

# Human Subjects Study Records activity in RAPPORT

Easy data entry into the new PHS Human Subjects and Clinical Trial Information form located on the proposal workspace:

**Funding Proposal: New FP Activity** FP00004786 Funding Submission

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OSP 7 Day Deadline: 1/25/2018 **OSP 2 Day Deadline:** 2/1/2018 Sponsor Submission Deadline: 2/5/2018

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**Current State**

**Draft**

Edit Funding Proposal

Printer Version

View Differences

View SmartForm Progress

**Change Management**

Create Update SF424

**Human Subjects Study Records**

**Routing and Approvals**

Forward to DRA

**Proposal Team Actions**

Update Edit-Read Access

Cancel Funding Proposal

**Proposal Information** | Approver Checklist | Contacts | Comments | Sponsor Submission | Documentation | Follow-on Submissions

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**PROPOSAL INFORMATION**

**Primary Sponsor:** National Institutes of Health (NIH)

**PI:** Test PINine

**Title:** Professor

**Rank:**

**DRA:** Test Resadmin3

**Application Type:** New

**Sponsor ID:**

**Abstract:**

**This project requires the following additional resources:** Not Applicable (N/

**Additional resource comments:**

**Cost Sharing involved?** No

**To Be Submitted By:**

**BUDGET TOTALS**

**Start Date:** 7/1/2018

| Period | Start Date | End Date  | Type of Costs  | Costs |
|--------|------------|-----------|----------------|-------|
|        |            |           | Direct Costs   | \$0   |
|        |            |           | Indirect Costs | \$0   |
|        |            |           | Direct Costs   | \$0   |
|        |            |           | Indirect Costs | \$0   |
|        |            |           | Direct Costs   | \$0   |
|        |            |           | Indirect Costs | \$0   |
|        |            |           | Direct Costs   | \$0   |
|        |            |           | Indirect Costs | \$0   |
| 5      | 7/1/2022   | 6/30/2023 | Direct Costs   | \$0   |
|        |            |           | Indirect Costs | \$0   |

**When a FP is being submitted via Grants.gov (S2S)**

**The 'Human Subjects Study Records' activity will appear on the FP workspace**

RAPPORT Human Subjects Study Record Instructions

1 | Page

To complete Study Records in a SF424 application, simply click on this button and the PHS Human Subjects and Clinical Trials Information form opens for completion:

RESEARCH PORTAL

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: PHS Human Subjects and Clinical Trials Information V1.0

## PHS Human Subjects and Clinical Trials Information

### Research & Related Other Project Information

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.

1. Are Human Subjects Involved? Yes
2. Is the Project Exempt from Federal regulations? No
3. Exemption Number:

**A new window opens displaying the new Form in the SF424 Application**

### PHS Human Subjects and Clinical Trials Information

You can add Study Records here:

2. Other Requested Information: [None] Add
3. Study Record(s) - Attach human subject study records using unique Study Titles.  
Add  
Study Title Display Order  
There are no items to display
4. Delayed Onset Study(ies):  
Add  
Study Title Anticipated Clinical Trial? Justification Display Order  
There are no items to display

**Click on the Add button to enter Study Records as needed**

A second, new window opens and displays the new Study Record you are creating:

**1. Does the proposed research involve the collection, use, or storage of human specimens and/or data?**

If Yes, provide an explanation of how the application does not involve human subjects research.

Skip the rest of the PHS

**If Yes to Human Subjects**

Add a record for each study. Click 'Add' on 'Delayed Clinical Trial' if there is no well-defined policy on Delayed Clinical Trial justification for om

**2. Other Requested Information**

**3. Study Record(s) - Attach human subjects study records using unique identifiers**

Add  
Study Title      Display Order  
There are no items to display

**4. Delayed Onset Study(ies):**

Add  
Study Title      Anticipated Clinical Trial?      Justification  
There are no items to display

Add SF424\_HumanSubjectStudy

## Study Record: PHS Human Subjects and Clinical Trials Information

### Section 1 - Basic Information

- \* Study Title (each study title must be unique)**
- \* Is this Study Exempt from Federal Regulations?**  Yes  No [Clear](#)
- Exemption Number**
- Clinical Trial Questionnaire** If the answers to all four questions below are yes, this is a Clinical Trial.
  - \* Does the study involve human participants?**  Yes  No [Clear](#)
  - \* Are the participants prospectively assigned to an intervention?**  Yes  No [Clear](#)
  - \* Is the study designed to evaluate the effect of the intervention on the participants?**  Yes  No [Clear](#)
  - \* Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome?**  Yes  No [Clear](#)

**A second new window opens up  
This is where you enter the Study  
Record information**

If you do not have all the information to enter for the study record, you can enter what you have and save your changes.

**NOTE: You must complete Questions 1-4 on the Study Record** before you can save your data entry and/or changes as these are required questions on the form.

**BEST PRACTICE:**

Open the Study Record window to Full Screen viewing. This will save you time when you need to look for the 'OK' button to SAVE your changes (see below).

**Remember to click 'OK' when you are done or your data entry will NOT be saved!**

**3. Outcomes Measures**  
Add  
Outcome Name Outcome Type Time Frame Outcome Description  
There are no items to display

**4. Statistical Design and Power** [None] Add

**5. Subject Participation Duration**

**6. Will the study use an FDA-regulated intervention?**  
 Yes  No  
If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status [None] Add

**7. Dissemination Plan** [None] Add

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

**1. Other Clinical Trial-related Attachments**  
Add  
Name Description  
There are no items to display

\* Required

OK OK and Add Another Cancel

After clicking 'OK' you can add another Study Record or...

If your data entry is done, then click 'Save' before you close the browser window.

**IMPORTANT: Your changes will NOT be saved unless you click 'Save':**

**3. Study Record(s) - Attach human subject study records using unique Study Titles.**

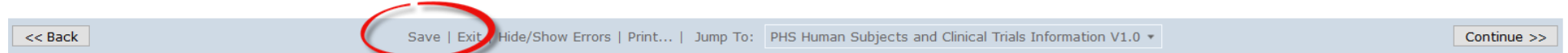
| Study Title | Display Order                       |                                       |
|-------------|-------------------------------------|---------------------------------------|
| Study Title | <input type="text" value="150.00"/> | <input type="button" value="Delete"/> |

**4. Delayed Onset Study(ies):**

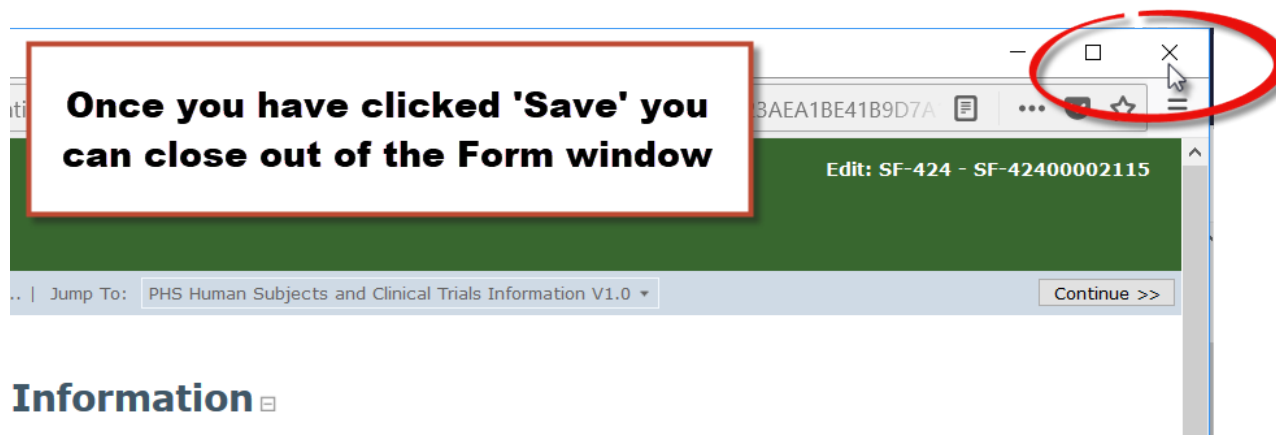
| StudyTitle                    | Anticipated Clinical Trial? | Justification | Display Order |
|-------------------------------|-----------------------------|---------------|---------------|
| There are no items to display |                             |               |               |

**You MUST click 'Save' before closing the form window**

**Your changes will NOT be saved until you click 'Save'**



Once you have saved your work, then you can safely close the browser window:



**Information**

The Human Subjects Study Records activity **is available in all proposal states**, which means that even in a review state, this button will appear and users can click on it to complete the new form in the SF424.

This activity is available to all users who have access to the proposal in RAPPORT.