

**OUTLINE OF PROTOCOL FOR RESEARCH INVOLVING HUMAN SUBJECTS
GRIFFIN HOSPITAL**

I. Face sheet with COI

II. DESCRIPTION OF STUDY:

- A. Purpose:
- B. Background:
- C. Specific Location(s) of Study:
- D. Probable Duration of Study:
- E. Research Plan (include sampling method, sample size, research design, etc.)
- F. Economic Considerations (payments to study subjects, protection for added costs):
- G. Data and Safety Monitoring (if applicable)
- H. References

III. HUMAN SUBJECTS INFORMATION:

- A. Subject Population:
- B. Risks:
- C. Consent Procedures:
- D. Protection of Subjects:
- E. Potential Benefits:
- F. Risk/Benefit Ratio of Study
- G. Study Budget

July 9, 2004