

# 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: \_\_\_

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

 \_\_\_\_

**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:

1. obtain voluntary and knowing informed consent of subjects capable of providing consent who are requested to participate in this project;
2. 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;
3. cooperate with the IRB with the continuing review of this project;
4. obtain prior approval from the IRB before amending or altering the scope of the project of implementing changes in approved consent form;
5. maintain documentation of consent form and progress reports as required by institutional and federal policies;
6. accept the responsibility for the conduct of this research and the supervision of human subjects as required by law;
7. 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

# 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**

**Submit all completed forms to** **mcnirbcontact@migrantclinician.org** **with a subject name to include “IRB”**

**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**