**DO NOT DELETE OR ALTER ANY PART OF THIS FORM**

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| --- | --- |
| **Principal Investigator:** | [REQUIRED FIELD] |
| **Study Title:** | [REQUIRED FIELD] |
| **IRB #:** |  |

# ADDENDUM: FOOD AND DRUG ADMINSTRATION REGULATED RESEARCH DRUGS, DEVICES, & BIOLOGICS

**Instructions:**

* Read the guidance provided below before answering the questions.
* Do not leave questions/[REQUIRED FIELD] blank; write or check "**N/A**" if not applicable.

**Guidance:**

* Drug: A drug is defined as:
  + A substance recognized by an official pharmacopoeia or formulary.
  + A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
  + A substance (other than food) intended to affect the structure or any function of the body.
  + A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
  + Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)
* Investigational New Drug (IND)**:** Defined as either a new drug or biological drug, or a currently approved drug when they will be used in a manner that differs from the current approval (“off-label use”), including dosing, route of administration, or proposed indication that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes.
* Investigational Device Exemption (IDE)**:** New medical devices, or the proposed off-label use of currently approved medical devices, may require an IDE application to the FDA. Determining the need for an IDE depends on several factors, including intended use and indications, risk level of the test object (significant (SR) vs. non-significant (NSR)) and qualification for device exemption (e.g., most Class 1 and some Class 2 devices).
* Biologic: A biologic is a substance either made by a living organism or a living organism’s products, like blood, proteins, and viruses.
* Medical devices**:** Defined, in part, as any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. Medical devices include, among other things: surgical lasers, wheelchairs, sutures, pacemakers, vascular grafts, intraocular lenses, and orthopedic pins.

Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis (IVD) of disease and other medical conditions such as pregnancy. In certain circumstances, software can be considered a medical device.

According to the FDA, a medical device is defined per Section 201(h)(1) of the Food, Drug, and Cosmetic Act as:

* + An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
    - (A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
    - (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
    - (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o)

Further FDA guidance on investigational drugs, biologics, and devices can be found at: <http://www.fda.gov/>

## SECTION 1. INVESTIGATOR QUALIFICATIONS AND RESEARCH SITE INFORMATION

1. **Please include verification that the PI is qualified to conduct the proposed project. This can include previously approved WSU IRB protocols, a statement from the department chair, the PI’s (or other sub investigators or study staff) CV:** [REQUIRED FIELD]
2. **If vulnerable populations be included in the study, what previous experience (i.e., recent presentations, publications, prior clinical experience with the test article or study-related procedures) do the investigators have working with this population?** [REQUIRED FIELD]
3. **Where will the research be take place?**
   1. **WSU or a major medical institution** 
      1. **Please describe the space where the research will take place:** [REQUIRED FIELD]
   2. **Research outside of WSU or a major medical institution**
      1. **Is there documentation from an appropriate person(s) at the site or institution stating the facility is adequate:** [REQUIRED FIELD]
      2. **Please provide a description of the facility where the research will take place, including any staffing or resources relevant to the research under review:** [REQUIRED FIELD]

## SECTION 2. RESEARCH USING INVESTIGATIONAL NEW DRUGS (IND)/BIOLOGICS

1. **This research utilizes investigational new drug(s) or biologic(s)**

**AND/OR**

1. **This research involves an off-label use of a currently approved drug(s)**
2. **Provide the name and source of the drug(s)/biologic(s):** [REQUIRED FIELD]
3. **Describe if the drug(s) /biologic(s) is FDA approved and its classification (e.g., over the counter/prescription):** [REQUIRED FIELD]
4. **Describe the planned dosage of the drug(s) biologic(s):** [REQUIRED FIELD]
5. **Provide available toxicity data on the drug(s) /biologic(s):** [REQUIRED FIELD]
6. **Describe previous studies on humans:** [REQUIRED FIELD]
7. **Provide any available literature for review:** [REQUIRED FIELD]
8. **If this is a Phase I study, please provide available reports of the animal studies:** [REQUIRED FIELD]
9. **Address whether this study will have a Data Safety Monitoring Board in place:** [REQUIRED FIELD]

## SECTION 3. RESEARCH USING DRUGS OR BIOLOGICS EXEMPT FROM AN IND

*Note: If a study will utilize supplements or other substances regulated by the FDA as food or food additives, these supplements or other substances should be treated as drugs or biologics if they will be tested in a way that requires an IND application.*

1. **This research utilizes drugs or biologics that do not require an IND and/or that are not currently FDA approved.**
2. **Provide the name and source of the drug(s) biologic(s):** [REQUIRED FIELD]
3. **Describe if the drug(s) /biologic(s) is FDA approved and its classification (e.g., over the counter/prescription):** [REQUIRED FIELD]
4. **Describe the planned dosage of the drug(s) biologic(s):** [REQUIRED FIELD]
5. **Provide any relevant toxicity data on the drug(s) biologic(s):** [REQUIRED FIELD]
6. **Describe the relevant previous studies on humans in relation to the proposed research and this drug:** [REQUIRED FIELD]
7. **Provide any available literature for review in relation to the proposed research and this drug:** [REQUIRED FIELD]

**Address whether this study will have a data safety monitoring board in place:** [REQUIRED FIELD]

1. **For a drug to be exempt from an IND and not require IND approval from the FDA, all of the criteria in one of the following categories must be met. Please select the most appropriate category for the research and provide responses or attestations to each criterion.** 
   1. **Category 1 – Exemption for Marketed Drugs [21 CFR 312.2(b)(1)]**
      1. **Is the drug is lawfully marketed in the United States?** [REQUIRED FIELD]
      2. **Is the result of research not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor is it intended to be used to support any significant change in the drug labeling?** [REQUIRED FIELD]

*FDA guidance*: “Certain investigator-initiated research in an academic setting has the potential to influence labeling or promotion, notwithstanding the investigator’s intent (e.g., a controlled trial with an endpoint representing improvement of a serious disease)… Similarly, certain studies of effectiveness conducted by government agencies (e.g., NIH) have the potential to influence labeling. FDA strongly encourages submission of IND submissions for these types of studies.”

* + 1. **For research involving a prescription drug: Will the research intend to support a significant change in the advertising of the drug?** [REQUIRED FIELD]
    2. **The research does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug.** [REQUIRED FIELD]

*FDA guidance*: FDA comments made with the publication of the IND regulations, “This exemption was not intended to require an investigator to use the drug in exactly the same dosage form, dosage levels, and patient populations described in the marketed labeling for the product, but rather to permit changes to the lawfully marketed drug product that do not increase risks… over the risk presented by use of the product in conformance with its marking labeling” 52 Federal Register 8798 at 8801, March 19, 1987.

* + 1. **The research is conducted in compliance with all the marketing limitations described in 21 CFR 312.7 (the research is not intended to promote or commercialize the drug).** [REQUIRED FIELD]
  1. **Category 2 - In Vitro Diagnostic Biological Products [21 CFR 312.2(b)(2)]**
     1. **The study is an investigation for an in vitro diagnostic biological product that involves one or more of the following: (1) blood grouping serum; (2) reagent red blood cells; or (3) anti-human globulin.** [REQUIRED FIELD]
     2. **The diagnostic product is intended to be used in a diagnostic procedure that confirms diagnosis made by another, medically established, diagnostic product or procedure.** [REQUIRED FIELD]
     3. **Shipping attestations:**
        1. **The product will be shipped only if it is labeled as follows: “CAUTION: Contains a biological product for investigational in vitro diagnostic test only.”** [REQUIRED FIELD]
        2. **The shipper of the product will use due diligence to assure that the recipient is regularly engaged in conducting tests and that the shipment of the product will actually be used for tests in vitro.** [REQUIRED FIELD]
        3. **The shipper of the product will maintain adequate records showing the name and post office address of the expert to whom the product is shipped and the date, quantity, and batch or code mark of each shipment and delivery. Shipment records will be maintained for 2 years after the shipment and will be available for copying/verification by any properly authorized officer or employee of the FDA.** [REQUIRED FIELD]
        4. **The shipper of the product will assure the return of all unused supplies of the product from individual investigators whenever the investigation discontinues, or the investigation is terminated. This may include authorization in writing of alternative dispositions, provided this alternative does not expose humans to risks from the product, either directly or indirectly (e.g., through food producing animals) and provided that the shipper maintains records of any alternative disposition.** [REQUIRED FIELD]
  2. **Category 3 – Placebos** [21 CFR 312.2(b)(5)]

1. **The investigation involves the use of a placebo but otherwise does not require an IND.** [REQUIRED FIELD]
   1. **Category 4 – Bioavailability/Bioequivalence Studies** [21 CFR 312.2(c); 21 CFR 320.31]
2. **The active ingredient is chemically identical to the active ingredient in an FDA approved drug.** [REQUIRED FIELD]
3. **The drug is not radioactively labeled.** [REQUIRED FIELD]
4. **The drug is not cytotoxic.** [REQUIRED FIELD]
5. **The dose (single dose or total daily dose) does not exceed the dose specified in the labeling of the approved version of the drug.** [REQUIRED FIELD]
6. **For multiple dose studies of an extended-release drug: a single dose study has already been completed.** [REQUIRED FIELD]
7. **The sponsor will meet the requirements for retention of drug samples, as described in 21 CFR 320.31(d)(1).** [REQUIRED FIELD]
8. **The sponsor (or contact research organization) will notify the FDA and all participating investigators of any serious adverse event as soon as possible but in no case later than 15 calendar days after becoming aware of its occurrence, as described in 21 CFR 320.31(d)(3).** [REQUIRED FIELD]
   1. **Category 5 – Radioactive Drugs for Research Use [21 CFR 361.1]**
9. **The drug has been approved by the Radioactive Drug Research Committee as a radioactive drug for certain research uses, per the criteria described in 21 CFR 361.1(b).** [REQUIRED FIELD]
10. **The amount of active ingredients or combination of active ingredients to be administered shall be known to not cause any clinically detectable pharmacological effects in humans.** [REQUIRED FIELD]
11. **The amount of radioactive material to be administered shall be such that the subject receives the smallest radiation dose with which it is practical to perform the study without jeopardizing the benefits to be obtained from the study.** [REQUIRED FIELD]
12. **The radiation dose to an adult research subject from a single study or cumulatively from number of studies conducted within 1 year will not exceed the limits described in 21 CFR 361.1(b)(3).** [REQUIRED FIELD]
    1. **Category 6 – Cold Isotopes for Research Use**
13. **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.** [REQUIRED FIELD]
14. **The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the subject.** [REQUIRED FIELD]
15. **The dose to be administered is known to not cause any clinically detectable pharmacological effect in humans based on clinical data from published literature or other valid human studies.** [REQUIRED FIELD]
16. **The quality of the cold isotope meets relevant quality standards.** [REQUIRED FIELD]
    1. **Category 7 – FDA Determination**
17. **The FDA has provided a documented determination that an IND is not required for the use of this drug.** [REQUIRED FIELD]

## SECTION 4. RESEARCH USING BIOLOGICS AND NON-IND DRUGS

*Note: If a study will utilize supplements or other substances regulated by the FDA as food or food additives, these supplements or other substances should be treated as drugs or biologics if they will be tested in a way that requires an IND application.*

1. **This research utilizes drugs or biologics that do not require an IND and/or that are not currently FDA approved.**
2. **Provide the name and source of the drug(s):** [REQUIRED FIELD]
3. **Describe if the drug(s) is FDA approved and its classification (e.g., over the counter/prescription):** [REQUIRED FIELD]
4. **Describe the planned dosage of the drug(s):** [REQUIRED FIELD]
5. **Provide any relevant toxicity data on the drug(s):** [REQUIRED FIELD]
6. **Describe the relevant previous studies on humans in relation to the proposed research and this drug:** [REQUIRED FIELD]
7. **Provide any available literature for review in relation to the proposed research and this drug:** [REQUIRED FIELD]
8. **Address whether this study will have a data safety monitoring board in place:** [REQUIRED FIELD]

## SECTION 5. RESEARCH USING INVESTIGATIONAL DEVICES (IDE)

1. **This research utilizes investigational devices (IDE), including any proposed use of a currently approved device that differs from the current FDA approval.**
2. **Provide the name and source of the device(s):** [REQUIRED FIELD]
3. **Provide the current FDA status of the device(s) and IDE number:** [REQUIRED FIELD]
4. **Indicate the risk level assignment as determined by the sponsor ( e.g., non-significant or significant risk).** Note that 21CFR312.2(a) places responsibility for risk level determinations with the sponsor, however, the IRB will inform the PI/Sponsor if it disagrees with these determinations**:** [REQUIRED FIELD]
5. **Based on the risk level of the device (SR or NSR) indicated above, as determined by the PI and/or sponsor, address the associated risks of the device and provide any relevant documentation or justification:** [REQUIRED FIELD]