

PROTOCOL SUBMISSION CHECKLIST

The following is a protocol submission checklist to facilitate full and accurate submission of all protocols to the Institutional Review Board (IRB). The checklist outlines some valuable questions the researcher should ask when planning and submitting a protocol for approval.

Procedure

In conducting the initial standard or full board review of proposed research, the IRB must obtain information in sufficient detail to make determinations required under Federal Regulations, as described in Policy: Initial Review – Criteria for IRB Approval (See IRB Standard Operating Procedures <http://www.stjohn.org/irb>).

Materials To Be Provided to the IRB

Copies of the following documents are to be provided to the IRB Office at least two and a half (2 1/2) weeks before the next scheduled meeting (See IRB website for Meeting Schedule with submission deadline dates <http://www.stjohn.org/irb/>).

One (1) Copy of the following documents:

- A completed IRB application with a signed signature page. Please make sure all appropriate signatures are obtained.
- Proposed informed consent document(s) and/or consent script, as appropriate. No subjects may be enrolled until IRB approval of informed consent has been attained.
- Copy of relevant surveys, questionnaires, data gathering tools or videotapes that will be used in the research project.
- Subject recruitment procedures and materials (e.g. advertising, fliers, e-mail, commercial scripts, etc.).
- Any other documents that the IRB may require to fulfill its responsibilities.

Four (4) Copies of the following documents:

- A complete protocol.
- Investigator Brochure, Device Manual, or Package Insert and/or a document that specifies safety experience, and warranty information, if applicable.

The following documents should be submitted if not already on file in the IRB Office:

- CVs, dated within the last three (3) years, and initialed, for all investigators and co-investigators.
- Verification of the on-line Human Subjects Training for all members of the research team that will have access to study data. **Note:** Effective July 1, 2010, re-certification of human subjects training will be required every three (3) years. (<http://phrp.nihtraining.com/users/login.php>)
- Budget and contract information, if available and relevant.
- Any other documents that the IRB may require to fulfill its responsibilities.