Tarrant County College District
Institutional Review Board
Continued Research Form **IRB#:**

Date: **Campus:**

Principal Investigator Name:

Phone: **Email:**

Federal Regulations **mandate** that all human subject research receive continuing review and approval **not less than once per year.** In order to comply with this policy on research involving human subjects, sufficient information must be collected to allow the IRB to conduct a substantive and meaningful review. Therefore, in order for the District IRB to comply with this and other directives and to grant continuing approval of your protocol, the following information/documents are required: (a) a completed continuing review questionnaire, (b) copies of all informed consent documents and (c) copies of all surveys and/or questionnaires currently being used.

In addition, please respond complete the information below. If a question does not apply to your research, indicate (e.g., "Not Applicable" or "N/A").

I. Briefly summarize the study objectives and procedures: (attach additional pages if required).

II. Dates covered by this progress report:

III. Project Summary

(a) **Leadership:** Have there been any changes in leadership, responsibility or major personnel? Yes No

If Yes, fully describe the changes:

(b) **Objectives:** Have there been any changes? Yes No

If Yes, fully describe the changes:

(c) **Procedures:** Have there been any changes? Yes No

If Yes, fully describe the changes:

(d) **Informed consent documents:** Have there been any changes? Yes No

If Yes, fully describe the changes:

(e) **Research subjects:**

1. List each group, cohort, etc., if applicable, including control groups, on separate lines. If there is only one group, description would be "All."

NUMBER OF SUBJECTS (at all sites for which you are the PI)		**AGE RANGE OF SUBJECTS** (at all sites for which you are the PI)		**GENDER** (of subjects to date)	
This Period	Next Period (anticipated)	This Period	Next Period (anticipated)	% Male	% Female

2. Was the subject population representative of the population base from which subjects could be selected with respect to:

   a. Gender representation? Yes No

   If No, explain:

   b. Minority representation? Yes No

   If No, explain:

3. Have any subjects withdrawn from study since the study began? Yes No

   If No, explain:

4. Are you aware of any breach in confidentiality? (e.g., unauthorized access to records) Yes No

   If No, explain:

A. **Adverse Events**:

1. Have there been any adverse events? Yes No

   If Yes, please summarize these unexpected problems, including the number of occurrences and indicate if they required consent document changes, particularly in the risks section. If risks are affected, describe how they are minimized and reasonable in relation to expected benefits. Attach any adverse effect reports.

B. **Proposed Revisions/Amendments/Modifications:**

1. Are there revisions/amendments to the protocol, consent form(s), questionnaires, etc., that are included with this renewal? Yes No

   If Yes, provide a brief description below, and highlight the changes on the document(s) to be reviewed.

2. Will the revisions/amendments change the scope or research objectives of the protocol? Following are examples of actions considered to change the scope or research objectives: A change in the specific aims approved at the time of award (funding); a change from the previously approved use of human subjects; shifting the emphasis of the research from one disease to another. Yes No

   If Yes, provide sufficient information/documentation to allow the IRB to review and approve prior to initiation.

3. Will the revisions/amendments change risks to subjects? Yes No

   If Yes, provide sufficient information/documentation to allow the IRB to review and approve prior to initiation. In particular, describe how risks are minimized and reasonable in relation to expected benefits.

C. **Publications, Presentations, Reports:** Provide a listing of all publications, presentations and reports that have resulted from this work since the last review. If none, so state.

As **Principal Investigator**, I acknowledge that I am responsible for reporting any: (a) emergent problems or (b) proposed procedural modifications to the IRB for its review and approval. Except where necessary to eliminate apparent immediate hazards, no such modifications will be put into effect without prior IRB approval. Unless otherwise directed by the IRB Chairperson, I will renew this application with the IRB no less than annually. The research project being conducted in compliance with the IRB's understanding and recommendations and the IRB has been provided all necessary information on the research project in order for a complete review. This research project will not be put into effect until final IRB approval is received.

Signature of Principal Investigator: **Date:**

Email forms and supporting documentation to: irb.irpe2@tccd.edu.