

Boys Town National Research Hospital
On-site Audit of Approved Research on Human Subjects

This form is to be used by the IRB and research compliance staff for audits of IRB-approved research protocols. The purpose of these activities is to ensure the protection of human research subjects.

Dates covered by audit (MM/YY): From _____ through _____

Name and title of person(s) conducting audit:

Date Principal Investigator(s) notified:

Date audit initiated:

Location(s) for audit:

Date audit completed:

Signature of audit team leader: _____

Research Audit Tool

1. Protocol Description

Information for this Section provided by:

A) IRB Protocol #

Protocol Title:

B) Principal Investigator:

C) IRB Review Classification: Full Expedited Exempt

D) Protocol expiration date:

E) Consent/Assent Forms approved by IRB? Yes No Oral Waived

F) Survey Instrument(s) approved by IRB? Yes No N/A

G) Recruitment materials approved by IRB? Yes No N/A

H) Brochure(s) approved by IRB? Yes No N/A

I) Is this a clinical trial? Yes No

2. Consent Process (skip this section if consent/assent process oral or waived)

Auditor(s) will go to the actual place where the records are stored (i.e., Core office, the PI's lab, etc.). The auditor(s) will verify that records are stored securely (locked file cabinet in an area that can be locked). They may then take the records to be reviewed to another area and return them when the review is completed.

- A) Does the consent process follow approved protocol? Yes No (may require observation of consent process.) If no, describe difference
- B) Date of IRB approval on consent/assent/permission forms:
- C) Total number of consent/assent/permission forms audited _____ (minimum is 10% or 30, whichever is larger. If less than 30 subjects, audit all form. If there are multiple forms per subject, include all forms.)
- D) Number and percentage of audited forms that match IRB-approved materials for both content and date stamp: _____ / _____ %
- E) Number and percentage of audited forms that are signed and dated by subject: _____ / _____ %
- F) Number and percentage of audited forms that match IRB-approved materials *and* are signed and dated by subject (i.e., correct for both D and E above): _____ / _____ %
- G) Auditor's notes on consent/assent/permission process:

3. Survey Process (skip if no survey instrument used)

- A) Does survey instrument match what was approved by the IRB? Yes No
If no: describe difference:
- B) Does survey process follow approved protocol? Yes No
If no: describe difference
- C) Auditor's notes on survey process:

4. Subjects

- A) Does recruitment process follow approved protocol? Yes No
(*may require audit of dissemination methods for advertisement(s)*)
If NO, describe difference:
- B) Does advertisement(s) match IRB-approved material(s)? Yes No
(*may require audit of posters, news releases, etc.*)
If NO, describe difference
- C) Number of subjects approved for inclusion in protocol by IRB:
- D) Number of subjects enrolled in protocol:
- E) Number of subjects enrolled who match protocol inclusion criteria:

- F) Does subject enrollment meet stated protocol goals for equity of recruitment (i.e. gender, ethnicity, etc)? Yes No. If NO, describe difference
- G) Auditor's notes on recruitment:
- H) Number of subjects who received compensation, as indicated on the consent/assent form(s):
- I) Number and percentage of *compensated* subjects for whom the amount of compensation can be verified as correct (e.g., payment records, etc): . N/A-no payment
- J) Auditor's notes on compensation:

5. Data

- A) If this is a Clinical Trial, does the therapeutic regime follow the approved protocol?
Yes No N/A-not clinical trial. If NO, describe difference:
- B) If other than a Clinical Trial, do procedures for data collection follow the approved protocol?
Yes No. If NO, describe difference:
- C) Does system for data organization and storage follow approved protocol for security and subject confidentiality?
Yes No. If NO, describe issues (e.g., who has access to data, subject names & IDs, insufficient or unorganized records, etc):

6. Education of Subjects (skip if no education materials used)

- A) Does brochure(s) match IRB-approved material?
Yes No. If NO, describe difference:

7. Other

- A) Cost center:
- B) Use this space for additional comments not covered in the sections above. If referring to prior sections, please note section (or question) number.

8. Summary and Action Plan

- A) Summary:
- B) Action plan: Yes not needed. Is YES, describe:

9. Researcher acknowledgement: I have received a copy of the completed audit tool.

Signature of Researchers

Date