**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
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| * 1. Complete the following if this drug/substance does not have an IND number.
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| [ ]  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. |
| * 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
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|  | 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
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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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|       |
| * 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:
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|  | * + 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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