Terms of IRB Oversight

Protocol Name/Number	

1. The information provided in this and other application(s)/ reports to Pearl IRB is complete and correct.
2. The Principal Investigator (PI) and his/her research staff are familiar with federal, state and local laws having impact on research, Good Clinical Practices, and must comply with all federal, state and local regulations regarding the conduct of research in addition to Pearl IRB's requirements as outlined here.
3. The PI and any personnel under the PI's supervision will complete training in Good Clinical Practices /human subject protections before engaging in any research study procedures including the informed consent process. The PI must provide time for prospective subjects to read an informed consent document, and must ensure that all information within an informed consent document will also be orally explained to all prospective subjects before obtaining their signature. Prospective subjects must be given the opportunity to ask questions and have them answered, and be able to take the consent document home to consider with family / friends / personal physician. The PI must develop and use a process to determine whether the subject (or legally authorized representative) has an understanding of what was explained about the research during the informed consent process. The PI must ensure that all subjects provide (voluntary and fully informed) consent prior to participating in any research activities.
4. The PI must use measures to protect vulnerable populations, including any patient for which the PI is also the Primary Care Provider.
5. The PI will delegate research responsibilities only to those individuals appropriately qualified and trained to perform those delegated responsibilities.
6. The PI will ensure that procedures required only for research (as opposed to treatment) purposes will not be performed prior to obtaining informed consent for the research study.
7. The PI will ensure that all research-related personal interactions will occur in a private setting, and that all information from subjects will be collected in such setting.
8. The PI will collect from subjects only information necessary for the research.
9. The PI authorizes release of IRB review documentation and correspondence to the sponsor and / or any designated agent of the sponsor, if requested.
10. The PI will maintain records of research according to federal and state regulations and guidelines.
11. Any study drug(s)/device(s) (including placebo, approved drugs or approved comparators) will be stored in a secure area with access limited to authorized research personnel.
12. Administrative, technical and physical safeguards must be in place to protect the privacy of protected health information. All study records must be physically/technologically secured with access limited to authorized research personnel (e.g., separated from subjects' medical records, locked area, firewall, strong passwords, etc.), and must be available for inspection by the IRB.
13. Approved research is subject to continuing review by the IRB. The PI will submit continuing review reports to Pearl IRB by the due date requested.

14. If a location where research will be conducted includes a nursing home/care facility, school or any facility where the subject may be a resident or student, the PI must have a written agreement in place with an authorized representative of the facility to permit the conduct of research at the facility.
15. Correspondence and notifications from Pearl IRB may be generated in electronic form. You will receive hard copy (printouts) of such electronic documents. The PI will treat all such printouts as originals.
16. The PI is accountable and accepts responsibility for the veracity and security of information submitted to Pearl IRB.
17. The PI must allow Pearl IRB staff or a third party to inspect the clinical site and observe the consent process, if requested.
18. The researcher or contract research organization must provide an attestation or other written statement that service contracts (e.g. work orders, or master agreements) with sponsors, contract research organizations or other funding agreements:
    A. Obligate the sponsor to promptly (no longer than within 30 days) report to the organization any findings that could:
        - Affect the safety of participants.
        - Influence the conduct of the study or alter the IRB's approval to continue the study.
    B. Obligate the sponsor to promptly (not more than 30 days) report any findings of study monitors that could affect the safety of participants or influence the conduct of the study to the investigator or organization conducting the research.
        - Investigator or the organization conducting the research is required to promptly (no longer than within 30 days) forward this information to the IRB.
    C. Obligate the sponsor to notify the investigator or organization conducting the research of any study results after the study has ended that could directly affect participant safety.
        - Specify a time frame after closure of the study during which the Sponsor will communicate such findings (e.g., two years). This should be based on the appropriate timeframe for each individual study.
        - Investigators or the organization conducting the research are required to forward this information to the IRB.
    D. Describe the steps followed to communicate findings from a closed research study to the researcher or organization when those findings directly affect participant safety.
        - Specify a time frame after closure of the study during which the sponsor will communicate such findings (e.g., two years). Alternatively, the time frame may be left open ended or the requirement can be included or referred to in a survivor clause.
    E. Indicate who will provide care and who is responsible to pay for it.
    F. Obligate the sponsor to send routine and urgent data and safety monitoring reports to the investigator or organization conducting the research.
    G. Specify the time frame for providing routine and urgent data and safety monitoring reports to the organization conducting the research.
        - Investigator or the organization conducting the research are required to forward this information to the IRB.

19. The researcher provides evidence of his or her qualifications through up-to-date curriculum vitae or other relevant documentation requested by the sponsor, the IRB, or the regulatory authority (when following ICH-GCP (E6)).
20. The consent document's disclosing provisions for medical care, or other care or services for research-related injury, are consistent with provisions in the contract or funding agreement.

The Principal Investigator will conduct research according to the terms presented above: ☐ **Agreed** ☐ **Not Agreed**

Protocol Commitments

1. The Principal Investigator (PI) has sufficient time and an adequate number of qualified study personnel to properly and safely conduct and complete this research study within the period defined by the protocol and sponsor.
2. The Principal Investigator (PI) is familiar with the appropriate use of the investigational product, as described in the protocol, in the current investigator brochure, in the product information, and in information sources provided by the sponsor.
3. The PI will ensure that each member of the study staff will be adequately informed about this research study and its requirements before participating in study conduct.
4. The PI will not initiate this research study until s/he has received final written approval documentation from Pearl IRB.
5. The PI will seek and obtain prior written approval from Pearl IRB for any changes to this research study (except where necessary to eliminate immediate hazard to the subjects). This includes changes in procedures, study staff, payments to subjects and addition of research locations.
6. The PI and study staff are qualified to use equipment available, including any acquired, to address potential research risks.
7. The PI must report any unexpected and related adverse events involving the research subjects to Pearl IRB within 5 working days.
8. The PI must report any protocol deviations or exceptions that involve the consent process or subjects' safety, and any unanticipated problems to subjects or others identified during the course of this research to Pearl IRB within 5 working days.
9. The PI will comply with all other Pearl IRB requests to report, within 10 working days, on the status of this research study.
10. The PI must notify Pearl IRB immediately if a subject participating in this research study becomes incarcerated.
11. The PI will submit new recruitment material or changes to previously approved recruitment material to Pearl IRB prior to use. Audio visual ads should be submitted in final form after receiving IRB approval for the written script.
12. Any payments to subjects must be provided no later than the end of each subject's participation in the study. Pearl IRB does not allow payment to be withheld until all

enrolled subjects complete their participation. Pearl IRB also does not allow payment to be withheld until the research site's receipt of payment from the sponsor/CRO.

13. If the PI plans to utilize a "finder's fee" in recruitment efforts, the PI will notify Pearl IRB. If the PI/site plans to participate in any sponsor/CRO arranged incentive/bonus program for subject enrollment/retention, the PI will notify Pearl IRB.

I agree and confirm that I will comply with all of the above terms and commitments: ☐ **Agreed** ☐ **Not Agreed**

Signature of Principal Investigator

_____ Date: _____

Printed name of Principal Investigator (including middle initial and highest earned degree)

_____

_____