LIBERTY IRB, Inc.
A CENTRAL INDEPENDENT REVIEW BOARD

Full Accreditation

Investigator Declaration

On behalf of myself and all my sub-investigators, and under penalty of law:

1. I acknowledge that I have thoroughly reviewed the information provided on this report form and agree that the information provided is true and accurate.
2. I acknowledge that I have thoroughly reviewed and am familiar with the appropriate use of the investigational product(s), as described in the protocol, in the current investigational brochure (if applicable), in the product information (if applicable) and in other information sources provided by the sponsor.
3. I agree to promptly report all changes in research activities and unanticipated problems involving risks to human subjects or others. This includes providing written reports to the sponsor, the IRB, and, where applicable, the organization on any changes significantly affecting the conduct of the clinical trial or increasing the risk to participants.
4. I agree to promptly report to the IRB the premature completion of a study. If I terminate or suspend a clinical trial without prior agreement of the sponsor, I will inform Liberty IRB and the sponsor. If the IRB terminates or suspends approval of the clinical trial, I will promptly notify the sponsor.
5. I agree that I will not make any changes in the research without prior approval from Liberty IRB, unless the change is necessary to reduce the immediate risk to the subject.
6. I understand that under federal regulation, I am fully responsible for the conduct of all study personnel under my supervision.
7. I agree to personally supervise the conduct of this research trial.
8. I understand that it is my responsibility to see that each research subject has been given an oral explanation of the informed consent, and has been provided the opportunity to ask questions, PRIOR to obtaining their signature on the consent document.
9. I agree to report all serious adverse events (SAEs) to the sponsor except for those SAEs that the protocol or other document (e.g., investigator's brochure) identifies as not needing immediate reporting. I will follow regulatory requirements related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and to the IRB.
10. I agree to report to Liberty IRB within 5 business days of becoming aware:
    - All unanticipated problems or other unanticipated information involving risks to participants or others;
    - Internal adverse events which are unexpected and related to the research;
    - External adverse events which are unanticipated problems involving risks to participants and others;
    - Changes made to the research without prior IRB approval in order to eliminate apparent immediate harm;

- Allegation or finding of non-compliance;
- Major protocol deviations or violations that might affect the rights, safety, and welfare of subjects; and
- Unanticipated adverse device effects;
- New information that may affect adversely the safety of participants or the conduct of the clinical trial

- Any changes significantly affecting the conduct of the clinical trial or increasing the risks to participants.

11. I acknowledge that I am familiar with and understand my responsibilities as an investigator as they pertain to Liberty IRB and the Code of Federal Regulations 21 CFR 50 and 21 CFR 56.

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Principal Investigator Signature Date

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Printed Name of Principal Investigator