**Drugs and Other Substances**

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

Instructions: Complete this form only if your research activities will include the use of drugs or other substances. Upload completed forms when submitting a New Study or Modification activity through the IRB Module of the Research Administration Portal (RAP).

* 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 in addition to this form when uploading to the RAP.
* Save this form to your computer before proceeding.

**General information for investigator’s reference (optional):**

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| Principal  Investigator (PI): |  | Faculty Advisor: |  |
| Study Title: |  | | |
| Drug: |  | | |

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| 1. Investigational Drug Information | |
| * 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. | | |
| * 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 | |  |  |
| * 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 | | |
| * 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: | | |
|  | | |
| * 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 |  |
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|  | * + 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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