Form K-2
Intent to Rely Form

This form should be completed to document centralized IRB review under a Broad or Reciprocal agreement. This form helps to ensure any outstanding concerns or requirements by the Deferring Site are addressed before the study is approved (or receives an Exempt determination) by the Reviewing IRB.

Information for the Overall Principal Investigator –A signed copy this form should be submitted to the Reviewing IRB with your Initial submission or Amendment when requesting the UT Health San Antonio IRB review of the Deferring Site.

Information for the off-site Site Principal Investigator - If your institution agrees to centralized IRB review (by signing this form), you may be required to submit additional materials in accordance with local policy to your local IRB or Research Office. The review of institutional issues by your institution is a separate process from the IRB approval being sought by the Overall PI.

Training and Qualification Requirements – verification of training and qualification requirements will be verified initially and throughout the life of the research study for all research team members prior to engaging in research activities by the ceding institution. Only in specific situations outlined below will **UT Health San Antonio require that an individual be named in the research application**.

Reminder: You are not authorized to initiate research at your institution until both processes are completed: 1) the study is approved (or receives an Exempt determination) by the Reviewing IRB and an *approval/determination* letter is issued, and 2) the local policy and institutional issues have been resolved and an *activation* letter or equivalent has been issued by your institution, if applicable.

1. Study Title	

2. Name and Address of Overall Principal Investigator (PI) – PI at the Reviewing IRB

Overall PI's Name (Last Name, First Name, MI): _____
Department: _____
PI's Telephone #: _____ PI's Cell or Pager Number: _____
PI's e-mail address: _____ PI's FAX Number: _____

3. Name and Address of Site Principal Investigator (PI) – PI at the Deferring Site

Site PI's Name (Last Name, First Name, MI): _____
Department: _____
PI's Telephone #: _____ PI's Cell or Pager Number: _____
PI's e-mail address: _____ PI's FAX Number: _____

4. Name of Reviewing IRB	

5. Name of Deferring Site	

6. Study Personnel

☐ Confirm understanding that it is the responsibility of the relying institution to verify training and qualification requirements for **ALL** engaged personnel at the relying institution's site. Only individuals who meet the following criteria are required to be listed on the UT Health SA IRB application:

- Personnel who will conduct research at UT Health San Antonio or a local affiliated study site.
- Personnel with required specialized skills or training (**evidence of training must accompany the submission to the IRB).**
- Personnel with a conflict of interest determined by the relying institution.
- Personnel listed in the informed consent document.
- The overall principal investigator, if not an agent of UT Health San Antonio.
- All site principal investigators.

7. Informed Consent Documents

☐ N/A Documentation for this requirement has been included on the **Communication Plan**

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☐ N/A Documentation for this requirement has been included on the **Agreement Implementation Checklist and Documentation Tool**
☐ N/A – Documentation for this requirement has been included on the **Single IRB Protocol Specific Form**
☐ No consent needs to be obtained for this study for this site as described below in Other/Comments
☐ Consent will be waived and no consent documents used for this site
☐ Consent template for the Reviewing IRB will be used for this site
☐ Other/Comments (*Specify*):

8. HIPAA Authorization
☐ N/A Documentation for this requirement has been included on the **Communication Plan**
☐ N/A Documentation for this requirement has been included on the **Agreement Implementation Checklist and Documentation Tool**
☐ N/A – Documentation for this requirement has been included on the **Single IRB Protocol Specific Form**
☐ No PHI will be used and/or disclosed at the deferring site
☐ A waiver or alteration of authorization will be granted for this site
☐ A limited data set will be used for this site *(Note: Disclosure is listed within the HIPAA Authorization or a Data Use Agreement is in place for a HIPAA Waiver)*
☐ Authorization template for Reviewing IRB will be used for this site
☐ Other/Comments (*Specify*):

9. Conflict of Interest Confirmation
☐ N/A Documentation for this requirement has been included on the **Communication Plan**
☐ N/A – Documentation for this requirement has been included on the **Single IRB Protocol Specific Form**
☐ By checking this box, the relying institution confirms that its key personnel are in compliance with its COI policy and
☐ Have no potential COI relating to the current study for which IRB oversight is being deferred
☐ Have attached the COI management plan

10. State/Local Regulatory and Other Issues
☐ N/A Documentation for this requirement has been included on the **Communication Plan**
☐ N/A – Documentation for this requirement has been included on the **Single IRB Protocol Specific Form**
Please describe any state or local laws that pertain to this study and should be considered by the reviewing IRB in its review. If none pertain, please state this.
Please describe any local regulatory issues that relying IRB/institution requests the reviewing IRB take into account during its review of this study, i.e., local standard of care, distinct subject populations (veterans, non-English speaking populations).

FOR RELYING INSTITUTION/DEFERRING SITE ADMINISTRATOR USE ONLY (INDICATED IN #5 ABOVE)

The Investigator's intention to include our institution as part of the Centralized IRB Review by the UTHSCSA IRB:

☐ Acceptable ☐ Not Acceptable

1. Federalwide Assurance Information – select the applicable statement(s):
   ☐ The box that applies Subpart A to all research is checked
   ☐ The box that applies Subparts B, C, and D to all research is checked

2. Which IRB Authorization Agreement will be used for this study? ☐ N/A Exempt Research

3. Official Authorized by the Institution:

Signature Date

Printed Name/Title Name of Institution