

“HSIRB Protocol Requirements”

To ensure an effective review by the HSIRB, a full description of the planned research must be submitted at the time of New/Initial Submission. A research protocol provides the reader with background information about the topic under study, including study rationale, a discussion of the potential importance of the research, and a detailed plan for conducting the research. The following is a “summary” of the basic elements that should be provided in the protocol (as appropriate to the research being conducted). For details, see “Protocol Requirements” on the HSIRB website: <http://www.research.buffalo.edu/rsp/irb/hsirb/default.cfm>

A. Purpose of the Study and Background

- Specific study objectives
- Background and Scientific or Scholarly Rationale
- Experimental or Study Design
- Sample size
- Identify the variables of interest and study endpoints
- Anticipated time to complete the study

B. Characteristics of the Research Population

- Gender, age range, and racial/ethnic origin of subjects
- Inclusion and Exclusion criteria
- Whether the research will involve vulnerable subjects

C. Methods and Procedures

- Recruitment and enrollment methods. Attach all advertising/recruitment materials (in their final form)
- Procedures for protecting the subject privacy interests
- Description of the research setting
- Summary of the research design and all procedures (sequentially) including any randomization procedures
- Description of the **Data & Safety and Monitoring Plan (DSMP)** *Note: all studies involving human subjects require some level of data and safety monitoring. For details see “Data & Safety Monitoring” on the HSIRB website: <http://www.research.buffalo.edu/rsp/irb/hsirb/default.cfm>*
- Data Storage and Confidentiality
- Amount and schedule of all payments/compensation
- Description of the Data Analysis



D. For FDA Regulated Research Studies

- If the study involves an investigational drug or investigational device: describe the plan for storage, control, and dispensing of the drug/device



A research protocol provides:

- *Background information about the topic under study, including study rationale*
- *Discussion of the potential importance of the research*
- *Detailed plan for conducting the research*

E. Risks and Potential Benefits of Participation in the Research

- Indicate types of risk and provisions for minimizing risk
- State potential direct benefits to the subjects, if any.
- State if there are no potential direct benefits
- State if there are potential benefits to others

F. Informed Consent Process: Consent/Permission/ Assent

- If requesting a waiver of consent or documentation of consent, provide justification for the request
- If obtaining written consent, provide a description of the process including:
 - Procedures for obtaining consent (e.g., how and where)
 - Person(s) who will **obtain** consent
 - Person who will be **providing** consent, permission, or assent
 - How consent will be documented
 - Other study-specific information
 - Attach all consent documents

(For additional details see “Informed Consent Process” on the HSIRB website: <http://www.research.buffalo.edu/rsp/irb/hsirb/default.cfm>)