

**SOP: 307**  
**COPY & DATA 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 maintains all IRB records in locked filing cabinets or a locked storage room.

Access to IRB records is limited to Office of Compliance staff, IRB Chairs, IRB Members, IRB Staff, and members of Federal or State regulatory agencies.

Investigators and study coordinators are provided reasonable access to individual files related to their research.

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

**1.2 Copying IRB Data**

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

Copies are not given to anyone else unless authorized by the HRPP Director, the Director of Compliance, or their designee.

**1.3 Written or Verbal Requests for IRB Records from Non-Authorized Individuals**

All requests for IRB records from non-authorized individuals (i.e. sponsor, study monitor, or an individual not listed as PI, co-PI, or study coordinator in the protocol) shall be directed to the HRPP Director, the Director of Compliance or their designee.

**2. SCOPE**

This policy and these procedures apply to all requests for IRB Data.

**3. RESPONSIBILITY**

The IRB Administrator is responsible for providing copies of requested materials to authorized persons and for directing inquiries from 'non-authorized' individuals to the HRPP Director, the Director of Compliance, or their designee for consideration.

The HRPP Director or designee is responsible for approving the distribution of IRB Data to non-authorized individuals on a case-by-case basis.

The Director of Compliance is responsible for providing guidance to the HRPP Director.

#### **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 study coordinator in a timely fashion.

7.2 The IRB Administrator notifies the HRPP Director if a request involves copying that will require greater than 10 minutes time (pull file, get document, copy document, re-file, provide to requester). If copying requires more than 10 minutes, 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 being made by the investigator, co-investigator, or study coordinator for any particular study.

7.4 The IRB Administrator notifies the HRPP Director of any request by non-authorized individuals requesting IRB records. The request is not fulfilled until approval has been granted by the HRPP Director, the Director of Compliance, 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 HRPP Director consults with Director of Compliance and/or Office of Legal Counsel for guidance as necessary.

**APPROVED BY:** \_\_\_\_\_ **DATE:** 09/01/2009

**NEXT ESTABLISHED REVIEW DATE:** MAY 2012