

GUIDELINES FOR SUBMITTING PROTOCOLS TO THE INSTITUTIONAL REVIEW BOARD

When submitting protocols for IRB review and approval, Principal Investigators will use the appropriate one of the following two procedures in order to satisfy the requirements of McDaniel College Policy for the Protection of Human Subjects in Research:

A. EXEMPT REVIEW

Usually, Principal Investigators may consider their research EXEMPT from the Federal regulations governing human research if it does not require obtaining informed consent from the subjects. If you believe your project qualifies as exempt, please supply the following for IRB review and confirmation of the exempt status of your project:

1. Completed (green) IRB Protocol Cover Sheet;
2. Completed (pink) Exempt Status Checklist;
3. A one page abstract of the project including
 - a.) descriptions of where and how subjects are to be obtained, and
 - b.) how subject anonymity is to be assured;
4. Evidence of approval to gather data at site, and
5. A copy of any non-standardized and/or unpublished instrument to be used.

B. FULL or EXPEDITED REVIEW

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. Completed "Principal Investigator Statement of Assurance";
3. 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
4. Description of potential risks to subjects;
5. Description of planned safeguards to reduce these risks;
6. Description of anticipated benefits, if any, to the subjects;
7. Statement of the ratio of risks to benefits;
8. Description of procedures to be followed in obtaining informed consent;
9. 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. business address, telephone number, and email)
 - c. scripts of statement or questions to be read to subjects
 - d. instrument(s) to be used (particularly non-standardized and/or unpublished instrument(s))

- 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.