

# **Bronson Methodist Hospital**

## **CONTENT GUIDELINES FOR WRITING RESEARCH PROTOCOLS**

The Bronson Methodist Hospital Institutional Review Board (IRB) is primarily responsible for safeguarding the rights and welfare of human research subjects. The principal investigator (PI) must provide a complete written description of the research protocol to the IRB for review and approval prior to initiating a research project. This description must include enough information for the IRB to determine that human subjects will be adequately protected and that the research will be conducted in full compliance with federal regulations. Specifically, the IRB review addresses the following:

- Selection of subjects
- Risk to subjects
- Informed consent
- Safety of subjects during data collection
- Protection of privacy of subjects and to maintain confidentiality of data

### **SECTIONS:**

#### **Abstract**

Summary statement of the research investigation that follows a logical sequence from purpose to methods to study implications

#### **Purpose**

A statement that reflects the intent of the research investigation and addresses all pertinent variables under study

#### **Background & Significance**

##### Review of Literature

- Describe the background, including research and references that are relevant to the design and conduct of the study
- Describe preliminary or early work if new techniques or procedures are to be used
- If an FDA investigational new drug (IND) is to be used, animal data on the drug should be included. Relevant features of a Clinical Investigator's Brochure (CIB) should be highlighted, if applicable.

##### Description of conceptual framework or model if appropriate

#### **Objectives**

State the objectives of the study, and whenever possible, as hypotheses or as a research question.

## **Study Design and Methods**

### Research Design

- Describe the design/methodology

### Method of Participant Selection

- Describe participant population and participant characteristics
- Method of selection
- Number of participants and rationale for sample size
- Inclusion and exclusion criteria with justification as appropriate
- Recruitment process
- Sampling method or randomization process
- Rationale for involving special classes of subjects, such as fetuses, pregnant women, children, cognitively impaired persons, prisoners, or institutionalized, or members of vulnerable populations.

### Research procedures

- Detailed explanation describing the process of how the study will be conducted, including procedures, frequency, timeframes.
- Indicate the differences between experiment and control treatment protocol if applicable.
- Description of data collection procedures including when and how each instrument will be administered. If the medical record is the data source, provide description of retrieval plan
- Brief description of measurement tools. Note reliability and validity measures if applicable.

### **Analysis of the Study**

- Delineate the outcomes to be measured and analyzed (variable to be tested)
- Describe how the results will be measured, statistically analyzed, and level of significance

### **Risks & Benefits**

#### Benefits

- Describe the potential benefits to subjects or to others that may reasonably be expected from the research.
- Describe the rationale for and the amount of any proposed compensation

#### Risks

- Describe any potential risks (physical, psychological, social, legal or other) and assess their likelihood and seriousness.
- Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.
- Describe the procedures for protecting against or minimizing any potential risks, such a violations of confidentiality, and assess their likely effectiveness.
- Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects

#### Evaluation of benefits and Risks

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be expected to result

### **Adverse Event Reporting and Data Monitoring**

- Provide a plan for reporting adverse events to the IRB
- Describe the provisions for monitoring the data collected to ensure the safety of subjects

### **Collection and Storage of Human Specimens or Data**

- Describe the intended use of the data/samples
- Describe how the data/samples will be stored and tracked
- Describe what will happen to the samples/data at the completion of the study

### **Informed Consent and Assent**

- Informed Consent - Describe the consent procedures to be followed, including the circumstances in which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent (Refer to the Bronson application packet which contains the Bronson IRB approved Informed Consent template). The proposed consent document must be attached. It should be written in the second person and understandable to someone who has not completed high school.
- Assent - Children are generally not legally empowered to give consent, but depending on their age, they may have the ability to give assent ("assent" means a child's affirmative agreement to participate in research). Every protocol involving children (those individuals under age 21) should include a discussion of how assent will be obtained for the particular study.

### **Reference List**

#### **Appendices**

- All recruitment materials or other correspondence with participants
- All instruments used for data collection
- Informed Consent
- Assent if applicable
- Copy of another institutions IRB approval is appropriate

### **PROTOCOL SUBMISSION TO THE IRB**

Bronson IRB application forms and instructions are available on the Bronson Web Page, <http://www.bronsonhealth.com/ForHealthProfessionals/LibraryAndResearch/page3203.html> or by contacting Bronson Research Services at 341-7898.

Reference:

National Institute of Health, "Guidelines for Writing Research protocols"  
<http://www.nihtraining.com/ohrsite/info/sheet5.html>