**All forms must be typewritten, signed, and submitted via email to** [IRBchair@sonoran.edu](mailto:IRBchair@sonoran.edu)

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| If this human subjects study involves the use of any devices, the study is subject to Food and Drug Administration (FDA) regulations. Researchers planning to use devices in human subjects’ research must complete this form and include it with an original or amended New Protocol application, as applicable.  **Note:**  **1. The word “experimental” must appear in the consent form as a modifier to the device name.**  **2. Documentation of FDA approval for the experimental use of these agents or devices must be provided.** |

**Section A:**

**A1 Responsible Project Investigator (RPI)**

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| --- | --- | --- | --- | --- | --- | --- |
| Last Name: | | First Name: | | | | Degree(s): |
| Dept. or Unit: | | Office Address: | | |  | |
| 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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**Section B:** (Please use a separate form for each device.)

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| **Device Name** | **Manufacturer** | **Diagnostic or Therapeutic Class** | **Proposed Use** |
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B1. Is the manufacturer of the device sponsoring this trial?

Yes

No

Name of sponsor:

B2. An investigator’s brochure (IB), device manual and/or FDA-approved product labeling **must be submitted** with this application.

**C: Investigational Status**

C1. This device is a Humanitarian Use Device (HUD). **Please contact the IRB Office.**

C2.  This device is exempt from the requirements for an Investigational Device Exemption (IDE). Please complete Section D.

C3. This is a **non-significant risk device.**

Has the FDA made a risk determination for the use of the device in this study?

Yes. Attach a copy of the FDA determination letter and proceed to Section F.

No. If NO, Proceed to Section E.

C4. This is a **significant risk device.** Answer questions 1-4 and then proceed to Section F.

1. Provide IDE Number:

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1. Please attach the IDE approval letter or conditional approval from FDA to allow verification of IDE number **and** the FDA’s risk determination.
2. Is the Sonoran campus investigator the IDE holder (sponsor)?

Yes. Attach a copy of the FDA letter approving the IDE application.

No

1. If an IDE is not available, please explain. IRB approval cannot be granted until an IDE is provided):

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**Section D: Category for Exemption from Requirement of an IDE**

***Complete only if seeking an exemption from the requirements for an IDE*.**

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 (Premarket Approval (PMA) or 510(k) application) device **and** the answer to all the following questions is **YES**.

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

Yes

No

1. The device will be used in accordance with FDA-approved indication.

Yes

No

Attach a copy of the FDA PMA or 510(k) approval letter or approved labeling.

**Category 3:** *In vitro* diagnostic device **and** the answer to all the following is YES:

1. The device is an in vitro diagnostic product.

Yes

No

1. The test device is non-invasive.

Yes

No

1. The use of the device in the study does **not** require an invasive sampling procedure that presents a significant risk.

Yes

No

1. The device, by design or intention, does **not** introduce energy into a subject.

Yes

No

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

Yes

No

**Category 4:** Consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution **and** the answer to all the following is YES.

1. The device is only undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution.

Yes

No

1. The testing is **not** for the purpose of determining safety or effectiveness.

Yes

No

1. The testing does not put subjects at risk.

Yes

No

**Category 5:** Custom Devices **and** the answer to all the following is YES.

1. The device is a custom device as defined in 21 CFR 812.3.

Yes

No

1. The custom device is not being studied to determine the safety and effectiveness of the device for commercial distribution.

Yes

No

**Category 6:** Devices in commercial distribution immediately before May 28, 1976 **and** the answer to one of the following is NO.

1. A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.

Yes

No

1. A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that the FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is investigated in accordance with the indications in the FDA approved labeling:

Yes

No

**Section E: Non-significant (NSR) and Significant Risk (SR) Devices**

The risk determination should consider the device, the proposed use of the device and any protocol-related procedures (e.g., surgery). The following criteria define a significant risk device. If you answer “**Yes**” to any of these for the device in this trial, **the device is a significant risk device and an IDE is required.**

Yes  No 1. Device is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

Yes  No 2. Device is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject;

Yes  No 3. Device is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

Yes  No 4. Device otherwise presents a potential for serious risk to a subject.

Explain why the sponsor considers the use of the device in this study to represent a non-significant risk device and include a description of the risks in relation to any benefits.

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**Section F: Handling and Control of Device**

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

**Sonoran**

The investigator is responsible for the storage and handling of the study device.

1. Describe how disposition of the study device 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 device will be stored

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**Other site(s)**

Specify:

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

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1. Indicate where the device 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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Is this application Complete? Please check that following documentation is attached:

Investigator’s Brochure (required for IDE devices), device manual and/or FDA-approved product labeling

If the FDA has made a risk determination, attach a copy of the FDA determination letter

If an IDE is required, please attach the following to allow verification of the IDE number and significant risk determination: IDE approval letter from FDA

If the investigator is the IDE holder (sponsor), please attach a copy of the IDE approval letter from the FDA.

If device is approved or cleared, attach a copy of the FDA PMA or 510(k) approval letter or approved labeling.

**INVESTIGATOR ASSURANCES**

The original signature of the Responsible Project Investigator is required before this form can be processed. Other investigators who are also responsible for these assurances 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