Migrant Clinicians Network

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 (circle): 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:

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

IRB Protocol Checklist: (attach 6 copies 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

Mail to: ***Migrant Clinicians Network***
P. O. Box 164285
Austin, TX 78716

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