PRINCIPAL INVESTIGATOR'S ATTESTATION

GRIFFIN HOSPITAL INSTITUTIONAL REVIEW BOARD IRB # _____

1. I agree to conduct the study(ies) in accordance with the relevant, current IRB approved protocol(s) and will only make changes to a protocol after notifying the sponsor and IRB Chairperson, except when immediately necessary to protect the safety, rights, or welfare of subjects.

2. I agree to personally conduct or supervise the described investigator(s).

3. I agree to inform any patients, or any persons used as controls, that the drugs, products, or procedures are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and IRB review and approval in 21 CFR Part 56 are met.

4. I agree to report to the sponsor and the IRB Chairperson adverse experiences that occur in the course of the investigation(s) in accordance with 21CFR 312.64.

5. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of any drug utilized in the project's protocol.

6. I agree to ensure that all associates, colleagues, staff, and employees assisting in the conduct of the study(ies) are informed about their obligations to meet the above commitments.

7. I agree to maintain complete and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection by the IRB Chairperson and in accordance with 21 CFR 312.68.

8. I will ensure that the Griffin Hospital IRB will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated occurrences involving risks to human subjects or others. Additionally, I will not make any changes to the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

9. I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312, or as might be established as part of the approval process by the Griffin Hospital IRB.

P.I. NAME: (PLEASE PRINT)_____

P.I. SIGNATURE_____DATE:_____

2016-07-07