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Date Submitted

**Brazosport College
Institutional Review Board**

File Number

**Change in Methods for Protocol Previously Approved
By Brazosport College IRB**

Principal Investigator:		Project Title:	
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Federal Regulations mandate that all human subject protocols receive another review in case there is a change in protocol. 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 Brazosport College IRB to comply with this and other directives and to grant renewed approval of your protocol, the following information/documents are required: ***a completed 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").
If more room is needed, please attach additional pages as needed.

I. Briefly summarize the study objectives and procedures:

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."

Group	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 any of the following?

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 Have any subjects withdrawn from study since the study began?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:	<input type="checkbox"/> Approved	<input type="checkbox"/> Approved with Conditions	<input type="checkbox"/> Refer to Full Committee Review