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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.
* 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.

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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)** |
|       |       |       |

| 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, complete Part IV for investigational drugs. |
| * 1. If FDA approved, is the drug being used in according to the FDA approved marketed use and intent (i.e., does not change dosage, route of administration, population, etc.)?
 |
|  | [ ]  Yes [ ]  No |  |
|  | Note: For FDA approved or regulated drugs/substances, include a copy of the package insert. If you answered ‘No’ to the above questions, complete Part IV. |
| * 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** |       |  |
|  | **Describe Risks if Change in Formulation** |       |  |
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| * 1. Dosage Information
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|  | **Number of Subjects Receiving Drug/Substance** |       |  |
|  | **Total Quantity Required**  |       |  |
|  | **Dose per Subject** |       |  |
|  | **Usual Dosage** |       |  |
|  | **Normal Dosage Range** |       |  |
|  | **Describe 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** |       |  |
|  | **Describe Risks Associated with Planned Study Administration** |       |  |
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| 1. Investigational Drug Information
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| Instructions: Complete this section only if the drug or substance is investigational (i.e., non-FDA approved or being used outside of the FDA approved marketed use or intent). See [FDA website](https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-procedures-exemptions-ind-requirements) for information on submission requirements and [Guidance on Use of Investigational Drugs](https://www.fda.gov/media/79386/download). |
| * 1. Complete the following if this drug/substance has an IND number.
 |
|  | **IND #:**  |       |
|  | **Who holds the IND?** | **Investigator:**  |       |
|  |  | **Manufacturer:**  |       |
| **Other:**  |       |
|  | NOTE: Include an Investigator Brochure for each investigational drug. |
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| * 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. 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:
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|  |       |  |
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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 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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|  |       |  |
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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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| 1. FDA Regulated Clinical Investigations
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| * The FDA defines *Clinical investigation* as any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58, regarding nonclinical laboratory studies.
* The [FDA defines an Applicable Clinical Trial (ACT)](https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered) as follows: (1) Trials of drugs and biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and (2) Trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance. The FDA has further elaborated the definition of an ACT which can be found [here](https://grants.nih.gov/clinicaltrials_fdaaa/docs/flow_chart-act_only.pdf).
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| If the investigator anticipates the study will be subject to FDA regulations, the following requirements apply:* GCP training: Must be completed, logged and tracked for clinical investigators and staff who are involved in the design, conduct, oversight, or management of the clinical trial. Recipients of GCP training are expected to retain documentation of their training. GCP training should be refreshed at least every three years in order to stay up to date with regulations, standards, and guidelines.
* Registering & reporting of results at clinicaltrials.gov: All ACTs are expected to register and submit results information to Clinicaltrials.gov, as per the Food and Drug Administration Amendments Act of 2017 (FDAAA).
* Consent Form Requirements: Informed consent documents for clinical trials are to include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov.

NOTE: If the study also falls under the HHS 2018 Revised Common Rule, a copy of the consent form must be posted to clinicaltrials.gov within the timeframe outlined in the HHS regulations as noted above. |
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| * 1. Describe how the investigator is complying with the FDA requirements for a clinical investigation as outlined above:
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