Institutional Review Board Office
Augusta University
1120 15th St., CJ-2103
Augusta GA 30912-7621
Email: IRB@augusta.edu
Phone: 706-721-3110
http://www.augusta.edu/research/irboffice/

DATE:	February 8, 2017
TO:	Gyanendra Sharma
FROM:	Augusta University (AU) Committee A
PROJECT TITLE:	[1016768-1] Impact of Anticoagulation on Resolution of Left Atrial and Left Atrial Appendage Thrombi
REFERENCE #:	
SUBMISSION TYPE:	New Project
ACTION:	APPROVED
APPROVAL DATE:	February 8, 2017
EXPIRATION DATE:	February 7, 2018
REVIEW TYPE:	Expedited Review
REVIEW CATEGORY:	Expedited review category # *5*

5- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Thank you for your submission of New Project materials for this project. The Augusta University (AU) Committee A has APPROVED your submission. This approval is based on an appropriate risk/benefit ratio and a project design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

This submission has received Expedited Review based on applicable federal regulations.

This project has been determined to be a Minimal Risk project. Based on the risks, this project requires continuing review by this committee on an annual basis. Please use the appropriate forms for this procedure. Your documentation for continuing review must be received with sufficient time for review and continued approval before the expiration date of February 7, 2018.

The approval includes the following documents:

- Augusta - Core Data Form - Augusta - Core Data Form (UPDATED: 02/3/2017)
- Conflict of Interest - Other - Attestation - COI.pdf (UPDATED: 01/30/2017)
- Consent Waiver - Waiver of consent.docx (UPDATED: 01/30/2017)
- Data Collection - Data Extraction - MRN-Study ID.xlsx (UPDATED: 01/30/2017)
- Data Collection - Data Extraction - Core 1.28.17.xlsx (UPDATED: 01/30/2017)
- HIPAA Waiver - Waiver of HIPAA Authorization Form.docx (UPDATED: 01/30/2017)
- Other - Attestation- Research Data Storage.pdf (UPDATED: 01/30/2017)

- Protocol - Protocol template 1.28.17.docx (UPDATED: 01/30/2017)

The IRB also grants approval for the use of electronic medical record data mining tools.

Please note that based upon your submission, the following special scenario(s) have been reviewed and approved by the IRB Committee.

A. Waiver of Consent 45 CFR 46.117 (Chart Review)

1. The research involves no more than minimal risks to subjects.
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

B. Waiver of HIPAA Authorization 45 CFR 164.512(i)(2) (Chart Review)

Waiver of HIPAA Authorization is granted based on the following criteria:

1. The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge may reasonably be expected to result from the research.
2. There is an adequate plan to protect the identifiers from improper use and disclosure.
3. There is an adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research unless there is a health or research justification for retaining the identifiers, or such retention is required by law.
4. There are adequate written assurances that the protected health information will not be reused or disclosed to any other entity or person except as required by law, for authorized oversight of the research project, or for other research for which the use of disclosure of the protected information will be permitted.

All Principal Investigators must comply with the following:

- Conduct the research in accordance with the protocol, applicable laws and regulations, and principles and research ethics as set forth in the Belmont Report.
- Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential participant sufficient opportunity to consider whether or not to participate.
    - Use only the most current approved consent form bearing the Augusta University IRB stamp.
    - Provide non-English speaking subjects with a certified translation of the approved consent form in the subject's first language. The translation must be approved by the IRB unless other arrangements have been made and approved by the IRB.
    - Obtain approval from the IRB for use of recruitment materials and other materials provided to subjects.
- Obtain approval from the IRB for changes/modification in research.
- Report all reportable events to the IRB within **5 days**, per IRB Policy: "Reportable Events."
- Ensure all applicable ancillary approvals are obtained **prior to initiating the study.** This includes:
    - Medical Center approval if Medical Center resources are used
    - Biosafety Approval, if applicable
    - Radiation Safety Approval, if applicable

- Chemical Safety Approval, if applicable

For information regarding records retentions, please visit:

- Augusta University IRB Policy: Records Retention located on the IRB Website: http://www.augusta.edu/research/irboffice/irb/gru-irb-policies.php.
- VA Studies- refer to the VHA RCS 10-1, Section IV, Office of Research and Development, Sequence Number 7.6, Research Investigator Files.

If you have any questions, please contact the IRB office at 706-721-3110 or irb@augusta.edu.