

**UNIVERSITY OF ALABAMA
INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS
RENEWAL APPLICATION**

Principal Investigator(s):

Title of Research Project:

IRB Project number:

Date of Last Approval:

Expiration Date of Last Approval:

Please attach a complete copy of your previous IRB application and signed approval from IRB for this project. Also attach a copy of the informed consent currently being used.

Have you altered your procedures from those you previously reported to the IRB?

____YES ____NO

If yes, please explain what procedures you changed. (Attach copies of any new or revised documents or study materials.)

Have you had any adverse responses to your procedures from your participants? (For multi-site studies or clinical trials include adverse events from other sites.)

____YES ____NO

If yes, please indicate how many adverse events there have been, detail these adverse responses, and indicate how you handled them. (Attach additional sheets, if necessary.)

How many subjects have you recruited for this study?

How many subjects have completed the study?

How many subjects are currently enrolled in the study?

Estimate the percentage of people who chose not to participate after being informed of the study procedures

What were the primary reasons given for choosing not to participate?

Estimate the percentage of people who chose not to complete the procedures after beginning the study.

What were the reasons given by these participants for choosing to discontinue their participation in the study?

Describe research results obtained thus far:

Provide a summary description of subject experiences, addressing benefits and adverse reactions

Current risk-benefit assessment based on study results:

Any other new information or unanticipated risks:

Date Submitted: _____
Revised 4/14/01