



**Institutional Review Board  
Initial Protocol Review Form**

Principal Investigator: \_\_\_\_\_

Signature: \_\_\_\_\_

Address: \_\_\_\_\_

Co-Investigators: \_\_\_\_\_

Protocol Title: \_\_\_\_\_

Source of Support: \_\_\_\_\_

Proposed Start Date: \_\_\_\_\_

Estimated End Date: \_\_\_\_\_

Approved By: \_\_\_\_\_

If your project has been/will be submitted to another Institutional Review Board, list name here:

\_\_\_\_\_

Status:  submitted     accepted.

Date: \_\_\_\_\_

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**Provide a brief description of study in lay language. Limit to space provided.  
Purpose and background:**

\_\_\_\_\_

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**Subjects, number, gender, source, and selection method: (circle if any subjects are classified as minors, prisoners, pregnant women, abortuses, mentally disabled, students > 18, non-English speaking)**

\_\_\_\_\_

**Inclusion/Exclusion criteria of subjects:**

\_\_\_\_\_

**Methods and Measures:**

\_\_\_\_\_

**Specify clearly the expected outcomes:**

\_\_\_\_\_

**Anticipated benefits to subjects:**

\_\_\_\_\_

**Describe risks and side effects (physical, psychological, or social) and precautions to minimize risk:**

\_\_\_\_\_

**Describe consent process, assurance of confidentiality, and any cost/remuneration to subjects:**

\_\_\_\_\_

**Principal Investigator Statement of Assurance:**

The proposed investigation involves the use of human subjects. I am submitting this form with a description of my project prepared in accordance with the MCN Institutional Review Board policies for the protection of human subjects participating in research. I certify that I have read

the summary of the Belmont Report. I understand IRB policies concerning research involving human subjects and agree to:

- a. obtain voluntary and knowing informed consent of subjects capable of providing consent who are requested to participate in this project;
- b. report to the IRB any unanticipated effects on subjects which become apparent during the course or as a result of experimentation and the actions taken as a result;
- c. cooperate with the IRB with the continuing review of this project;
- d. obtain prior approval from the IRB before amending or altering the scope of the project of implementing changes in approved consent form;
- e. maintain documentation of consent form and progress reports as required by institutional and federal policies;
- f. accept the responsibility for the conduct of this research and the supervision of human subjects as required by law;
- g. not profit economically and that I do not own a/any company or other commercial enterprise, wholly or in part, that will profit economically, directly or indirectly, from the execution of this study and/or the publication of its results.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Co-Principal Investigator

\_\_\_\_\_  
Date

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**IRB Protocol Checklist: (attach a copy of each item)**

**Description of study in lay language**

**Copy of consent form in subjects' primary language**

**Protocols with minors as participants, if applicable**

**Principal Investigator Statement of Assurance**

[Click Here To Submit Your Protocol Submission](#)

**Addendum:**

**Guidelines for Informed Consent with Checklist**

**Protocols with Minors as Participants**

**Form for Drugs, Devices, or other active agents**

**Summary of the Belmont Report / Helsinki Declaration**