

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

[View Burden Statement](#)

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](#)

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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 and 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 subject study information.

Other Requested Information

[Add Attachment](#)

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[Click here to extract the Human Subject Study Record Attachment](#)

Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1 [Add Attachment](#) [Delete Attachment](#) [View Attachment](#)

[Add New Study](#)

Delayed Onset Study(ies)

| | Study Title | Anticipated Clinical Trial? | Justification |
|-------------------------------------|-------------|-----------------------------|----------------------|
| <input checked="" type="checkbox"/> | | <input type="checkbox"/> | <input type="text"/> |

[Add New Delayed Onset](#)