NIH GRANTEE SUPPORT FOR MANAGEMENT OF HUMAN SUBJECTS AND CLINICAL TRIALS STUDY INFORMATION

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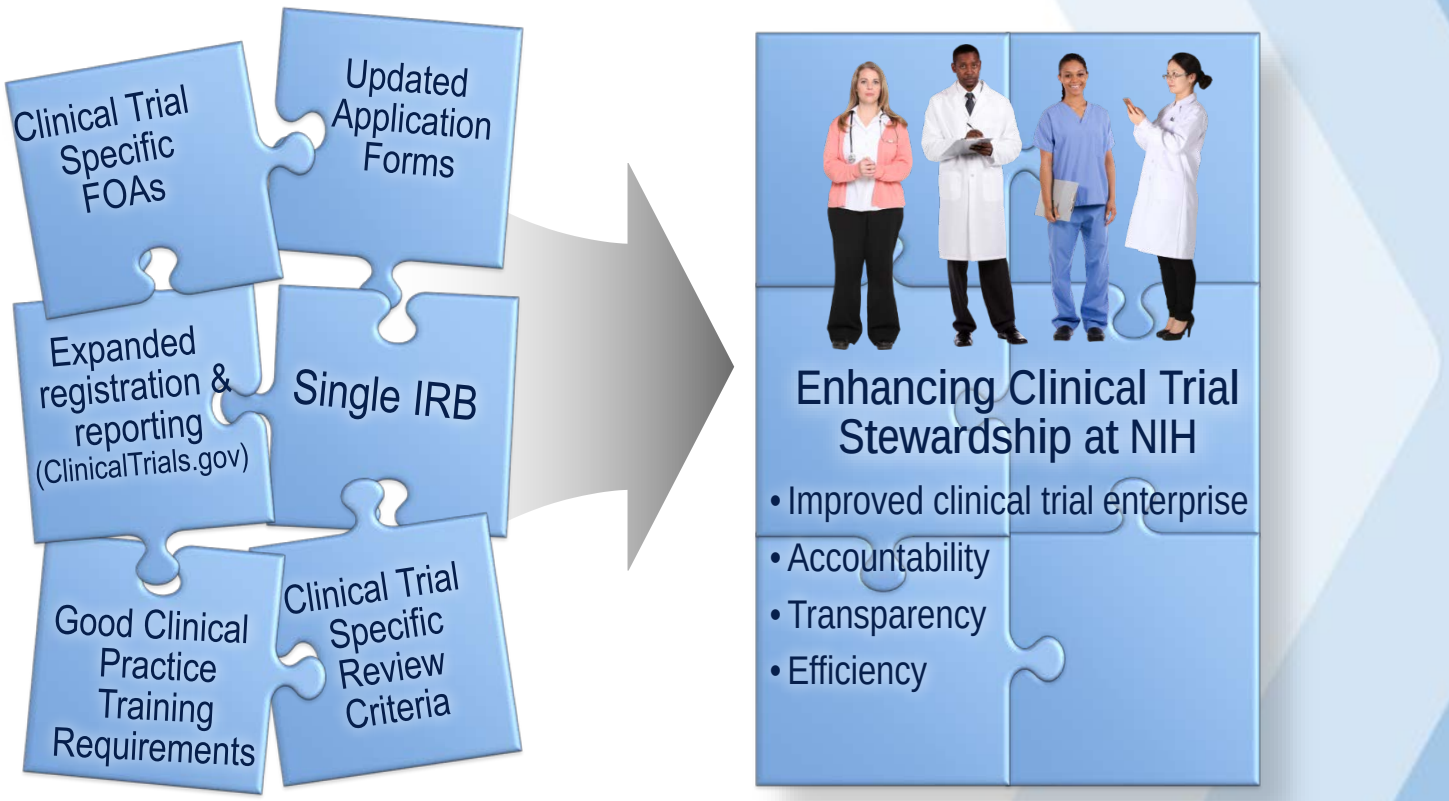
Office of Extramural Programs

KEY POINTS FOR TODAY'S DISCUSSION

- As part of its effort to enhance clinical trials stewardship, NIH is developing an electronic system to manage human subjects/clinical trial information
- System will streamline current processes, reduce duplicate entry, and improve data to enhance NIH's oversight of clinical trials

NIH INITIATIVES TO ENHANCE CLINICAL TRIAL STEWARDSHIP



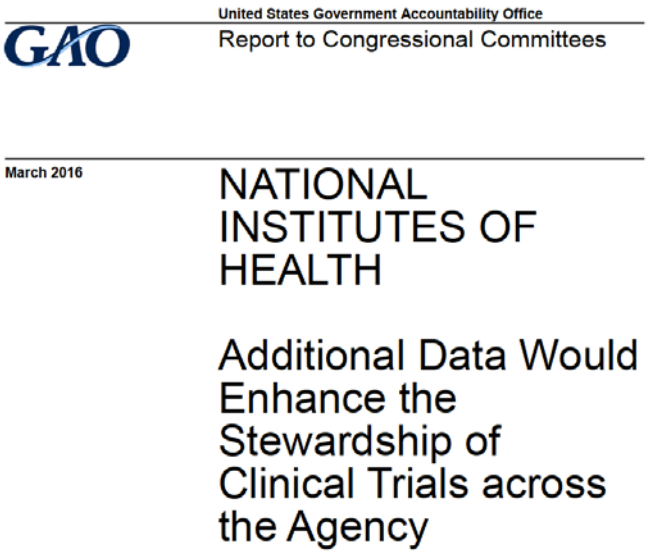
Learn more at https://grants.nih.gov/policy/clinical-trials.htm

"Recent performance in our clinical trials program is not acceptable: recruitment is too slow, registration in public databases is not consistent, and reporting takes too long to **meet the needs of the public**."

Tom Insel, MD

http://www.nimh.nih.gov/about/director/2014/a-new-approach-to-clinical-trials.shtml

NEED FOR BETTER DATA


United States Government Accountability Office

GAO

Report to Congressional Committees

March 2016

NATIONAL INSTITUTES OF HEALTH

Additional Data Would Enhance the Stewardship of Clinical Trials across the Agency

"NIH's OD reviews some data on clinical trial activity across NIH but has not finalized what additional data it needs or established a process for using these data to enhance its stewardship.

NIH is limited in its ability to make data-driven decisions regarding the use of its roughly $3 billion annual investment in clinical trials."

GAO-16-304

NIH CLINICAL TRIAL REFORMS

VIEWPOINT

Toward a New Era of Trust and Transparency in Clinical Trials

Kathy L. Hudson, PhD
National Institutes of Health, Bethesda, Maryland.

Michael S. Lauer, MD
National Institutes of Health, Bethesda, Maryland.

Francis S. Collins, MD, PhD
National Institutes of Health, Bethesda, Maryland.

The final effort in this suite of activities is the **development of a standardized electronic system** for NIH to use for management and oversight of NIH-funded clinical trials and ensure accountability to stakeholders. The system will permit the collection of clinical trial information across the NIH-supported biomedical research enterprise, **which will be used for strategic planning and identifying the best, safest, and least burdensome ways to gather important data to improve human health**.

JAMA 2016 (online pub September 16, 2016)

CONGRESS.GOV | Legislation

H.R.34 - 21st Century Cures Act

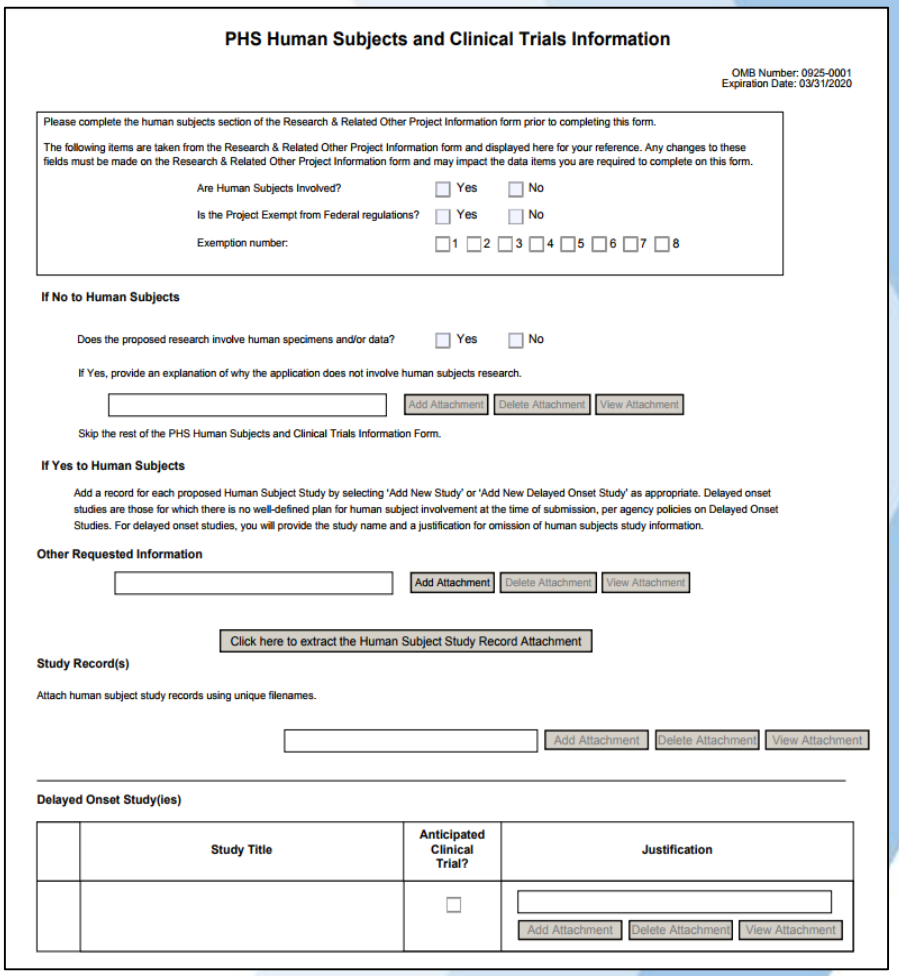
114th Congress (2015-2016) | Get alerts

SEC. 2038. COLLABORATION AND COORDINATION TO ENHANCE RESEARCH.

"NIH shall assemble accurate data to be used to assess research priorities, including . . . data on study populations of clinical research … which specifies inclusion of women, members of minority groups, [and] relevant age categories, including pediatric subgroups …"

HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM

- Consolidates all human subjects, inclusion, and clinical trial information into one form
- Information collected at study-level rather than application level
- Captures structured data on human subjects and clinical trials
- Aligns 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)

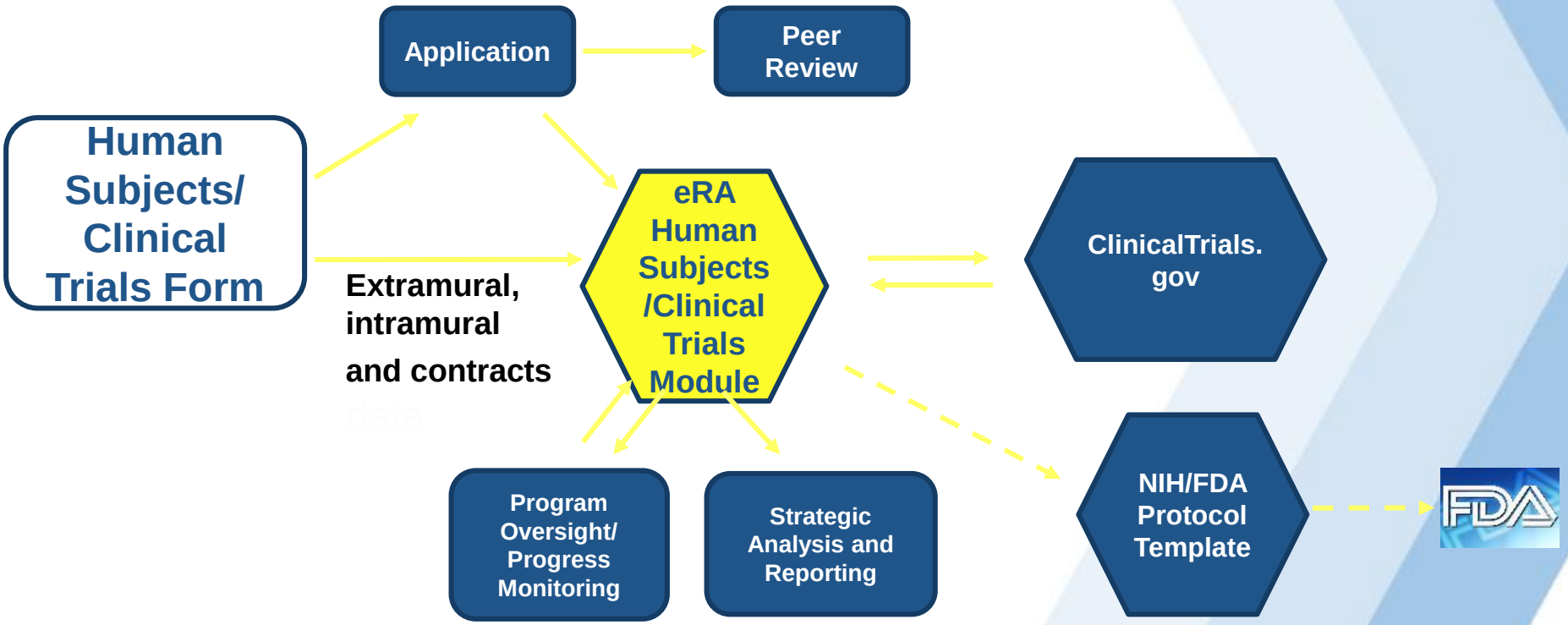
Attach human subject study records using unique filenames.

Add Attachment | Delete Attachment | View Attachment

Delayed Onset Study(ies)

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

VISION: DATA PIECES WORKING TOGETHER



USE OF HUMAN SUBJECTS/CLINICAL TRIAL SYSTEM POST-SUBMISSION

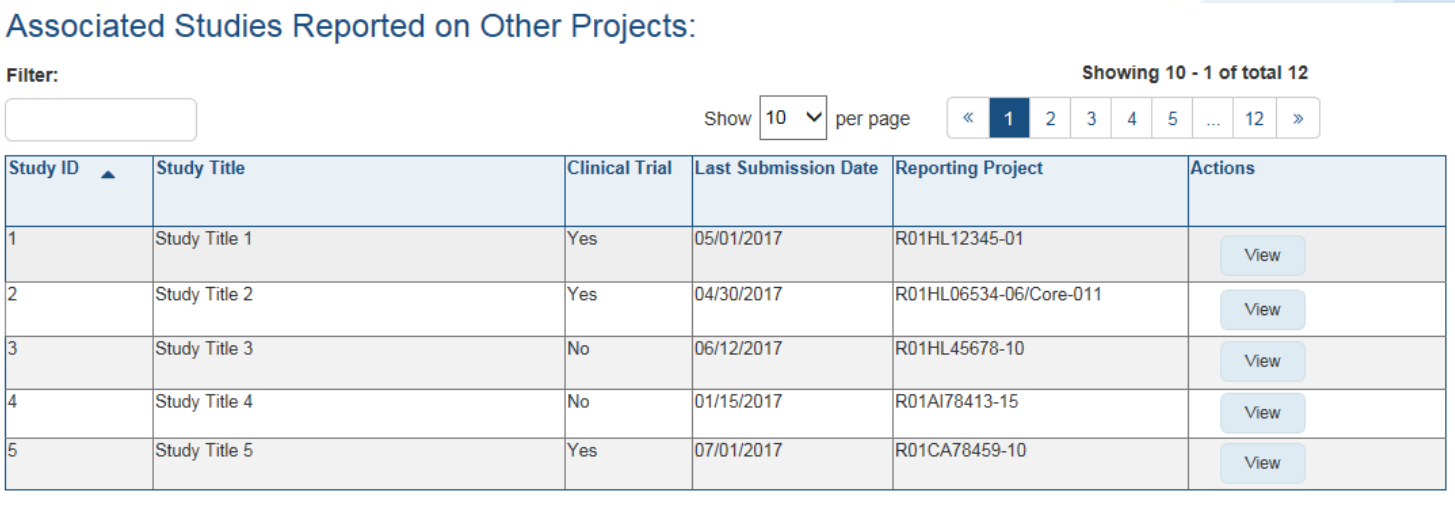
- Typically recipients will update information via RPPR
- Can also access via eRA Commons Status Module
  - Corrections after RPPR submission
  - Off-cycle updates (e.g. delayed onset studies)
  - Interim progress reports (e.g. recruitment)
- Users can add/update study information, update enrollment data, provide updates on adverse events, study milestones, Clinicaltrials.gov registration and reporting, etc.

CLINICALTRIALS.GOV SYNCHRONIZATION

- Data pulled directly from Clinicaltrials.gov into eRA Human Subjects/Clinical Trials system
  - Updates should be made in Clinicaltrials.gov/will overwrite data on form
- Future release will allow data to be pushed from eRA to Clinicaltrials.gov for registration purposes

ASSOCIATED STUDIES

- NIH staff may associate studies from other projects (e.g. grants, contracts, or cooperative agreements)
  - Reduces duplicate entry
  - Useful for collaborative studies funded by more than one grant/cooperative agreement
- All updates must be made by primary reporting project



Associated Studies Reported on Other Projects:

Filter:

Showing 10 - 1 of total 12

Show 10 per page « 1 2 3 4 5 ... 12 »

Study ID	Study Title	Clinical Trial	Last Submission Date	Reporting Project	Actions
1	Study Title 1	Yes	05/01/2017	R01HL12345-01	View
2	Study Title 2	Yes	04/30/2017	R01HL06534-06/Core-011	View
3	Study Title 3	No	06/12/2017	R01HL45678-10	View
4	Study Title 4	No	01/15/2017	R01AI78413-15	View
5	Study Title 5	Yes	07/01/2017	R01CA78459-10	View

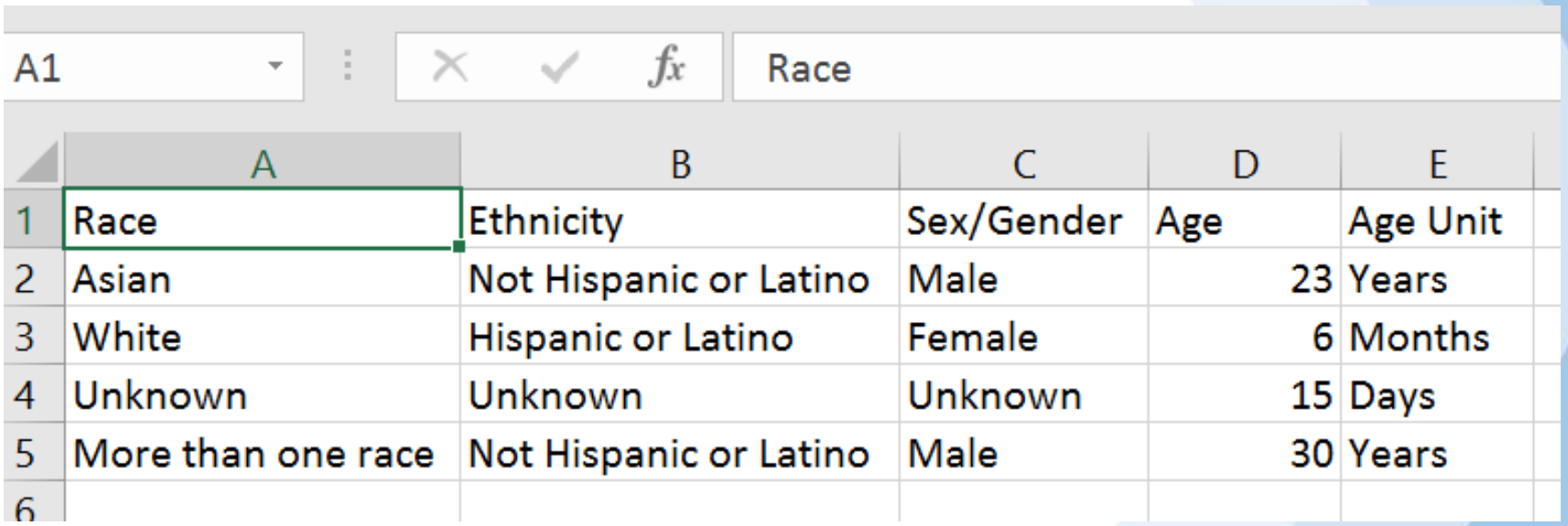
UPLOADING PARTICIPANT ENROLLMENT DATA

- Ability to upload individual-level data on sex/gender, race, ethnicity, and age of participants (.csv file)

Racial Categories	Ethnic Categories									
	Hispanic or Latino			Not Hispanic or Latino			Unknown/Not Reported			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

Participant level data file (CSV): Add Attachment

UPLOADING PARTICIPANT ENROLLMENT DATA (CONTINUED)



A1 | Race

	A	B	C	D	E
1	Race	Ethnicity	Sex/Gender	Age	Age Unit
2	Asian	Not Hispanic or Latino	Male	23	Years
3	White	Hispanic or Latino	Female	6	Months
4	Unknown	Unknown	Unknown	15	Days
5	More than one race	Not Hispanic or Latino	Male	30	Years
6					

NEXT STEPS

- System expected to deploy early summer 2018
- Later releases will incorporate Clinicaltrials.gov data push and other enhancements
- Individual-level data will be required for applications submitted January 25, 2019 or later


Q
&
A

ADDITIONAL SLIDES

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: 0925-0001
Expiration Date: 03/31/2020

* 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**

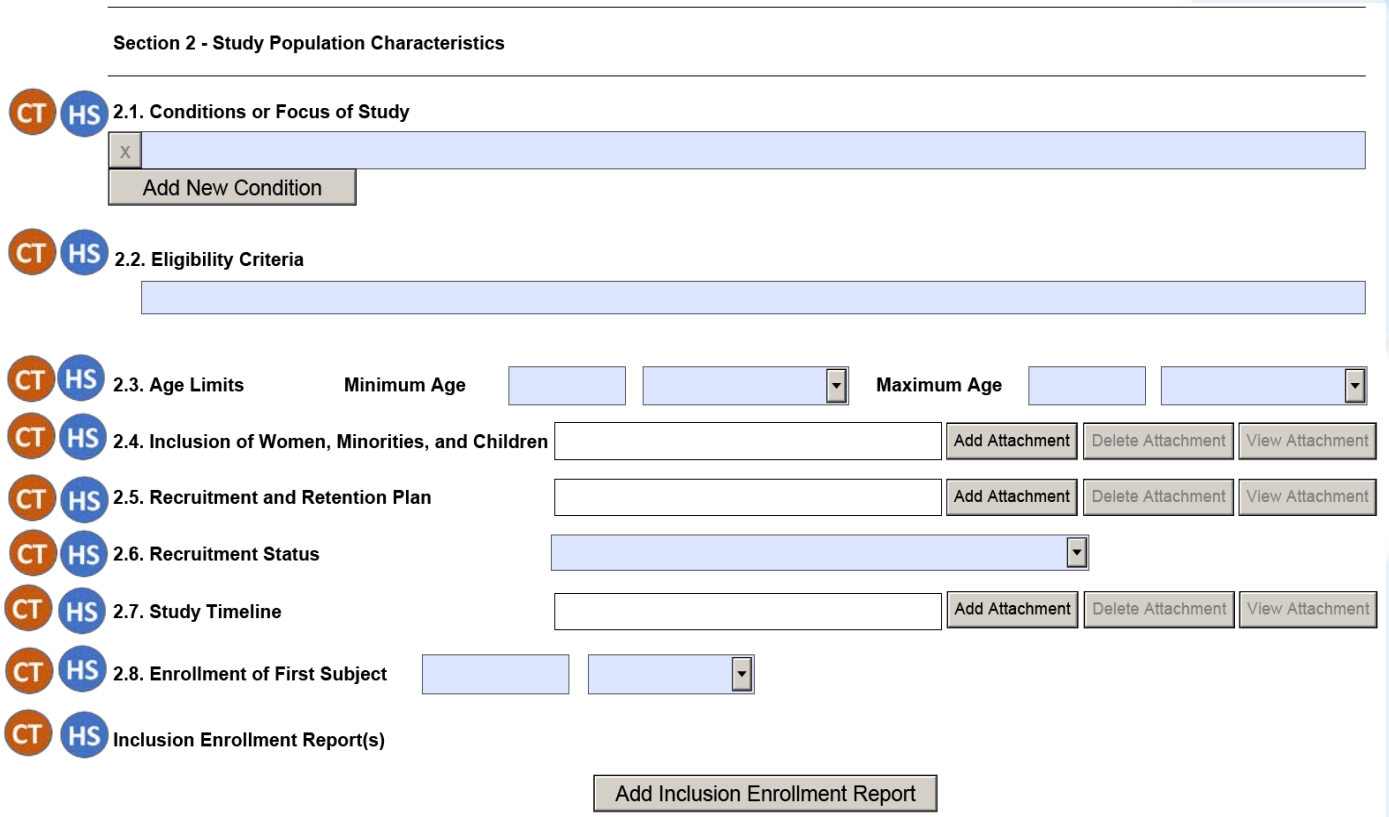
If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

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

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

SECTION 2 – STUDY POPULATION

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



Includes Inclusion Enrollment Reports

SECTION 3 – PROTECTION PLANS

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

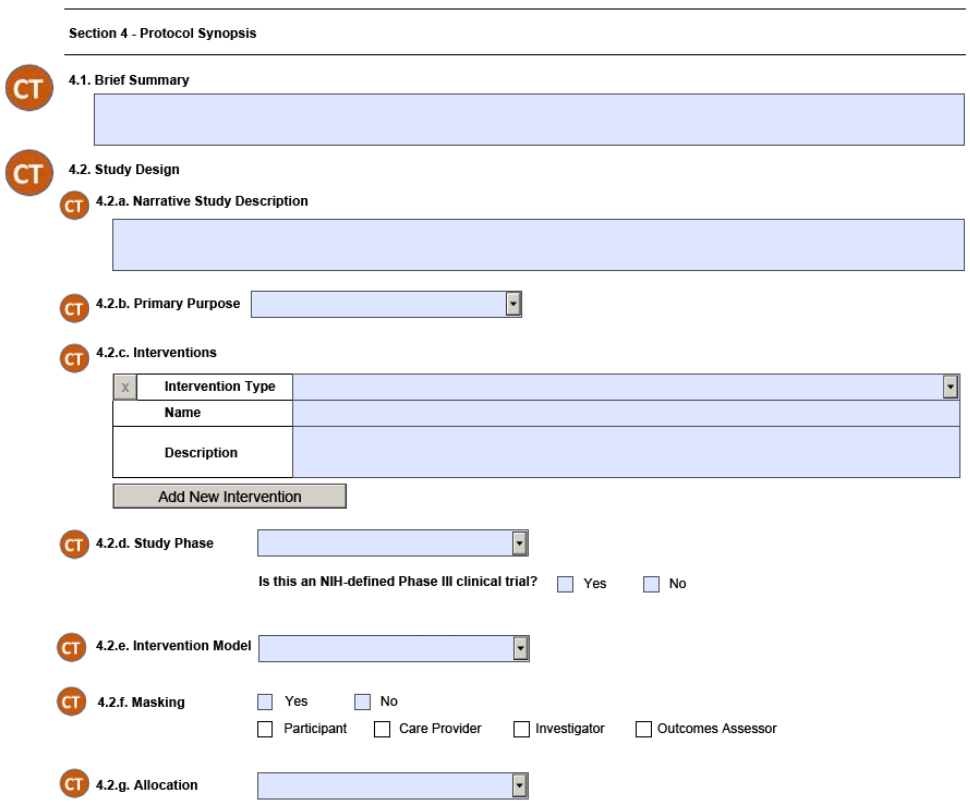
CT **3.4. Will a Data and Safety Monitoring Board be appointed for this study?**

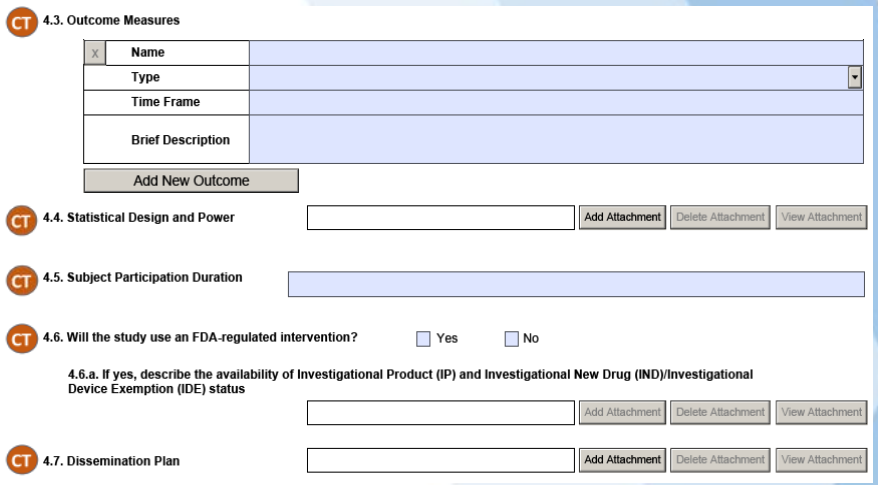
☐ Yes ☐ No

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

SECTION 4 – PROTOCOL SYNOPSIS

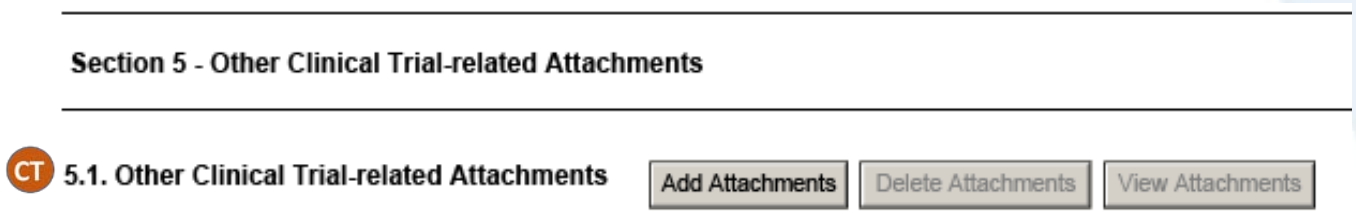
- Required for Clinical Trial studies





SECTION 5 – OTHER CT ATTACHMENTS

- Required for Clinical Trial studies



FOA-specific attachments only

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