|  |  |  |
| --- | --- | --- |
|  | EASTERN CONNECTICUT STATE UNIVERSITYOffice of the Vice President for Academic AffairsGelsi-Young Hall, Willimantic, CT 06226 Ph: 860-465-5245 | CUHSR use only: Protocol # Click or tap here to enter text.  |

COMMITTEE ON THE USE OF HUMAN SUBJECTS IN RESEARCH

OHRP IRB00005900 Eastern Connecticut State U IRB #1 Federalwide Assurance FWA00011898

**IRB-C Treatment Study Supplemental Form**

Read these important notes before completing this form:

1. There may be periodic updates to this form, so please be sure to use the current version.
2. Please complete this form if the proposed study is a treatment study; that is, if the study holds forth the possibility of a cure or therapy for the subject’s condition.
3. This form must be included when the IRB-1 protocol application is submitted for initial IRB review. Applications will not be reviewed until they are complete with all the required information and documentation.
4. Do not alter this form/convert it to another format (PDF, etc.). Altered forms will not be reviewed.
	1. Tap in the boxes to check/uncheck your selections.
	2. Use the “Click or tap here to enter text” to enter all information. The boxes will adjust to accommodate however much space you need. Do not bold the text you enter in the text boxes.

|  |
| --- |
| **Section 1: General Information** |
| **Name of Principal Investigator:** Click or tap here to enter text.**Department:** Click or tap here to enter text.**Email:** Click or tap here to enter text.**Phone:** Click or tap here to enter text.**Study title:** Click or tap here to enter text.Important Notes: *1. The Data Safety Monitoring section on the IRB-1 must be completed for all treatment studies*. **Is the Data Safety Monitoring section on the IRB-1 completed?** [ ]  Yes [ ]  No*2. If this study involves the use of drugs, devices, biological agents, or proprietary products, the IRB-1A form must also be completed and submitted.* **Does this study use drugs, devices, biological agents, or proprietary products?** [ ]  Yes [ ]  No**If yes, did you complete and attach the IRB-1A form with your application?** [ ]  Yes [ ]  No |

|  |
| --- |
| **Section 2: Description of Procedures** |
|  **1. Describe what the standard of care is and how the experimental procedures differ from this.**  Click or tap here to enter text.**2. State whether all participants will receive current therapy in addition to study procedures, or if current therapy will be stopped. If current therapy will be stopped, provide justification for doing so.** Click or tap here to enter text.**3. If applicable, justify inclusion of a placebo group.** [ ]  **N/A** Click or tap here to enter text.**4. If applicable, justify blinding or not blinding the study.** [ ]  **N/A** Click or tap here to enter text.**5. Describe the conditions under which participants will be removed from the study or have the experimental procedures stopped.**  Click or tap here to enter text.**6. Describe what happens with therapy when study ends (participant resumes original treatment plan, etc.).** Click or tap here to enter text. |