The Human Subjects Study Record

PRESENTERS:

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NICOLE COBB, HRPP OFFICER, OFFICE OF RESEARCH COMPLIANCE AND SECURITY

MENU

- Kid's Table.....Introductions
- Appetizers.....Why it Matters
- Casseroles.....How this Relates to Your IRB Protocol
- Turkey and Dressing.....Completing the Study Record
- Dessert.....Submission
- Nap in the Recliner.....You're Done!

Kid's Table

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Compliance and Security

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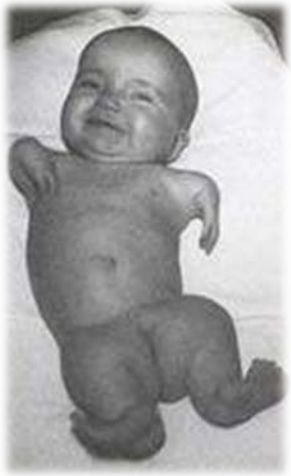
We're Here to Help!

Appetizers…….Why It Matters

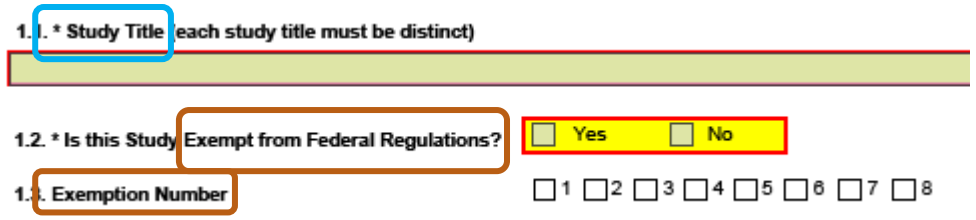


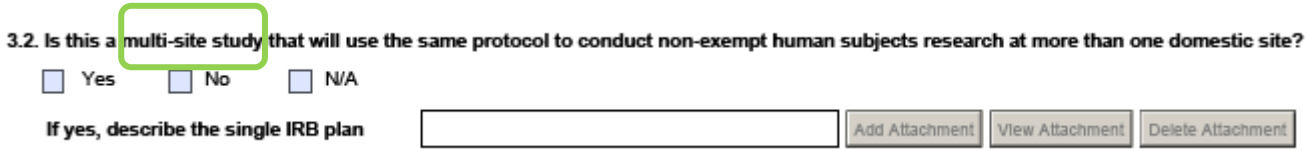
- How IRB Came to Be
- What We Do
- Training
  - https://www.orc.msstate.edu/human-subjects/training
  - IRB
  - GCP
- Protocol Submissions
  - https://www.orc.msstate.edu/
  - myProtocol

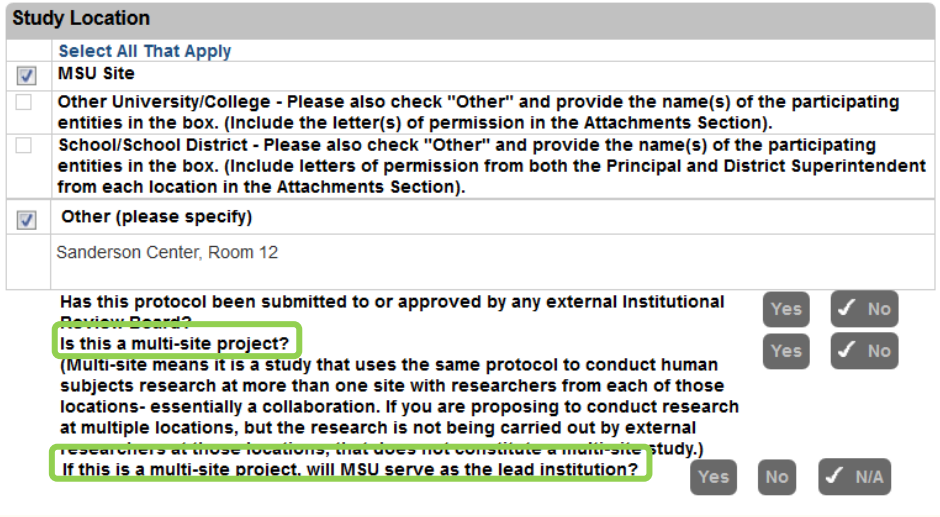
What is a Human Subjects Study Record & which proposals must include one?

- The Study Record is set of data elements about a research investigation involving human subjects that describes a proposed or on-going study.
- HS SR is only ONE part of your proposal. There are other pieces of information and questions if your project includes a clinical trial.
- What proposals require a study record?
  - Does your project involve Human subjects?
    - Is your study "exempt?"
    - What level of IRB approval is required for your proposal at submission time?
    - Study/delayed start vs. delayed onset
      - **Delayed Start**: your project DOES involve human subjects, but activities with subjects do not begin immediately. Add a study record for each proposed study involving human subjects.
      - **Delayed Onset:** Your study ANTICIPATES involving human subjects, within the performance period, but specific plans cannot be described in the application. You will include a justification (see the instructions for Delayed Onset Study(ies).)

Casseroles…….How this Relates to Your IRB Protocol







***While it is important to start these internal IRB processes early, best practice is to have completed your actual study record forms BEFORE you initiate the internal IRB protocol.**

Casseroles…….How this Relates to Your IRB Protocol

Section 4 - Protocol Synopsis

4.1. Brief Summary

4.2. Study Design

4.2.a. Narrative Study Description

4.5. Subject Participation Duration

1. Summary

a) Provide a brief summary of the scope of work of this project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.

TBD

2. Purpose

a) Describe the purpose, intention, or motive for conducting the proposed project. List your research questions or hypothesis to be examined.

3. Procedures

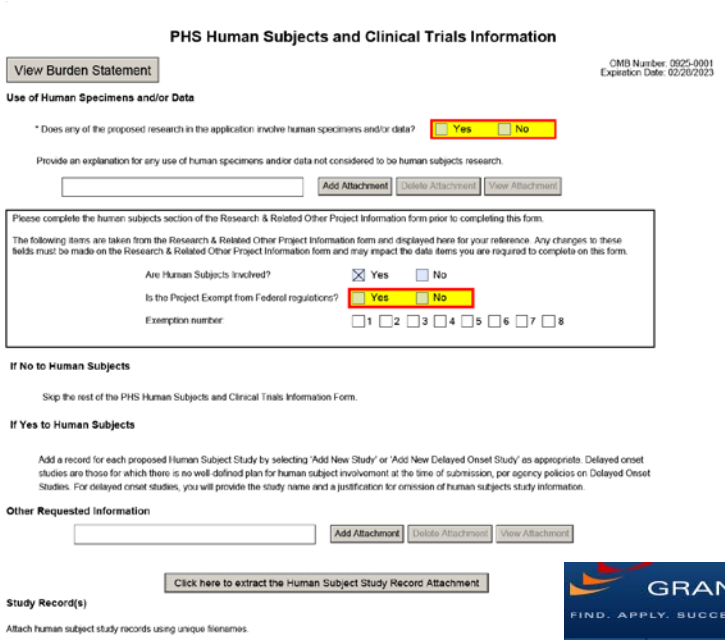
a) Provide a step-by-step description of what the participants will be asked to do (e.g. interventions/interactions with participants, data collection, photographing, audio and video recording), including follow up procedures.

In the Attachments Section, provide questionnaires, test instruments, interview questions etc.

b) What are the total number of test sessions and the total time commitment that participants are being asked to take part in for the study?

Turkey and Dressing.....the "main event!" Completing the Study Record

Where to start and how to get the form(s):
AT MSU, all PHS funded proposal are submitted via Cayuse. When you (or your designee) download and open a specific opportunity to begin the proposal package, you will answer several questions in the R&R "Other Project Information" section. If you answer "yes" to "does your project involve human subjects?" Your package will include the correct form/fields to complete.


PHS Human Subjects and Clinical Trials Information

View Burden Statement

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

Use of Human Specimens and/or Data

* Does any of the proposed research in the application involve human specimens and/or data? Yes No

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Add Attachment | Delete Attachment | View Attachment

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

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.

BUT...we advise that you ***actually go to*** the PHS link and download current version of the full form to prepare it. You want to do this before you begin your IRB protocol.
*because your BM or G&CM likely doesn't know enough about your plan to enter this for you in the submission platform.

https://apply07.grants.gov/apply/forms/sample/PHSHumanSubjectsAndClinicalTrialsInfo_3_0-V3.0.pdf '

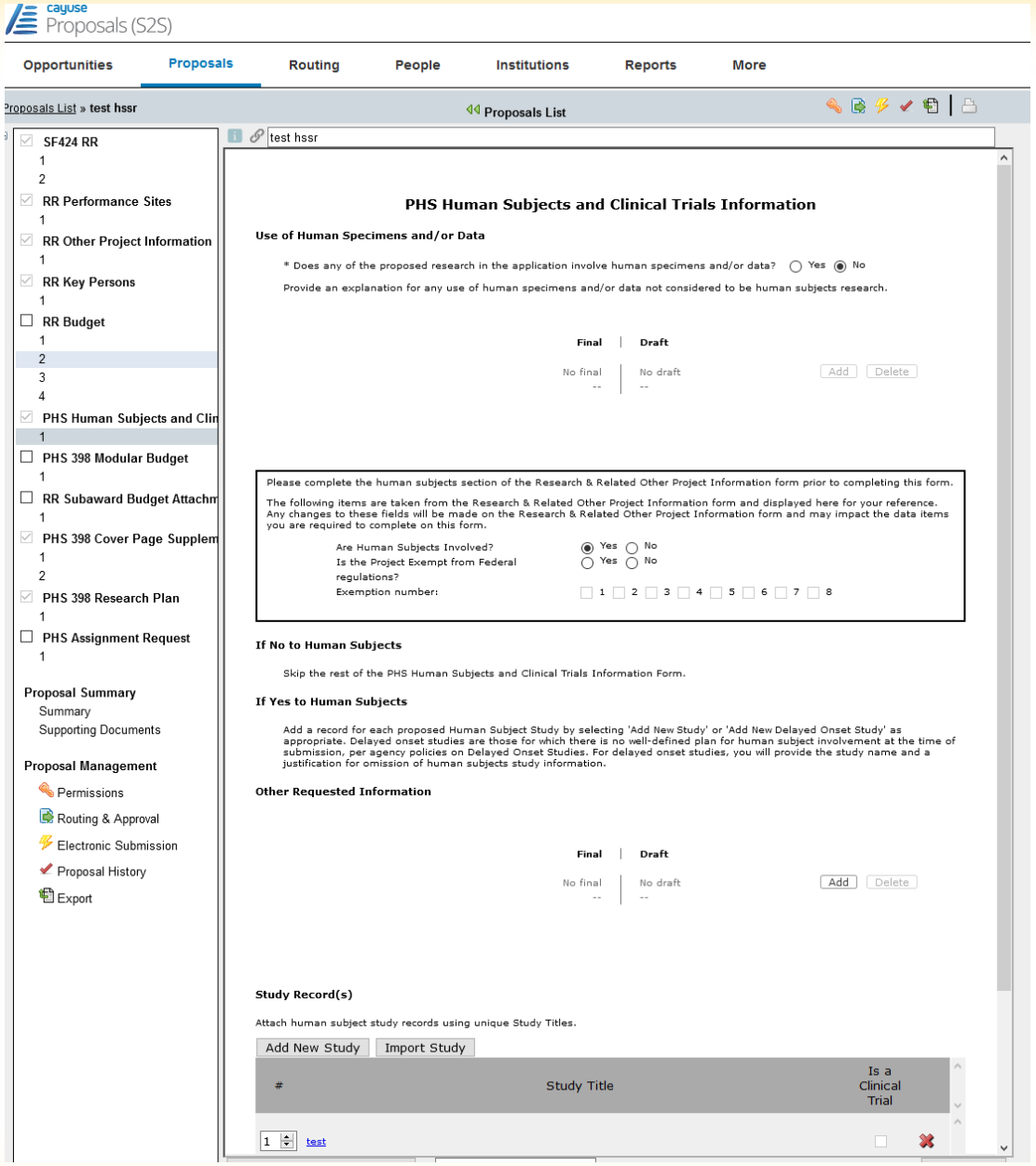

GRANTS.GOV
FIND. APPLY. SUCCEED.
HOME | LEARN GRANTS | SEARCH GRANTS | APPL
GRANTS.GOV 〉 Forms 〉 Forms Repository 〉 R&R Family
R&R FAMILY
» Forms Repository
» R&R Family
» SF-424 Family
» SF-424 Individual Family
» SF-424 Mandatory Family
» SF-424 Short Organization Family
» Post-Award Reporting Forms
» Retired Forms
» Forms Development

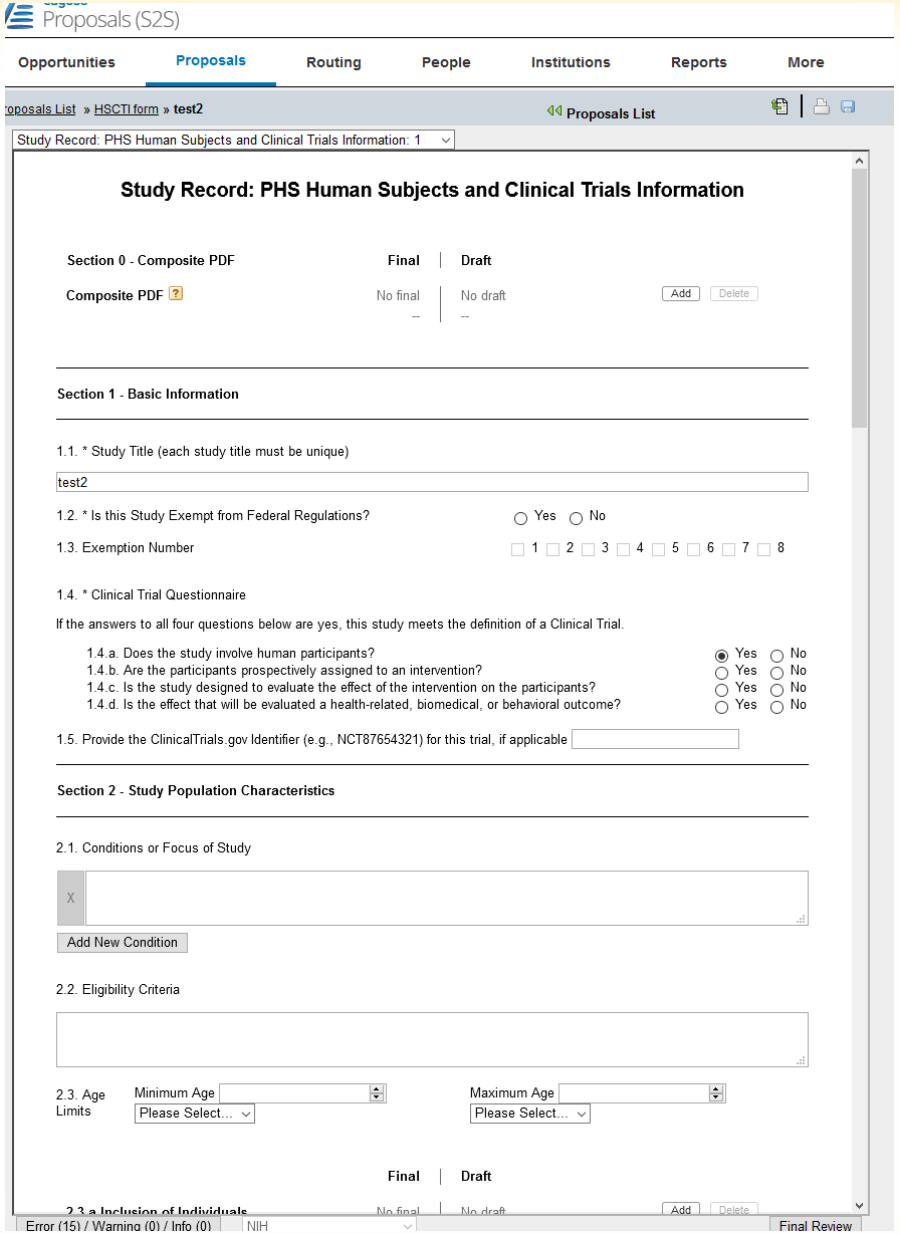
Official PHS Human Subjects & Clinical Trials Info Guidance

Study Record is broken into 5 Sections:

1. Basic Information
2. Study Population Characteristics
3. Protection & Monitoring Plan
4. Study Design
5. Other Clinical Trial Information*

Each "section" has numerous questions with fields/drop boxes, and/or space to upload attachments


cayuse
Proposals (S2S)
Opportunities
Proposals
Routing
People
Institutions
Reports
More
Proposals List » test hssr
Proposals List
SF424 RR
RR Performance Sites
RR Other Project Information
RR Key Persons
RR Budget
PHS Human Subjects and Clin
PHS 398 Modular Budget
RR Subaward Budget Attachm
PHS 398 Cover Page Supplem
PHS 398 Research Plan
PHS Assignment Request
Proposal Summary
Summary
Supporting Documents
Proposal Management
Permissions
Routing & Approval
Electronic Submission
Proposal History
Export
test hssr
PHS Human Subjects and Clinical Trials Information
Use of Human Specimens and/or Data
* Does any of the proposed research in the application involve human specimens and/or data? Yes No
Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.
Final | Draft
No final -- | No draft --
Add Delete
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 will 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
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
Final | Draft
No final -- | No draft --
Add Delete
Study Record(s)
Attach human subject study records using unique Study Titles.
Add New Study
Import Study
| Study Title | Is a Clinical Trial
1 test


Proposals (S2S)
Opportunities
Proposals
Routing
People
Institutions
Reports
More
Proposals List » HSCTI form » test2
Proposals List
Study Record: PHS Human Subjects and Clinical Trials Information: 1
Study Record: PHS Human Subjects and Clinical Trials Information
Section 0 - Composite PDF
Final | Draft
Composite PDF
No final -- | No draft --
Add Delete
Section 1 - Basic Information
1.1. * Study Title (each study title must be unique)
test2
1.2. * Is this Study Exempt from Federal Regulations? Yes No
1.3. Exemption Number 1 2 3 4 5 6 7 8
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 Characteristics
2.1. Conditions or Focus of Study
Add New Condition
2.2. Eligibility Criteria
2.3. Age Limits
Minimum Age
Please Select...
Maximum Age
Please Select...
Final | Draft
Add Delete
Error (15) / Warning (0) / Info (0)
NIH
Final Review

Let's graze through each "section" .

Section 1: Basic Information

1.1 Title – unique PER study (600 characters)

1.2 Exemption

1.3 Exemption Number

1.4 Clinical Trial Questionnaire (a-d) to determine if meets the definition of a clinical trial

1.5 Clinical Trial Identifier

Section 2 - Study Population Characteristics

(*not required if using existing data only)

2.1 Conditions or Focus: refers to primary condition/disease being studied (up to 20/255 char. per condition)

2.2 Eligibility Criteria: provide a brief description of inclusion and exclusion criteria (500 – 15,000 characters*)

2.3. Age limits (min/max)

2.3.a. Inclusion Across the Lifespan ATTACHMENT

2.4 Inclusion of Women & Minorities ATTACHMENT

2.5 Recruitment and Retention Plan ATTACHMENT (not required if exempt for #4)

2.6 Recruitment Status (drop down box) (not required if exempt for #4)

2.7 Study Timeline ATTACHMENT (optional if exempt for #4)

2.8 Enrollment of First Participant (date field) (not required if exempt for #4 or using existing dataset)

2.9 Inclusion Enrollment Report(s) FORM w/tables*****
minimum of one IER required PER study (unless exempt #4)

2.9 Inclusion Enrollment Report

- Not completed if using EXISTING datasets
- Completed for target/planned enrollment
- Location and racial categories are collected
- Individual and cumulative info
- Detailed descriptions/definitions provided in guidance

1. * Inclusion Enrollment Report Title

2. *Using an Existing Dataset or Resource ◯ Yes ◯ No
3. *Enrollment Location Type ◯ Domestic ◯ Foreign

4. Enrollment Country(ies)

X Please Select... Add New Country

5. Enrollment Location(s)

6. Comments

Planned

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

Actual

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

Section 3 – Protection and Monitoring Plans

3.1 Protection of Human Subjects ATTACHMENT

Four parts: Risks; Adequacy of Protections; Potential Benefits; Importance of Knowledge to be Gained

3.2 Multi/single-site IRB plan (Y/N - attachment if yes)

3.3 Data and Safety Monitoring Plan ATTACHMENT (required if clinical trial; optional if not)

3.4. Data and Safety Monitoring Board appointed? (Y/N)

3.5 Study Team structure/qualifications (optional) ATTACHMENT

Section 4 – Protocol Synopsis

If you answered "No" to any question in the "Clinical Trial Questionnaire:" Do not provide information in this section. Inputting information in this section will result in errors and will prevent your application from being accepted.

If you answered "Yes" to all the questions in the "Clinical Trial Questionnaire:" All the questions in the "Protocol Synopsis" section are required.

4.1 Study Design Description – fields (5000 –32,000)

4.2 Outcome Measures (fields/drop boxes) (up to 50 with up to 999 characters each)

4.3 Statistical Design and Power (ATTACHMENT)

4.4 Participation Duration (field)

4.5 FDA-regulated Intervention? (Y/N; ATTACHMENT if yes)

4.6. FDAAA Clinical Trial (field)

4.7 Dissemination Plan (ATTACHMENT; 1 plan PER study)

Section 5 – other clinical trial-related ATTACHMENT(S)

- Complete this section ONLY if specified as a requirement in the FOA; and only if your project meets the definition of a clinical trial (item 1.4)
- If required by FOA, there may be special additional requirements for the TYPE of proposal (career development, training, fellowship, etc.)
- If requested/required by FOA, be sure to use the requested filenames as instructed.

Dessert!!!

Submission

- All PHS agency proposals are submitted via Cayuse
- Rely on OSP and college/dept administrators and specialists. ORC and ORD
- The Cayuse submission platform will note errors (which prohibit submission) and warnings
- These are all reasons it is so important to do these tasks early!

Questions?

Be on the lookout for:

1. Slides from today
2. PDF of Study Record
3. At-a-glance checklist/ cheatsheet & attachment outline

ALL DONE!