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|  | EASTERN CONNECTICUT STATE UNIVERSITY  Office of the Vice President for Academic Affairs  Gelsi-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-1A Drug/Device/Biological Agent/Proprietary Product 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 involves the use of FDA approved drugs/devices, non-medical devices, investigational drugs/devices, biological agents, or proprietary products. *Note: The use of radiation or radioisotopes is not permitted on campus. For a study involving the use of radiation or radioisotopes, you will need to gain IRB approval from the Institution where you are collecting data.*
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.

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| **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 studies involving the use of drugs, devices, biological agents, or proprietary products*.  **Is the Data Safety Monitoring section on the IRB-1 completed?**  Yes  No  *2. If this is a treatment study, the IRB-1C form must also be completed and submitted.*  **Is this a treatment study?**  Yes  No  **If yes, did you complete and attach the IRB-1C form with your application?**  Yes  No |

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| **Section 2: Drugs** |
| 1. Does the study involve the use of an FDA approved drug?  Yes  No  **If yes, complete the information below and also complete section 6 (Description of Procedures):**  **Drug Name:** Click or tap here to enter text.  **Manufacturer:** Click or tap here to enter text.  **Dosage:** Click or tap here to enter text.  **Route of Administration:** Click or tap here to enter text.  **Is section 6 (Description of Procedures) completed?**  Yes  No  2. Will the drug be used in accordance with the manufacturer’s labeling?  Yes  No  **If no, describe how the use will differ from manufacturer’s instructions (dosage, route of administration, etc.). Please note that an Investigational New Drug (IND) application may be required**. Click or tap here to enter text.  3. Does the study involve the use of an Investigational New Drug (IND)?  Yes  No  **If yes, complete the information below and also complete section 6 (Description of Procedures):**  **IND Name:** Click or tap here to enter text.  **Number:** Click or tap here to enter text.  **Manufacturer:** Click or tap here to enter text.  **Dosage:** Click or tap here to enter text.  **Route of Administration:** Click or tap here to enter text.  **Reason/Rationale:** Click or tap here to enter text.  **Is section 6 (Description of Procedures) completed?**  Yes  No |

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| **Section 3: Devices** |
| 1. Does the study involve the use of an FDA approved medical device?  Yes  No  *Refer to the U.S. FDA Guidance Sheet on Medical Devices:* [*https://www.fda.gov/files/about%20fda/published/Frequently-Asked-Questions-About-Medical-Devices---Information-Sheet.pdf*](https://www.fda.gov/files/about%20fda/published/Frequently-Asked-Questions-About-Medical-Devices---Information-Sheet.pdf)  **If yes, complete the information below:**  **Device Name:** Click or tap here to enter text.  **Manufacturer:** Click or tap here to enter text.  **Will the device be used in accordance with the manufacturer’s labeling?**  Yes  No  **If no, please describe how the use will differ from the manufacturer’s instructions. Please note that an Investigational Device Exemption (IDE) may apply:** Click or tap here to enter text.  2. Does the study involve the use of a non-medical device?  Yes  No  *A non-medical device is one that cannot interact chemically with the body and it is not being studied or promoted for a medical purpose.*  **If yes, complete the information below:**  **Device Name:** Click or tap here to enter text.  **Manufacturer:** Click or tap here to enter text.  **Rationale for using the device:** Click or tap here to enter text.  **Device Name:** Click or tap here to enter text.  **Manufacturer:** Click or tap here to enter text.  **Rationale for using the device:** Click or tap here to enter text.  **Device Name:** Click or tap here to enter text.  **Manufacturer:** Click or tap here to enter text.  **Rationale for using the device:** Click or tap here to enter text.  3. Does the study involve the use of an Investigational device?  Yes  No  *Refer to U.S. FDA Center for Devices and Radiological Health:* [*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-decisions-investigational-device-exemption-clinical-investigations*](https://nam04.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.fda.gov%2Fregulatory-information%2Fsearch-fda-guidance-documents%2Ffda-decisions-investigational-device-exemption-clinical-investigations&data=02%7C01%7Ccuhsr%40easternct.edu%7Cf5da74dcd95043da634808d83f159fd3%7C00bc4ae8576c45e3949d4f129d8b670a%7C1%7C0%7C637328709395135173&sdata=9Nd1v17U9VbAHki8IvMPvGLCauGiCPfBF8HXwHbeWjY%3D&reserved=0)  **If yes, complete the information below:**  **Device Name:** Click or tap here to enter text.  **Device Number:** Click or tap here to enter text.  **Manufacturer:** Click or tap here to enter text.  **Rationale for using the device:** Click or tap here to enter text. |

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| **Section 4: Biological Agents** |
| 1. Does the study involve the use of biological agents?  Yes  No  **If yes, complete the information below and also complete section 6 (Description of Procedures):**  **Biological Agent:** Click or tap here to enter text.  **Describe its Physical State (supplied in powder, capsule, tablet, or liquid form):** Click or tap here to enter text.  **Manufacturer:** Click or tap here to enter text.  **State/Province and Country of Manufacturer:** Click or tap here to enter text.  **Is section 6 (Description of Procedures) completed:**  Yes  No |
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| **Section 5: Proprietary Products** |
| 1. Does the study involve the use of a proprietary product?  Yes  No  **If yes, complete the information below and also complete section 6 (Description of Procedures):**  **Product/Drug Name:** Click or tap here to enter text.  **Manufacturer:** Click or tap here to enter text.  **Individual Components/Dosage:** Click or tap here to enter text.  **Route of Administration:** Click or tap here to enter text.  **Is section 6 (Description of Procedures) completed:**  Yes  No |
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| **Section 6: Description of Procedures** |
| Complete the following if required from above sections:  **1. Clearly explain the timing of the drug/biological administration. Include the dosing schedules and dose parameters (i.e., detail calculations including contributory factors such as, body weight and surface area).**  Click or tap here to enter text.  **2. For drug/biological administration by artery, vein, peritoneum, etc., state the mode of administration with respect to time (IV over 6 hours, constant infusion over 24 hours, etc.). Indicate preferred diluents and volume to be used. Indicate appropriate supportive care should extravasation occur. State the preferred order of administration if regimen involves multiple drug/biologicals administered subsequently.**  Click or tap here to enter text.  **3. Define duration of therapy including treatment stopping points and explain how to proceed when this point is reached. Explain transition from IV to PO administration of therapy.**  Click or tap here to enter text.  **4. Indicate any adverse reactions or toxicities that may be expected. Indicate the nature and the timing of the toxicity (e.g., leukopenia usually occurs between 9-14 days).**  Click or tap here to enter text.  **5. Include instructions for management of toxicity and how this will be monitored**.  Click or tap here to enter text. |