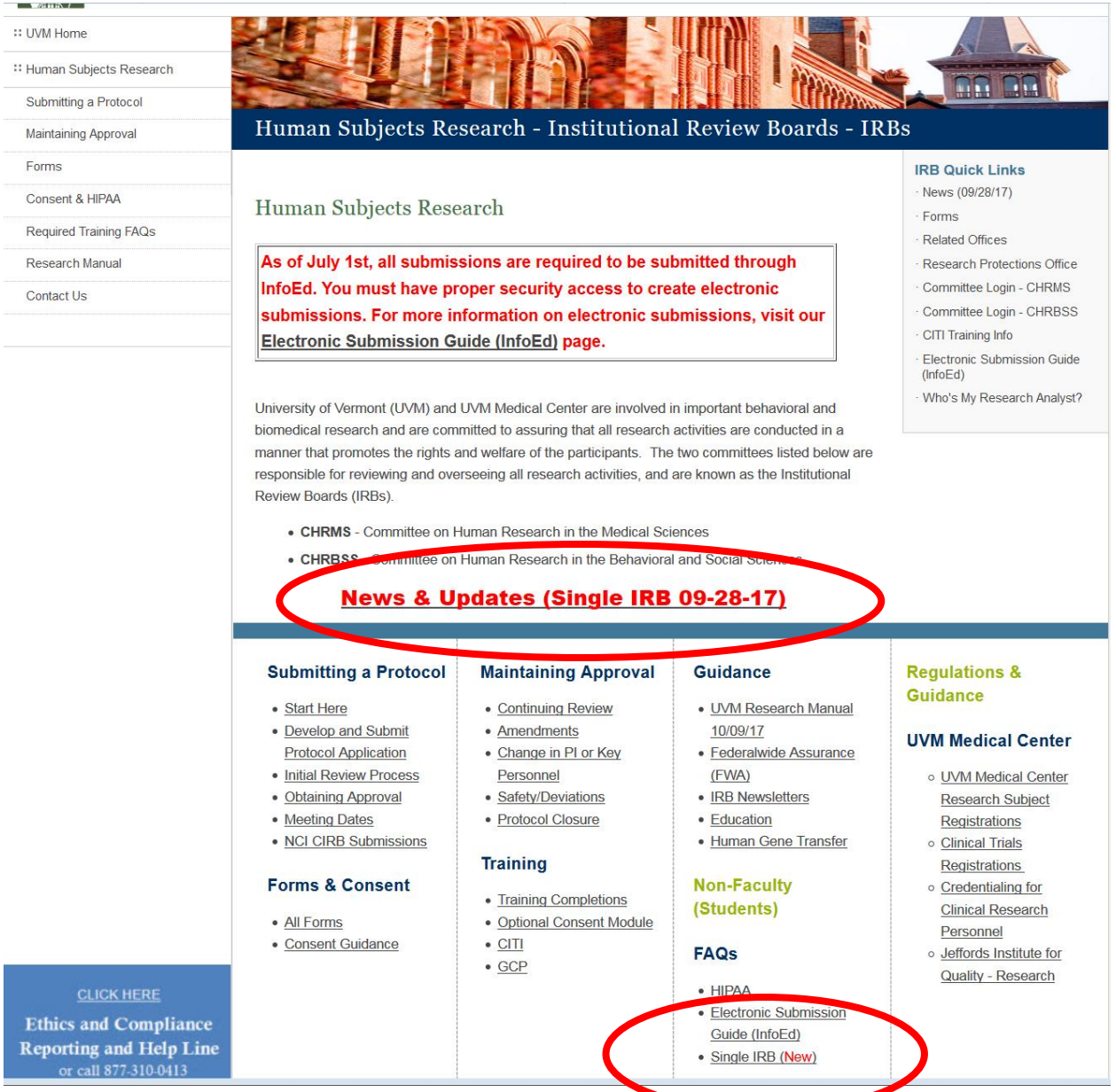
Application/proposal must include a plan that:

- ✓ Describes the use of an sIRB that will be selected to serve as the IRB of record for all study sites
- ✓ Confirms that participating sites will adhere to the sIRB Policy and describes how communications between sites and sIRB will be handled

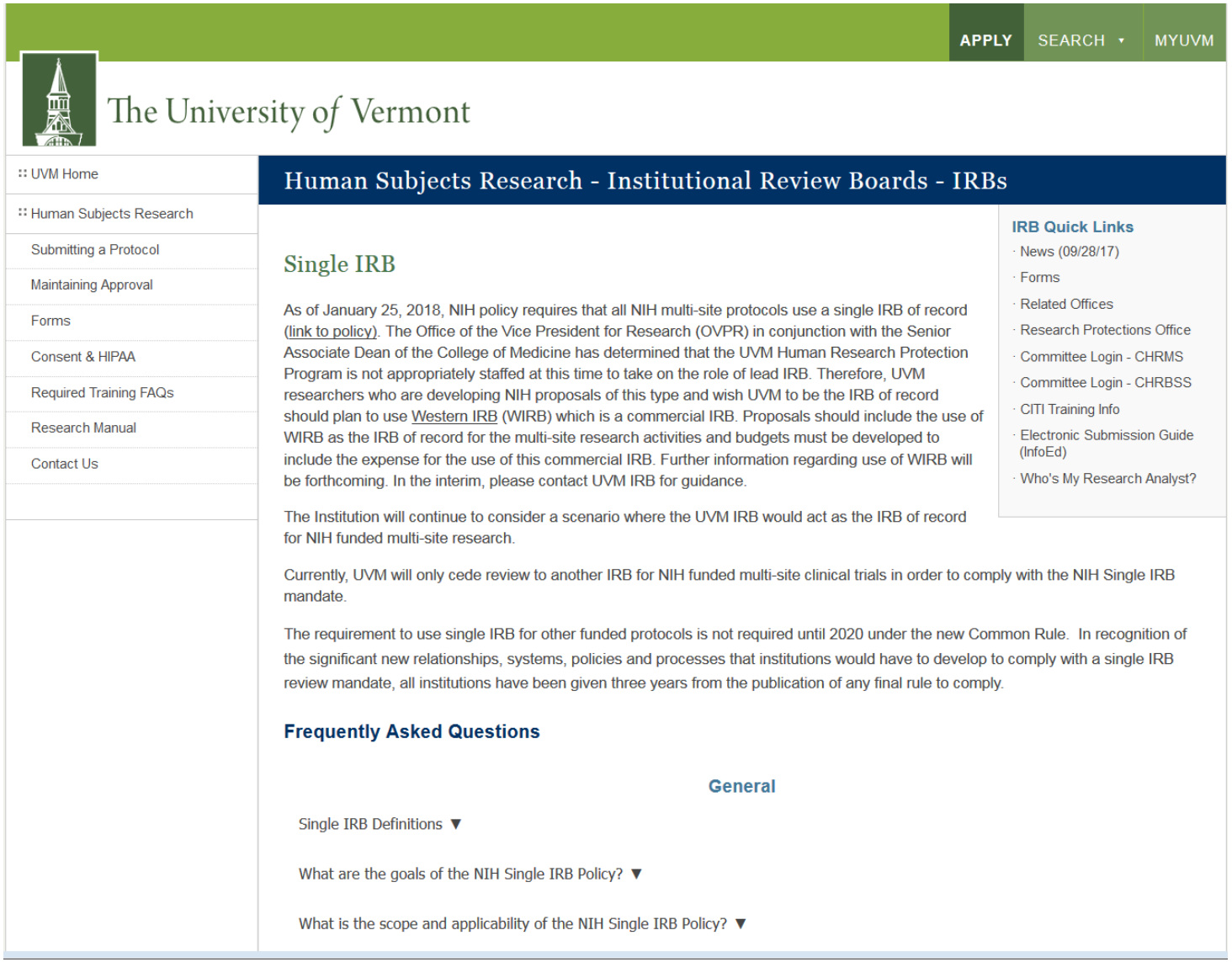
Tip: sIRB Plan attachment will be included in the new Human Subjects & Clinical Trials Information form

NIH National Institutes of Health

Resources: UVM - RPO



Resources: UVM - RPO



APPLY SEARCH MYUVM

The University of Vermont

- UVM Home
- Human Subjects Research
  - Submitting a Protocol
  - Maintaining Approval
  - Forms
  - Consent & HIPAA
  - Required Training FAQs
  - Research Manual
  - Contact Us

Human Subjects Research - Institutional Review Boards - IRBs

Single IRB

As of January 25, 2018, NIH policy requires that all NIH multi-site protocols use a single IRB of record (link to policy). The Office of the Vice President for Research (OVPR) in conjunction with the Senior Associate Dean of the College of Medicine has determined that the UVM Human Research Protection Program is not appropriately staffed at this time to take on the role of lead IRB. Therefore, UVM researchers who are developing NIH proposals of this type and wish UVM to be the IRB of record should plan to use Western IRB (WIRB) which is a commercial IRB. Proposals should include the use of WIRB as the IRB of record for the multi-site research activities and budgets must be developed to include the expense for the use of this commercial IRB. Further information regarding use of WIRB will be forthcoming. In the interim, please contact UVM IRB for guidance.

The Institution will continue to consider a scenario where the UVM IRB would act as the IRB of record for NIH funded multi-site research.

Currently, UVM will only cede review to another IRB for NIH funded multi-site clinical trials in order to comply with the NIH Single IRB mandate.

The requirement to use single IRB for other funded protocols is not required until 2020 under the new Common Rule. In recognition of the significant new relationships, systems, policies and processes that institutions would have to develop to comply with a single IRB review mandate, all institutions have been given three years from the publication of any final rule to comply.

IRB Quick Links

- News (09/28/17)
- Forms
- Related Offices
- Research Protections Office
- Committee Login - CHRMS
- Committee Login - CHRBSS
- CITI Training Info
- Electronic Submission Guide (InfoEd)
- Who's My Research Analyst?

Frequently Asked Questions

General

Single IRB Definitions ▼

What are the goals of the NIH Single IRB Policy? ▼

What is the scope and applicability of the NIH Single IRB Policy? ▼

How will UVM Comply with the sIRB Policy?

- UVM investigators should **coordinate with RPO** early to determine:
  - Will UVM serve as the single IRB of record?
  - Will UVM cede to another institution?
- If UVM will be the single IRB of record:
  - we will use an external vendor – Western IRB
  - Western IRB costs will need to be budgeted
  - Costs will be available soon
- A Single IRB Plan will need to be included in NIH proposals at the time of application – RPO is developing text that can be included

Summary: How Does This Affect My Grant Application?

- Use **appropriate FOA**
- Read FOA carefully, ensure your proposal addresses **review criteria**
- Complete **new Human Subjects and Clinical Trials Information form**
- Research strategy: **do not duplicate info** provided in new form
- **Describe sIRB and plan** for communication, if applicable
- **Retain documentation** of GCP training
- Ensure **appendix materials** comply with new policy: no protocol

Key Dates for the Human Subjects & Clinical Trials Information Form

September 25, 2017 – New FORMS-E Application Instructions available

October 25, 2017 – FORMS-E Application Packages will start being published for FOAs with due dates on/after January 25, 2018

January 25, 2018 – First due dates for new FORMS-E Application Packages

Tip: During the transition period from FORMS-D to FORMS-E, both form packages will be available for some FOAs. ***It is important that applicants pay close attention and choose the announcement specific for their due date.***

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Resources: NIH

Clinical Trial Requirements for Grants and Contracts:

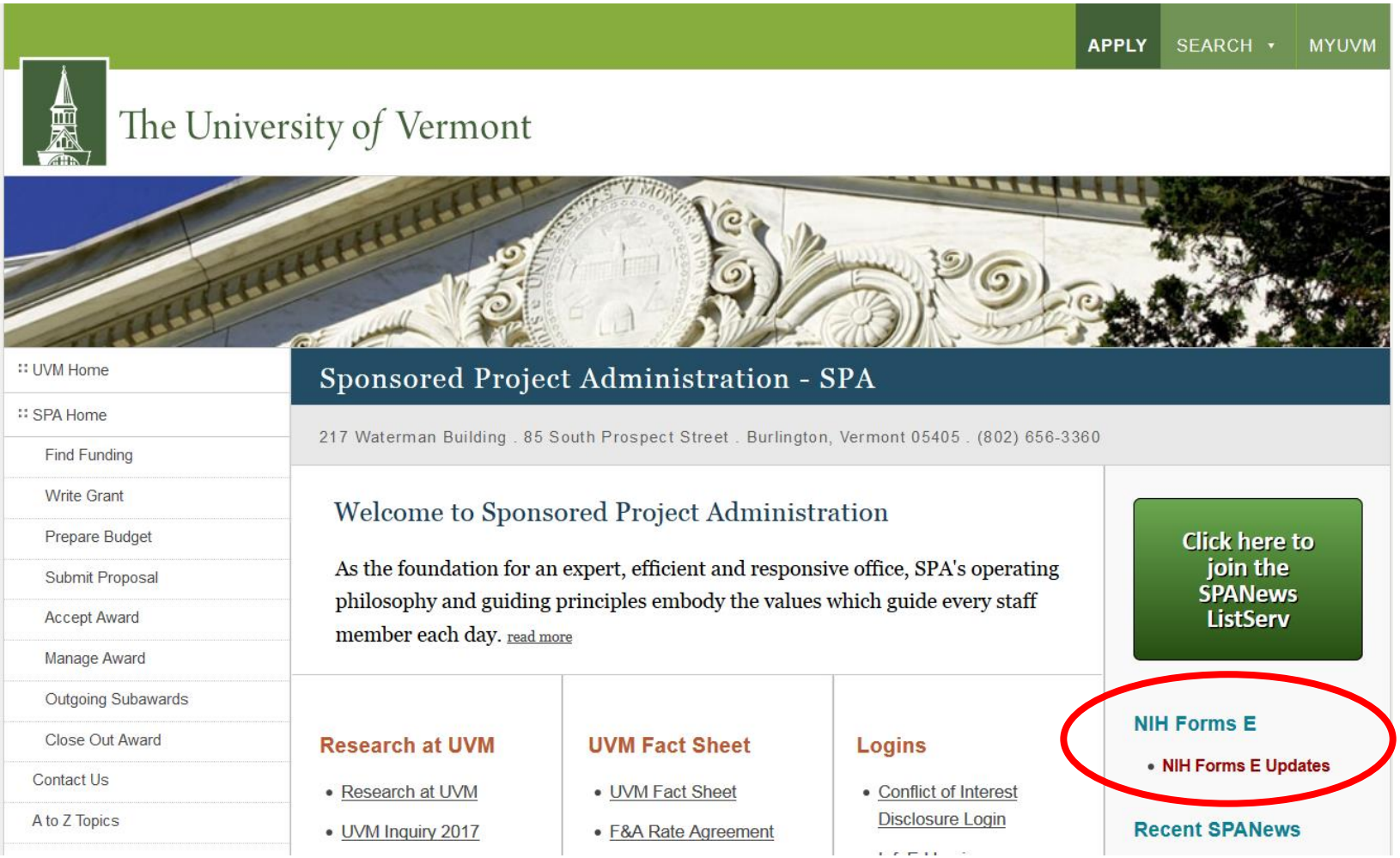
- ✓Definition
- ✓Decision Tool
- ✓Case Studies
- ✓FAQs

Training Resources:

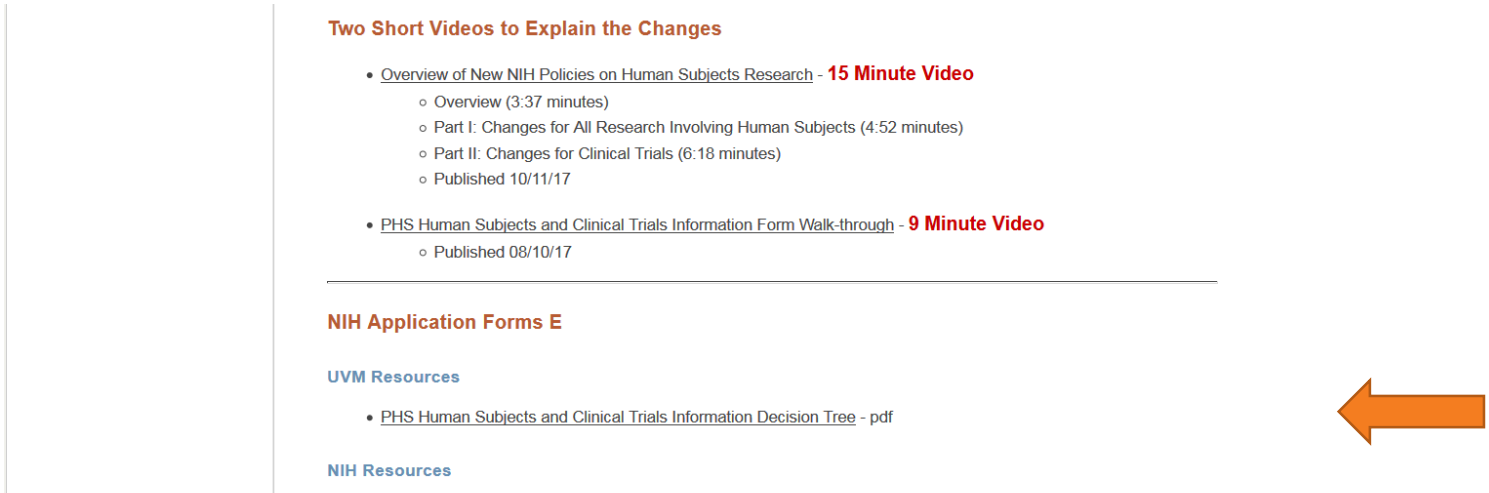
- ✓Slides
- ✓Human Subjects/Clinical Trials Questionnaire
- ✓Videos
- ✓Training opportunities

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

Resources: UVM - SPA



Resources: UVM - SPA



Who Can I Contact With Questions?

Sponsored Projects Administration	
Julie Macy	Team Lead Proposal Submission & Award Administration
Karin Bourassa	Research Administrator
Joshua Tyack	Research Administrator
Gretchen Argraves	Research Administrator
Research Protections Office	
Gale Weld, CIP	Research Analyst
Office of Clinical Trials Research	
Kimberly Luebbers, MSHS, RN, BSN, OCN	Director Assistant Dean for Clinical Research
Office of the Vice President for Research	
Jeralyn Haraldsen, PhD	Grant Proposal Manager

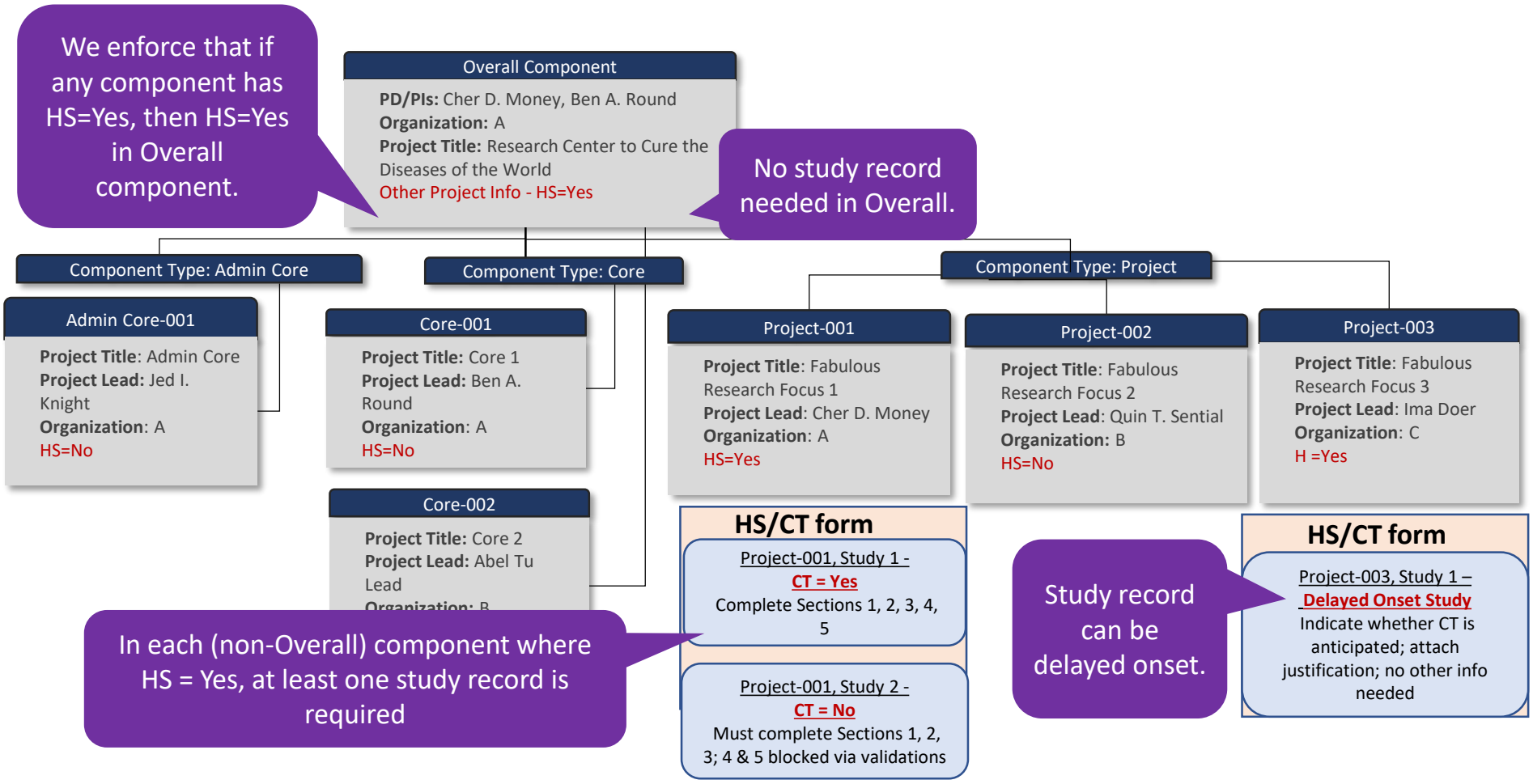
Thank you!

Jeralyn Haraldsen, PhD
Grant Proposal Manager
UVM, Office of the Vice President for Research
Jeralyn.Haraldsen@uvm.edu

Multi-project

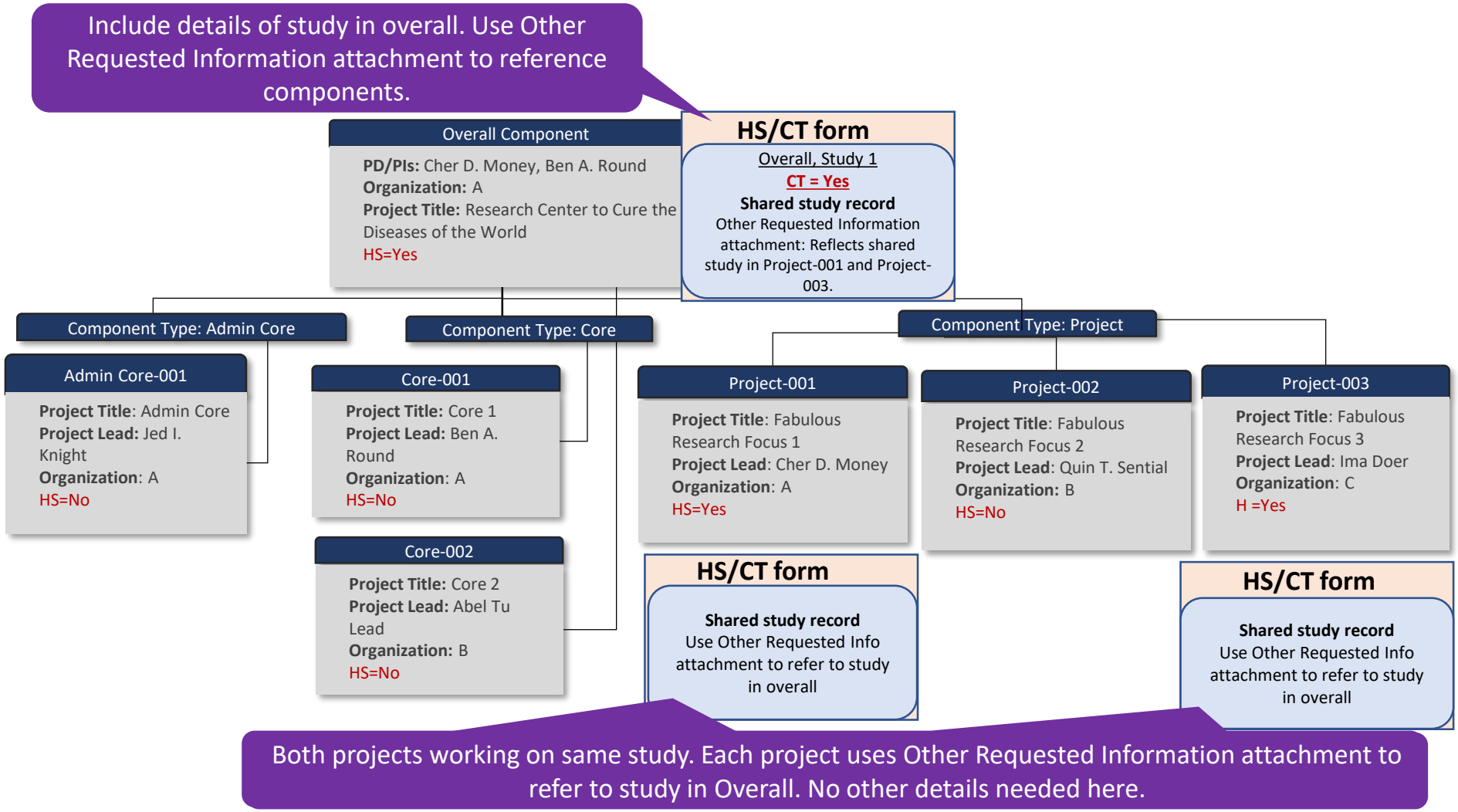
- FORM included in all components (i.e., Overall and Other Components)
- Each study must be specified only once in an application and not repeated
  - Each study title must be unique
- Any HS=Yes component (except Overall) must have at least one proposed study record (can be delayed onset if meets the policy definition)
  - Exception: for studies that cross projects in a multi-project application, components must refer to study associated with Overall using the Other Requested Information attachment on the HS/CT form. The Other Requested Information attachment in the Overall must reference all involved components.

Multi-Project
Scenario A: Studies self-contained in components



Multi-Project

Scenario B: Multiple components working on same study



Unpacking the Definition (Part I)

Prospectively Assigned: a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

Intervention: a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.

Examples include:

- drugs/small molecules/compounds, biologics, devices
- procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews)
- strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits)
- treatment strategies, prevention strategies, and diagnostic strategies

Unpacking the Definition (Part II)

Health-related Biomedical or Behavioral Outcome: the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life.

Examples include:

- positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression)
- positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers, reading comprehension and/or information retention)
- positive or negative changes to disease processes
- positive or negative changes to health-related behaviors
- positive or negative changes to quality of life

Updated Certificates of Confidentiality (CoC) Policy

Effective October 1, 2017 - CoCs will be issued automatically for any NIH-funded project using identifiable, sensitive information that was on-going on/after December 13, 2016

- ✓ Eliminates the need for NIH funded investigators to apply for a CoC
- ✓ Enhances the privacy protections of individuals participating in NIH-funded research
- ✓ Requires investigators to only disclose information under specific circumstances
- ✓ Applies to NIH awards funded wholly, or in part, by NIH
- ✓ Disclosure restrictions also apply to anyone who receives a copy of identifiable sensitive information protected by the policy, even if they are not funded by NIH
- ✓ CoC is issued as a term and condition of award (no physical certificate)

Learn more at https://humansubjects.nih.gov/coc/index

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Significance Criterion

- Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention **well supported** by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms?
- For trials focusing on clinical or public health endpoints, is this clinical trial **necessary for testing the safety, efficacy or effectiveness** of an intervention that could lead to a change in clinical practice, community behaviors or health care policy?
- For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial **needed to advance scientific understanding**?

Investigator(s) Criterion

- With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to **organize, manage and implement** the proposed clinical trial and **meet milestones** and **timelines**?
- Do they have appropriate expertise in **study coordination, data management** and **statistics**?
- For a **multicenter trial**, is the **organizational structure appropriate** and does the application identify a core of potential center **investigators and staffing for a coordinating center**?

Innovation Criterion

- Does the design/research plan include **innovative** elements, as appropriate, that:
  - enhance its sensitivity,
  - potential for information or
  - potential to advance scientific knowledge or clinical practice?

Approach Criterion

Study Design

- Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested?
- Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research?
- Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results?
- Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Approach Criterion (continued)

Study Design

- Are potential ethical issues adequately addressed?
- Is the process for obtaining informed consent or assent appropriate?
- Is the eligible population available?
- Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection?
- Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate?
- Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed?
- Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Approach Criterion (continued)

Study Design

- Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate?
- Is there a plan to obtain required study agent(s)?
- Does the application propose to use existing available resources, as applicable?

Approach Criterion (continued)

Data Management and Statistical Analysis

- Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions?
- Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable?
- Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed?
- Is there a plan to complete data analysis within the proposed period of the award?

Environment Criterion

- If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?
- Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?
- If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?
- If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Additional Review Criteria

Study Timeline

- Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment?
- Is the projected timeline feasible and well justified?
- Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?
- Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Single IRB PLAN

- Name of the sIRB of record
- Indicate that:
  - All sites, including any added after award, agree to rely on sIRB
  - Sites will sign reliance agreement that will include a communication plan
  - Indicate who will maintain records of this agreement
- If sIRB cannot be identified at time of application/proposal state that awardee will follow the policy and will provide information prior to initiating the study
- Exceptions
  - **Policy-based exceptions** - legal or regulatory: provide specific citation and indicate which sites are impacted
  - **Other consideration**, “ad hoc” exceptions, provide compelling justification
- Several protocols may have one sIRB plan for all
- If delayed onset, in justification include statement that awardee will follow the policy and will provide sIRB info prior to start