Protocol Amendment Request Form

INSTITUTIONAL REVIEW BOARD
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THE CLINICIANS' NETWORK FOR MIGRATION HEALTH

Changes to approved research may not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants.

Examples of changes requiring IRB review include but are not limited to changes in: investigators or research team members, purpose/ scope of research, recruitment procedures, compensation strategy, research setting, interventions involving participants, data collection procedures, or surveys, measures or other data forms.

Protocol Information

Protocol # _____ Title _____

Review Category: ☐ Exempt ☐ Expedited ☐ Full Board

Principal Investigator _____

Email Address _____

Department _____

Co-Investigator _____

Email Address _____

Department _____

Principal Investigator Signature, Date _____

In lieu of a written signature, submission via the Principal Investigator's email constitutes an acceptable electronic signature.

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Protocol Amendment Request Form

Description of Proposed Changes

1. Date of proposed implementation of change(s)* _____

**Cannot be implemented prior to IRB approval unless the IRB Chair has determined that the change is necessary to eliminate apparent immediate hazards to participants.*

2. Describe proposed change(s), including justification _____

3. Will the change involve a change in principal or co-investigator?

☐ No – Skip to Question 4

☐ Yes:

- Include an Investigator's Assurance (last page of protocol form), signed by the new PI or co-investigator
- Conflict of Interest disclosure. Does any investigator responsible for the design, conduct or reporting of the project (including their immediate family members) have a financial, personal or political interest that may conflict with their responsibility for protecting human participants in the research?

☐ No – As PI, I attest that I have conferred with my co-investigators and key personnel and confirmed that no financial, personal or political interests currently exist related to this research.

☐ Yes – Describe the related financial, personal or political interest, and *attach documentation of COI disclosure and review* (as applicable).

Financial, personal or political interests related to the research (the sponsor, product or service being tested, or a competing product or service) may include:

- Compensation (e.g., salary, payment for services, consulting fees)
- Intellectual property rights or equity interests
- Board memberships or executive positions
- Enrollment or recruitment bonus payments

Note: If the change is limited to addition/change in research team members, skip the rest of this form.

4. Will the change(s) increase any risks, or present new risks *(physical, economic, psychological, or sociological)* to participants?

☐ No ☐ Yes: *In the appropriate section of the protocol form, describe new or altered risks and how they will be minimized.*

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Protocol Amendment Request Form

5. Does the proposed change involve the addition of a vulnerable group of participants?
Children: ☐ No ☐ Yes – include the *Children in Research* attachment form
Prisoners: ☐ No ☐ Yes – include the *Prisoners in Research* attachment form
Cognitively impaired individuals: ☐ No ☐ Yes*
Economically or educationally disadvantaged individuals: ☐ No ☐ Yes*
**Provide additional information where applicable in the revised protocol form.*

6. Does the proposed change involve a request to waive some or all the elements of informed consent or documentation of consent?
☐ No ☐ Yes – attach the *Informed Consent Waiver or Alteration Request*

7. Does the proposed change involve a new research site?
☐ No ☐ Yes

If the information in your previously approved protocol has changed, or additional information is being added, incorporate the changes into relevant section(s) of the protocol. Highlight (e.g., print and highlight the hard copy, or indicate changes using all caps, asterisks, etc.) the changed section(s) and attach a copy of the revised protocol to this form. *(If the changes are limited to addition/change in research team members, a revised protocol form is not needed.)*

Impact for Participants (future, current, or prior)

1. Will the change(s) alter information on previously approved versions of the recruitment materials, informed consent, or other documents, or require new documents?
☐ No ☐ Yes - attach revised/new document(s)

2. Could the change(s) affect the willingness of *currently* enrolled participants to continue in the research?
☐ No ☐ Yes - describe procedures that will be used to inform current participants, and re-consent, if necessary:

3. Will the change(s) have any impact to *previously* enrolled participants?
☐ No ☐ Yes - describe impact, and any procedures that will be taken to protect the rights and welfare of participants:

----- FOR IRB OFFICE USE ONLY -----

Request is: ☐ **Approved** ☐ **Not Approved**
Review: ☐ **Exempt, category#** _____ ☐ **Expedited method, category #** _____ ☐ **Convened meeting, date** _____
☐ **Expedited review of minor change**
IRB Signature _____ **Date** _____
Comments: