

For these studies Principal Investigators will supply each of the items listed below for FULL or EXPEDITED REVIEW by the IRB:

1. Completed(green) IRB Protocol Cover Sheet;
2. A summary of the proposed research including;
 - a. rationale for the study
 - b. methods and procedures
 - c. description of how and where subjects will be obtained
 - d. description of how data will be handled so as to insure anonymity/confidentiality.
3. Description of potential risks to subjects;
4. Description of planned safeguards to reduce these risks;
5. Description of anticipated benefits, if any, to the subjects;
6. Statement of the ratio of risks to benefits;
7. Description of procedures to be followed in obtaining informed consent;
8. An appendix of copies of all pertinent materials, such as:
 - a. authorization(s) to access confidential information
 - b. informed consent statement (which includes P.I. address and telephone number)
 - c. scripts of statements or questions to be read to subjects
 - d. instrument(s) to be used (particularly non-standardized and/or unpublished instruments)
 - e. letters of permission from schools, corporations, organizations, etc.
 - f. letters of permission to conduct research at other institutions.
 - g. copyright approvals
 - h. IRB approval from another institution.

The Institutional Review Board may request additional information under certain circumstances.