

PROTOCOL MODIFICATION OF APPROVED IRB RESEARCH PROJECT

Principal Investigator: _____ **Contact Number:** _____

Title of Proposal: _____ **IRB Proposal #:** _____

Initial approval date was: _____

Federal policy requires that IRBs review protocol modifications of approved projects. Please complete the following form and return it as soon as possible. The IRB must have this form signed and completed to approve changes in the following aspects of this study:

- Recruitment procedures, including means of obtaining informed consent
- Compensation for participation
- Number of participants
- Sample characteristics
- Data collection instruments such as survey or interview questions
- Data collection procedures
- Addition of video or audio taping
- Use or reporting of data

1. Are changes in recruitment procedures, including means of obtaining informed consent, proposed?

YES NO

If YES, please describe the proposed changes (including original plan, new plan, and rationale):

2. Are changes in compensation for participation proposed?

YES NO

If YES, please describe the proposed changes (including original plan, new plan, and rationale):

3. Are any changes in your subject sample (numbers, age, gender, race, etc.) proposed?

YES NO

If YES, please describe the proposed changes (including original plan, new plan, and rationale):

4. Are changes in data collection instruments or procedures proposed?

YES NO

If YES, please describe the proposed changes (including original plan, new plan, and rationale):

5. Is addition of video or audio taping proposed?

YES NO

If YES, describe recording procedures and how recorded material will be handled to ensure confidentiality:

6. Are changes in the use or reporting of data proposed?

YES NO

If YES, please describe the proposed changes (including original plan, new plan, and rationale):

7. Was this incident or event reported to the IRB?

YES NO

If yes, explain in detail.

8. Have there been any complaints about the research?

YES NO

If yes, provide complete information on complaints made.

9. Has the PI's contact information changed since the original proposal was submitted?

YES NO

If yes, provide current information.

***If Spelman College is to be mentioned in any publications or presentations, a preliminary draft of the manuscript must be submitted to the IRB.**

Researcher's Signature: _____

Date: _____