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| **Purpose:**  This appendix is designed to provide information to the IRB for human subjects research involving the use of drugs and other substances. |

**Instructions:**

* Complete only if your research activities will include the use of drugs or other substances.
* Investigators must fill out a form for **each** drug or other substance associated with study procedures, including gases, gas mixtures, biologics, compounds, saline, etc.
* Respond to every question on this application. Incomplete applications will be returned, and will result in a delay of your study being reviewed. If a question does not apply, answer N/A. Do not leave any question blank.
* If available, include a product information sheet for each drug or other substance.
* This appendix is a part of the Research Plan and must be included with each Research Plan submission.
* Save this form to your computer before proceeding.

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| 1. General Information
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|  **Principal Investigator:**        | **Version Date:**       |
|  **Faculty Advisor:**       | **Protocol Number:**       |
|  **Study Title:**       |

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| 1. Drug/Substance Name
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| **Chemical Name(s)** | **Generic Name(s)** | **Brand Name(s)** |
|       |       |       |

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| 1. Investigational Drug Information
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| * 1. Complete the following if this drug/substance has an IND number.
 |
|  | **IND #:**  |       |
|  | **Who holds the IND?** | **Investigator:**  |       |
|  |  | **Manufacturer:**  |       |
| **Other:**  |       |
|  |
| * 1. Complete the following if this drug/substance does not have an IND number.
 |
|  | **[ ]**  Yes **[ ]**  No | Are you or your funding source intending to report the study results to the FDA to support a new indication or labeling change? |
|  | **[ ]**  Yes **[ ]**  No | Are you or your funding source intending to report the study results to the FDA to support a change in the advertising? |
|  | **[ ]**  Yes **[ ]**  No | Does the planned use of the study drug increase the risks or decrease the acceptability of the risks to the subjects being studied? |
|  | **[ ]**  Yes **[ ]**  No | Does the study require any change in the approved formulation, dosage form, or route of administration of the drug? |
|  | **[ ]**  Yes **[ ]**  No | If Yes to the previous question, will this change the risks to subjects participating in the research? |
|  | **[ ]**  Yes **[ ]**  No | Will the subjects be charged for the investigational drug? |
|  | **[ ]**  Yes **[ ]**  No | Are there other FDA approved drugs used to treat the condition you plan to study? |
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| 1. Drug/Substance Information, Dosage, Administration and Risks
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| * 1. Is this drug/substance FDA approved?
 |
|  | [ ]  Yes [ ]  No |  |
|  | Note: For non-FDA approved or regulated drugs/substances, attach copies of study related scientific literature documenting appropriate levels for human use and indication. |  |
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| * 1. Drug/Substance and Risk(s) Information According to Manufacturer
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|  | **Source** |       |  |
|  | **Preparation Purity** |       |  |
|  | **Sterility Procedures** |       |  |
|  | **Stability** |       |  |
|  | **Storage Requirements** |       |  |
|  | **Known Side Effects/Risks** |       |  |
|  | **Precautions, Warnings and Contraindications** |       |  |
|  | **FDA Restrictions on Use** |       |  |
|  | **Increased Risks if Change in Formulation** |       |  |
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| * 1. Dosage Information
 |
|  | **Number of Subjects Receiving Drug/Substance** |       |  |
|  | **Total Quantity Required**  |       |  |
|  | **Dose per Subject** |       |  |
|  | **Usual Dosage** |       |  |
|  | **Normal Dosage Range** |       |  |
|  | **Increased Risks Associated with Planned Dosage** |       |  |
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| * 1. Drug/Substance Administration
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|  | **Approved Method(s) of Administration** |       |  |
|  | **Proposed Method(s) of Administration** |       |  |
|  | **Restrictions on Who May Administer Drug/Substance** |       |  |
|  | **Increased Risks Associated with Planned Study Administration** |       |  |
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| 1. Personnel Information and Laboratory Procedures
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| * 1. Person/people who will be responsible for ordering and/or purchasing the drug/substance:
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|  |       |  |
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| * 1. If a prescription is required to obtain drug/substance, indicate name, location, and affiliation of prescribing physician:
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|  |       |  |
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| * 1. Specific training/consultation/permission required to administer the drug/substance:
 |
|  |       |  |
|  |
| * 1. Personnel administering drug/substance and any drug/substance-specific training, consultation, or permission information for each individual:
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|  | * + 1. List name of individual(s) who will administer the drug or chemical

       |  |
|  | * + 1. Describe training, consultation or permission information for each individual listed above.

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| * 1. Name and location (building, room number) of facility or lab where drug/substance will be administered:
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|  |       |  |
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| * 1. Site storage procedures including sterility, security, temperature and monitoring:
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|  |       |  |
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| * 1. Emergency procedures and personnel available in the event of an emergency:
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|  |       |  |