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Date Submitted

Southwestern Community College
Institutional Review Board

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File Number

Continuing Review Questionnaire

Principal Investigator:		**Project Title:**	

Federal Regulations mandate that all human subject protocols 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 Southwestern IRB to comply with this and other directives and to grant continuing approval of your protocol, the following information/documents are required: ***a completed continuing review questionnaire and copies of all informed consent documents, surveys and/or questionnaires currently being used.***

If a question does not apply to your protocol, so 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: ☐ Previous 12 months ☐ Other period as described:

III. Project Summary

A. **Leadership:** have there been any changes in leadership, responsibility, or major personnel?

Yes ☐ No ☐

If Yes, then fully describe:

B. **Objectives:** have there been any changes?

Yes ☐ No ☐

If Yes, then fully describe:

C. **Procedures:** have there been any changes?

Yes ☐ No ☐

If Yes, then fully describe:

D. **Informed consent documents:** have there been any changes?

Yes ☐ No ☐

If Yes, then fully describe:

E. **Research subjects:**

1. List each group, cohort, etc., if applicable, including control groups, on separate lines. If 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)	
Group	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 Have any subjects withdrawn from study since the study began?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 Yes, explain:

4. Are you aware of any breach in confidentiality? (e.g., unauthorized access to records)

   Yes ☐ No ☐

   If Yes, describe:

F. **Unexpected problems**:

1. Have there been any **unexpected** problems?

   Yes ☐ No ☐ N/A ☐

   If Yes, please summarize these unexpected problems, 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. If available, attach copies of data safety monitoring reports.

G. **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 ☐ N/A ☐

   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 ☐ N/A ☐

   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.

H. **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 emergent problems; that I will submit any proposed procedural modifications to the IRB for its review and approval and, except where necessary to eliminate apparent immediate hazards, no such modifications will be put into effect without prior IRB approval; that unless otherwise directed by the IRB Chairperson, I will renew this application with the IRB no less than annually; that the research project is being conducted in compliance with the IRB's understanding and recommendations; that the IRB is provided all the information on the research project necessary for its complete review; and that this research project will not be put into effect until final IRB approval is received.

_____ _____
Signature of Principal Investigator Date

_____ _____
Signature of Faculty Advisor (if student) Date

Signature of IRB Committee Chair:			**Date:**__/__/__
IRB Chair: Check 1 box:	☐ **Approved**	☐ **Approved with Conditions**	☐ **Refer to Full Committee Review**