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](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](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

**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](http://www.research.buffalo.edu/rsp/irb/hsirb/default.cfm)

Comments and suggestions for future “HRPP Topics” are welcome and may be submitted to: Dorothy Wright at: dswright@buffalo.edu