COVER LETTER GUIDELINES FOR RESEARCH PROJECTS INVOLVING QUESTIONNAIRES, INTERVIEWS OR SURVEYS

Federal regulations allow for a waiver of the requirement to use a consent form in most minimal-risk research involving only questionnaires, interviews, or surveys. However, this does not rule out the need to provide complete information about the project so that subjects can make an informed decision about whether to participate. Usually this information is provided in a cover letter.

Note: For subjects (participants) under eighteen (18) years of age, documentation of informed consent will be needed even though the project involves only a questionnaire, survey, or interview. This documentation normally involves obtaining the written agreement of the minor subject and the written permission of the subject's parents/guardians.

If your project involves a cover letter, please use the following guidelines in drafting this document.

The cover letter is to be distributed prior to their interview, survey/questionnaire completion, or other involvement. **Items which should be included in the letter are:**

- identify the project as research and invite subject's participation in the project;
- identify the principal investigator (i.e., introduce yourself) and explain why you are doing the research:
- indicate the general nature of the research project and briefly detail the anticipated role of the subjects in the project;
- state that participation is voluntary and subjects' confidentiality/anonymity will be maintained;
- state that they are free to terminate their participation at any time and without prejudice;
- state that completion and return of the questionnaire/survey or participation in the interview implies their consent to participate;
- include a realistic estimate of the time required of the subjects to participate in the project;
- include a description of any anticipated risks and benefits;*
- include a description of how and when the *group*, *not individual*, results may be obtained;
- identify who may be contacted (e.g., principal investigator, faculty advisor, IRB) if subjects have any questions or concerns about the research or their rights as a research subject, and how those individuals may be contacted; and
- provide the name(s), contact address(es) and phone number(s) for the principal investigator(s) and faculty advisors (if applicable).

The letter should be printed on official letterhead and signed by the Principal Investigator (and Faculty Advisor if the PI is a student).

As part of the protocol document submitted to the IRB (section IV.), <u>you must request a waiver of the requirement to obtain a signed consent form</u> from subjects, stating as your reason that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

^{*}Typically the cover letter for an anonymous survey will state that there are no known risks and that the subject will receive no direct benefit. Non-anonymous surveys might have the risk of breach of confidentiality. Very long surveys might have the risk of fatigue.