**THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO**

**Request for Determination That a Proposed Activity is Not Human Research**

**(Not Human Research Activity)**

Using this form – To check the checkboxes, double click on the box. To enter text in the text boxes, click once on the gray box and then type your response

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| UTHSCSA Tracking Number      |

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| **1. Date:**  |  |

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| **2. Title:**  |  |

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| **3. Name and Address of Project Director (PD):** (This is the primary local contact information used by the IRB. Indicate where mail can most reliably reach the PD.) |
| PD Name *(Last Name, First Name, MI):* |       |
| Employer(s):  |       |
| Department:  |       |
| PD’s Telephone # |       |
| PD’s e-mail address: |       |
| PD’s Position Title: |       |
| Point of contact name: |       |
| Point of contact email |       |
| Point of contact telephone #: |       |

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| **4. Project Sites - List all sites where your project will occur** |
| **Check all that apply** | **Name of Institution / Site** *(list all participating sites below)* |
| **[ ]**  | **UTHSCSA / Department or Clinic:**       |
| **[ ]**  | **South Texas Veteran’s Healthcare System (STVHS) / Department or Clinic:**      *Note: VA research is research conducted by VA investigators (serving on compensated, work without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded.* |
| **[ ]**  | **University Health System (UHS) / Department or Clinic:**       |
| **[ ]**  | **Texas Biomedical Research Institute (TBRI) / Department or Clinic:**       |
| **[ ]**  | **Southwest Research Institute (SwRI) / Department or Clinic:**       |
| **[ ]**  | **Christus Santa Rosa Health Care (CSRHC) / Department or Clinic:**       |
| **[ ]**  | **Baptist Health System (BHS) / Department or Clinic:**       |
| **[ ]**  | **Other ⭢**       **/ Department or Clinic:**       |

The Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) regulations have different definitions of the term [Human Research](https://www.uthscsa.edu/vpr/services/glossary#Human-Subjects-Research). Use the following series of questions in order to determine whether or not the activity you propose is Human Research for either agency.

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| **Item 5: Is this research which doesn’t require IRB approval?**If you answer **No** to all questions below, then IRB review and approval **IS NOT** required. Upon review, the OIRB will issue you with a determination letter that your research does not require IRB review and approval. If you have questions, call the IRB office for further guidance. |
|  | **Yes** | **No** |
| 1. Will the HSC or an affiliated institution receive a direct federal (DHHS) award to conduct **human subjects’ research**?

*Research Funding from the Department of Health and Human Services (DHHS) (e.g., Agency for Healthcare Research and Quality (AHRQ); Centers for Disease Control and Prevention (CDC); National Institutes of Health (NIH); etc.)* | **[ ]** Complete [*Item 2*](#Item2) | **[ ]** Skip to [*Item 3*](#Item3) |
| 1.
 | **[ ]** Local activities will not include human subjects**[ ]** Activities involving human subjects are carried out by a non-HSC entity(ies) for which IRB approval has been or will be obtained*Note: A congruency review is required for all projects receiving federal funding to ensure that the work described in the proposal comports with submission; therefore, it may be necessary to submit grant application with this submission.* | If either statement is false, C:\Users\oilepo\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\NVSY3N9F\6503264653_40dc082989_z[1].jpg **Not Eligible** for this type of determination  | If both statements are true, continue to [*Item 3*](#Item3). |
|  1. Does the project involve a drug or device used outside of usual medical practice, including non-FDA-approved agents, or off-label uses of FDA-approved drugs or devices being administered to one or more humans?
 | **[ ]**  | **[ ]**  |
|  1. Will the safety and/ or effectiveness of a drug (FDA approved or non-FDA approved) or regulated device being administered to one or more humans be evaluated or be compared to that of another?
 | **[ ]**  | **[ ]**  |
| 1. Will data from the activity of an active group or a control group be submitted to, or held for inspection by the FDA in support of a marketing or research application for an FDA-regulated product (drug or device)?
 | **[ ]**  | **[ ]**  |
| 1. Will data obtained from use of a device on human tissue specimens be submitted to, or held for inspection by, the FDA in support of a marketing application or research application for an FDA regulated product?
 | **[ ]**  | **[ ]**  |
| 1. The investigator will **obtain**, **use**, **study**, **analyze**, or **generate** identifiable private information and/or identifiable biospecimens through an **intervention**¹ or **interaction**² with **living individuals**
* ***¹Intervention i****ncludes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.*
* ***²Interaction i****ncludes communication or interpersonal contact between investigator and subject.*
 | **[ ]**  | **[ ]**  |
| 1. The information obtained by the investigator is***both* private*³* and identifiable*4***.
* ***3***The information is **private** because it includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
* *4*The information is **individually identifiable** because the identity of the participant is or may be ascertained by the investigator or associated with the information
 | **[ ]**  | **[ ]**  |
| 1. Obtaining newborn screening blood spots for research purposes (regardless of funding or identifiability)
 | **[ ]**  | **[ ]**  |

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| **Item 6: Research Activities Not Considered Human Research by DHHS or FDA regulations** ***(Check the best choice*)** |
| **[ ]**  | **Using anonymous pre-existing data or specimens.** This refers to uses of anonymous pre-existing data or specimens (anonymous materials are either those with no personally identifiable information contained in the original data or attached to the original specimen). |
| **[ ]**  | [**Publicly available**](https://www.uthscsa.edu/vpr/services/glossary#Publicly-Available-Data/Specimens)information that is **not private**. The information may or may not be identifiable**.** |
| **[ ]**  | **Using coded pre-existing or coded prospective data or specimens. If this choice is selected, choose the applicable statements below:** |
|  | **[ ]**  | the private information/specimens were not/will not be collected specifically for the currently proposed research through an interaction or intervention with living individuals.  |
|  | **[ ]**  | the investigator(s) never obtains identifiable data/specimens because: *(choose one below)* |
|  |  | **[ ]**  | the holder of the key to decipher the code, destroys the key before the data is provided to the investigator. |
|  |  | **[ ]**  | the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, or until the individuals are deceased; (Attach a [signed agreement](https://www.uthscsa.edu/sites/default/files/Services/forms/form_i.docx) between the source of anonymous pre-existing data/specimen sets and the investigator. ) |
|  |  | **[ ]**  | there are laws or IRB-approved written policies for a repository/data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased. |

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| **Item 7: Summary of the Research:** Provide a summary of the proposed research activity. Provide sufficient detail for the reviewer to verify whether or not the activity requires IRB approval as you have indicated above. If a separate research description/written plan is available, attach it to this document. |
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| **Item 8:****Other individuals working on this project** | In addition to the PD/PI, will other individuals be working on this project? | **[ ]** Yes | **[ ]** No |
| If yes, provide the following information for each provider: *To add rows use copy & paste* |
| Is this PI or any of the individuals listed below conducting this research on their VA time or with VA resources?  | **[ ]** Yes | **[ ]** No |
| Provider’s Name (Last, First) | Degree(s) and US Licensure | Employer(s) |
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