# Investigator Review

**INVESTIGATOR CONTACT INFORMATION**.

| | |
|---|---|
| Name: | |
| Direct telephone number: | |
| Name of research site: | |
| Site address: | |

**EXPERIENCE AND TRAINING** *It is the Investigator's responsibility to ensure that all research staff assisting in the conduct of this research are informed about their obligations in meeting the requirements of 21 CFR Parts 50, 56 and 45 CFR 46, and have the training and education to follow the requirements. Please, answer each question below.*

| | Yes | No |
|---|---|---|
| Has the Principal Investigator successfully completed human subjects protection training? | | |
| Are any other members of the Principal Investigator staff trained in human subject protections? | | |
| Please describe any experience or training which will aid the PI in the conduct of the study. | | |
| How many years has the PI been conducting research? | | |

**REGULATORY INSPECTIONS**

| | Yes | No |
|---|---|---|
| Are there any pending or active legal, regulatory, or professional actions or restrictions related to the practice of medicine or research at the site? | | |
| Has the Principal Investigator or any members of the research staff been disciplined or restricted by the FDA, DHHS or other regulatory agencies? | | |
| Has the Principal Investigator been subject to a FDA, DHHS or other regulatory agency inspection within the past 2 years? | | |
| Has the Principal Investigator been debarred by the FDA, DHHS or other regulatory agency? | | |
| Is there any pending disciplinary action against the PI from ANY state licensing Board? | | |

**CERTIFICATION STATEMENT**

By making this application, I certify that I have read and understand Heartland Institutional Review Board's policies and procedures governing human subjects research. I agree to comply with the letter and spirit of those policies. I acknowledge my obligations include:

1. Accept responsibility for the research described, including work by others under my direction.

2. Obtain written approval from Heartland Institutional Review Board of any changes from the originally approved protocol **BEFORE** implementing those changes.

3. Retain signed consent forms in a secure location separate from the data for at least three years after research ends.

4. Immediately report adverse effects on the subjects to Heartland Institutional Review Board.

5. Reviewing the protocol/study plan in its entirety, and conducting research according to the protocol/study plan approved by HIRB. Ensuring that all research staff complies with the requirements of the protocol/study plan, and for reporting all incidences of non-compliance to HIRB.

6. Ensuring adequate and reliable financial and/or other resources are available to conduct the research and halt research procedures should any of these resources become unavailable.

7. Ensuring that all research staff assisting in the conduct of the research are informed about their obligations in meeting the requirements of 45 CFR 46 and/or 21 CFR Parts 50, 56 (if applicable) and have the training and education to follow the requirements. Ensuring consideration of all applicable federal regulations, local and/or state laws pertinent to the research site, and consideration of community attitudes in terms of religious, ethnic, or economic status of the community from which research subjects will be drawn, relative to the research at my site.

8. Ensuring that no member of the study staff has an actual or perceived Conflict of Interest with the study, and if such a conflict is present, it will be managed so as to not interfere with the progression of the study and/or data collection.

9. Providing a copy of the HIRB-approved Informed Consent Document (if applicable) to research participants at the time of consent, and for not enrolling any individual into this research study until voluntary consent has been appropriately obtained and documented (if applicable). Ensuring that each potential subject is provided with the information needed to understand the nature and potential risks of the research, and for taking necessary steps for the individual to gain that comprehension.

10. Ensuring that no individual is recruited into this research: (a) until the study has been approved in writing by HIRB; (b) during any period wherein HIRB approval of this research study has lapsed; (c) during any period wherein HIRB approval of the research or participant enrollment has been suspended, or wherein the sponsor has suspended research study enrollment; (d) following termination of HIRB approval of the research; or (e) following expiration of the approval period as established by HIRB.

11. Promptly assessing and reporting all unanticipated problems and safety reports that require reporting to the IRB within the required timeframe, and ensuring that participants who have suffered an unanticipated problem or adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the event to the extent possible. Arranging for the treatment of a research related injury, whether psychological or physical, with the Sponsor.

12. Promptly reporting all proposed changes in previously approved research to HIRB. Making no changes in approved research except when necessary to eliminate an apparent immediate hazard to research participants, and for promptly reporting to HIRB any non-adherence to the currently approved research protocol/study plan. Making no changes to the information provided to research potential or active participants, such as study material in electronic or print format.

Promptly reporting any changes in the Principal Investigator's address or other contact information and seeking approval for an additional research facility prior to initiation. Promptly reporting any changes to the Financial Disclosure/Conflict of Interest information that was initially disclosed; or occurrences of undue influence.

13. Ensuring that research participants are kept fully informed of any new information that may affect their willingness to continue participation in the research. For responding appropriately and adequately to all inquiries, complaints, or concerns from research participants and reporting any concerns that affect the safety, rights, or welfare of the participant. Promptly reporting any changes to the participant population, or in the vulnerability of participants.

14. Keeping adequate, current, and accurate records of research data, outcomes, and unanticipated problems to permit an ongoing assessment of the risks/benefit ratio. Storing this information in a secure and confidential manner such as a password protected database, or locked filing cabinet to which direct access is controlled and/or monitored. Maintaining each participant's information in such a way as to protect the privacy of the individual and the confidentiality of the data.

15. Seeking timely review and approval for continuing the research in accordance with 45 CFR 46.109(e) and/or 21 CFR 56.109(f) (if applicable), prior to the expiration date to avoid, suspension and/or termination of the research. Notifying HIRB upon completion of the research and promptly submitting a Final Report prior to the expiration date of the approval period. Responding promptly to all requests for information or materials from HIRB Board Members or Staff.

16. I understand that **Finder's fees** (referral fees) provided by the PI/Sponsor to research staff or other Physicians for potential participant referrals are not allowed by HIRB. HIRB will allow the Sponsor or Investigator to pay a referral fee to a research participant for referring another research participant and some stipulations will apply. I further understand that **Recruitment bonuses** (payments from the Sponsor to an Investigator or organization designed to accelerate recruitment based on the rate or timing of participant enrollment) should be disclosed to HIRB and will be considered by HIRB on a case-by-case basis.

Project Title:_____

RESEARCHER'S ASSURANCE: My signature certifies that I am knowledgeable about the regulations and policies governing human subjects research. I am aware of my obligations stated above and will be available to supervise the research. When necessary, I will arrange for another properly trained researcher to assume responsibility during my absence. I will advise the Heartland Institutional Review Board formally in writing of such arrangements**.**

_____

Researcher or Principal Investigator signature Date

_____

Please, print or type name on this line.

**CONFLICT OF INTEREST:**

Directions: This checklist serves to assist HIRB and the research in identifying any potential conflict of interest. Read each item below and indicate with an "X" in the appropriate box your answer. If you answer "YES" to any of the questions below, please explain how the Conflict of Interest will be managed to not adversely affect the protection of participants or the integrity of the research. Upon completion of the questions, review the paragraph at the end of this form. Print your name, then sign and date this form.

| | | |
|---|---|---|
| Do any investigators in this research now have, or expect to have during the term of the project, any financial interest in a business entity that could reasonably be expected to bias the activities described in this application, or that could create a perception of bias on the part of the investigators? | Yes | No |
| If yes, explain: | | |
| Do you have a financial arrangement with the Sponsor funding this research, whereby the value of compensation could be influenced by the outcome of the study? This includes compensation that could be greater for a favorable clinical result, compensation in the form of an equity interest in the Sponsor funding this research or compensation tied to sales of the investigational product tested in the above study such as a royalty interest? | Yes | No |
| If yes, explain: | | |
| Do you have a proprietary interest in the investigational product tested such as patent rights or rights under a patent, trademark, copyright or licensing agreement? | Yes | No |
| If yes, explain: | | |
| Do you have a significant equity interest with the Sponsor funding this research or in the product or service being tested such as an ownership interest, stock options or any other financial interest whose value cannot be readily determined through reference to public prices, or any equity interest with the Sponsor funding this research (if publicly traded) exceeding $10,000, or more than 5% ownership (or any combination of these), in the sponsoring company or business entity? | Yes | No |
| If yes, explain: | | |
| Have you received payments from the Sponsor funding this research or payments related to the product or service being tested in excess of $10,000, when aggregated for immediate family members, exclusive of the costs of conducting the clinical studies, such as honoraria, a grant or grants to fund ongoing research, compensation in the form of equipment, or retainers for ongoing consultation? | Yes | No |
| If yes, explain: | | |

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| Have you accepted payment arrangements from the Sponsor such as financial incentives for early enrollment or high enrollment, i.e., recruitment bonus incentive? | Yes | No |
| If yes, explain: | | |
| Do you have any Board or executive relationship to the Sponsor or the product or service being tested, regardless of the compensation? | Yes | No |
| If yes, explain: | | |
| Does any of the research staff or their immediate family members have financial or other Conflict of Interest with the Sponsor/protocol, as listed above? *HIRB defines Research Staff as anyone designated by the Principal Investigator to perform research-related procedures per the protocol, such as sub-investigators, research coordinators.* | Yes | No |
| If yes, explain: | | |

***I certify that the above information is true and correct to the best of my knowledge. Further, I understand that I am responsible for notifying Heartland Institutional Review Board formally in writing of any change in my status or the research staff's status as declared on this document.***

_____
Printed Name of Principal Investigator/Researcher

_____ _____
Signature of Principal Investigator/Researcher Date

**ATTACHMENTS:**

The following documents must be included with this submission:

1) Any applicable, current professional license held by the Principal Investigator.
2) The Principal Investigator's current Curriculum Vita or resumé.