**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 in research. |

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. if they are specified by the research.
* Respond to every question on this application unless you are instructed to skip questions/sections. Incomplete applications will be returned and will result in a delay of your study being reviewed.
* If available, include a package insert or investigator’s brochure for each drug/substance in addition to this form when uploading to the RAP. If a package insert or investigator’s brochure are not available, provide scientific literature or FDA materials to support your claims.
* Save this form to your computer before proceeding. This form should be uploaded to the Drugs section of the RAP (note: this section will appear if you respond Yes to question #1 in the Study Scope section).

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

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| 1. Test Article
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| * 1. Describe the drug or substance specified by the research:
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|        |
| * 1. Are you obtaining safety or effectiveness information about the drug or substance?
 |
| [ ]  Yes [ ]  No |  |
| Please explain your answer: |        |
| * 1. Is the drug/substance being administered or dispensed to one or more human subjects specifically because of the research?
 |
| [ ]  Yes [ ]  NoIf yes, is it a marketed drug being given in the course of medical practice (i.e., practitioner providing an FDA approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient)? For example, giving participants a lidocaine injection to minimize pain during a muscle biopsy. [ ]  Yes [ ]  No |
| Please explain your answer: |        |
| * 1. Is the drug or substance a biological product (i.e., a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein except any chemically synthesized polypeptide, or analogous product, or arsphenamine or derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings)?

Note: If the drug/substance involves biological materials, recombinant or synthetic nucleic acids, infectious pathogens, biological toxins, unfixed human tissues/blood, and/or human cell cultures, your study may also require review by the [Institutional Biosafety Committee (IBC)](https://safety.uoregon.edu/institutional-biosafety-committee).  |
| [ ]  Yes [ ]  No |  |
| If yes, identify type or describe: |        |
| * 1. Is the drug or substance intended to diagnose, cure, mitigate, treat or prevent a disease?

(Note: if the drug/substance is intended for those purposes in any context, please respond yes even if that is not why it is being given in the proposed research. If it is being used differently than labeled for the purposes of research, please explain below) |
| [ ]  Yes [ ]  No |  |
| Please explain your answer: |        |
| * 1. Is the drug or substance intended to affect the structure or function of the body?
 |
| [ ]  Yes [ ]  No |  |
| Please explain your answer: |        |
| * 1. Is the drug or substance lawfully marketed in the United States?
 |
| [ ]  Yes [ ]  No |
| Please explain your answer: |        |
| * 1. Is the substance a dietary supplement (i.e., product intended to supplement the diet that is intended for ingestion and is not for use as a conventional food or as the sole item of a meal or diet)? Examples include vitamins, minerals, herbs/botanicals, amino acids, concentrates, metabolites, constituents, extracts or any combination of the above.
 |
| [ ]  Yes [ ]  No |  |
| If yes, is it being used or studied for possible therapeutic purposes (e.g., diagnose, cure, mitigate, treat or prevent a disease or symptoms of a disease?[ ]  Yes [ ]  No |
| Please explain your answer: |        |
| 1. Investigational Drug Information
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| * 1. Complete the following if this is a drug/substance that is legally marketed in the United States and does not have an IND number.

[ ]  N/A - Not legally marketed in the United States (skip to question 2 in Part II below)[ ]  N/A - IND number obtained from the FDA for this clinical investigation (skip to Part III below) |
| [ ]  Yes [ ]  No | 1. Are you or the sponsor intending to report the study results to the FDA to support a new indication or labeling change?

If yes, describe:       |
| [ ]  Yes [ ]  No  | 1. Are you or the sponsor intending to report the study results to the FDA to support a change in the advertising?

If yes, describe:       |
| [ ]  Yes [ ]  No | 1. Does the research use of the drug or substance involve a **route of administration** that differs from the approved use in the label?

If yes:1. Describe how it differs:

     1. Explain why this change does or does not significantly increase risk to participants or decrease acceptability of the risks for participants:

      |
| [ ]  Yes [ ]  No | 1. Does the research use of the drug or substance involve a **dosage level** that differs from the approved use in the label?

If yes:1. Describe how it differs:

     1. Explain why this change does or does not significantly increase risk to participants or decrease acceptability of the risks for participants:

      |
| [ ]  Yes [ ]  No | 1. Are you giving the drug or substance to a **population** that differs from the approved use in the label (e.g., provided to children when only approved for adults)?

If yes:1. Describe how it differs:

     1. Explain why this change does or does not significantly increase risk to participants or decrease acceptability of the risks for participants:

      |
| [ ]  Yes [ ]  No | 1. Are there any other factors in your intended use of the drug/substance that could significantly increase risk to participants or decrease acceptability of the risks for participants?

If yes or unknown, please explain:       |
| [ ]  Yes [ ]  No | 1. Is the study intended to promote or commercialize the drug?

If yes: 1. Please explain:

     1. Confirm you will do so in compliance with the marketing limitations described in [21 CFR 312.7](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.7).

[ ]  Yes, confirmed[ ]  No (explain below):       |
| * 1. Complete the following if the drug/substance is an in vitro diagnostic (IVD) biological product (i.e., those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. IVD products are devices as defined in section 201(h) of the Act and may also be biological products subject to section 351 of the Public Health Service Act).

 [ ]  N/A – Not an in vitro diagnostic biological product (skip to question 3 in Part II below) [ ]  N/A - IND number obtained from the FDA for this clinical investigation (skip to Part III below) |
| [ ]  Yes [ ]  No | 1. Does the IVD involve one or more of the following (check all that apply):

[ ]  Blood grouping serum[ ]  Reagent red blood cells[ ]  Anti-human globulin[ ]  N/A none of the above |
| [ ]  Yes [ ]  No | 1. Is the IVD intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure?

If yes, describe the other medically established, diagnostic product or procedure:       |
| [ ]  Yes [ ]  No | 1. Will the IVD be shipped in compliance with [21 CFR 312.160](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.160)?

If yes, describe:       |
| * 1. Rare IND Exemptions
 |
| [ ]  Yes [ ]  No | 1. Is the study an in vivo bioavailability or bioequivalence study?

If yes, check all those that apply: **[ ]** The active moiety in the drug product is identical to that in an FDA approved drug**[ ]** The drug product is not radioactively labeled.**[ ]** The drug product is not cytotoxic.**[ ]** The dose (single or total daily) does not exceed the dose in the labeling of the approved version of the drug product.**[ ]** The sponsor meets the requirements for retention of test article samples in [21 CFR 320.31(d)(1)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=320.31). Provide an explanation for any boxes that are unchecked above:      |
| [ ]  Yes [ ]  No | 1. Is the drug/substance a radioactive drug containing unstable isotopes?

Note: radio-labeled materials/radioisotopes require review by the [Radiation Safety Committee](https://safety.uoregon.edu/radiation-safety). If yes, check all those that apply:**[ ]** Study involves basic research not intended for immediate therapeutic, diagnostic, or similar purposes, or otherwise to determine the safety and efficacy of the product**[ ]** The use in humans is approved by a Radioactive Drug Research Committee (RDRC) that is composed and approved by FDA. Note: please provide a copy of the RDRC approval with your submission. **[ ]** The dose to be administered is known not to cause any clinically detectable pharmacological effect in humans**[ ]** The total amount of radiation to be administered as part of the study is the smallest radiation dose practical to perform the study without jeopardizing the benefits of the study and is within specified limits**[ ]** The radiation exposure is justified by the quality of the study being undertaken and the importance of the information it seeks to obtain**[ ]** The study meets the other requirements set forth in [21 CFR 361.1](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=361.1) regarding qualifications of the investigator, proper licensure for handling radioactive materials, selection and consent of research subjects, quality of radioactive drugs used, research protocol design, reporting of adverse reactions, and approval by an appropriate Institutional Review CommitteeProvide an explanation for any boxes that are unchecked above:      |
| [ ]  Yes [ ]  No | 1. Is the drug/substance a cold isotope that lacks radioactivity?

If yes, check all those that apply:**[ ]** The research is intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a drug labeled with a cold isotope or regarding human physiology, pathophysiology, or biochemistry.**[ ]** The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the study subject.**[ ]** The dose to be administered is known not to cause any clinically detectable pharmacologic effect in humans based on clinical data from published literature or other valid human studies**[ ]** The quality of the cold isotope meets relevant quality standards**[ ]** The investigation is conducted in compliance with the requirements for review by an IRB ([21 CFR part 56](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56)) and the requirements for informed consent ([21 CFR part 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50))Provide an explanation for any boxes that are unchecked above:      |
|  |
| 1. Additional Information
 |
| [ ]  Yes [ ]  No | * 1. Will the participants and/or their insurance be charged for the drug/substance?

If yes:1. Provide rationale for charging participants:

     1. Explain why the charge is necessary to facilitate development of a promising new drug or indication that might not otherwise be developed or to obtain important safety information that might not otherwise be obtained.

     1. Explain how there is evidence of potential clinical benefit that, if demonstrated in clinical investigations, would provide a significant advantage over available products in the diagnosis, treatment, mitigation or prevention of a disease or condition.

     1. Explain why charging is necessary for the development of the drug and the data to be obtained from the research would be essential to establishing that the drug is effective and/or safe or would support a significant change in the label of an approved drug.

     1. Explain why the clinical development of the drug could not be done without charging as the cost of the drug is extraordinary or due to manufacturing complexity

     1. Explain how only direct costs (e.g., costs in raw materials labor and un-reusable supplies per unit to manufacture the drug, costs to ship/store drug) will be recovered from participants.

      |
| [ ]  Yes [ ]  No | * 1. Are there other FDA approved drugs used to treat the condition you plan to study?

If yes, explain why this drug/substance was selected:     [ ]  N/A not treating a condition |
| [ ]  Yes [ ]  No | * 1. Will participants be randomized to receive this drug/substance or an alternative product/procedure (e.g., placebo, standard of care, other drug)?

If yes:1. Describe the probability that participants will receive this drug/substance:

     1. Either confirm that all participants will have a chance to receive the study drug/substance or explain why this is not appropriate and/or possible:

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| Part IV: Drug/Substance Information, Dosage, Administration and Risks |
| * 1. Is this drug/substance FDA approved?
 |
| [ ]  Yes [ ]  No | Note: Regardless of the FDA status, please provide details documenting appropriate levels for human use, approved indications, and safety details (e.g., Package Insert, Investigator Brochure, scientific literature) |
| * 1. Drug/Substance and Risk(s) Information (note: this information must be consistent with the package insert, investigator brochure or other manufacturer details/documents)
 |
|  | 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 for all participants  |       |  |
|  | Dose per Subject (per administration) |       |  |
|  | Usual Dosage (include as range if needed) |       |  |
|  | Dosing Schedule (e.g., frequency and timing of doses) |       |  |
|  | Increased Risks Associated with Planned route of administration dosage, population etc. |       |  |
| * 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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| Part V: 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:
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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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