**All forms must be typewritten, signed, and submitted via email to** IRBchair@sonoran.edu.

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| --- |
| If this human subject study involves the use of any drugs or chemical or biological agents, the study is subject to Food and Drug Administration (FDA) regulations. Researchers planning to use these agents in human subjects’ research must complete this form and include it with an original or amended New Protocol Application Form, as applicable.**Note: For drugs or biologics that are investigational, the consent document must clearly indicate that the agent is “investigational (experimental)” and that “an investigational drug is one that is not approved by the Food and Drug Administration (FDA) for the use being studied.”** |

**Section A**

**A1. Responsible Project Investigator (RPI)**

|  |  |  |
| --- | --- | --- |
| Last Name:       | First Name:       | Academic Degree(s):       |
| Dept. or Unit:       | Office Address:       |  |
| Street Address:       | City:        | State:    | Zip Code:       |
| Phone:       | Fax:       | E-mail:       |
| Sonoran Status: Non-visiting member of (Mark One) [ ]  Faculty [ ]  Staff |

**A2. Project Title**

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|       |

**B. Drug or Biologic**

|  |  |  |  |
| --- | --- | --- | --- |
| **Drug Name (Generic/Trade)** | **Manufacturer** | **Formulation** | **Route of Administration** |
|  |  |  |  |

1. Is the manufacturer of the drug sponsoring this trial?

**[ ]**  Yes

**[ ]** No. List the sponsor:

1. An investigator’s brochure (IB) or FDA-approved product information (package insert) must be submitted with this application. Please indicate which document is being submitted**.**

**[ ]** Investigator’s brochure (IB): required when the drug’s status is investigational

**[ ]** FDA-approved product information (package insert)

[ ]  Or Sonoran Required Product Information

**C. Investigational Status**

Please indicate the status of the drug or biologic being used in the study.

**[ ]** Use of the drug in this study is exempt from the requirements for an Investigational New Drug (IND) application. If checked, go to **Section D: Exemption Category**.

**[ ]** Use of drug in this study requires an Investigational New Drug (IND) application.

1. Provide IND Number:
2. Attach **one of the following** to allow verification of IND number (do not submit and IB to verify this):
	1. IND approval letter from FDA, IND printed in sponsor’s protocol, **OR**
	2. Letter from sponsor.
3. Is the Sonoran investigator the IND holder (sponsor)?

 [ ]  Yes. Attach a copy of the FDA letter approving the IND application and submit Appendix O.

 [ ]  No

1. If IND is not available, please explain (NOTE: IRB approval cannot occur until IND is provided):

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**Continue to Section E: Handling and Control of Drugs and Biologics**

**D. Category for Exemption from Requirement of an IND.** Complete this section **only if seeking an exemption from the requirements for an IND.**

**Please select the most appropriate exemption category and answer any questions associated with that category.**

**[ ]  Category 1:** FDA Determination of Exemption

 Please attach a copy of the FDA determination letter.

**[ ]  Category 2:** FDA-approved drug **and** the answer to all the following questions is “y**es**”:

1. The drug is lawfully marketed in the United States.

[ ]  Yes

[ ]  No

1. The research is **not intended** to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.

[ ]  Yes

[ ]  No

1. The research is **not intended** to support a significant change in the advertising for the product.

[ ]  Yes

[ ]  No

1. The research **does not involve** a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.

[ ]  Yes. Justify:

[ ]  No

1. The investigation will be conducted in compliance with the FDA requirements for promotion and charging for investigational drugs (21 CFR 312.7).

[ ]  Yes

[ ]  No

**[ ]  Category 3:** *In vitro* diagnostic biological product **and** the answer to all the following is “**yes**”

1. The test article is an in vitro diagnostic biological product.

[ ]  Yes

[ ]  No

1. The *in vitro* diagnostic product is either blood grouping serum, reagent blood cells, or anti-human globulin.

[ ]  Yes

[ ]  No

1. The diagnosis made with the *in vitro* biological product will be confirmed by another, medically established, diagnostic product or procedure.

[ ]  Yes

[ ]  No

1. The in vitro diagnostic product will be shipped in compliance with FDA requirements at 21 CFR 312.160.

[ ]  Yes

[ ]  No

**[ ]  Category 4:** *In vitro* or animal use **and** the answer to all the following is “**yes**”.

1. The drug is intended solely for tests *in vitro* or laboratory research animals.

[ ]  Yes

[ ]  No

1. The drug is shipped in compliance with FDA requirements at 21 CFR 312.160.

[ ]  Yes

[ ]  No

**[ ]  Category 5:** Bioavailability or bioequivalence study **and** the answer to all the following is “**no**”:

1. A bioavailability or bioequivalence study involving a drug product that contains a new chemical entity, radioactively labeled drug product or cytoxic product.

[ ]  Yes

[ ]  No

1. A bioavailability or bioequivalence study involving a drug product containing an already approved, non-new chemical entity and is:
	* + - 1. a single-dose study in normal subjects or patients where either the maximum single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application.

[ ]  Yes

[ ]  No

* + - * 1. a multiple-dose study in normal subjects or patients where either the single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application.

[ ]  Yes

[ ]  No

* + - * 1. a multiple-dose study on an extended-release product on which no single-dose study has been completed.

[ ]  Yes

[ ]  No

**[ ]  Category 6:** Clinical bioavailability or bioequivalence study for approval of an abbreviated new drug application or supplemental new drug application **and** the answer to all the following is “**yes**”:

1. Clinical bioavailability or bioequivalence study being conducted for approval of an abbreviated new drug application or supplemental new drug application other than studies described in Category 5.

[ ]  Yes

[ ]  No

1. Samples of the reference standard and test article will be retained as described in 21 CFR 320.38 and 320.63.

[ ]  Yes

[ ]  No

**E. Handling and Control of Drugs and Biologics**

Select below the site(s) at which the research will be conducted and describe how the study drug will be handled at each site.

[ ]  **Sonoran**

[ ]  The investigator will be responsible for the storage and handling of the study drug.

1. Describe how disposition of the study drug will be controlled, including procedures for storage, dispensing, limiting access to individuals listed as study personnel on the protocol and accountability.

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1. Indicate where the drug will be stored.

|  |
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 [ ]  Other:

[ ]  **Other site**

Specify:

|  |
| --- |
|       |

1. Describe how disposition of the study drug will be controlled, including procedures for storage, limiting access to individuals listed as study personnel on the protocol, dispensing, and accountability.

|  |
| --- |
|  |

1. Indicate where the drug will be stored.

|  |
| --- |
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1. Provide a contact person at the site who can verify the institution’s approval of these procedures.

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**INVESTIGATOR ASSURANCES** The original, inked signature of the Responsible Project Investigator is required before this form can be processed. Other investigators are also responsible for these assurances and are encouraged to sign.

I certify that the information provided in this form and in all attachments is complete and correct.

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Responsible Principal Investigator Date Investigator Date

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Investigator Date Investigator Date