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HUMAN SUBJECT ETHICS COMMITTEE APPROVAL

1. Who are your subjects? Briefly outline your criteria for subject selection, including information regarding the number of subjects and their anticipated ages. If your study involves the use of abnormal subjects, explain any psychological or physical characteristics they will possess.

2. How will your subjects be recruited? Describe your procedures for finding subjects and obtaining informed consent.

3. Is there a cost involved? Does consenting to be a subject lead to additional costs in tests, medical care, etc. for the subject? If so, who is responsible for the costs?

4. What are your procedures? Outline what you will do to, or require of, your subjects. Who will be your data collectors, and what training will they have or require?

5. What are the potential risks for the subject?. In your estimation, do the procedures explained above involve any potential risk for the subjects - physically, psychologically, socially, or legally? Could the type of data you are collecting from each subject possibly be construed an invasion of privacy? If any of your procedures create potential risks for any of the subjects, describe:

- Other methods, if any, that were considered and why they will not be used;
- What precautions you plan to take to reduce the possibility of such risks.

6. What deception may be in your study? If your research involves any deception on the part of your subjects, explain how it will be handled.

7. Who will benefit from this study? What is the significance of potential benefits to be gained by:

- The subjects used in this investigation;
- Persons similarly situated;
- The scientific community;
- Human kind in general.

8. How will subjects' privacy be protected? What are your procedures for safeguarding each subject's rights with respect to the following:

- Safety and security of the individual (as described in #5);
- Privacy and confidentially (including protection and anonymity of data);
- Embarrassment, discomfort, and harassment i.e., would there be any stigma or repercussions from having participated?).

A copy of the Informed Consent Form must be attached to this application (refer to "Writing an Informed Consent" and see attached sample).

This application will not be reviewed unless it is signed and dated on the front cover by both the principal investigator and faculty advisor.

Source: **Coker, AL; Sanderson, M**. *EPID 741: Epidemiologic Methods I. Course materials*. Spring 1999. University of South Carolina