**North Texas Regional Institutional Review Board**

**Continuing Review Form**

Federal regulations require an Institutional Review Board (IRB) to conduct a Continuing Review of all research projects involving the use of human subjects **at least** annually, or more frequently, appropriate to the degree of risk. Please use this form to provide information about your research project. The responses you provide will be the basis for the re-review of your project. **Answer all questions.** **Do not leave items blank** (if not applicable, mark N/A). Please note that INCOMPLETE or INACCURATE forms (attachments missing, faulty data entries, illegible writing, etc.) will not be reviewed and will delay the re-review of your protocol which could result in protocol suspension or termination. Please see the last page of this document for instructions on submitting the Continuing Review materials in IRBNet.

IRB Project #:

Project Title:

Principal Investigator (PI):

Phone Number:

Contact Person/Study Coordinator and Phone # (if different from P.I.)

Institution:

Department/Institute:

Sponsor Protocol Number (or Funding Agency Award Number) [If not applicable, include “N/A”]:

**STATUS OF THE PROJECT:**

 [ ]  Actively Enrolling new subjects

 [ ]  Enrollment complete, but research intervention continues

 [ ]  Enrollment and research intervention complete; subject follow-up continues

 [ ]  Enrollment, research intervention, and subject follow-up complete; data analysis only continues

 [ ]  Project NOT YET STARTED (list reason and date expected to begin)

 [ ]  Project ON HOLD (list reason and date expected to resume)

**SERIOUS ADVERSE EVENTS:**

Did any **on-site** serious adverse events (SAEs) occur since you last reported on this study? Yes [ ]  No [ ]

If yes, indicate number of the following: **On-site** SAEs: Initial       Follow-up:

Was it necessary to modify the consent form as a result of the on-site and off-site SAE reports? Yes [ ]  No [ ]

If yes, indicate date of the IRB approved revised consent form:

**COMPLAINTS:**

Have any **complaints** from subjects been received about this research study since the last review of this study?

Yes [ ]  No [ ]  If yes, explain:

**Subject Enrollment**:

|  |  |
| --- | --- |
| **Maximum Number of Subjects Approved by the IRB** |  |
| **Date FIRST subject consented (mo / yr)** |  |
| **Date MOST RECENT subject consented (mo / yr)** |  |
| **Total number of subjects reported previously \*** |  |
| **Number of new subjects \*\*** |  |
| **Total number of subjects reported to date** |  |

**\*** *If this is the first continuing review of your study, enter a zero here.*

***\*\**** *This is the number of* ***new subjects*** *since the**last continuing review. If this is the first continuing review of your study, report the total number of subjects enrolled to date.*

|  |  |
| --- | --- |
|  | *Number of Subjects \** |
| **Undergoing Research Protocol** |  |
| **Undergoing Follow-Up Data Collection *Only*** |  |
| **Completed Research Protocol AND Follow-Up** |  |
| **Lost to Follow-Up** |  |
| **Subjects who were Withdrawn by Principal Investigator (including Screen Failures)** |  |
| **Subjects who Withdrew from Study** |  |
| **Deaths \*\*** |  |

**\*** *Of the total number of subjects you*

 *have reported, please provide information in order to capture the status of the study participants. The numbers in these boxes should add up and equal the total number of subjects reported to date.*

*\*\* Note that DEATHS must be reported to the IRB Immediately.*

**Reasons subjects were Withdrawn by Investigator (DURING THIS REPORTING PERIOD):**

**Reasons Subjects Withdrew from study (their decision) DURING THIS REPORTING PERIOD:**

**Of the total number of subjects reported to date, how many are:**

|  |  |
| --- | --- |
|  | *Number of Subjects* |
| **Male** |  |
| **Female** |  |



*For some protocols, a DSMB is required. All DSMB reports* ***MUST*** *be submitted to the IRB within 10 working days of receipt. If your study requires a DSMB, please indicate the date(s) of the DSMB Meeting(s) during this reporting period:* ***\_\_\_\_\_\_\_\_\_\_******Submit a copy of the DSMB Report(s) in IRBNet***

**RISK/BENEFIT ASSESSMENT:**

Has anything occurred since **initial** IRB review and approval which may have altered the risk/benefit relationship? Yes [ ]  No [ ]  If the answer is yes, provide your current assessment of the risk/benefit relationship of the research based upon the results obtained, on-site and off site SAEs, and other factors:

Has any new literature or findings been reported since you last reported on this study which would significantly impact the design of this study or the risks associated with this study? Yes [ ]  No [ ]  If response is yes, attach a summary of these findings.

**BIOSAFETY (*For UNTHSC Projects Only*)**

Does the study involve the collection, storage or analysis of ANY *unfixed* human biospecimen (blood, saliva, urine, tissue, etc.)?

No [ ]

Yes [ ]  If yes, submit a copy of the UNTHSC Institutional Biosafety Committee (IBC)/ Safety Office approval

 letter.

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**PRINCIPAL INVESTIGATOR ASSURANCES:**

In accordance with federal regulations, all individuals identified as "key personnel" must complete aConflict of Interest (COI) disclosure at the beginning and during continuing review for each research project involving human subjects.

As a condition of continuing approval, the Principal Investigator certifies that the above research project and protocol has been and will continue to be conducted in full compliance with all federal regulations and IRB policies governing human subject research. Further, the Principal Investigator asserts that the information in this document is accurate. The Principal Investigator also notes that any changes in the research activity, study procedures and/or consent forms must be approved by the IRB prior to implementation, and that all serious adverse events must be reported to the IRB. The Principal Investigator states that any new literature or findings that would significantly impact this study or risk associated with this study have been duly noted and reported to the IRB. The Principal Investigator also assures that all key personnel associated with the project have successfully completed educational training in the protection of human research subjects, and that all key personnel have completed and signed a new Conflict of Interest Disclosure relevant to this research project.

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Principal Investigator’s Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contact Person/Study Coordinator’s Signature (if applicable) Date

**Instructions for submitting continuing review materials in IRBNet**

**(please note that these instructions are for investigators whose project has NOT yet been reviewed/approved via the IRBNet system)**

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

All of the continuing review materials must be submitted in IRBNet ([www.irbnet.org](http://www.irbnet.org)). You will need to register as a New User if you haven’t do so already. Select “Create New Project” (from left-side navigation bar), provide the requested information about your project, attach the relevant project documents, and submit the package for IRB review.

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 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.

**For Continuing Reviews of projects that have not yet been reviewed and approved via the IRBNet system,** please submit the following documents in IRBNet:

* IRB Continuing Review Form (completed and signed by Principal Investigator)
* All project-related documents (protocol synopsis, consent forms, HIPAA Research Authorization, survey instruments/questionnaires, scripts, recruitment materials, etc.)
* A CLEAN (un-stamped) versionof Consent Form\*
* New (updated) Conflict of Interest (COI) forms (completed and signed) for key personnel
* Current CITI certificates (if they are not linked to researcher’s profile) for each key personnel listed on the study.
* As applicable, please include:
	+ Data safety committee report(s)
	+ Documentation of Institutional Biosafety Committee Approval for UNTHSC projects involving collection, storage or analysis of unfixed human biospecimens

*\*Note: For studies with multiple consent form types or versions, upload a copy of* ***each*** *version.*

**IMPORTANT NOTE**: If **Protocol Modifications** are being requested at the time of Continuing Review, please also submit:

* **A TRACK CHANGES / REDLINE** version of the revised documents
* A **CLEAN (unmarked)** version of the revised documents.
* A **MEMO**, requesting the modifications (signed by the PI, along with a brief justification for the changes)