1. POLICY

The IRB shall review all human participant research prior to the investigator’s collection of data from medical records, charts, and case reports. The IRB shall give consideration to the protection of the privacy of the participants, purpose of the research, and the investigator’s ability to meet the objectives of the research project.

Specific Policy

1.1 Medical Records and Chart Reviews

The IRB shall review all requests for access to medical records and chart reviews for research. Inappropriate use of private, confidential information can result in harm to a human research participant.

1.1.1 Potentially Exempt Research Activities

A. Research utilizing information available in public documents in the United States (i.e., court records, police records) is not “human participant research” if the activity does not involve the collection of private identifiable information. Since “private information” is defined as “information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public,” most research utilizing information available in public documents in the United States, is not “human participant research.” Human participant research that involves the collection of existing public information is not FDA-regulated and may be exempt, regardless of whether the information is recorded in such a way that participants can be identified directly or through linkage. All use of public documents from another country for a research project is subject to the applicable laws and regulations of that country, and the investigator is responsible to assure compliance with those laws and regulations.

B. Human participant research that involves the collection of retrospective data (records that exist prior to the start of the research project) from medical records can be exempt from IRB review if the information is recorded by the investigator in such a manner that the participants cannot be identified, directly or through identifiers linked to the participants.

C. Research that involves collection of data from medical records of patients no longer living is not considered human participant research, provided a related living person is not put at risk (as in some types of infectious disease or genetics research). Note, however, that these records remain subject to and protected by HIPAA for 50 years from the patient’s death.

1.1.2 Potentially Expedited Research Activities

A. Research implemented with reasonable and appropriate protections so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

B. Research limited to the review of data that has been (or will be) collected solely for the purpose of medical treatment or diagnosis (non-research purposes).

1.2 Case Reports
Retrospective review of three (3) or more medical case reports qualify as a research project and must be submitted to the IRB for review.

Publication of one (1) medical case report that will include the addition of a procedure that is outside of standard of care qualifies as research and must be submitted to the IRB for review.

2. SCOPE

This SOP applies to all research projects involving medical records, chart reviews, and case report research projects submitted to the IRB.

3. RESPONSIBILITY

3.1 The IRB Administrator is responsible for conducting pre-review and assigning the research project to the IRB Chair or IRB designee for evaluation of type of initial review, if unclear. If the research project qualifies for "expedited" review, the IRB Administrator processes the submission in the IRB’s electronic information system for expedited review by the IRB Chair or IRB designee. If the submission qualifies for "full board" review, the IRB Administrator posts the submission on the next available IRB meeting agenda for review.

3.2 The HRPP Director or IRB designee is responsible for maintaining up-to-date review tools for review of this type of research.

3.3 The IRB Chair or IRB designee is responsible for providing IRB members adequate submission review training and ongoing guidance, and for selecting one primary and one secondary reviewer with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with primary and secondary reviewers with the relevant expertise or obtains consultation for that expertise.

3.4 The IRB Reviewer is responsible for conducting appropriate review of research planned for this category in consultation with appropriate experts and resources and for utilizing the IRB reviewer checklist to review the submission of the proposed research project.

3.5 The IRB is responsible for verifying appropriate measures are instituted for the protection of human rights and confidentiality.

3.6 Communication with the FDA is the responsibility of the IRB, the sponsor, and the sponsor-investigator as appropriate. The IRB Staff is responsible for assisting the IRB, the IRB Reviewer, and the investigator with the appropriate HIPAA form for the research project. The IRB Staff shall elicit guidance on HIPAA questions from the University Privacy Official, as necessary.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 301: Research Submission Requirements
SOP 401: Exempt Review
SOP 402: Expedited Review

6. ATTACHMENTS

203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist
1001-A  Research Privacy Form 1- Authorization To Use or Disclose PHI
1001-B  Research Privacy Form 2- Authorization To Use or Disclose Psychotherapy Notes for Research
1001-C  Research Privacy Form 3- Authorization To Use or Disclose PHI for Repository Research
1001-D  Research Privacy Form 4- Authorization To Use or Disclose PHI for Research That Also Includes Repository Research
1001-E  Research Privacy Form 5 – Waiver of Authorization
1001-F  Research Privacy Form 6 - Review Preparatory to Research
1001-G  Research Privacy Form 7 - Decedent’s Information
1001-H  Research Privacy Form 8 - De-Identified Information
1001-I  Research Privacy Form 9 - Limited Data Sets
1001-J  Research Privacy Form 10 – Data Use Agreement on Limited Data Sets

7. PROCESS OVERVIEW

Typically, medical record/chart reviews and case reports are minimal risk and may be approved under the expedited or exempt categories. However, the IRB Chair or IRB designee has the option of forwarding any request to the convened IRB for consideration.

7.1 The investigator or investigator’s staff submits a new study application and uploads all applicable documents into the IRB electronic information system.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403 – Initial Review – Criteria for IRB Approval). The submission with all applicable documents is made available to all IRB members.

7.3 The IRB Administrator conducts a pre-review of the submission and verifies all required documents are received including the appropriate HIPAA authorization or request for waiver of authorization form.

7.4 The IRB Administrator assigns the submission either to (1) the appropriate Board agenda or (2) to the IRB Chair/IRB designee (b).

7.4.1 If to an IRB agenda, the process follows SOP 403: Initial Review – IRB Criteria for Approval.
7.4.2 If to IRB Chair / IRB Designee, the process follows SOP 401: Exempt Review, or SOP 402: Expedited Review.

7.5 Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the Investigator. The IRB Administrator posts the final IRB approval to the next appropriate IRB agenda

7.6 Enrollment into the research project may not commence until all required University committees have completed their review and the research contract is signed, if applicable.

APPROVED BY:_____________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020