

c. **A brief description of your proposed data analysis:**

7. **Describe in detail the research procedure related to subjects' participation; minimally, the following information must be included:**

a) **How will the subject(s) be selected and/or recruited? (Append copy of letter and/or transcript of verbal announcement).**

b) **What inducement is offered, if any?**

c) **Number and salient characteristics of subjects, i.e., age range, sex, institutional affiliation, other pertinent characterization(s).**

d) **If a cooperating institution (school, hospital, prison, etc.) is involved, prior written permission must be obtained. (Append approval letter.)**

e) **Number of times observations will be made?**

f) **What do the subject's do, or what is done to them, in the study? (You must append a copy of questionnaires or test instruments and description of procedure to be conducted on the participant.)**

g) **How is it made clear to the subject that their participation is fully voluntary?**

h) **How is it made clear to the subject that they may withdraw at any time?**

- i) How is it made clear to the subjects that they may refuse to answer any specific question that may be asked of them?
 - j) Cite your experience with this type of research. If you are a student, what is your advisor's experience?
8. How do you intend to obtain the subjects' informed consent? If in writing, attach a copy of the consent form. If not in writing, include a summary of what is said to the participant(s) and justify the reason that oral rather than written consent is being used. Also explain how you will ascertain that the subjects understand what they are agreeing to.
9. Justify:
- a. Why is human subject participation in this research necessary? (Consider if your research could be completed with secondary data.)
 - b. What will your research add to the body of scientific literature?
- 10.
- a. What are the benefits gained by the individual for participation in your project?
 - b. Do you see any chance that subjects might be harmed in any way?
 - c. Are there any physical risks?
 - d. Psychological risks? (Might a subject feel demeaned or embarrassed or worried or upset? All research has some psychological risk.)
 - e. Social? (Possible loss of status, privacy, reputation?)

11. Do you deceive them in any way? If yes, explain why deception is justified and provide information about how the participants will be debriefed about your project.
12. How do you ensure confidentiality of the information collected? (By Federal Law, you must state where and who will be responsible for maintaining your data for a period of 3 years.)
13. **STUDENT APPLICATIONS ONLY:** Has your committee reviewed and approved your proposal prior to submitting your IRB application? Yes No
14. **STUDENT APPLICATIONS ONLY:** If no, have you reviewed the approval process with your department? Yes No . If you answered no, please see your advisor or chair of your committee for their approval process.
15. Due to recent changes in the Federal Regulations, the IRB is requiring that students, faculty, and researchers obtain a certificate from a tutorial regarding research with human subjects. This may be obtained online.
- a. **Research Certification**
<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>
http://137.187.172.152/cbttng_ohrp/cbts/assurance/login.asp
<http://www.miami.edu/citireg/> (chose the demo option)
 This requires 30-40 minutes and allows you to start and stop until all sections are completed.
- b. At the recommendation of OHRP, the Board is requiring that students, faculty, and researchers read “The Belmont Report.” This may be found at <http://ohrp.osophs.dhhs.gov/educmat.htm>. Go to (1) Policy Guidance, and scroll down (2) under Guidance Materials to the link.
- c. The final recommendation for the IRB is a requirement that all students, faculty, and researchers read the ethical principals for research with human subjects from their respective disciplines.

Please sign the following, I _____ and my
 Advisor _____ have completed all three requirements as of
 this date _____.

16. As of January 16, 2003, the researcher must use a consent form that has been stamped with an approval date and expiration date. This will be mailed to you along with your approval letter. Failure to use the stamped consent form may result in suspension of data collection until the proper form is utilized. Please notify the IRB when your data collection has been completed.

Applicant's Name (type)

Faculty Advisor's Name (type)

Date

Applicant's Signature

Faculty Advisor's Signature

Date

Faculty Advisor's Telephone No.

Faculty Advisor's Fax No.

Faculty Email Address (if available)