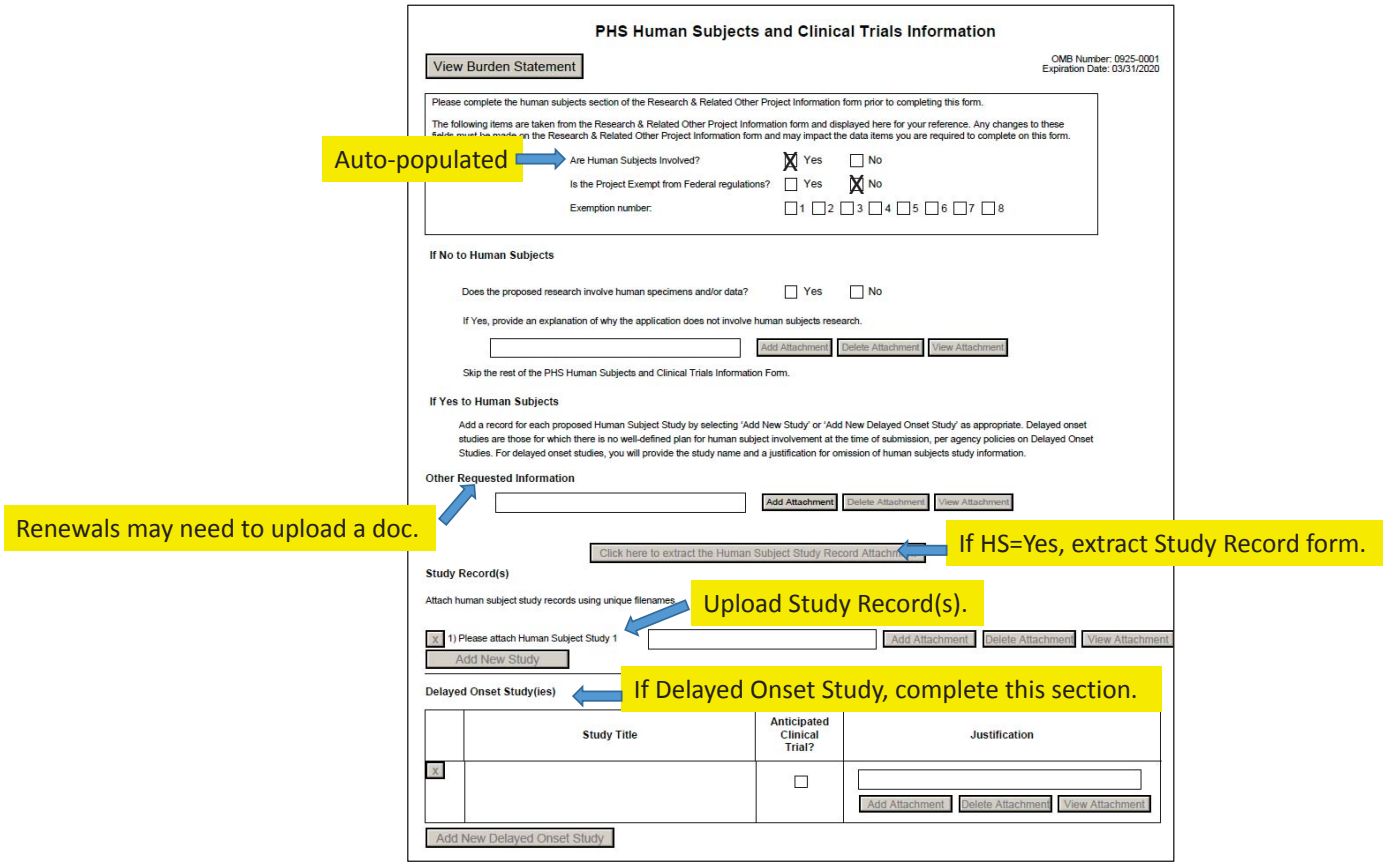
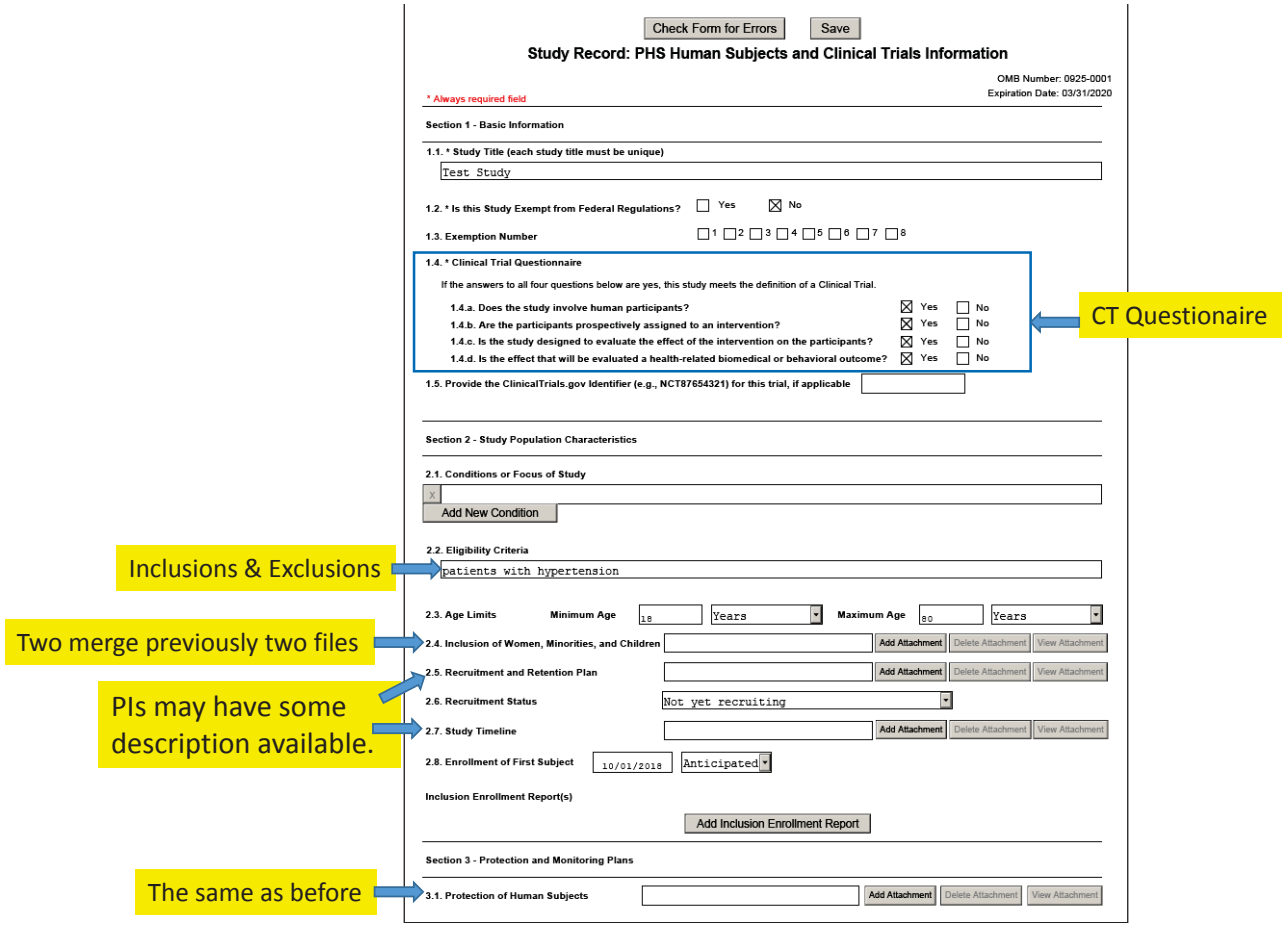
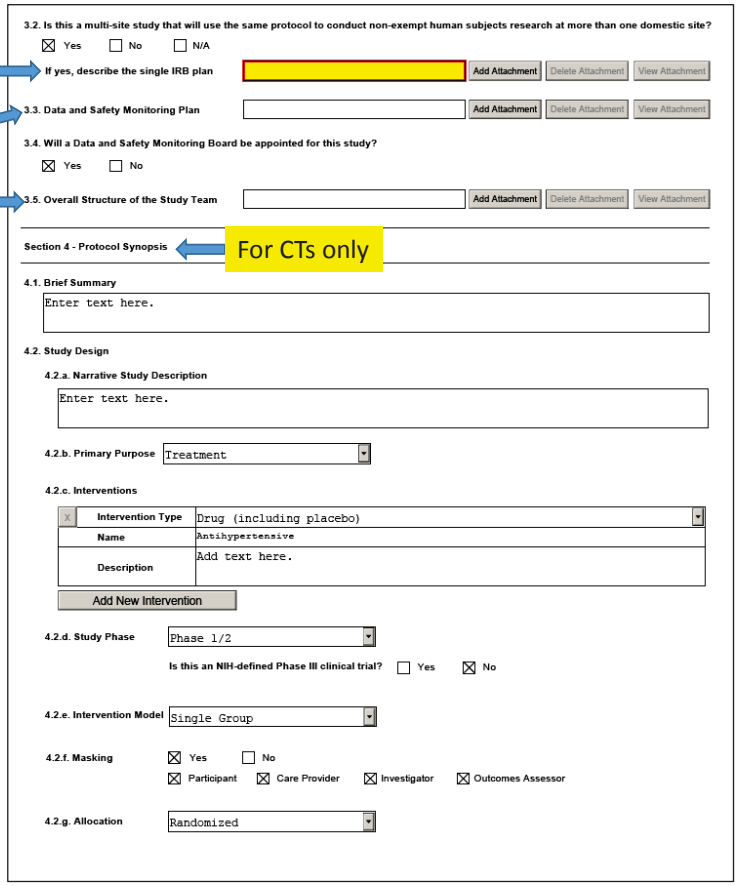

PHS Human Subjects and Clinical Trials Information
View Burden Statement
OMB Number: 0925-0001
Expiration Date: 03/31/2020
Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.
The following items are taken from the Research & 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.
Auto-populated
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
Renewals may need to upload a doc.
Click here to extract the Human Subject Study Record Attachm
If HS=Yes, extract Study Record form.
Study Record(s)
Attach human subject study records using unique filenames.
Upload Study Record(s).
1) Please attach Human Subject Study 1
Add Attachment Delete Attachment View Attachment
Add New Study
Delayed Onset Study(ies)
If Delayed Onset Study, complete this section.
Study Title
Anticipated Clinical Trial?
Justification
Add Attachment Delete Attachment View Attachment
Add New Delayed Onset Study

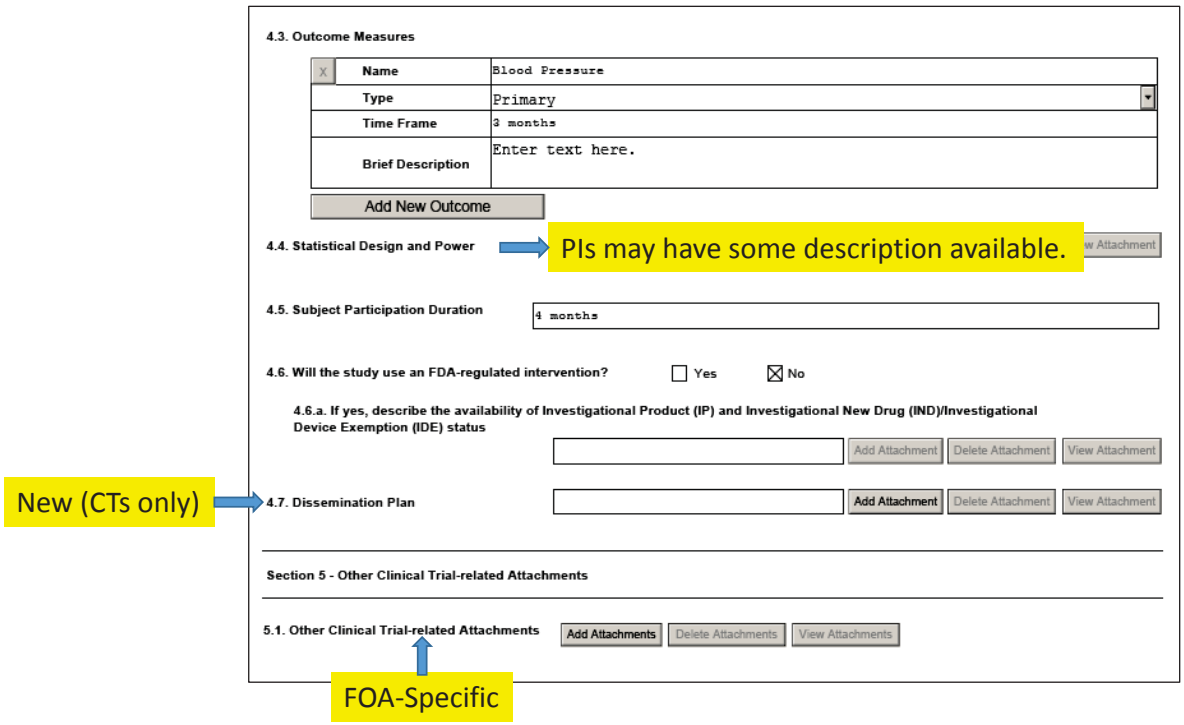

Check Form for Errors
Save
Study Record: PHS Human Subjects and Clinical Trials Information
OMB Number: 0925-0001
Expiration Date: 03/31/2020
* Always required field
Section 1 - Basic Information
1.1. * Study Title (each study title must be unique)
Test Study
1.2. * Is this Study Exempt from Federal 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
patients with hypertension
2.3. Age Limits Minimum Age 18 Years Maximum Age 80 Years
2.4. Inclusion of Women, Minorities, and Children Add Attachment Delete Attachment View Attachment
2.5. Recruitment and Retention Plan Add Attachment Delete Attachment View Attachment
2.6. Recruitment Status Not yet recruiting
2.7. Study Timeline Add Attachment Delete Attachment View Attachment
2.8. Enrollment of First Subject 10/01/2018 Anticipated
Inclusion Enrollment Report(s)
Add Inclusion Enrollment Report
Section 3 - Protection and Monitoring Plans
3.1. Protection of Human Subjects Add Attachment Delete Attachment View Attachment
CT Questionaire
Inclusions & Exclusions
Two merge previously two files
PIs may have some description available.
The same as before

If sIRB, engage IRBMED early.

The same as before

Non-CTs: Optional
CTs: Mandatory




4.3. Outcome Measures
Name
Blood Pressure
Type
Primary
Time Frame
3 months
Brief Description
Enter text here.
Add New Outcome
4.4. Statistical Design and Power
PIs may have some description available.
4.5. Subject Participation Duration
4 months
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
New (CTs only)
4.7. Dissemination Plan
Add Attachment
Delete Attachment
View Attachment
Section 5 - Other Clinical Trial-related Attachments
5.1. Other Clinical Trial-related Attachments
Add Attachments
Delete Attachments
View Attachments
FOA-Specific

Attachments in the Study Record Form

Attachments	Non-Clinical Trials	Clinical Trials
2.4 Inclusion of Women, Minorities, and Children	Yes	Yes
2.5 Recruitment & Retention Plan	Yes	Yes
2.7 Timeline	Yes	Yes
3.1 Protection of Human Subjects	Yes	Yes
3.2 sIRB Plan	Yes	Yes
3.3 Data and Safety Monitoring Plan	Optional	Yes
3.5 Overall Structure of the Study Team	Optional	Yes
4.4 Statistical Design & Power	No	Yes
4.7 Dissemination Plan	No	Yes