Institutional Review Board Office
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http://www.augusta.edu/research/irboffice/

DATE: November 11, 2019

TO: John Yap, MD
FROM: Augusta University (AU) Committee C

PROJECT TITLE: [1494636-3] The Safety of Endoscopy among Patients on Antiangiogenic Agents: A Retrospective Study

REFERENCE #:
SUBMISSION TYPE: New Project (Response/Follow-Up)

ACTION: DETERMINATION OF EXEMPT STATUS
DECISION DATE: November 8, 2019

REVIEW CATEGORY: Exemption category #4

4- Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

a. The identifiable private information or identifiable biospecimens are publicly available;
b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearched activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information

used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

Thank you for your submission of Response/Follow-Up materials for this New Project. The Augusta University (AU) Committee C has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations, 45 CFR 46 (DHHS) 2018 Requirements.

Research determined to be exempt does not require continuing review or protocol amendments (revisions and personnel changes). However, it must be noted that if the scope of the exempt protocol changes, the protocol must be re-submitted to the IRB for review.

The approval includes the following documents:

- Augusta - Core Data Form - Augusta - Core Data Form (UPDATED: 10/30/2019)
- Conflict of Interest - Declaration - COI form.pdf (UPDATED: 11/7/2019)
- Data Collection - The Safety of Endoscopy Table.docx (UPDATED: 10/30/2019)
- HIPAA Waiver - Waiver of HIPAA Authorization Form 8.7.docx (UPDATED: 11/4/2019)
- Letter - Getting Started_Submitting a Response_Follow-up Package for Modification 10-20-19.docx (UPDATED: 11/4/2019)
- Other - 2018 Exemption Determination Request_03.12.19.docx (UPDATED: 11/7/2019)
- Other - data storage.pdf (UPDATED: 11/4/2019)
- Protocol - IRB protocol Dr. Yap.docx (UPDATED: 11/8/2019)

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

A. Waiver of HIPAA Authorization 45 CFR 164.512(i)(2) (for Retrospective Chart Review)
A Waiver of HIPAA Authorization is granted based on the following criteria:

1. The use or disclosure of protected health information (PHI) involves no more than minimal risk to the privacy of individuals based on the presence of:
    a. an adequate plan to protect PHI identifiers from improper use and disclosure;
    b. an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and
    c. adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except
        i. as required by law;
        ii. for authorized oversight of the research study, or
        iii. for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule
2. The research could not practicably be conducted without the requested waiver or alteration.
3. The research could not practicably be conducted without access to and use of the PHI.

B. Data Mining

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

All Principal Investigators must comply with the following:

- If the project is funded by a non-Augusta University source, the Division of Sponsored Program Administration (DSPA) must also be notified of the change of scope and re-submission.
- Conduct the research in accordance with the protocol, applicable laws and regulations, and principles and research ethics as set forth in the Belmont Report.
- If applicable, 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 Augusta University IRB current approved consent form
    - 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.
- 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, Chapter 8 Research Investigator Files: https://www.va.gov/vhapublications/RCS10/rcs10-1.pdf

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