

## Statement of Investigator Compliance

If the Borgess Medical Center Institutional Review Board approves this project, I agree:

- √ That the information contained in this IRB submission and all attachments are true and correct;
- √ To execute the research plan as described in this submission, including obtaining informed consent from all subjects as deemed appropriate by the IRB;
- √ Not to implement any changes in the protocol until such changes have been approved by the Borgess IRB;
- √ To submit all recruitment materials for IRB approval prior to use;
- √ To report within 3-5 business days (of occurrence or notification by sponsor) to the IRB any problems which arise in connection with human subjects including any serious and unexpected adverse events;
- √ To submit Continuation Review Applications at least annually;
- √ To notify the IRB when the study has closed;
- √ To maintain records of research, including informed consent documents, for a minimum of six (6) years beyond the termination of the study or, if longer, as specified by the funding agency/sponsor of the project;
- √ To report to sponsors and agencies as required;
- √ To comply with all Federal, State regulations, and Institutional policies and guidelines governing this research;
- √ To cooperate with the IRB;
- √ To personally conduct or supervise the described investigation(s); and
- √ To ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments

There may be random audits of research protocols by Borgess Research Institute and/or the IRB.

Failure to comply with any of the above requirements may result in CLOSURE OF THE STUDY by the IRB.

I certify that I have received approval to conduct this research from all persons named as collaborators and from officials of the project sites. I hereby assure compliance to the above and take full responsibility for all activities and investigators involved in this project.

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**Principal Investigator's Signature**

\_\_\_\_\_  
**Date**

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**Principal Investigator's Printed Name**