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 --

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 [x] 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.