Human Participants Research Protocol #

CORRECTIVE ACTION REQUEST

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Please address noted areas of concern and/or recommendations presented in this document. Submit changes immediately so that your application may be processed. Until such time, your application is placed "on hold." For additional information contact Dr. Monique McCallister: 615-963-7619 or irb@tnstate.edu.

Corrections to IRB application

1. [] Please complete **all** segments of title page
2. [] All sections of application must be type-written
3. [] Please answer all segments of all questions
4. [] More detail on **where** participants will be recruited. (e.g. Psychology subject pool, Metro Nashville Public Schools)
5. [] More detail on **how** participants are to be recruited. If you plan to use flyers include a copy of that flyer. If you plan to get participants from a class, include written permission from instructor. If you plan to use archival data or data from an external agency, include letter of cooperation. If you plan to get participants from a church give the name of the church and state exactly how it will occur. (Will flyers be passed out at the church? Will the pastor make an announcement during the service?)There must be enough detail so that anyone wanting to replicate your study would be able to recruit participants in the same manner you did. The following examples **do not** give enough information to clearly show how participants will be recruited:
   - I will get volunteers from my school or church
   - I will get volunteers from the Nashville area
   - I will get students from Tennessee State University
6. [] Specify number of participants necessary for research; if it is difficult to predict how many participants will be eligible or attracted to your study, specify optimum number; if there is a problem in recruiting participants, and include a discussion of the problem
7. [] Specify age of participants, participants under the age of 18 require parental or guardian consent
8. [] Include a copy of the questionnaire(s), interview(s), survey(s), or other instrument(s) to be used in the **EXACT** form to be issued or presented to participants. Do not just copy the survey from a textbook. If participants will be asked to do some form of activity, include description of what they will be asked to do along with the form that you will use to score participant responses.
9. [] **Approval** of instructor(s), adviser(s), principal researcher(s), department head and/or director required
10. [] Copy of **letter of cooperation** or equivalent required. This is a letter from the external agency from which you are gathering data giving permission for you to access their data or participants. This must be on their company letterhead and signed by the appropriate supervisor.
11. [] How is **confidentiality** of human participants to be maintained
12. [] More detail on what precautions will be taken where potential risk may be involved.
13. [] Means of **securing** questions and other applicable documentation and data is not acceptable; needs to be secured on Campus, preferably by the researching department
14. [] What is the **correct** title of protocol
15. [] There is no **anonymity** once a name is given
16. [] Include more detail on procedure section. This should contain enough detail to allow another researcher to replicate your study.
17. [] Incentive described in order to obtain subject participation is **coercive**
18. [] If the test instrument is a **copyrighted** document an approval for usage is required
19. [] **Course credit** is not considered a benefit
20. [] As a rule researchers should avoid using their own patients, students, clients, etc. As research participants; subtle coercion often occurs when a potential research participants is also one of the aforementioned; if there is good scientific rationale for using these participants the following issues should receive special consideration.
21. [] Did not complete IRB Training. Please see http://www.tnstate.edu/interior.asp?ptid=1&mid=1136 **Complete training course and submit certificate of completion.**

Corrections to Informed Consent Form

22. []	Tell participants–	Amount of time required to complete surveys
23. []	Tell participants –	Participation is voluntary
24. []	Tell participants –	Participants may refuse to answer any questions they choose or withdraw from the study at any time with no negative consequences.
25. []	Tell participants –	Any potential risks of participation. If there are none anticipated, state that.
26. []	Tell participants –	Exactly what participants will be expected to do. (eg. Fill out a survey, have blood pressure measured)
27. []	Tell participants -	Contact information. They need to know whom to contact if they have questions or concerns. Typically a phone number is given since many people who are not college related do not have email addresses. Make sure that you give them a copy of the consent form to keep.
28. []		Missing Informed Consent Document. Please submit.

Additional Comments: Item