***North Texas Regional Institutional Review Board***

***Protocol Synopsis for Research Involving Human Biological Materials (Biospecimens) and Related Behavioral/Health Data***

***Please see the last page for instructions on submitting the project in IRBNet.***

|  |  |  |
| --- | --- | --- |
| **Protocol Information** | | |
| ***Title of Project*:** |  | |
| ***Name of Principal Investigator:***  ***Institution:***  ***Department:*** |  | |
| ***Name of Co-Investigator (s):*** |  | |
| ***Sponsoring Agency/Company (if applicable):*** | |  |
| ***Sponsor’s Protocol Number (if applicable):*** | |  |

|  |
| --- |
| 1. **Purpose of the Study-** *State the scientific objectives of the research.* |
|  |

|  |
| --- |
| 1. **Background and Significance** **–** *Briefly sketch the background leading to the present proposal.* |
|  |

|  |
| --- |
| 1. **Preliminary Studies-** *Summarize preliminary studies conducted by the investigator pertinent to this proposal. State “none” if applicable.* |
|  |

|  |
| --- |
| 1. **INvestigator experience** |
|  |

|  |
| --- |
| 1. **Description of Associated Research Projects** |
| **1. Description of the parent project-***Describe the original project from which the biospecimens and data originated from, including where the biospecimens and related data are currently stored.* |
|  |
| **2. Description of the project to which the biospecimens and data will be transferred.** |
|  |

|  |
| --- |
| 1. **Description of THe biospecimens and Behavioral/health data that will be used in this study** |
| **1. Description of the biospecimens**- *Describe the biospecimens that will be analyzed in this study. Describe if the biospecimens are existing or prospective (or both), the number of biospecimens that will be included, classification of the biospecimens (i.e. unidentified, unlinked, identifiable, coded, etc), the type of human biological material (tissue, blood, sputum, urine, bone marrow, cell aspirates), and how the biospecimens will be labeled.* |
|  |
| **2. Description of the related data-***Describe the data that will be analyzed in this study, including the source of the data (survey/questionnaire, medical record, research record, etc), the type of health information present, the format of the data (i.e. electronic or hard copy), and how the data will be labeled.* |
|  |
| **3. When appropriate, describe the process for “stripping” the biospecimens and related data of identifiers-***Describe where and when this will occur, who will perform the process, where the master list will be maintained (if appropriate), what identifiers will remain after this process, and who will have access to the identifiable information.* |
|  |

|  |
| --- |
| 1. **prospective (Future) collection of biospecimens from human subjects** |
| * 1. **Biospecimen collection activities-***Describe the process/procedures that will be in place during the collection of biospecimens. Specify which key personnel will collect the biospecimens and their credentials, the location(s) where sample collection will occur, and how the specimens will be transferred to the laboratory for analysis/storage.* |
|  |
| **2. Description of the Human Subjects**-*Describe the human subjects who will be in this study. Include a description of the inclusion/exclusion criteria, the number of subjects who will be enrolled, age range, gender, and race/ethnicity.* |
|  |
| **3. Informed Consent**-*Describe the informed consent process that will be in place for the human subjects and specify which key personnel will obtain consent. If requesting a waiver of documentation of informed consent, describe as appropriate (note that a “Waiver of Documentation of Informed Consent (Form A)” should be submitted with the IRB Application)* |
|  |

|  |
| --- |
| 1. **Transfer of the Biospecimens and Related Data** |
| **1. Transfer in of biospecimens and data to your institution from outside researchers.** *In this section, describe the process for how the biospecimens and data will be transferred to investigators. List the name of the organization(s) they will be received from, and the person(s) at that organization (s) responsible for overseeing the transfer of the biospecimens to your institution. If biospecimens and/or data will be received from more than one entity, please describe appropriately.* |
|  |
| **2. Transfer out of the biospecimens and related data from your institution to outside researchers:** *In this section, describe the process for how the biospecimens and data will be transferred from your institution to outside organizations or individuals. List the name of the organization(s) and individuals they will be sent to, and the person(s) who will be responsible for receiving the biospecimens and data at that organization.* |
|  |
| **3. Transfer of the biospecimens and related data internally (to/from other collaborating researchers)-***In this section, describe the process for how the biospecimens and data will be transferred from or to other investigators within your institution. Note: IRB review and approval of the investigator’s research project to which the biospecimens and related data will transferred to is required before the transfer can occur.* |
|  |

|  |
| --- |
| 1. **Analysis of the biospecimens and related data** |
| **1. Setting/Location**-*Describe where the biospecimens and related data will be analyzed.* |
|  |
| **2. Laboratory methods and facilities**-*Describe the procedures/process that will be used to analyze the biospecimens, including the laboratory, equipment, and key personnel that will be involved.* |
|  |
| **3. Procedures for Data Analysis-***Describe where the data analysis will occur, plans for statistical analysis of data when appropriate, and key personnel that will be involved.* |
|  |
| **4. Estimated Period of Time to Complete the Study-***Describe the stage and overall time for the entire study (start to completion).* **­** |
|  |

|  |
| --- |
| 1. **Storage of the biospecimens and related data** |
| **1. Short term storage of the biospecimens and related data -***Describe where the biospecimens and data will be stored when they are received at your institution and during analysis.* |
|  |
| **2. Long term storage and biospecimens and related data-***Describe where the biospecimens and related data will be stored after this project is completed.* |
|  |

|  |
| --- |
| 1. **RISK/BENEFIT assessment** |
| **1. Potential Risks-** *Describe any* ***informational risks*** *(including breach of privacy, confidentiality risk, document access, risk of embarrassment, and other “risks” related to how sensitive information is stored, accessed, and managed) as well as any* ***procedural risks*** *(risks associated with the actual process or procedures associated with the study) to the human subjects whose biospecimens and data will be used for this project.* |
|  |
| **2. Potential Benefits-** *Describe any potential benefits to the human subjects, society and/or science that may result from this research project.* |
|  |
| **3. Risk/Benefit Assessment –***Describe how the anticipated benefit of the research justifies the risk to the human subjects whose biospecimens and data will be used for this project.* |
|  |

|  |
| --- |
| 1. **Special precautions-** |
| **1. Human Biospecimen Storage and Security***-Describe how the human biospecimens will be secured while being stored. The investigator must take necessary steps to maintain confidentiality of the human biospecimens. This includes coding human biospecimens and choosing an appropriate and secure sample storage mechanism which will prevent unauthorized access to the biospecimens. State who will have access to the human biospecimens. If human biospecimens with subject identifiers will be released, specify the person(s) or agency to whom the information will be related and the purpose of the release.* |
|  |
| **2. Data Storage and Security-** *Describe how the data will be secured during storage. The investigator must take necessary steps to maintain confidentiality of the data. This includes coding data and choosing an appropriate and secure data storage mechanism which will prevent unauthorized access to the data. State who will have access to the data. If data with subject identifiers will be released, specify the person(s) or agency to whom the information will be related and the purpose of the release.* |
|  |
| **3. Ensuring biospecimens and related data are legally and ethically obtained-***Describe how it was verified that the human biospecimens and related data that will be used in this study were obtained legally and ethically. This may be demonstrated by obtaining a copy of the IRB approval for the collection of biospecimens from the outside entity, as well as a clinical consent document or research consent form indicating that the subjects gave their permission for the biospecimens and data to be used for research purposes. A copy of this documentation should be submitted with the IRB Application.* |
|  |

|  |
| --- |
| 1. **Subject compensation/subject costs** |
|  |

|  |
| --- |
| 1. **Ownership of biospecimens-** *Describe what individual/entity will own the biospecimens and related data after they are transferred to your institution. Indicate if the outside entity will retain any ownership, or access to the biospecimens, after they are transferred.* |
|  |

|  |
| --- |
| 1. **Key personnel-** *List all individuals directly involved in the conduct, design, or reporting of research involving human subjects in the study, and describe their role.* |
|  |

|  |
| --- |
| **INVESTIGATOR’S CERTIFICATION / ASSURANCE**  I certify that the information provided in this request for protocol review is complete and correct. I understand that I have the ultimate responsibility for protecting the confidential information of individuals and ensuring the privacy of their protected health information. I agree that subjects will not be identified by name in any presentation or publication related to this research project. Further, I attest that I, and any person listed as key personnel on this protocol has legal and institutional authorization to access and examine the medical records to be studied in this project, and take full responsibility for their access and use of these records. Finally, my signature below is my representation that I and any individual listed as research personnel on this protocol have ***no* financial or other conflict of interest** that could adversely affect a subject or their data in this study. I acknowledge that I am required to notify the IRB within 10 business days if a change in my, or any individual listed as key personnel on the protocol, disclosure status occurs. *(Signature of Principal Investigator is required.)*  **Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

***North Texas Regional Institutional Review Board***

***Instructions for submitting this project in IRBNet***

***(Do NOT submit this instruction page!)***

**Please submit all documents in IRBNet (**[**www.IRBNet.org**](http://www.IRBNet.org)**). Register as a New User (if you haven’t done so already) and select “Create New Project” in the left-hand navigation bar.**

* Please note the following:
  + **THE PRINCIPAL INVESTIGATOR MUST HAVE FULL ACCESS TO THE IRBNET PROTOCOL PACKAGE IN ORDER FOR IT TO BE REVIEWED BY THE IRB.**
  + Please be sure to use a very descriptive file name for each document submitted as a pdf or word.doc file.  Example: “MMSE scale” is much better than “Scale 1”…. “Recruiting flyer” is better than “Ad 1”, and so forth.
  + Refer to the “Read Me First” document located in IRBNet under “Forms and Templates” for additional guidance.
* In addition to the application, please upload the following documents in IRBNet:
  + Evidence of adequate training in human subjects research (e.g., CITI) for all study personnel. Note: It is also acceptable for the CITI trainings of study personnel to be linked to this project in IRBNet.
  + Signed conflict of interest (COI) forms for all persons listed as key personnel on this protocol. (Note: COI forms are *not* required for Exempt category projects.)
  + Consent Form associated with prospective collection of biospecimens or medical records. For the analysis of existing data, a request for a Waiver of Informed Consent may be permissible. Contact IRB staff for guidance.
  + If the project involves use of subjects’ protected health information, submit a HIPAA Research Authorization OR an appropriate request for a Waiver of HIPAA Research Authorization. Contact IRB staff for guidance.
  + For use of unfixed human biospecimens at UNTHSC only, submit evidence of UNTHSC Institutional Biosafety Committee (IBC) approval (e.g., copy of IBC approval letter for a protocol, etc.).