SOP 307: COPY AND RECORD REQUESTS

1. POLICY

The IRB shall prepare and maintain adequate documentation of IRB activities as described in SOP 304, Documentation, Document and Data Management. IRB records are defined as all documents that describe IRB activities.

Specific Policies

1.1 Access to IRB Records.

The IRB staff shall maintain all IRB records in locked filing cabinets or a locked storage room and in the IRB’s electronic information system.

Access to IRB records shall be limited to authorized IRB Staff, HRPP Staff, IRB Chairs and Vice Chairs, IRB members, Institutional Officials, authorized federal agency employees, and University officials from the offices of Legal Counsel, Internal Audit, and Compliance. Upon request and signature of a confidentiality agreement, VA R&DC employees may also access certain IRB records.

Investigators and research project coordinators are provided reasonable access to IRB files related to their research upon advance notice to the IRB.

All other access to IRB records is limited to those who have legitimate business need for them, as determined by the HRPP Director, for the NC the Director of Compliance and for HSC the HSC VPR, or their designee.

1.2 Copying IRB Records

Requested copies of IRB records are given only to the principal investigator (PI), co-principal investigator (co-PI), the research coordinator/project contact listed on the particular research project, and members of the IRB.

Copies are not given to anyone else unless authorized by the HRPP Director, for NC the Director of Compliance and for HSC the HSC VPR, or their designee or as required by applicable law.

All IRB records maintained in the IRB’s electronic information system are available to those who have authorization to access the system, according to their role.

1.3 Requests for IRB Records from Non-Authorized Individuals

All requests for IRB records from non-authorized individuals (i.e., sponsor, research project monitor, or an individual not listed as PI, co-PI, or research project coordinator in the protocol) shall be made in writing to the HRPP Director, for the NC the Director of Compliance and for HSC the HSC VPR, or their designee.

2. SCOPE

This SOP applies to all requests for IRB Records.

3. RESPONSIBILITY

3.1 The IRB Administrator is responsible for providing copies of requested paper materials to authorized persons and for directing inquiries from non-authorized individuals to the HRPP Director, for the NC the Director of Compliance and for HSC the HSC VPR, or their designee for consideration.
3.2 The HRPP Director or designee is responsible for approving the distribution of IRB records to non-authorized individuals on a case-by-case basis.

3.3 The Director of Compliance is responsible for providing guidance to the NC HRPP Director and the HSC VPR is responsible for providing guidance to the HSC HRPP Director in the determination of approving distribution of IRB records to non-authorized individuals.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.115
45 CFR 46.115

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 304, Documentation, Document and Data Management.

6. ATTACHMENTS

None

7. PROCESS OVERVIEW

7.1 The IRB Administrator or designee processes requests for IRB records from the principal investigator, co-investigator, or research project coordinator in a timely fashion.

7.2 The IRB Administrator notifies the HRPP Director if a request involves copying that will require a significant amount of time to complete (pull file, get document, copy document, re-file, provide to requester) or access the IRB record in the IRB’s electronic information system and print. If copying or printing requires a significant amount of time, the HRPP Director will assign the task to an available IRB staff member.

7.3 The IRB Administrator notifies the HRPP Director if multiple requests are made by the investigator, co-investigator, or research project coordinator for any particular research project.

7.4 No request for IRB records by a non-authorized individual shall be fulfilled until approval for the access has been granted by the HRPP Director, for the NC the Director of Compliance and for HSC the HSC VPR, or their designee.

7.5 The HRPP Director reviews, on a case-by-case basis, all requests for IRB records from any non-authorized individual and either approves or denies the distribution of IRB records.

7.6 The NC HRPP Director shall consult with the Director of Compliance and the HSC HRPP Director shall consult with the HSC VPR, and/or Office of Legal Counsel or the Open Records Office for guidance as necessary.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020