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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 | |
| **Principal Investigator:** | **Version Date:** |
| **Faculty Advisor:** | **Protocol Number:** |
| **Study Title:** | |

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| 1. Drug/Substance Name | | |
| **Chemical Name(s)** | **Generic Name(s)** | **Brand Name(s)** |
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| 1. Investigational Drug Information | | | | | | |
| * 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 | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| * 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 | | | | | | |
|  | **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** | |  | | |  |
|  | | | | | | |
| * 1. Drug/Substance Administration | | | | | | |
|  | **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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| * 1. If a prescription is required to obtain drug/substance, indicate name, location, and affiliation of prescribing physician: | | |
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| * 1. Specific training/consultation/permission required to administer the drug/substance: | | |
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| * 1. Personnel administering drug/substance and any drug/substance-specific training, consultation, or permission information for each individual: | | |
|  | * + 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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| * 1. Site storage procedures including sterility, security, temperature and monitoring: | | |
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| * 1. Emergency procedures and personnel available in the event of an emergency: | | |
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