Human Samples, Human Subjects, Human Data… OH MY!

Navigating the new NIH Human Subjects and Clinical Trials section

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GOALS OF TODAY'S PRESENTATION

- Understand what category your research falls into (Human Subjects, Human Data, Clinical Trials, etc.)
- Understand the nuances of the new 'Human Subjects and Clinical Trial' tab, so you don't underestimate the time that is needed
  - New information, but most was previously required in various components of applications
- NIH online resources

NIH Human Subjects and Clinical Trials Section

WHO DOES THIS APPLY TO?

WHO DOES THIS APPLY TO?

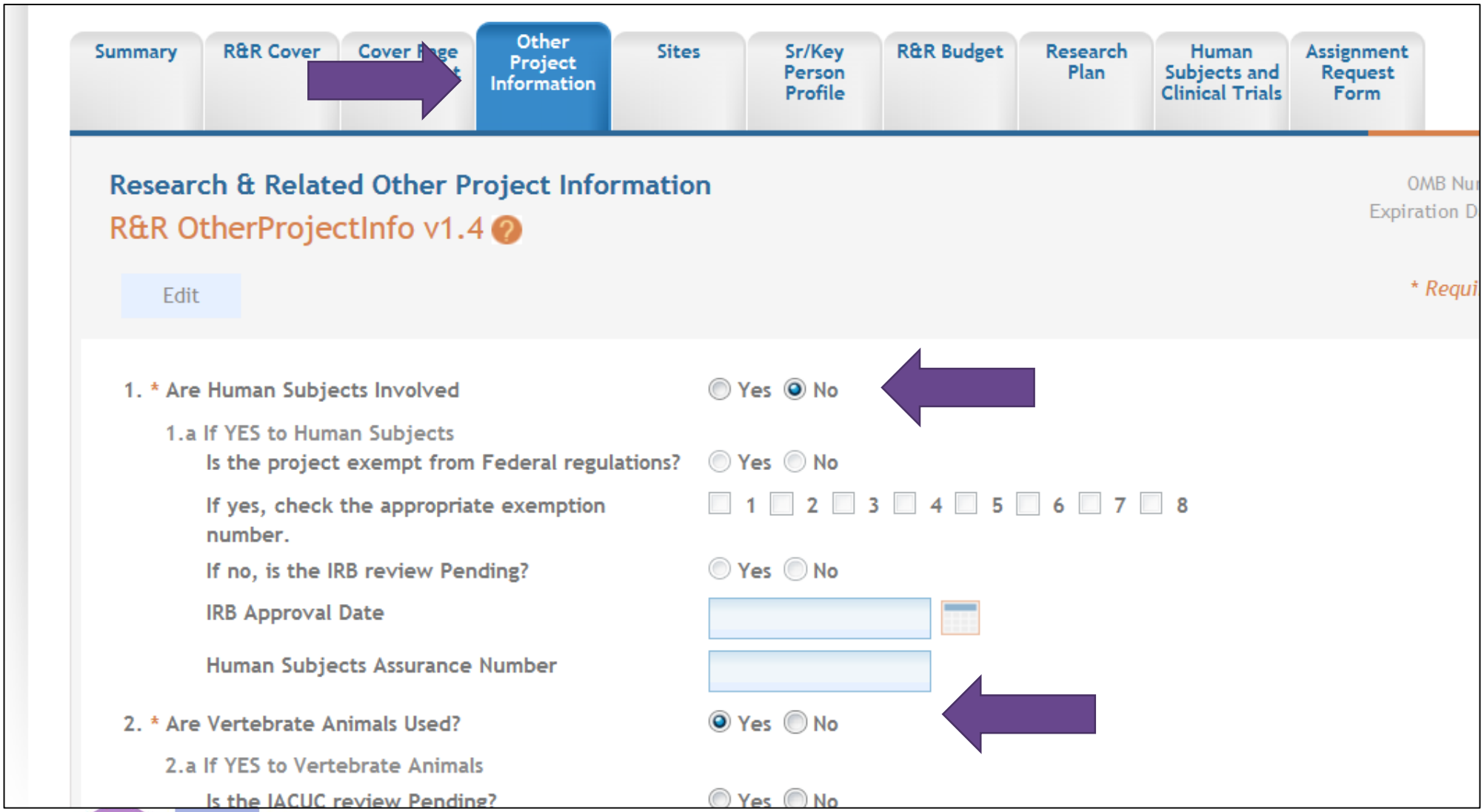
Everyone!

- Tissue samples
- Blood samples
- Surveys, evaluations, etc.
- Anything that came from a live human being

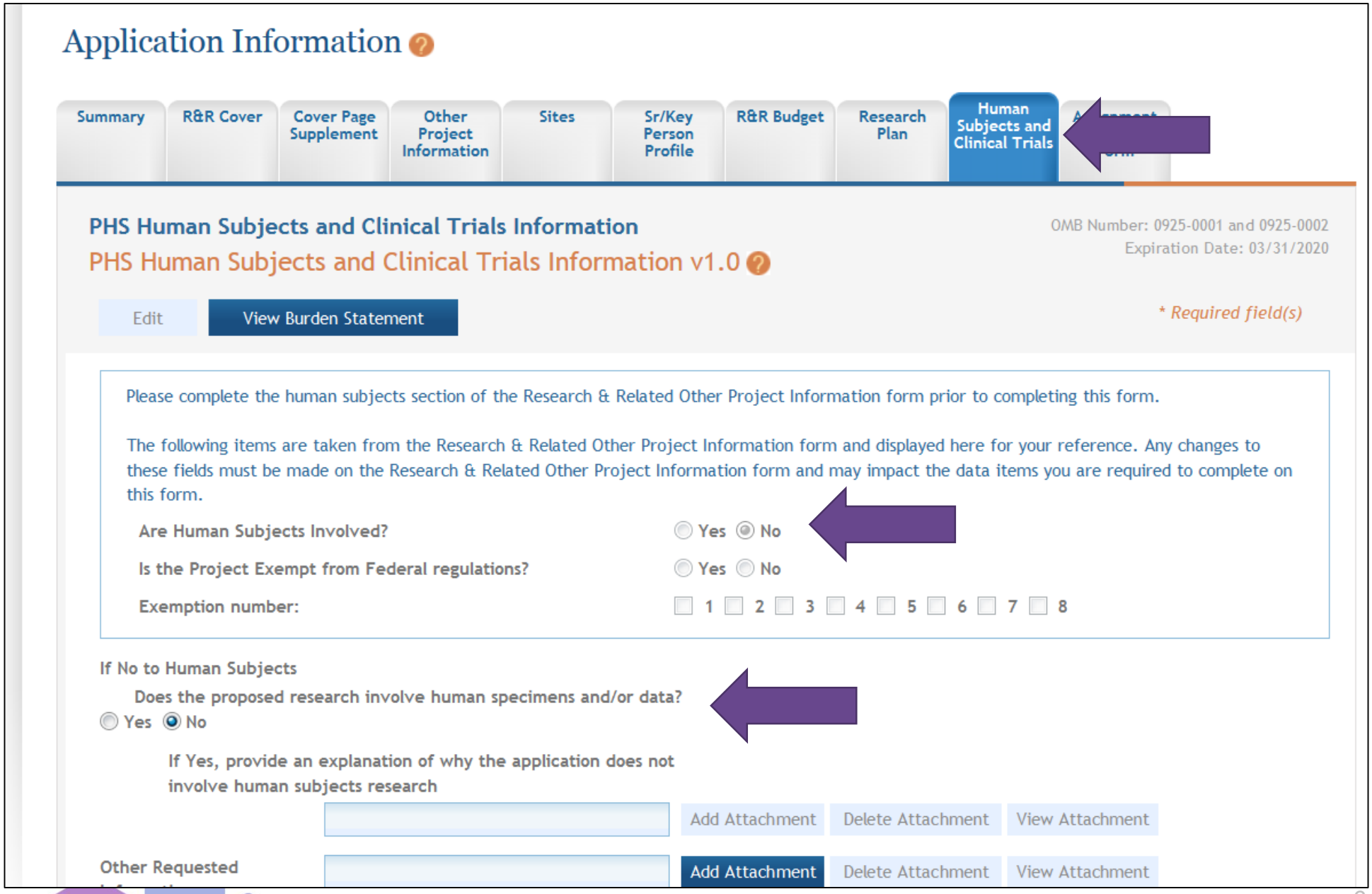
- Doesn’t pertain to you? Using animals only? You still have to answer ‘no’!

WHAT IF I'M ONLY USING ANIMALS?

- You will still need to answer a few questions to complete your application

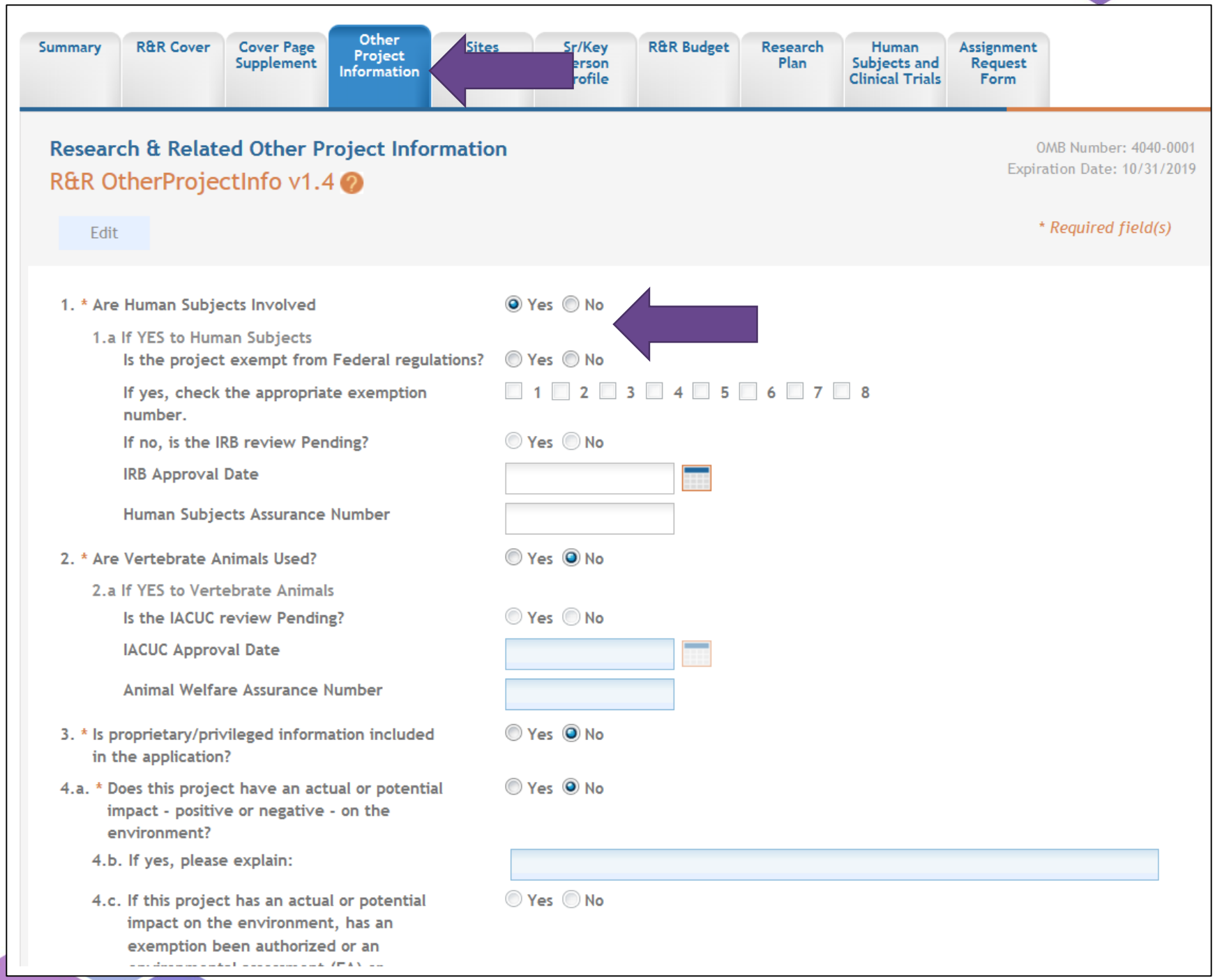


WHAT IF I'M ONLY USING ANIMALS?



FILLING OUT YOUR APPLICATION

OTHER PROJECT INFO TAB



WHAT DOES NIH SAY?

Human subjects research is research involving:

- A living individual
- About whom an investigator (whether professional or student) conducting research obtains:
  - Data through intervention or interaction with the individual, or
  - Identifiable private information

NIH Human Subjects webpage:
https://humansubjects.nih.gov/

SCRIHS: 545-7602

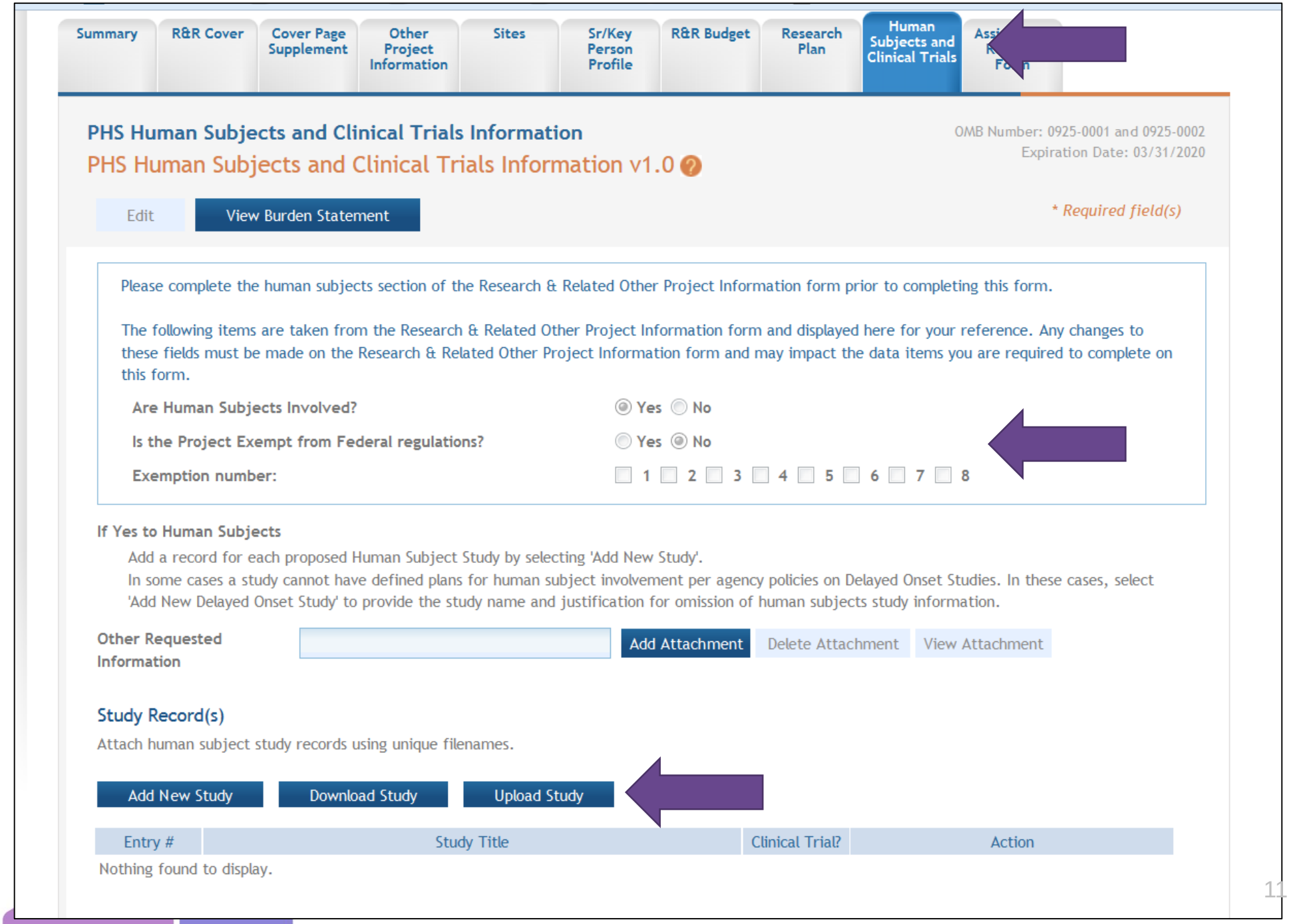
Grants and Contracts: 545-8034

ARE HUMAN SUBJECTS INVOLVED?

- NIH provides a short survey to determine which forms you should fill out
- Only 4 questions!

NIH Questionnaire:
https://humansubjects.nih.gov/questionnaire

HUMAN SUBJECTS AND CLINICAL TRIALS



PROJECT EXEMPT VS. STUDY RECORD EXEMPT

- 1 non-exempt study record will make the entire project non-exempt
- The project is only exempt if all study records are exempt

STUDY RECORDS

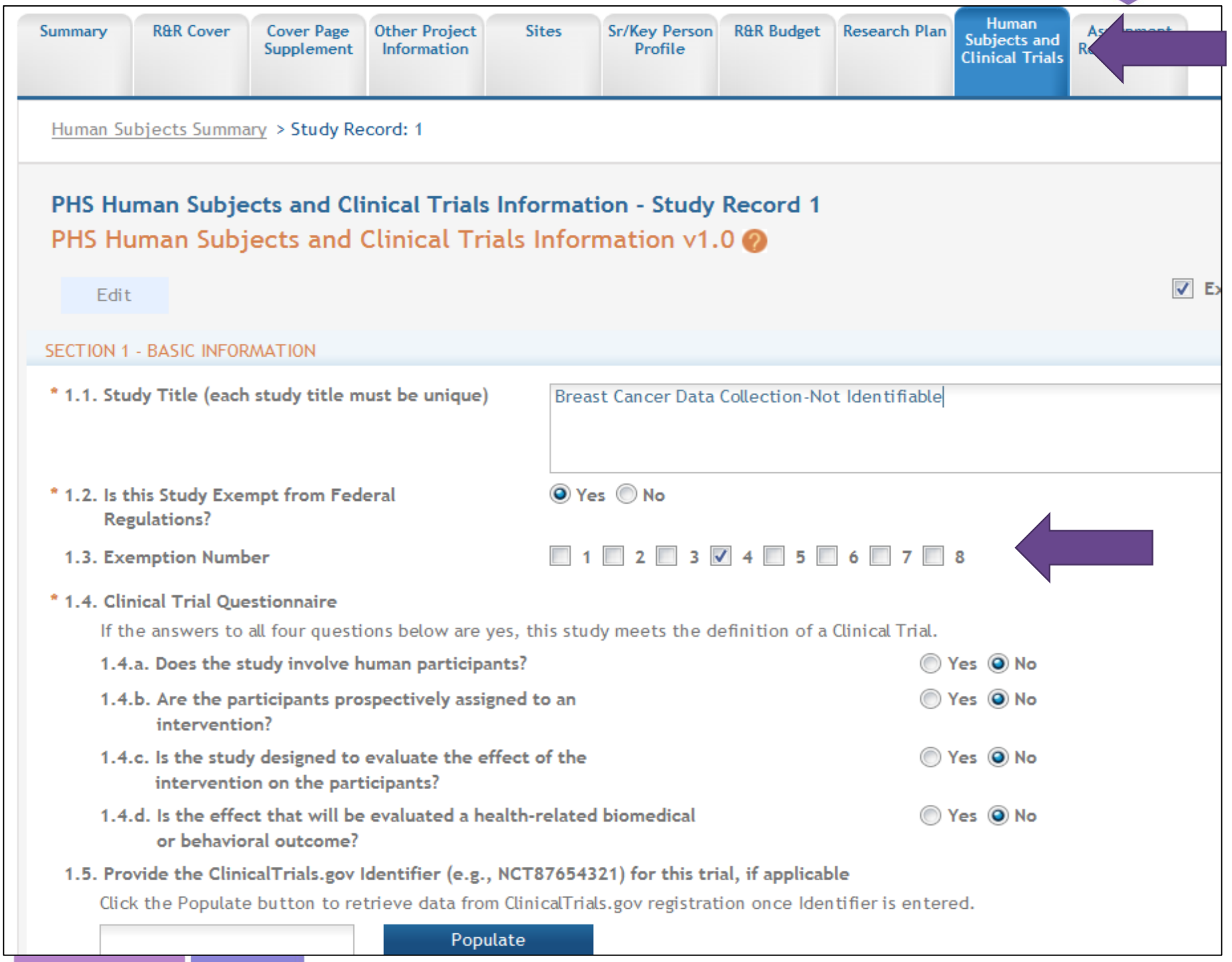
STUDY RECORDS

Think of Study Records as..

- Specific Aims, or
- The “mini” projects within your grant, or
- The different processes by which you are obtaining data

Section 1:
Basic Information

SECTION 1: BASIC INFORMATION



EXEMPTIONS

- Exempt human subjects research meets the definition of human subjects research but meets the criteria of one of the following six exempt study designs.

- Friendly Reminder: Investigators involved in research considered exempt must still meet the Human Subjects education requirement (CITI Training)

EXEMPTIONS 1-6

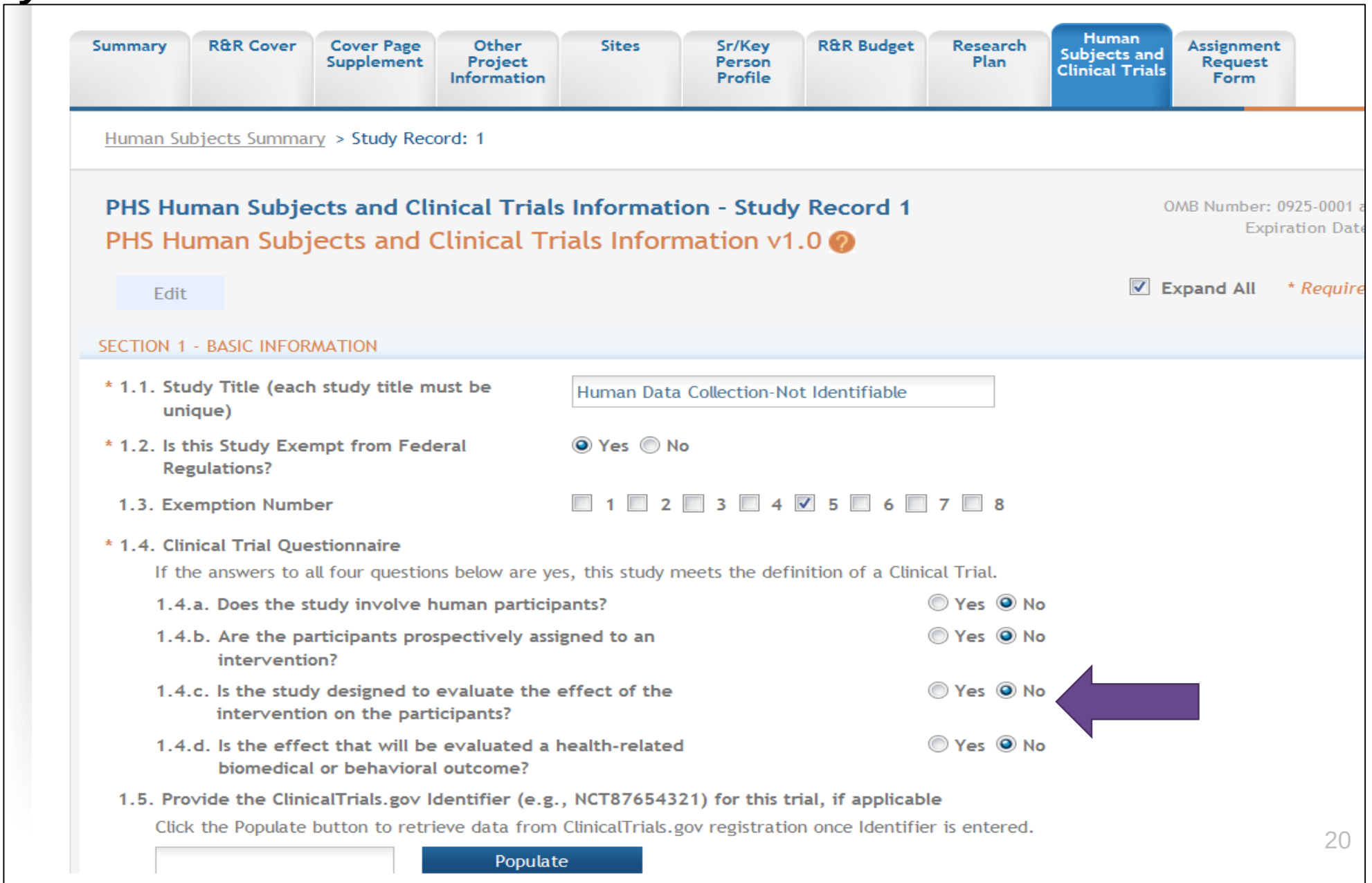
- **Exemption 1** - Research conducted in an educational setting involving normal educational practice.
- **Exemption 2** - Research using educational tests, survey procedures; interviews; or observations of public behavior, unless subjects are identifiable and disclosure could place them at risk. This exemption for parts involving educational tests is applicable to children. However, this exemption for parts involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.
- **Exemption 3** - Research using educational tests, survey procedures; interviews; or observations of public behavior, if the subjects are public officials or candidates for public office or federal law requires that confidentiality be maintained. **Not typically used in NIH research projects.**
- **Exemption 4** - Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens; if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified. Since 2008 guidance from OHRP, E4 is seldom applicable; most research with existing data or specimens is either non-exempt human subjects research (code 30) or not human subjects research (code 10).
- **Exemption 5** - Research and demonstration projects that evaluate public benefit or service programs. **Not typically applicable to NIH research projects.**
- **Exemption 6** - Research that evaluates taste and food quality; or consumer acceptance of foods. **Not typically applicable to NIH research projects.**

RELEVANT EXEMPTIONS TO HUMAN SUBJECTS RESEARCH (NIH GRANTS)

- Exemption 1
  - Research conducted in an educational setting involving normal educational practice
- Exemption 2
  - Research involving observation of public behavior when the investigator(s) do not participate in the activities being observed
- Exemption 4
  - Human subjects and samples that cannot be identified

1.4: CLINICAL TRIAL QUESTIONNAIRE

Asks basic information to determine whether or not you have a clinical trial



IS THIS CONSIDERED A CLINICAL TRIAL?

1. Does the study involve human participants? Yes/No

2. Are the participants prospectively assigned to an intervention? Yes/No

3. Is the study designed to evaluate the effect of the intervention on the participant? Yes/No

4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? Yes/No

IS THIS CONSIDERED A CLINICAL TRIAL?

If you answered **YES to ALL** of the previous questions, this study would meet the definition of a **clinical trial**.

Form Section	If you answered YES to ANY of the previous questions:
Section 2-Study Population Characteristics	Required
Section 3-Protection and Monitoring Plans	Required
Section 4-Protocol Synopsis	Required
Section 5-Other Clinical Trial-related Attachments	Required if specified in FOA

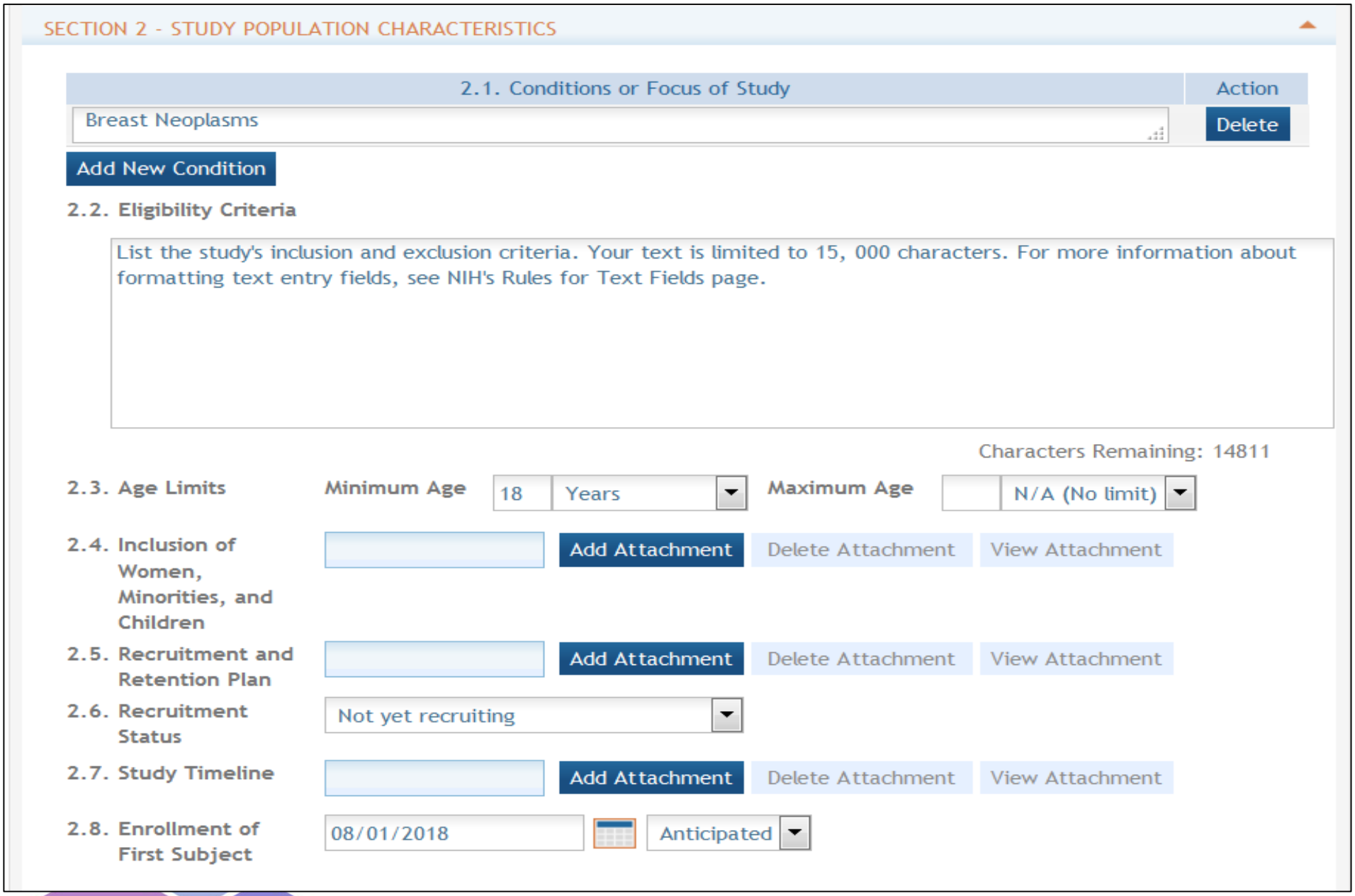
IS THIS CONSIDERED A CLINICAL TRIAL?

If you answered **NO to ANY** of the previous questions, this study would **NOT** meet the definition of **a clinical trial**.

Form Section	If you answered NO to ANY of the previous questions:
Section 2-Study Population Characteristics	Required
Section 3-Protection and Monitoring Plans	Required
Section 4-Protocol Synopsis	Do not complete
Section 5-Other Clinical Trial-related Attachments	Do not complete

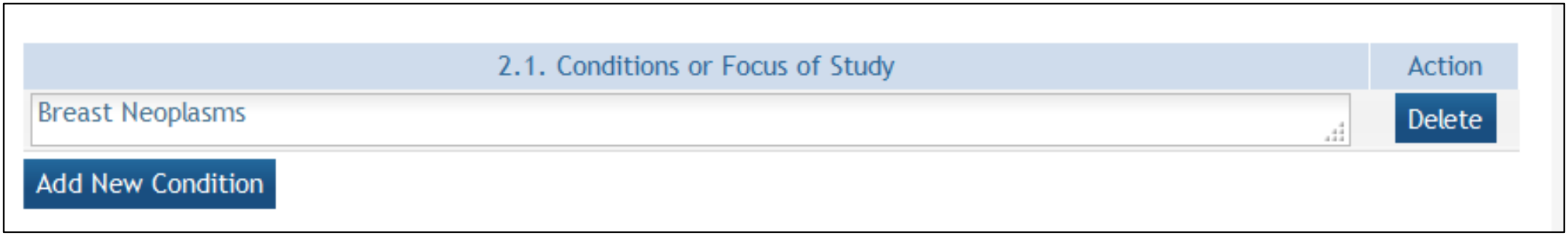
Section 2: Study Population and Characteristics

SECTION 2: STUDY POPULATION CHARACTERISTICS



2.1: CONDITIONS OR FOCUS OF STUDY

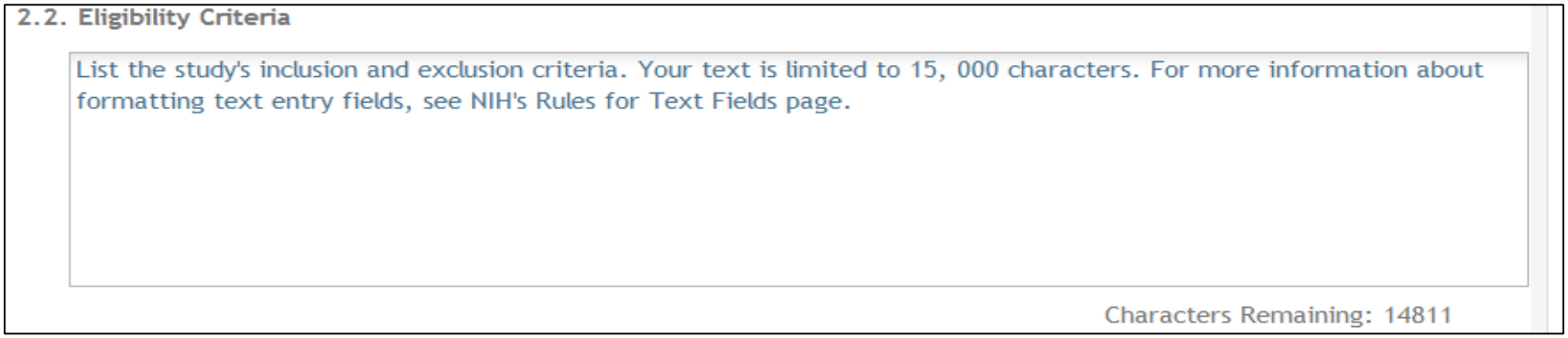
- Identify the name(s) of the disease(s)/condition(s) that you are studying
- Use NLM's Medical Subject Headings (MeSH)
  - https://meshb.nlm.nih.gov/search



2.2-2.3: STUDY POPULATION CHARACTERISTICS

2.2. Eligibility Criteria

- Use the text box to list the study's inclusion and exclusion criteria



2.3 Age Limits

- Enter the numerical value for the minimum and maximum age
- Provide the relevant units of time

2.4: INCLUSION OF WOMEN, MINORITIES, AND CHILDREN

- Women and Minority Requirements
  - Distribution of subjects by sex/gender, race, ethnicity
  - The rationale for selection
  - Proposed outreach programs for recruitment
  - Provide a reason for any inclusion or exclusion of any group

2.4: INCLUSION OF WOMEN, MINORITIES, AND CHILDREN

- Children
  - Rationale for inclusion or exclusion of children
  - Expertise of the investigative team to work with children
  - The facilities to accommodate children
  - How children can contribute to a meaningful analysis relative to the purpose of the study

2.5: RECRUITMENT AND RETENTION PLAN

- Describe how you will recruit and retain participants
- Address planned recruitment strategies
- Address proposed engagement strategies for retention
  - NIH Policy and Guidelines on the Inclusion of Children

CCR RECRUITMENT STRATEGIES

- Press Release
- All School Email
- Clinic Room Flyer
- Staff Areas
- Presentations
- Brochures/Posters
- Letter to Current Patients
- Letter to EHR List
- SIU Community Outreach
- Health Fair
- Lunch and Learns
- Recruitment Events

Contact CCR Director for additional assistance:
Dr. Joe Milbrandt: jmilbrandt@siumed.edu

2.6: RECRUITMENT STATUS

Drop down menu options that best describes the proposed study:

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Completed
- Suspended
- Terminated (Halted Prematurely)
- Withdrawn (No Participants Enrolled)

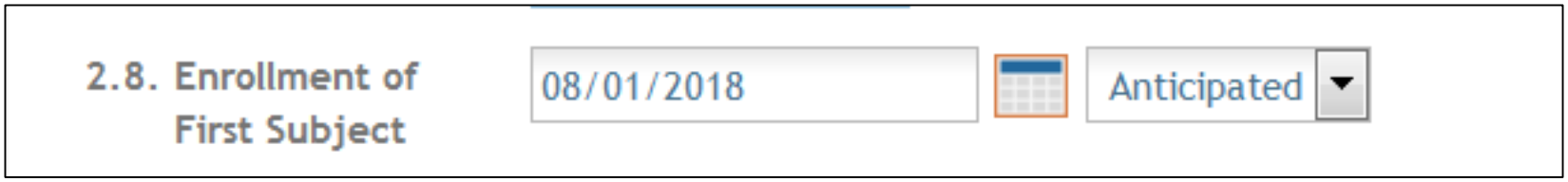
2.7-2.8: TIMELINE AND ENROLLMENT

2.7 Study Timeline

- Can be a description or a diagram
- Do not include specific dates
  - Instead list as 1 year after award, month 1, etc.

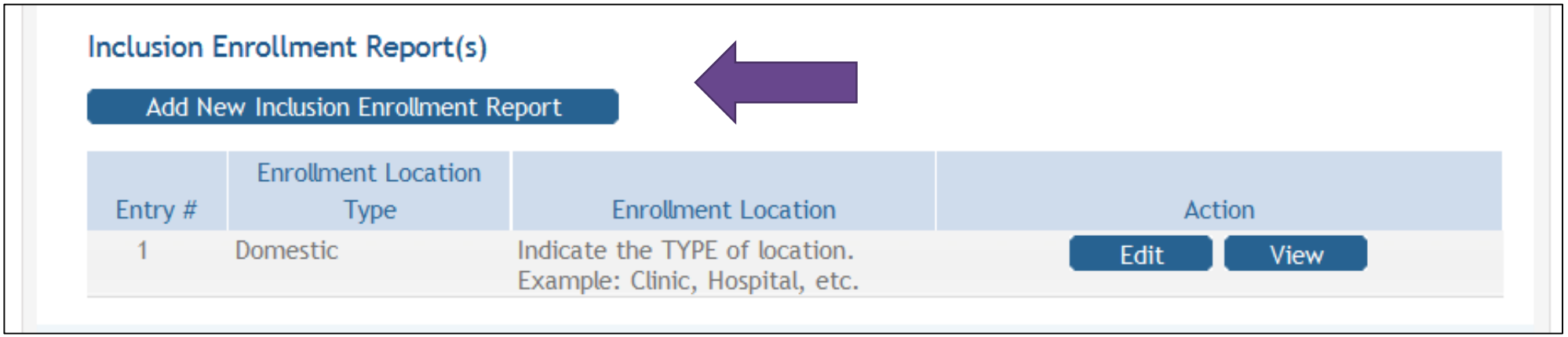
2.8 Enrollment of First Subject

- Specific date
- Choose ‘Actual’ or ‘Anticipated’ from drop down

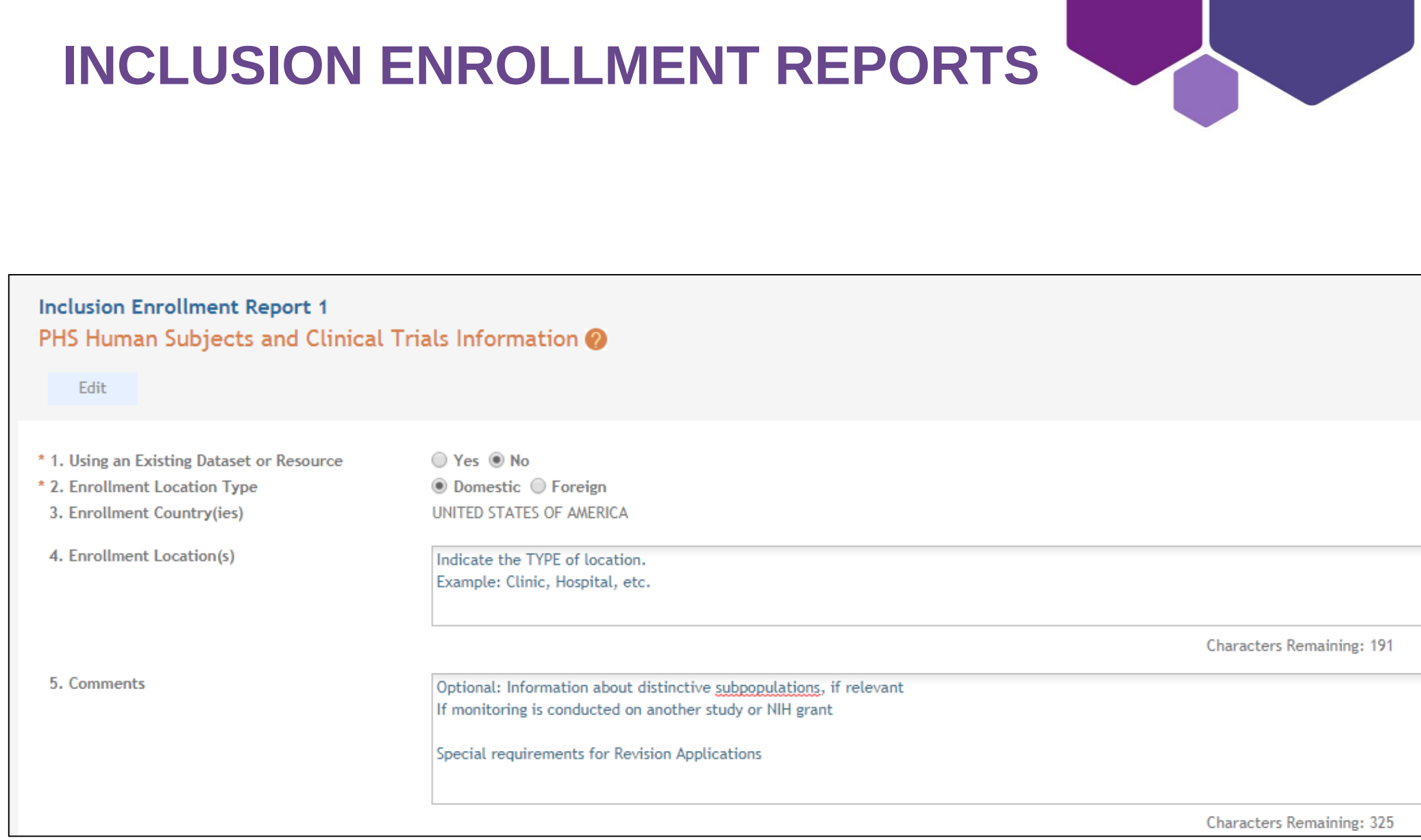


INCLUSION ENROLLMENT REPORTS

The last requirement of Section 2 is the ‘Inclusion Enrollment Report’



INCLUSION ENROLLMENT REPORTS



Inclusion Enrollment Report 1

PHS Human Subjects and Clinical Trials Information

Edit

* 1. Using an Existing Dataset or Resource	○ Yes ◉ No
* 2. Enrollment Location Type	◉ Domestic ○ Foreign
3. Enrollment Country(ies)	UNITED STATES OF AMERICA
4. Enrollment Location(s)	Indicate the TYPE of location. Example: Clinic, Hospital, etc. Characters Remaining: 191
5. Comments	Optional: Information about distinctive subpopulations, if relevant If monitoring is conducted on another study or NIH grant Special requirements for Revision Applications Characters Remaining: 325

INCLUSION ENROLLMENT REPORTS

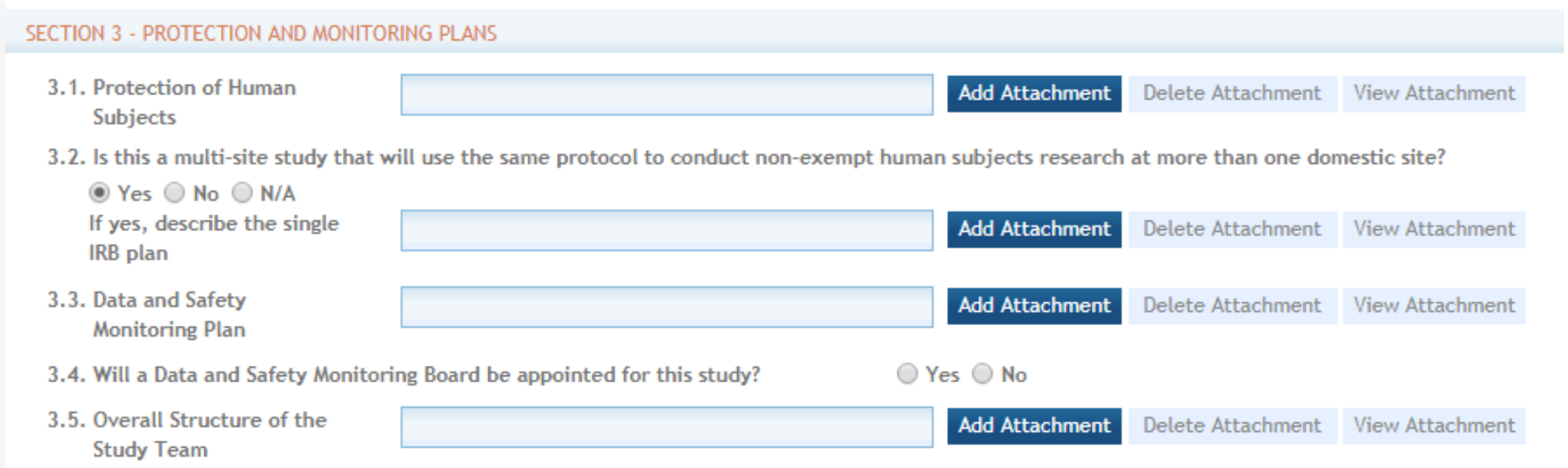
Planned

	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
Racial Categories	Female	Male	Female	Male	
American Indian/Alaska Native	1	1	0	0	2
Asian	3	3	0	0	6
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	19	19	1	1	40
White	65	65	5	5	140
More than One Race	5	5	1	1	12
Total	93	93	7	7	200

Reports from Electronic Health Record (EHR) can be obtained
Contact grants@siumed.edu for assistance

Section 3: Protection and Monitoring Plans

SECTION 3: PROTECTION AND MONITORING PLANS



3.1: PROTECTION OF HUMAN SUBJECTS

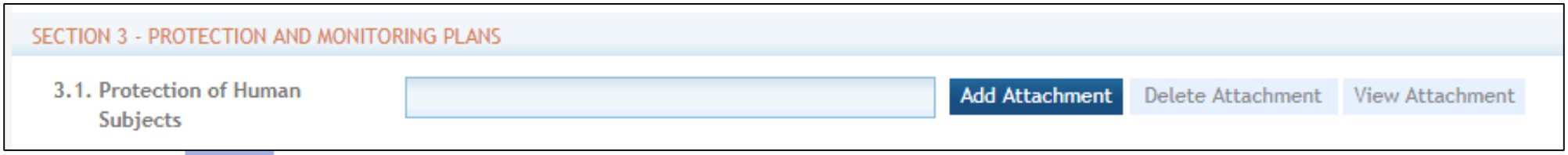
Everyone must have an attachment

- If any exemption claimed, justification goes in Protection of Human Subjects attachment
- Do not repeat the definitions of the exemptions

3.1: PROTECTION OF HUMAN SUBJECTS

Document headings:

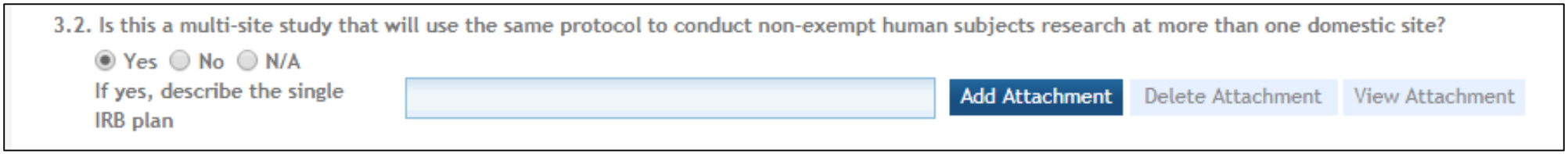
- Risks to Human Subjects
  - Human Subjects Involvement, Characteristics, and Design
  - Study Procedures, Materials, and Potential Risks
- Adequacy of Protection Against Risks
  - Informed Consent and Assent
  - Protections Against Risk
  - Vulnerable Subjects, if relevant to your study
- Potential Benefits of the Proposed Research
- Importance of the Knowledge to be Gained



3.2 MULTI-SITE STUDY

Multi-site study using same protocol? YES/NO

- If NO, nothing else required
- If YES, attach a description of the single IRB plan
  - Must comply with NIH Policy on the Use of sIRB for Multi-Site Research



3.3: DATA AND SAFETY MONITORING PLAN

Optional for non-clinical trials human subjects research, mandatory for clinical trials

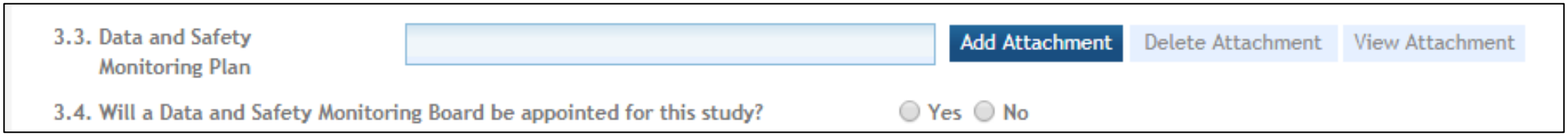
Describe:

- Overall framework and frequency of monitoring
- Adverse events and serious adverse events reporting process
- The individual(s) or group responsible for trial monitoring
- DSMB

3.4: DATA SAFETY AND MONITORING BOARD (DSMB)

Will a Data and Safety Monitoring Board (DSMB) be appointed for this study? YES/NO

- Optional for non-clinical trials, mandatory for clinical trials
- If NO, nothing further required
- If YES, describe DSMB in Data and Safety Monitoring Plan



3.5: STUDY TEAM STRUCTURE

Optional for non-clinical trials, mandatory for clinical trials

Describe:

- Organizational structure
- Administrative sites
- Data coordinating sites
- Enrollment/participating sites
- Any separate labs or testing centers

Section 4 and 5: Clinical Trials ONLY

Call Grants Office & SCRIHS

Info posted to website

SECTION 4: PROTOCOL SYNOPSIS

SECTION 4 - PROTOCOL SYNOPSIS

4.1. Brief Summary

Enter up to 5000 Characters

Characters Remaining: 5000

4.2. Study Design

4.2.a. Narrative Study Description

Enter up to 32000 Characters

Characters Remaining: 32000

4.2.b. Primary Purpose

4.2.c. Interventions

Intervention Type	Name	Description	Action
Nothing found to display			

Add New Intervention

4.2.d. Study Phase

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

4.2.e. Intervention Model

4.2.f. Masking

Yes No

Participant Care Provider Investigator Outcomes Assessor

4.2.g. Allocation

4.1: BRIEF SUMMARY

- Enter a brief description of objectives of the protocol
- Include the primary and secondary endpoints
- Limited to 5,000 characters

4.2: STUDY DESIGN

- Narrative description of the protocol
  - Describe your plans for assignment of participants and delivery of interventions.
  - Explain methods for sample size and data analysis are appropriate given those plans.
  - Limited to 32,000 characters
  - For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the Research Methods Resources webpage
  - https://researchmethodsresources.nih.gov/

4.2B: PRIMARY PURPOSE

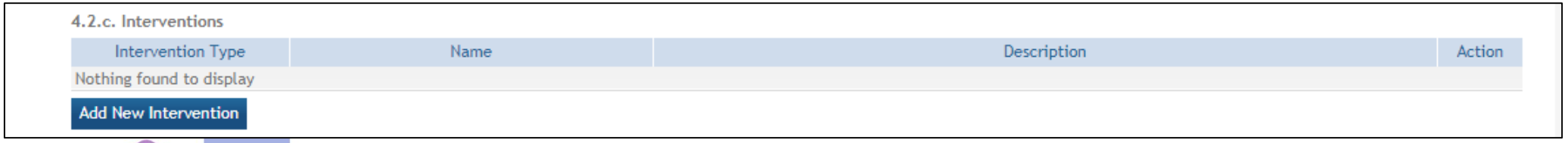
Drop down choices:

- Treatment
- Prevention
- Diagnostics
- Supportive Care
- Screening
- Health Services Research
- Basic Science
- Device Feasibility
- Other (If you select “Other,” provide a description in the space provided. Your response is limited to 255 characters.)

4.2C: INTERVENTION

Include Name, Description, and Action of each Type:

- Drug (including placebo)
- Device (including sham)
- Biological/Vaccine
- Procedure/Surgery
- Radiation
- Behavioral (e.g., Psychotherapy, Lifestyle Counseling)
- Genetic (including gene transfer, stem cell, and recombinant DNA)
- Dietary Supplement (e.g., vitamins, minerals)
- Combination Product
- Diagnostic Test
- Other



4.2D: STUDY PHASE

Drop down choices:

- Early Phase 1 (or Phase 0)
- Phase 1
- Phase 1/2
- Phase 2
- Phase 2/3
- Phase 3
- Phase 4
- Other (If you select “Other,” provide a description in the space provided. Your response is limited to 255 characters.)

- Is this an NIH-defined Phase III Clinical Trial? YES/NO

4.2E: INTERVENTION MODEL

Drop down choices:

- Single Group
- Parallel
- Cross-Over
- Factorial
- Sequential
- Other (If you select “Other,” provide a description in the space provided. Your response is limited to 255 characters.)

4.2F: MASKING (BLINDING)

- YES/NO

- If Yes, select:
  - Participant
  - Care Provider
  - Investigator
  - Outcomes Assessor

4.2G: ALLOCATION

- N/A
- Randomized
- Non-randomized

SECTION 4: PROTOCOL SYNOPSIS

4.3. Outcome Measures

Type	Name	Time Frame	Brief Description	Action
Nothing found to display				

Add New Outcome

4.4. Statistical Design and Power — Add Attachment | Delete Attachment | View Attachment

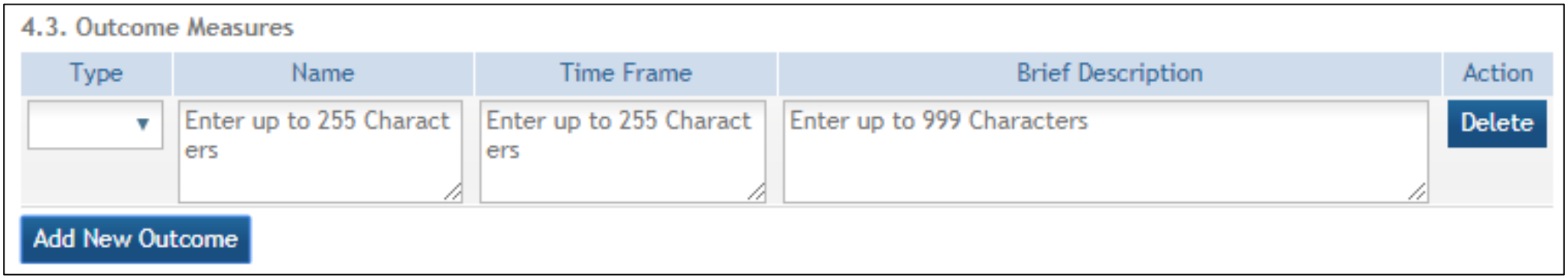
4.5. Subject Participation Duration

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

4.7. Dissemination Plan — Add Attachment | Delete Attachment | View Attachment

4.3: OUTCOME MEASURES



- Type: Primary, Secondary, or Other

4.4: STATISTICAL DESIGN

- Number of subjects projected to enroll
- Expected effect size
- Power and Statistical Methods
  - According to Outcome Measures listed in 4.3
- Methods for sample size and data analysis
- Plans for assignment and delivery of interventions
- Randomization
  - https://researchmethodsresources.nih.gov/

4.5: SUBJECT PARTICIPATION DURATION

- Enter the time for each participant to complete the study (For example, 3 months)
- Unknown or Not Applicable

4.6: FDA REGULATIONS

- Will the study use an FDA-regulated intervention? YES/NO
- 4.6a: If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status:
  - Describe the availability of study agents and support for the acquisition and administration of the study agent(s)
  - Indicate the IND/IDE status of the study agent, if applicable
  - Whether or not the investigators have had any interactions with the FDA
  - If the study agent currently has an IND/IDE number
  - **Note:** The awarding component may request consultation with the FDA and the IND/IDE sponsor about the proposed clinical trial after peer review and prior to award

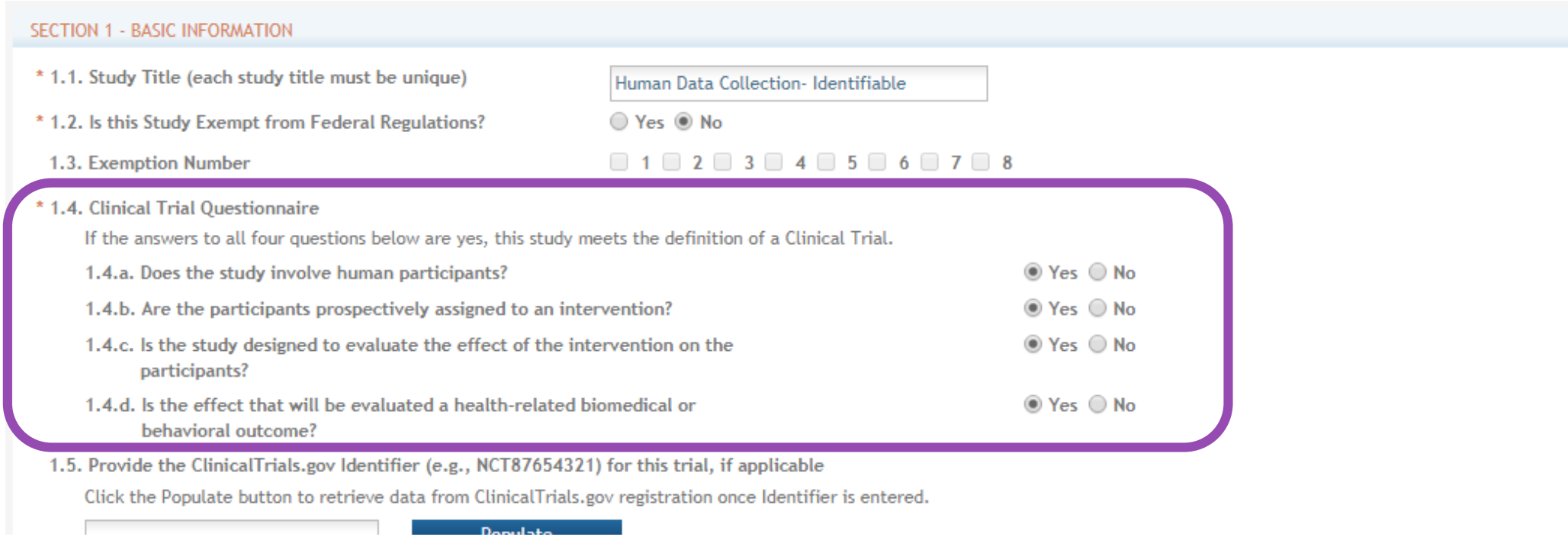
4.7: DISSEMINATION PLAN

- 1 per study, can be the same plan for multiple studies

- Registration on ClinicalTrials.gov
- Information is presented in Informed Consent
- Institution has internal policies that adhere to registration and reporting on ClincalTrials.gov

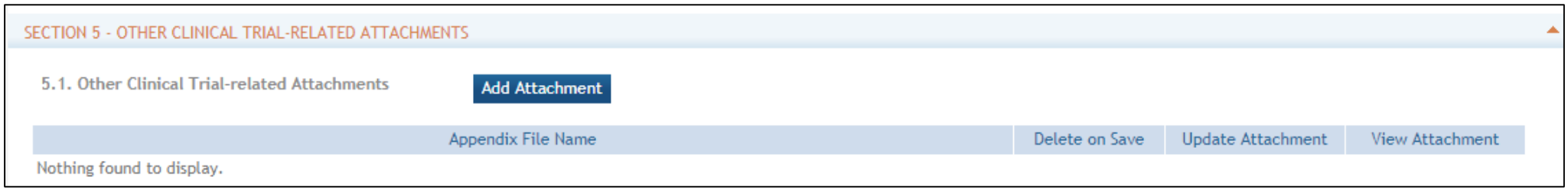
SECTION 5: OTHER ATTACHMENTS

- Must answer YES to all 4 Clinical Trial questions for Section 5 to appear



5.1 OTHER ATTACHMENTS

- Will be described in the FOA



ADD AN ADDITIONAL STUDY RECORD

Study Record(s)

Attach human subject study records using unique filenames.

Add New Study | Download Study | Upload Study

Entry #	Study Title	Clinical Trial?	Action
1	Human Data Collection-Not Identifiable	No	Edit View

Delayed Onset Study(ies)

Add New Delayed Onset Study

Entry #	Study Title	Anticipated Clinical Trial?	Justification	Delete on Save	Add/Update Attachment	View Attachment

Nothing found to display.

Save and Keep Lock | Save and Release Lock | Cancel and Release Lock

ADDITIONAL RESOURCES

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ADDITIONAL RESOURCES FOR THIS SECTION

- YouTube video for ASSIST: https://www.youtube.com/watch?v=nz9NWFhYOG8&list=PLOEUwSnjvqBJeHcb4yai7_fDnFZFPEmQK&index=1

- YouTube video for Workspace: https://www.youtube.com/watch?v=V9vzcOcx_BA

DR. TORRY'S SUMMARY

- Start early
- Submit to Grants Office for review early
  - Schedule a meeting with us in advance!
- Work with IRB, if necessary
- Mostly same information
  - New drop downs, YES/NO questions, and attachments

Questions?

Grants Office:
grants@siumed.edu

SCRIHS Office:
emeyer@siumed.edu

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