MIT RESEARCH ADMINISTRATION SUPPORT GUIDE TO:

THE PHS HUMAN SUBJECTS & CLINICAL TRIAL INFORMATION FORM & EXTRACTED STUDY RECORD

SUPPORTS VERSIONS 2 & 3 FOR **NIH FORM SERIES F FOR WORKSPACE**

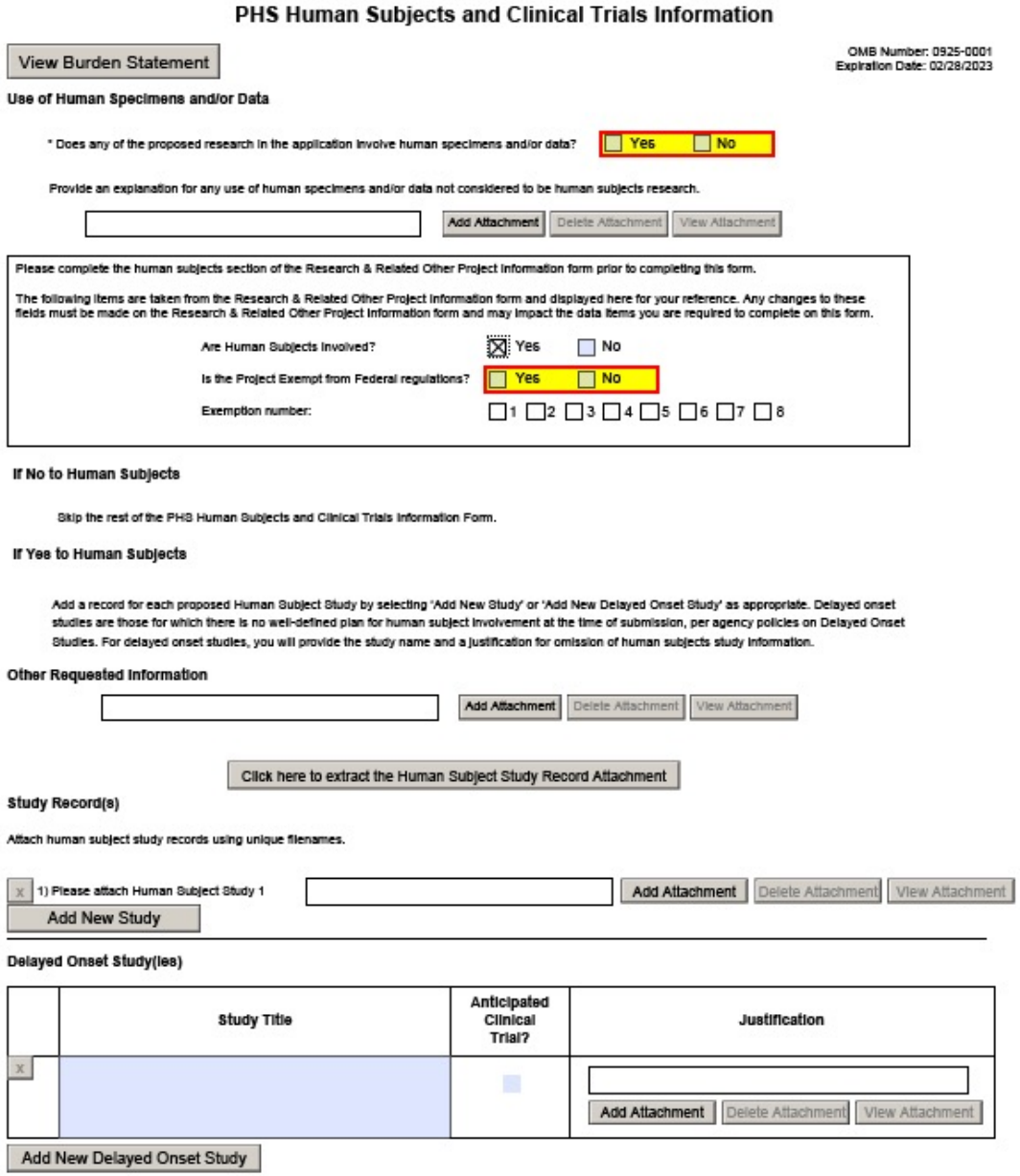
October 2021

OVERVIEW OF THE HUMAN STUDIES & CLINICAL TRIAL INFORMATION (HSCT) FORM

The HSCT form is present in **all** NIH funding opportunities: it is required whether or not human subjects are a part of your project. The form consists of a "cover" page that provides features to:

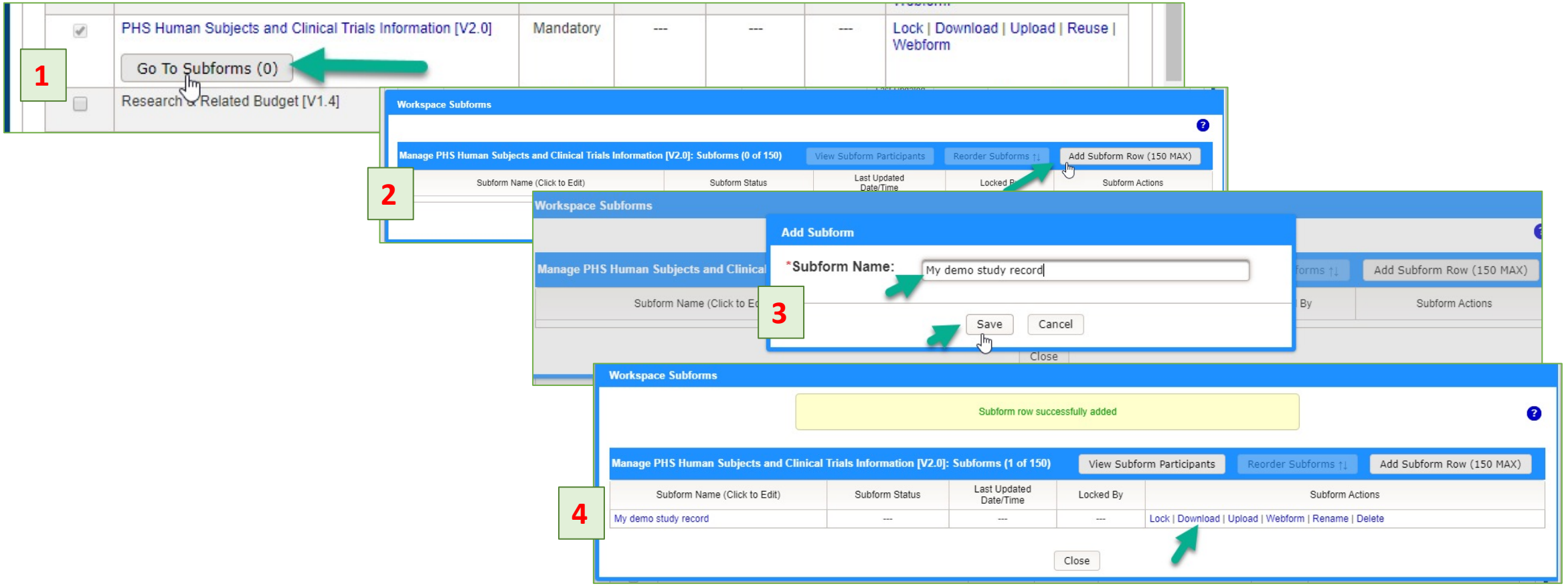
- attach a file for specimens/data use
- attach a delayed onset justification
- attach other information specified in the announcement
- an extractable Study Record, and a place to attach completed Study Record(s)

In G.G Workspace, the specimen use, other materials, and delayed onset files are uploaded to this form. But the Study Record must be either filled out or uploaded in the **Sub Form row/window**.



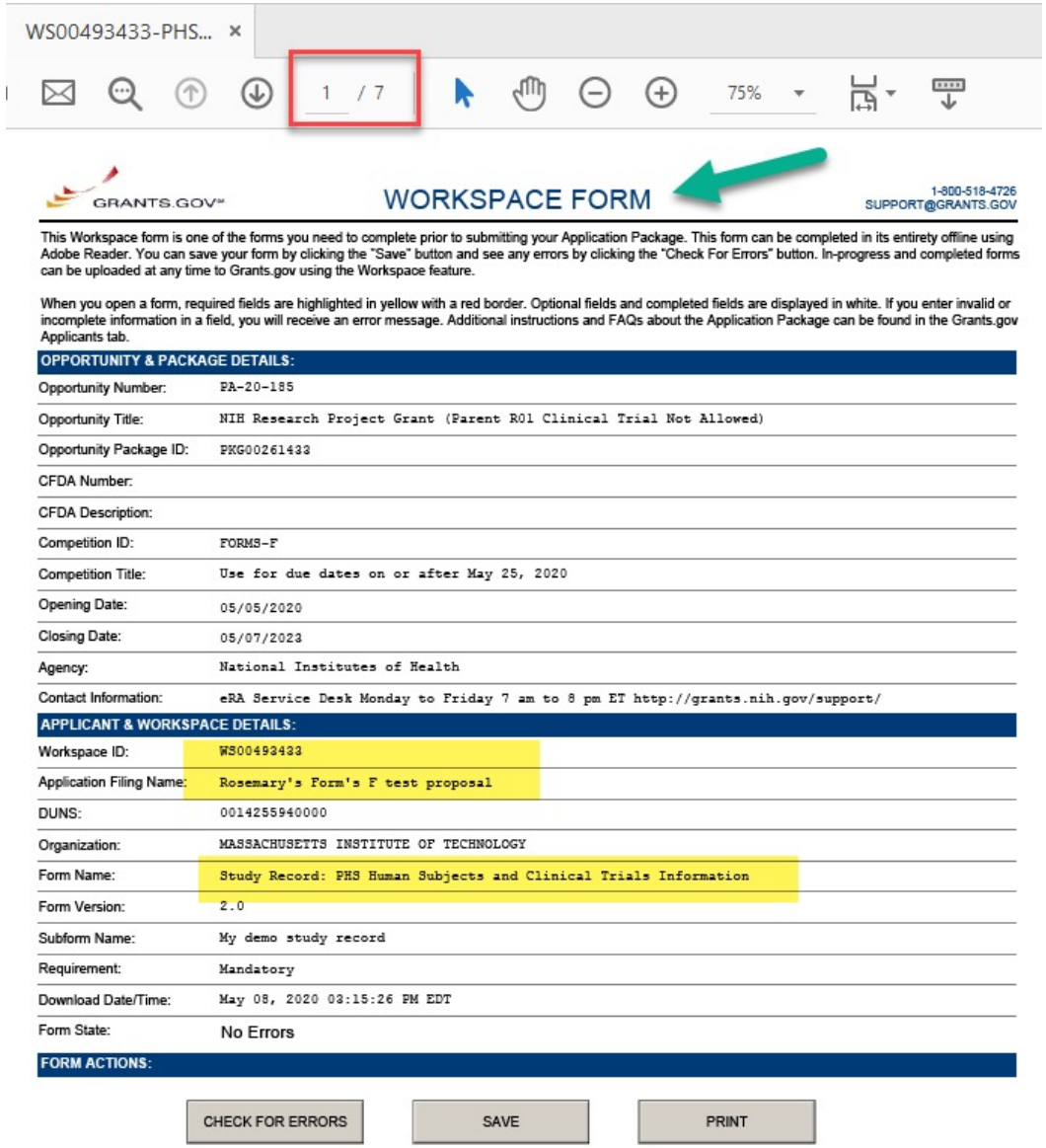
DOWNLOADING THE PHS STUDY RECORD FORM

1. **In Workspace**: In the PHS Human Subjects & Clinical Trials (HSCT) Information form row, use Go To Subforms to open that window.
2. Click Add Subform Row
3. Enter a name that helps you identify this study record, especially if there will be multiple, and then save.
4. Download the form to work offline, or open the webform to complete it that way.



OVERVIEW OF THE PHS STUDY RECORD DOWNLOADED FORM

Workspace Form information cover page.
Scroll down to access the Study Record pages.



WS00493433-PHS... ×

1 / 7 75%

GRANTS.GOV™

WORKSPACE FORM

1-800-518-4726
SUPPORT@GRANTS.GOV

This Workspace form is one of the forms you need to complete prior to submitting your Application Package. This form can be completed in its entirety offline using Adobe Reader. You can save your form by clicking the "Save" button and see any errors by clicking the "Check For Errors" button. In-progress and completed forms can be uploaded at any time to Grants.gov using the Workspace feature.

When you open a form, required fields are highlighted in yellow with a red border. Optional fields and completed fields are displayed in white. If you enter invalid or incomplete information in a field, you will receive an error message. Additional instructions and FAQs about the Application Package can be found in the Grants.gov Applicants tab.

OPPORTUNITY & PACKAGE DETAILS:

Opportunity Number:	PA-20-185
Opportunity Title:	NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)
Opportunity Package ID:	PKG00261433
CFDA Number:	
CFDA Description:	
Competition ID:	FORMS-F
Competition Title:	Use for due dates on or after May 25, 2020
Opening Date:	05/05/2020
Closing Date:	05/07/2023
Agency:	National Institutes of Health
Contact Information:	eRA Service Desk Monday to Friday 7 am to 8 pm ET http://grants.nih.gov/support/

APPLICANT & WORKSPACE DETAILS:

Workspace ID:	WS00493433
Application Filing Name:	Rosemary's Form's F test proposal
DUNS:	0014255940000
Organization:	MASSACHUSETTS INSTITUTE OF TECHNOLOGY
Form Name:	Study Record: PHS Human Subjects and Clinical Trials Information
Form Version:	2.0
Subform Name:	My demo study record
Requirement:	Mandatory
Download Date/Time:	May 08, 2020 03:15:26 PM EDT
Form State:	No Errors

FORM ACTIONS:

CHECK FOR ERRORS SAVE PRINT

DON'T COMPLETE A STUDY RECORD WHEN…

- Research uses qualified **biospecimens** or **biospecimen data.**
- All the specimens or data comes from **cadavers** or otherwise deceased individuals.

Instead of the study record:

- Provide an explanation for any use of human specimens and/or data not considered to be human subjects research. This explanation should include:
  - Who is providing the data/biological specimens and their role in the proposed research;
  - Description of the identifiers that will be associated with the human specimens and data;
  - List of who has access to subjects' identities; and
  - Describe how the privacy of research participants and confidentiality of data will be protected.
- In **Workspace**, this **PDF file** is uploaded directly to the PHS HSCT Information form.

  (**Not uploaded as the study record**, **which is added as a Subform**).

DON'T COMPLETE A STUDY RECORD WHEN...

Study meets definition of Delayed Onset - human subjects research is anticipated within the period of award but definite plans for this involvement cannot be described in the application (because it depends on the outcomes of the planned research).

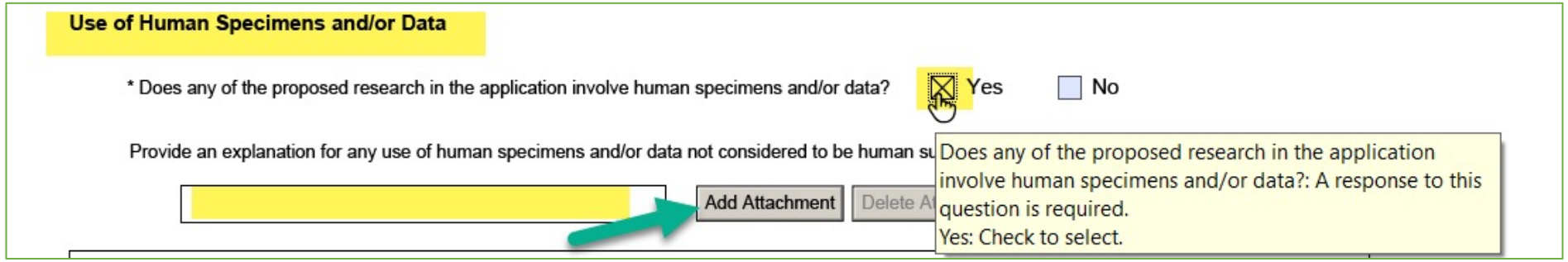
Instead of a study record:

- Provide at **Study Title -** Enter a brief, unique title that describes the study the participants will be involved in.
- Provide a **justification** explaining why human subjects study information is not available at the time of application.
- If NIH's **Single Institutional Review Board** (sIRB) policy will apply to your study, this justification must also include information regarding how the study will comply with the policy. The applicant must provide a **statement naming the sIRB** of record in the Just-in-Time submission prior to award.
- If NIH's Policy on the **Dissemination** of NIH-Funded Clinical Trial Information will apply to your study, this justification must also **include the dissemination plan**.

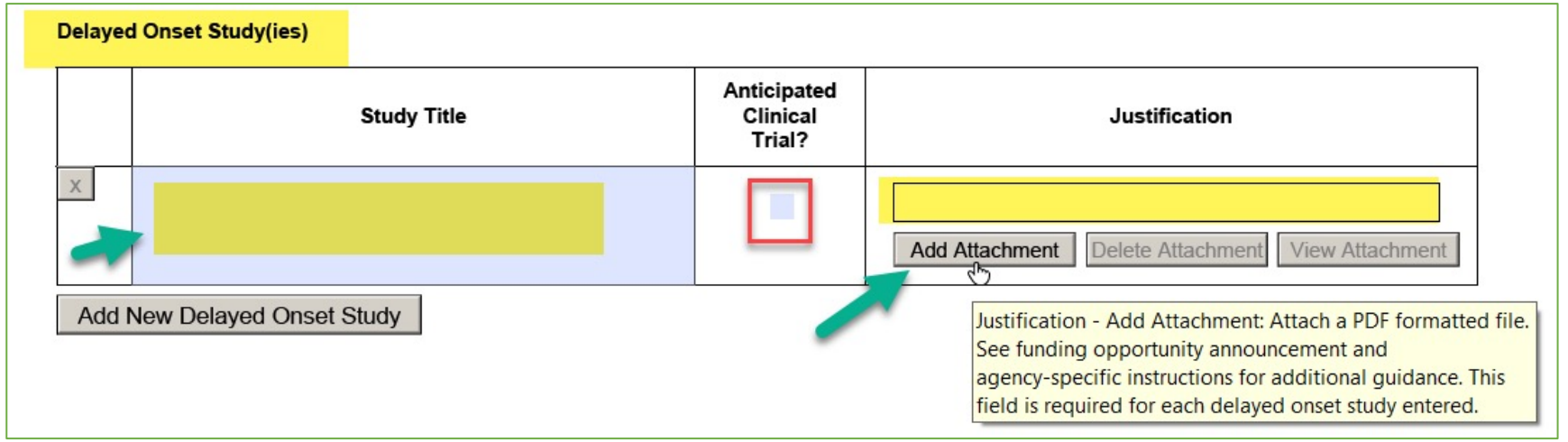
In Workspace: On the PHS HSCT Information form, Delayed Onset Study(ies) section, enter the Title in Study Title field, use the Add Attachment button upload the Justification file.

SPECIMEN AND DELAYED ONSET UPLOAD/ATTACHMENT DETAILS

In Workspace, if the research is not using human subjects, but will use **biospecimens or specimen data**: Check "Yes," and Add Attachment (file name must be **50 characters or less**, and not use any special characters.



In Workspace, if **delayed onset**: Enter the title, check if it clinical trial is anticipated, and Add Attachment (file name must be 50 characters or less, and not use any special characters.



EXEMPT STUDIES & THE STUDY …

All exempt categories require sections 1 and 3, but only Exempt 4 allows leaving section 2 unfilled.

Please note that eCommons will not accept (e.g. error) your proposal if the study record is improperly filled out.

Completing the PHS HS/CT Information Form – Exempt HS Research

	Section 1 Basic Information	Section 2 Study Population Characteristics	Section 3 Protection and Monitoring Plan	Section 4 Protocol Synopsis (Clinical Trials only)	Section 5 Other Clinical Trial Related Attachments (Clinical Trials only)
Exemption 1	Complete	Complete	Complete	Complete, if clinical trial	Complete, if clinical trial
Exemption 2	Complete	Complete	Complete	Complete, if clinical trial	Complete, if clinical trial
Exemption 3	Complete	Complete	Complete	Complete, if clinical trial	Complete, if clinical trial
Exemption 4	Complete	No	Complete	No	No
Exemption 5	Complete	Complete	Complete	Complete, if clinical trial	Complete, if clinical trial
Exemption 6	Complete	Complete	Complete	Complete, if clinical trial	Complete, if clinical trial

Identify your study type: HUMAN SUBJECTS OR CLINICAL TRIAL

- NIH now posts clinical trial specific funding opportunities. If you select a ***clinical trial required*** opportunity and do ***not*** include a clinical trial study report in your proposal, it will ERROR at eCommons.
- It is imperative to determine if your study meets the NIH definition of a clinical trial so you connect and submit with the correct funding opportunity.
- Use the **Decision Tree** on the next slide, review the NIH website resources, or contact the MIT COUHES office for help identifying if your project is defined as a Clinical Trial.

For more information and definitions, please refer to the NIH compliance website:

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

MIT Clinical Trial Decision Tree

Does the research ***prospectively assign*** participants to an intervention?

- No → The study is **NOT** a clinical trial
- Yes ↓

Is the research designed to evaluate an effect of the **intervention** on the participants?

- No → The study is **NOT** a clinical trial
- Yes ↓

Is the effect being evaluated a **health-related biomedical or behavioral** outcome?

- No → The study is **NOT** a clinical trial
- Yes ↓

Study meets the NIH definition of clinical trial. COUHES reviews research if the following criteria are met.

The research does **not** involve significantly **greater than minimal risk**.

- No → **Contact COUHES** 617-253-6787
- Yes ↓

MIT has the **appropriate resources** necessary to facilitate the research.

- No → **Contact COUHES** 617-253-6787
- Yes ↓

Research required to follow policies and procedures set forth by the COUHES office.
http://couhes.mit.edu/policies-procedures

Definitions for MIT clinical trial decision tree

Prospectively assigned term refers to 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 is defined as 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.

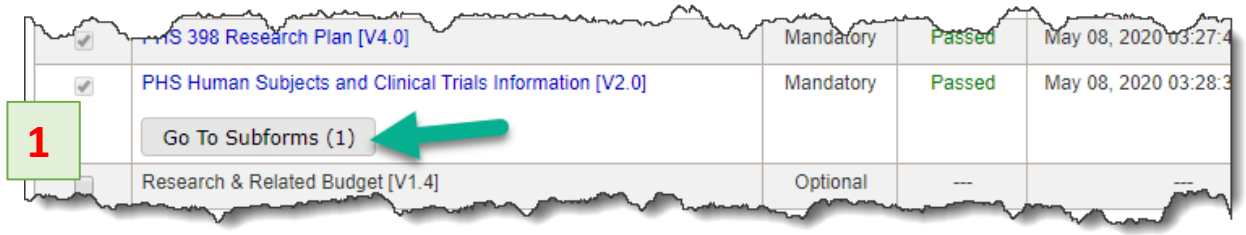
Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological 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 and, positive or negative changes to quality of life.

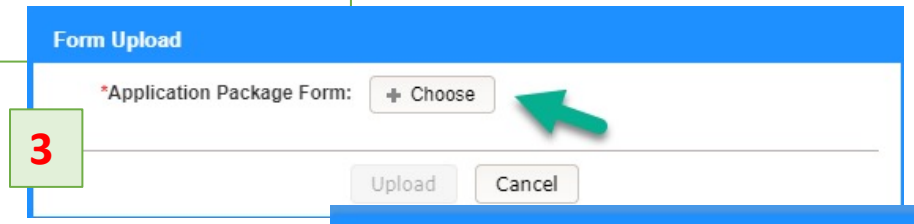
Significantly greater than minimal risk to subjects means that there is a probability of an event that is serious, prolonged and/or permanent occurring as a result of study participation or there is significant uncertainty about the nature or likelihood of adverse events.

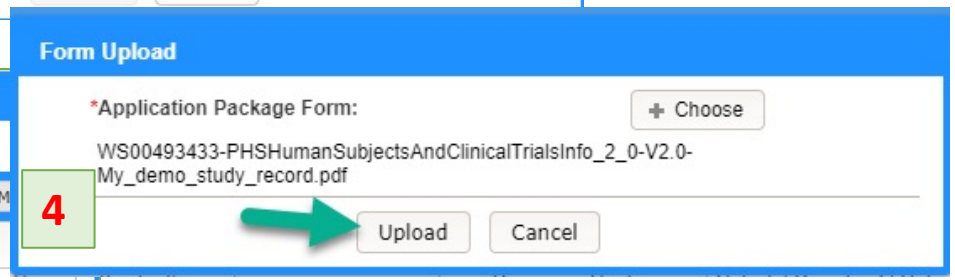
Appropriate resources: see website COUHES.MIT.EDU for list of available resources at MIT.

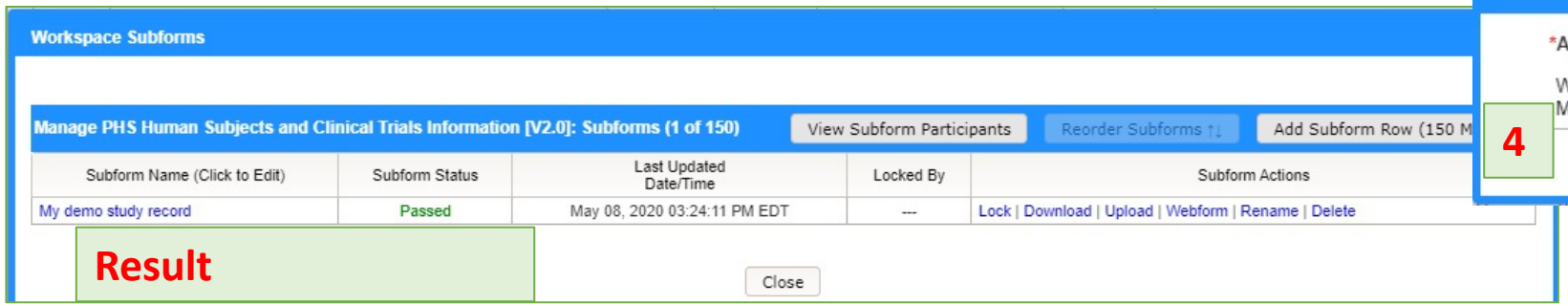
Upload the Study Record Workspace

1. **Upload**: In the PHS HSCT form row, use Go To Subforms to open that window.
2. In the Subform Row, click Upload to open the search window.
3. Click Choose & locate the file.
4. Click Upload, then close the SubForm window.









Study Record TIPS – eCommons enforced!

- **Human Subject** studies must complete **sections 1 through 3.2**.
- At least **one Enrollment Report** must be added, unless the study is Exempt 4.
- **Clinical Trials** must complete ***all* Sections 1 through 4.** (5 - only if the FOA requests it.)
- All narrative uploads must be plain PDF format.
- File names must be **50 characters or less**.
- File names must be **unique** – so if you have more than one study record-the file names cannot be identical (e.g. 'timeline.pdf")**.**
- Use the **correct version** for the F series: initial FOA's will use V-2.0, but will transition to V-3.0 at NIH's discretion.

HS **Required for Human Subjects studies**

CT **Required for Clinical Trial studies**

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 02/28/2023

* Always required field

Section 1 - Basic Information

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

Required and system enforced. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

CT HS **1.2. * Is this Study Exempt from Federal Regulations?** ☐ Yes ☐ No ← Answer required and system enforced.

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

If Study Exempt is Yes, must provide exemption number. Exemption must also be selected on Other Project Information form.

CT HS **1.4. * Clinical Trial Questionnaire** ← Answers to questionnaire required and system enforced.

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

1.4.a defaults to Yes and is not editable.

1.4.a. Does the study involve human participants? ☒ Yes ☐ No

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

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

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

If four questions are all Yes AND FOA allows clinical trials, then study will be flagged as a Clinical Trial (CT) study.*

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

Do NOT provide an answer in 1.5 UNLESS it is the Clinical Trial Identifier ID number in the DEFINED Format.

Optional. Provide NCT# for this study, if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application. If building on an existing study, enter NCT# for ancillary study (if available), not the parent study.

HS Required for Human Subjects studies

CT Required for Clinical Trial studies

Section 2 - Study Population Characteristics

CT HS **2.1. Conditions or Focus of Study**

Required and system enforced unless study is exemption 4. Up to 20 conditions at 255 characters each.

CT HS **2.2. Eligibility Criteria**

Required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

Age limits are required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

CT HS **2.3. Age Limits** **Minimum Age** **Maximum Age**

Dropdown list: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

Dropdown list: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

If "N/A (No Limit)" selected, do not provide numerical min/ max age.

CT HS **2.3.a. Inclusion of Individuals Across the Lifespan**

Required and system enforced unless study is exemption 4.

CT HS **2.4. Inclusion of Women and Minorities**

Required and system enforced unless study is exemption 4.

CT HS **2.5. Recruitment and Retention Plan**

Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

CT HS **2.6. Recruitment Status**

Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

CT HS **2.7. Study Timeline**

Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

View Attachment

CT HS **2.8. Enrollment of First Participant**

Date: MM/DD/YYYY.

Dropdown list: Anticipated, Actual

Dropdown selection required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

CT HS **2.9. Inclusion Enrollment Report(s)**

Inclusion Enrollment Reports required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

Add Inclusion Enrollment Report

Click the button to add

Up to 20 Inclusion Enrollment Reports can be added.

At least **one Enrollment Report** must be added & completed, unless the study is Exempt 4.

CT HS

Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

Required. Up to 600 characters.

2. * Using an Existing Dataset or Resource ☐ Yes ☐ No

Answer required and system enforced.

3. * Enrollment Location Type ☐ Domestic ☐ Foreign

Answer required and system enforced. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report.

4. Enrollment Country(ies)

Multi-select from list of countries.

No: fill in Planned Enrollment Report
Yes; fill in Cumulative/Actual Enrollment Report

5. Enrollment Location(s)

6. Comments

Up to 500 characters.

CT HS

Planned

Planned enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is No. System enforcement relaxed if Comment is provided.

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	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	0	0	0	0	0

Cumulative (Actual)

Cumulative (Actual) enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is Yes. System enforcement relaxed if Comment is provided.

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

Report 1 of 1

3.1 and 3.2 are required for **human subjects** (3.3-3.5 are optional).

All fields in Section 3 are required for **clinical trials.**

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**

Required and system enforced.

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

Answer required and system enforced. "N/A" is only a valid option if study is exempt from federal regulations (i.e., Question 1.2a is Yes).

If yes, describe the single IRB plan

NIH: If Yes, not required.
AHRQ: If Yes, required.

Add Attachment | Delete Attachment | View Attachment

CT **3.3. Data and Safety Monitoring Plan**

Required and system enforced for CT study. Optional for HS study.

Delete Attachment | View Attachment

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

☐ Yes ☐ No

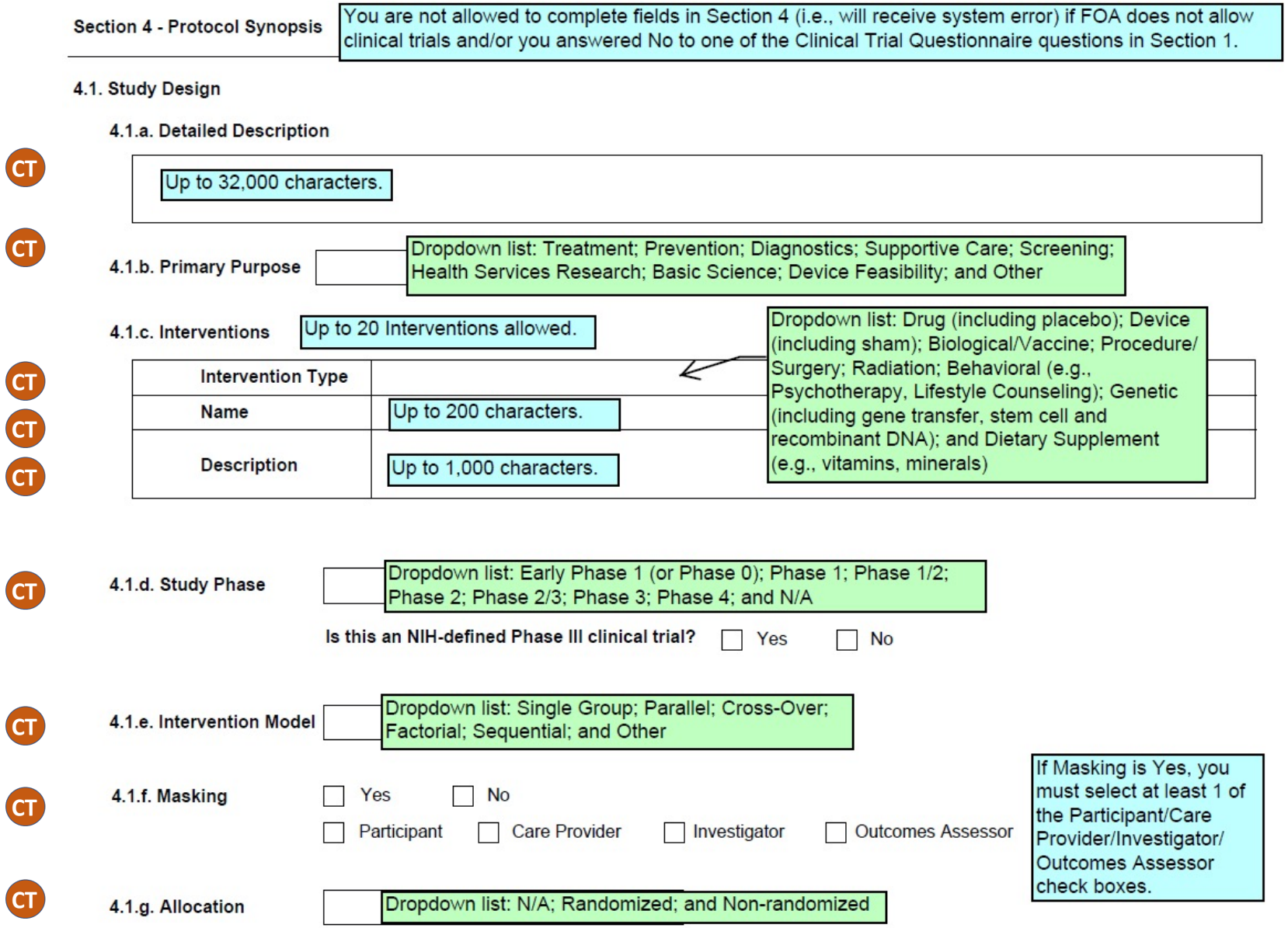
Answer required and system enforced for CT study unless otherwise noted in opportunity. Optional for HS study.

CT **3.5. Overall Structure of the Study Team**

Optional.

Add Attachment | Delete Attachment | View Attachment

Do NOT complete Section 4 when Human Subjects – but ALL fields required for Clinical Trials



CT Required for Clinical Trial studies

Only complete Section 4 when your study is a Clinical Trial.

CT Required for Clinical Trial studies

4.2. Outcome Measures At least one Outcome Measure required and system enforced for CT studies unless otherwise noted in opportunity. Up to 50 Outcome Measures allowed.

CT **Name**	Up to 255 characters.
CT **Type**	Dropdown list: Primary; Secondary; and Other
CT **Time Frame**	Up to 255 characters.
CT **Brief Description**	Up to 999 characters.

CT **4.3. Statistical Design and Power** ☐ Required and system enforced for CT study unless otherwise noted in opportunity. Attachment | Delete Attachment | View Attachment

CT **4.4. Subject Participation Duration** Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

CT **4.5. Will the study use an FDA-regulated intervention?** ☐ Yes ☐ No Answer required and system enforced for CT study unless otherwise noted in opportunity.

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

☐ Required and system enforced if Yes. Add Attachment | Delete Attachment | View Attachment

CT **4.6. Is this an applicable clinical trial under FDAAA?** ☐ Yes ☐ No

CT **4.7. Dissemination Plan** ☐ Required and system enforced for CT study. Generally one Dissemination Plan per application is sufficient. Can attach same plan (unique filenames) in multiple studies.

Section 5 - Other Clinical Trial-related Attachments

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

Form supports up to 10 attachments. Attachments only allowed for CT studies. Only include attachments requested in opportunity.