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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 and supervision information for each individual listed above. |  |
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| * 1. Describe the name and location (building, room number) of facility or lab where drug/substance will be administered: | | |
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| * 1. Describe the location, procedures and study personnel responsible for the oversight of the drug/substance storage. Include procedures for monitoring access, sterility, expiration, temperature, security, etc.: | | |
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| * 1. Describe the procedures and study personnel responsible for monitoring drug safety including notifications of recall, safety and changes in indication from regulating agencies and manufacturers (i.e., monitoring for FDA recalls prior to drug administration, etc.): | | |
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| * 1. Emergency procedures and personnel available in the event of an emergency: | | |
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