Application Number: 2009F5128

**Responses to IRB Reviewers’ Concerns**

As you can see from the comments below, reviewers have requested significant revisions to your application. Please submit your revisions, along with a document that details how you addressed the reviewers\' concerns, item by item. Following these steps, the application will go through a second round of review.

08/27/09 17:09:50

As I understand this study, it will collect data in two steps.  First, participants will be recruited to complete a survey.  Then, from those participants who completed the survey, and who volunteered to participate in the focus group, you will invite some participants to  be involved in a focus group discussion.

Because of this design, I believe that you will need two levels of informed consent.  You will need informed consent for participation in the online survey, and then you will need an additional and separate consent form for participation in the focus group (completed at the time of the focus group).  The consent form before the survey is not adequate for participation in the focus group.

***Response: We developed two consent forms – one for the survey and a separate one for the focus group participation. Both are attached.***

Changes necessary in recruitment:

Ads and emails should only be addressed to female faculty if female faculty are the only intended participants at this time.  (as noted in synopsis 1, 2)

If later you choose to research other groups of participants, you may file an amendment for this IRB approval.

***Response: The flier focuses on recruitment of female faculty, staff, and students. The researchers are only recruiting female participants for the research project at this time. The flier is attached.***

Changes necessary in the Consent Form for the survey:

1.      “Consent Form” must be the title of the document.

2.      Give the researcher(s)’ name(s), contact information and affiliation(s) in the very first paragraph.

3.      A statement that the study involves research should be included in one of the first few sentences of the consent form.

4.      A statement that identifies the funding source of the research project (if applicable).

5.      Provide the reason(s) why the participant has been chosen/asked to participate.

6.      Describe procedures (including length of time assessment/participation will require, number of questions included in a survey, etc.) that will be used to collect data in easily understandable terms and language.

7.      List the benefits to the participants.

8.      List the physical and/or psychological risks to participants.

9.      You must be more explicit in your statement in this area.  A statement that participation is voluntary and participants may withdraw from the study at any time without prejudice or jeopardy to their standing with the University and any other relevant organization/entity with which the participant is associated.

10.     A statement that participants may choose to not answer any question(s) for any reason.

11.     A statement that pertinent questions about the research, research participants\' rights, and/or research-related injuries to participants should be directed to the IRB chair, Dr. Jon Lasser (512-245-3413 – lasser@txstate.edu), or to Ms. Becky Northcut, Compliance Specialist (512-245-2102).

12.     Regarding the data collection procedures, the consent form must include a statement of confidentiality or anonymity.  If the data collection is conducted in such a fashion where the participant is known to the researcher and the participant’s name can be matched to his/her data, the data collection procedure is confidential.  If not, then the data collection procedure is anonymous.  Your data collection is confidential if the participants supply their email addresses and/or participate in the focus group. Otherwise it may be considered anonymous, but you need to explain that.

13.     Regarding data records and record keeping, include a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained, and how and where they will be secured.

14.     The location and length of time the survey data, videotapes, audio recordings etc. will be kept must be explicitly stated.

15.     The consent form must state that a summary of the findings will be provided to participants upon completion of the study, if requested. Researcher should include instructions for participant with regard to how to access results of study.

16.     If the data is collected via an internet-based survey, the consent form must be included for the respondent to review before starting the online survey. Furthermore, each participant must indicate that he/she fully understands the consent form and its contents before participation is allowed. This is typically done by including a “check box” or some similar “field” that would allow the participant to consent/agree to participate simply by clicking on the field/box.   This needs to be added to your survey.

17.     Participants must receive a copy of the consent form for all data collection protocols. For internet-based surveys, participants should be instructed to print the consent document for their records.

***Response: The consent form for the survey has been modified based on the recommended changes listed above. The focus group consent form was modified to include the same information. They are both attached.***

Recommended changes in the survey

1)      You offer a self-selected choice for race/ethnicity, but not for religion.  There are other religions than the ones you have listed.

***Response: An additional response option for religion was added to the survey.***

Information necessary for the Consent Form for the focus groups:

You need a separate consent form for participation in the focus groups.  Please review the Consent Form Checkist to construct this.  You will need to be explicit that you are audiotaping and videotaping their participation which will be a threat to confidentiality.

***Response: A separate consent form related to audio and videotaping was developed by the researchers. It is attached.***

08/29/09 18:35:49

I concur with the suggestions made by the other reviewer and must be completely addressed.

in addition, I have the following concerns, the onus of reducing the risk to the participants apparently rests on the participants themselves, as they have the right to disclose the extent of their experiences with race. however, there is no certain way how this can be controlled, being an emotional topic, some participants might review more at that instance and may have second thoughts about it, causing unrest. To avoid such scenarios, I would like the investigators to expand their focus group questionnaire and include questions which would guide the participants properly, if there are certain questions that they do not wish to answer they can then  choose to refrain. In its present form, the questionnaire does not allow participants to decide when it is beyond their comfort level.

I would also like to see the potential questions that are being included for the survey and consent forms for both the steps of the investigation.

***Response: The focus group question guide will be utilized as a guide for the researchers only. The consent forms have been modified and now provide participants the option of responding to only those questions they desire to answer. The consent forms, focus group questions, and survey are attached.***

Please provide the contact information of the \'Therapist\' that the investigators have suggested in their synopsis, this should be given in the consent forms.

***Response: Contact information for the University Counseling Center has been added to the consent forms.***

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Institutional Review Board

Office of Research Compliance

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