



MAINTENANCE OF VA CENTRAL IRB RECORDS

Document No.: RD- IRB-SOP 116

Revision:
01

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1 SCOPE AND APPLICABILITY

- 1.1 This SOP sets forth the policies and procedures the VA Central IRB follows in the organization, maintenance, retention, and storage of required files and databases pertaining to the operation of the VA Central IRB. See **Attachment 1** for a detailed process map.
- 1.2 VA Central IRB administrative staff and VA Central IRB members will abide by all federal and VA requirements for document management, retention, and storage, to include the VHA Records Control Schedule (RCS). VA Central IRB records are the property and responsibility of the Program for Research Integrity and Development (PRIDE), a division within the Office of Research and Development (ORD).
- 1.3 All records regarding a submitted project, regardless of whether it is approved, must be retained in an appropriate manner as required by regulatory requirements and/or institutional policy. Each project file is maintained in a manner that contains a complete history of all VA Central IRB actions relating to its review and approval/disapproval/withdrawal, to include initial and continuing reviews, amendments, unanticipated serious adverse events, unanticipated problems involving risks to participants or others, complaints, protocol deviations, project closure reports, audit reports, reports of serious noncompliance, and any other documentation sent or received by the project investigators and/or the local participating sites regarding study actions.
- 1.4 In addition to project files, the VA Central IRB must also maintain the following records regarding its operations:
 - Records pertaining to the recruitment, appointment, and continuing education requirements of VA Central IRB members
 - Electronic tracking databases currently used to document the status of VA Central IRB actions :
 - SharePoint
 - Shared Drive
 - Access database
 - Excel Spreadsheets and Word Tables
 - Copies of the VA Central IRB standard operating procedures and forms; both current and obsolete versions must be retained in accordance with the VHA Records Control Schedule
 - Approved minutes of VA Central IRB meetings
 - Other correspondence with oversight agencies or accrediting organizations
 - VHA Central Office Human Research Protection Program (HRPP) Federal-wide Assurance (FWA) and IRB Registrations
 - Memoranda of Agreement with VA Facilities for which the VA Central IRB serves as an IRB of Record.
- 1.5 Records must be maintained so that they are readily accessible at reasonable times and in a reasonable manner for inspection and copying by authorized representatives of funding agencies, sponsors, regulatory agencies, institutional auditors, and oversight authorities. Applicable portions of the files must also be readily available for release to local facility representatives in accordance with VA requirements and stipulations of the Memoranda of Understanding (MOU) between local facilities and the VHA HRPP.



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- 1.6 All records containing sensitive research information, to include all project folders, meeting minutes, VA Central IRB member files, are maintained in a safe, confidential environment that adheres to all VA and other requirements for maintenance of information security and privacy.

2 DEFINITIONS

- 2.1 **Assurance.** A written commitment by the institution to protect human subjects participating in research and to comply with the requirements of 38 CFR Part 16 (VHA Handbook 1058.03). For the purposes of the VA Central IRB SOPs, “assurance” is synonymous with “Federalwide Assurance.”
- 2.2 **Health Information (HI).** Any information created or received by a health care provider or health plan that relates to: the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or payment for the provision of health care to an individual. This encompasses information pertaining to examination, medical history, diagnosis, and findings or treatment, including such info as: laboratory examinations, x-rays, microscopic slides, photographs, prescriptions, etc. (VHA Handbook 1605.1).
- 2.3 **Human Protections Administrator (HPA).** The individual named in an FWA as a primary contact responsible for directing, or having in-depth knowledge of, the daily operations of an Institution’s program for protecting human research subjects (VHA Handbook 1058.03).
- 2.4 **Human Research Protections Program (HRPP).** An HRPP is a comprehensive system to ensure the protection of human subjects participating in research. The HRPP consists of consists of a variety of individuals and committees such as: the VA Facility Director, Associate Chief of Staff (ACOS) for Research and Development (R&D), the Administrative Officer (AO) for R&D, the R&D Committee, the Institutional Review Board (IRB), other committees or subcommittees addressing human subjects protection (e.g., Biosafety, Radiation Safety Committee, Radioactive Drug Research, Conflict of Interest, investigators, IRB staff, research staff, health and safety staff (e.g., Biosafety Officer, Radiation Safety Officer), compliance officers, information security officers, privacy officers, and research pharmacy staff. The objective of this system is to assist the institution in meeting ethical principles and regulatory requirements for the protection of human subjects (VHA Handbook 1200.05). The VHA Central Office HRPP is composed of the VA Central IRB, the institutional leadership (the Principal Deputy Under Secretary for Health is the Institutional Official), ORD, PRIDE, investigators of VA multi-site projects approved by the VA Central IRB, local medical center directors and Research and Development Committees at participating local facilities, ORO, and many others who are not involved in human research. The VHA Central Office HRPP does not replace or duplicate the efforts of the local VA facilities’ HRPPs. Instead, it serves as the HRPP for VA multi-site projects that are reviewed and approved by the VA Central IRB. The VHA Office of Research Oversight (ORO) has oversight responsibility for the VHA Central Office HRPP.
- 2.5 **Individually Identifiable Information (III).** Individually-identifiable information is a subset of health information, including demographic information collected from an individual, that is (VHA Handbook 1605.1):
- Created or received by a health care provider, health plan, or health care clearinghouse;
 - Relates to the past, present, or future condition of an individual and provision of, or payment for, health care; and
 - Identifies the individual, or a reasonable basis exists to believe that the information can be used to identify the individual.

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2.6 Institutional Official (IO). The IO is the individual legally authorized as Signatory Official to commit an institution to an Assurance. The IO is responsible for ensuring that the Institution's HRPP functions effectively and the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The Principal Deputy Undersecretary for Health Affairs is the IO for VHA Central Office and VA facility Directors are the IOs for local VA facilities. The IO serves as the official representative of the institution to external entities and oversight bodies and provides all written communication with external departments, agencies, and oversight bodies. (VHA Handbook 1200.05).

2.7 Memorandum of Understanding (MOU). A written agreement between two VA facilities or between a VA facility and a non-VA Institution documenting their relationship and defining their respective roles and responsibilities within that relationship (VHA Handbook 1058.03, paragraph 4n).

2.8 Non-Profit Corporation (NPC). VA-affiliated nonprofit research and education corporations are authorized by Congress under 38 U.S.C. 7361-7366 to provide flexible funding mechanisms for the conduct of research and education at one or more VA facilities. Research approved by a facility R&D Committee and education approved by the facility Education Committee is considered to be a VA research project or a VA education activity respectively, regardless of the source of funding, the entity administering the funds, or the research or education site. (VHA Handbook 1200.05)

2.9 Protected Health Information (PHI). PHI is individually-identifiable health information maintained in any form or medium. *NOTE: PHI excludes employment records held by a covered entity in its role as an employer (VHA Handbook 1605.1, p.4ss)*


2.10 VA Sensitive Information. All departmental data, on any storage media or in any form or format, which requires protection due to the risk of harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes information whose improper use or disclosure could adversely affect the liability of an agency to accomplish its mission, proprietary information, records about specific individuals requiring protection under various confidentiality provisions such as the Privacy Act and the Health Insurance Portability and Accountability Act (HIPPA) Privacy Rule, and information that can be withheld under the FOIA.

3 RESPONSIBILITY

3.1 It is the responsibility of all VA Central IRB administrative staff and VA Central IRB members to maintain the security and confidentiality of all VA Central IRB records described above as applicable in accordance with VA and other federal requirements. It is also the responsibility of those VA personnel from local sites and study teams given access to the SharePoint data base to ensure they follow appropriate access control procedures and that they maintain the security and confidentiality of the posted documents, to include maintaining the security and confidentiality of downloaded documents as applicable.

3.2 The VA Central IRB Administrator is responsible for the following:

- Ensuring that VA and other requirements for maintenance of files are followed
- Ensuring that all required information security and privacy safeguards are in place
- Identifying resources required to ensure the confidentiality and security of the files

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- Reporting any security or confidentiality breach through the appropriate channels
- Ensuring all documents on the VA Central IRB website are kept up-to-date
- Ensuring SOPs, work instructions, and forms are current and reviewed annually

3.3 The VA Central IRB Managers are responsible for the day-to-day management and upkeep of project documents. This includes the official hard copy folders for FDA-regulated studies and other studies currently stored using a mixture of both paper and electronic files. In addition, VA Central IRB Managers are required to ensure that the SharePoint folders for all active, approved studies are kept up-to-date with the most currently approved study documents. Managers are also required to update all applicable VA Central IRB project tracking databases and/or spreadsheets or tables in a timely and accurate manner. VA Central IRB Managers will ensure project documents are properly maintained in accordance with the provisions of this SOP and any associated work instructions.

3.4 VA Central IRB members are responsible for maintaining the confidentiality and security of all VA Central IRB documents to which they have access, to include project documents and other documents made available to them for review at convened IRB meetings or as part of an expedited review process. When hard copy documents are no longer needed by members for their review functions, members are responsible for destroying the documents through an approved method or returning them to the VA Central IRB Administrative Office for destruction as applicable.

3.5 The VHA Central Office Human Protections Administrator (HPA), is responsible for reviewing, approving, and signing all VA Central IRB SOPs on behalf of the VHA Central Office HRPP Institutional Official (IO). The VHA Central Office HPA is also responsible for ensuring that sufficient resources are provided to maintain the confidentiality and security of all VA Central IRB records.


4 PROCEDURES

4.1 Security of VA Central IRB Records. All VA Central IRB records will be kept secure when not in use.

4.1.1 Hard copy files will be kept in a locked drawer or filing cabinet, or kept in a locked office when not in use. No VA sensitive documents may be left out overnight and must be put into secure storage at the end of each duty day. All filing cabinets containing VA sensitive documents will be kept locked when not in use. No sensitive data may be removed from the premises without the permission of the VHA Central Office HPA and the Office of Research and Development (ORD) ISO. Duplicate hard copies of VA sensitive documents will be destroyed through shredding or through an authorized commercial vendor.

4.1.2 Access to the VA Central IRB Shared Drive will only be granted by the VA Central IRB Administrator to authorized employees within PRIDE actively working with study documents. Access will be removed when employees are no longer employed within PRIDE or their duties no longer require access to project folders. Access to non-PRIDE employees will only be granted on an "as needed" basis and will be restricted to specific folders.

4.1.3 Access to the VA Central IRB SharePoint site will be controlled by the VA Central IRB SharePoint Administrator. Access will be granted to applicable folders on the SharePoint site on an as needed basis as follows: 1) VA Central IRB administrative staff, 2) VA Central IRB members, 3) local VA facility research personnel per the MOU between the VHA Central Office

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HRPP and the local sites, 4) local study teams per project and site, and 5) national study team and study coordinating center staff. Requests for access not falling under these access categories will be referred to the VA Central IRB Administrator. If access is granted, it will be restricted to only the folders needed and if applicable, for a limited period of time.

4.1.4 VA Central IRB members must also maintain all project information they receive for review in a secure manner. The VA Central IRB staff makes boxes available during convened meetings for members to deposit their hard copy project documents after a Board meeting for disposal in accordance with a method approved by the National Institute of Standards and Technology (NIST), usually shredding by the VHA-approved contractor. If members wish to save personal notes from their review, or the project documents for review at a later date, either electronically or in hard copy, these must be protected as VA sensitive information and destroyed in accordance with a NIST-approved method when no longer needed.

4.1.5 On an annual basis, the VA Central IRB staff will ask all VA facilities to confirm their local contact list and to submit updates as necessary. Study teams notify VA Central IRB staff of the need for SharePoint access changes via submission of study amendments or at the time of continuing review. See VA Central IRB Work Instruction 401, Granting and Maintaining Access to VA Central IRB SharePoint Sites, for SharePoint access and update procedures.

4.1.6 If any VA Central IRB administrative personnel or a VA Central IRB member detects a lapse in security in which sensitive information may have been compromised or lost, the incident must be reported immediately (within one hour) to the VA Central IRB Administrator; the VHA Central Office HPA, the Chief Information Officer for ORD, and the ORD Information Security Officer (ISO). If the loss also involved Private Identifiable Information, notification will also be made to the ORD Privacy Officer.

4.2 Project or Study Folders. Study folders can be kept in up to three different formats to facilitate maintenance, storage, and accessibility, as well as for adherence to regulatory requirements. Each of these formats is discussed below.

4.2.1 Hard copies. These are considered the official project or study file for FDA-regulated studies. Each project may be composed of up to three different types of folders, with each type of folder having multiple volumes. The three different types of folders are: 1) Principal Investigator/Study Chair (PI/SC) Folder, 2) Local Site Investigator (LSI) Folders, and 3) Study Administrative Folder. Hard copies of non-FDA regulated studies that were already maintained in hard copy prior to Oct 1, 2014, will still be kept and maintained in accordance with the VA Records Control Schedule but these hard copies will no longer serve as the sole official file for these studies. (See paragraph 4.2.2)

4.2.1.1 The PI/SC folder consists of all the documents the PI/SC or other personnel submit for review by the VA Central IRB, as well as the VA Central IRB determinations concerning the submitted documents. These include but are not limited to the following:

- VA Central IRB Form 108, PI/SC Application and associated documents
- Continuing Review Applications



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- Requests for Amendments
- Reports of Unanticipated Serious Adverse Events (SAEs) or Unanticipated Problems involving Risks to Subjects or Others
- Summaries of Data Monitoring Committee (DMC) or Data Safety and Monitoring Board (DSMB) findings
- Research Compliance Officer (RCO) audit reports and audit reports by other oversight bodies, personnel, or entities
- Reports of protocol deviations or apparent serious noncompliance
- Any significant new findings
- All formal communications between the VA Central IRB and the investigators or local sites
- Copies of e-mails that relay a decision, requirement, or request for additional information regarding a project from the VA Central IRB or its staff and any responses by the study team; this does not include e-mail messages concerning logistical or administrative issues
- Other documents as required.

4.2.1.2 The LSI folders for each site are filed in a similar manner as the PI/SC Application. This file also contains correspondence with the local sites, to include the provision of any local site comments for review. These include, but are not limited to, the following:

- Local Site Investigator Application and associated documents
- Requests for Amendments
- Continuing Review Applications
- Reports of Serious Adverse Events or Unanticipated Problems Involving Risks to Subject or Others (includes participant injuries)
- Documentation of noncompliance, to include protocol deviations, and remedial plans with progress reports as applicable
- Complaints from subjects or others
- Research Compliance Officer Audit Reports and audit reports from other entities or agencies
- Local site comments as applicable
- All formal communications between the VA Central IRB and the investigator or local sites
- Informal correspondence, to include e-mail, containing information about the review and/or content of a study. This does not include e-mail messages concerning logistical and administrative issues.

4.2.1.3 Each study folder will also have an administrative file. The administrative file will house all Reviewer Checklists (initial, continuing, informed consent, amendment reviews) except for review of serious adverse events, serious unanticipated problems involving risks to subjects or others, and protocol deviations or violations.

4.2.1.4 The PI/SC Application, the LSI Application, and all other project documents will be filed in the applicable folders as specified in VA Central IRB Work Instruction 200,

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Maintenance of VA Central IRB Project Files, which details internal filing formats and procedures.

4.2.1.5 All hard copies are kept in secure, locked storage when not in active use.

4.2.1.6 Upon receipt of a closure report, the entire project file is archived. The files are maintained for the minimum amount of time as required by the current VHA Records Control Schedule and then destroyed per a NIST-approved method.


4.2.2 Electronic Copies on Shared Drive. Each project also has an electronic project folder on the PRIDE shared drive. These folders will serve as the official study files for all non-FDA regulated studies. For those non-FDA studies that were in the past stored mainly in paper format, the official file will consist of both the hard copies and the more recent documents on the shared drive. Hard copy files for the non-FDA studies will not be converted but will be maintained in accordance with the Records Control Schedule and used in conjunction with the electronic files on the shared drive to constitute the official file for the study. All current documents generated for non-FDA-regulated studies will be maintained solely in electronic format. The file set-up and the requirements for posting documents on the shared drive can be found in VA Central IRB Work Instruction 200, Maintenance of VA Central IRB Project Files. The shared drive is accessible only to VA Central IRB and other authorized PRIDE personnel. These electronic records are retained per the VHA Records Control Schedule.

4.2.3 Electronic Copies on SharePoint. The VA Central IRB uses its SharePoint site as a document distribution system. It is not to be used as an official file or regulatory binder by the VA Central IRB, the study teams, or the local sites. Documents are loaded and removed as needed for the appropriate reviews to be performed and notifications made. Only documents reviewed and approved by the VA Central IRB are generally posted as part of an approved study submission. Other documents, such as investigator CVs or COI determinations and other types of background information such as the merit review letters and minutes are not posted.

4.2.3.1 The VA Central IRB will load copies of approved documents, notifications of continuing review requirements, and VA Central IRB determination letters to SharePoint and provide the study teams and site contacts with links via email when the documents are available. Study teams and sites should download these documents to their own electronic systems or make hard copy files.

4.2.3.2 Access to the PI/SC folder is limited to the PI/SC study team, the LSI study team, and designated local site personnel. Access to the LSI subfolder is limited to the local LSI study team and, local PI/SC study team. VA Central IRB members and staff have access to all project folders.

4.2.3.3. All approved study documents will remain on the site until the study is closed. Other documents will be removed when no longer needed. The entire study folder will be removed from the active site and archived 30 days after notification has been made to study team members having access to SharePoint that the study is closed.

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4.2.3.4 See VA Central IRB Work Instruction 400, Posting and Maintenance of Project Documents on VA Central IRB SharePoint Site for further information about SharePoint file layout and document posting and deletion procedures.

4.3 VA Central IRB Minutes. The minutes of all VA Central IRB meetings are maintained permanently.

4.3.1 After approval of the minutes at a subsequent meeting of the VA Central IRB, correction of any issues identified by the VA Central IRB during its review, and signature of the Recorder, a copy of the signed meeting minutes is placed in a designated notebook filed by month/year, which is kept in a locked cabinet.

4.3.2 A PDF electronic file of the signed minutes is also made and is archived and distributed as follows:

4.3.2.1 A copy is archived on the VA Central IRB shared drive, in a “Minutes” folder labeled with the date of the meeting. If redacted copies of the minutes are released for any reason, a copy of the redacted minutes is kept on file, along with the reason for the release.


4.3.2.2 A copy is uploaded to the VA Central IRB SharePoint Site under the VA Central IRB Local Site Liaison Minutes folder. A notice is sent to each VA Central IRB Local Site Liaison that the minutes are available to download, process, and review in accordance with their local R&D procedures.

4.4 VA Central IRB Member Records. The VA Central IRB keeps the following records concerning VA Central IRB members:

4.4.1 Rosters of voting, nonvoting, and alternate VA Central IRB members identified by name, earned degrees, representative capacity and indications of experience sufficient to describe each regular member’s chief anticipated contribution to the deliberations of the VA Central IRB are kept up-to-date in various formats as needed and published on SharePoint for access by sites and study teams.

4.4.2 The rosters submitted to the Office for Human Research Protections (OHRP) and the VA Office of Research Oversight (ORO) upon changes in membership are maintained permanently. Updates to the roster are printed out for the file and kept with the applicable registration notice. A copy is also maintained on the VA Central IRB shared drive. See VA Central IRB Work Instruction 201, Maintenance of Federalwide Assurance (FWA), Memoranda of Understanding (MOUs), and IRB Registration Files for internal filing formats and procedures.

4.4.3 A folder for each appointed member of the board is maintained permanently. It contains the members’ appointment letters, CVs, training certifications, evaluations, copies of Without Compensation appointment paperwork if applicable, travel documentation, facility reimbursement documentation, and other pertinent paperwork. Procedures for maintenance of these files can be found in VA Central IRB Work Instruction 202, Maintenance of VA Central IRB Membership Files.

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4.4.4 In addition, various electronic spreadsheets or Access database reports are used to track member training, meeting attendance, reimbursements to member facilities, and appointment expiration dates. These are temporary and kept as long as needed for tracking purposes. Hard copies of individual member actions are on file in each member's folder.

4.5 Reports from Oversight Authorities. Copies of all reports received from outside organizations, regulatory agencies, oversight authorities, site visitors, accreditation monitors, or any other type of agency or institution that concerns the operations and functioning of the VA Central IRB or any of the projects it oversees are kept, both in hard copy and in an electronic file if applicable, in accordance with the VHA Records Control Schedule. The electronic folder is kept on the shared drive under a folder with the agency name. The hard copies of these files are kept locked in the secure storage when not in use.

4.6 FWA documentation, IRB Registration, and MOUs. These files will be maintained permanently as follows

4.6.1 Hard copies of the VHA HRPP FWA submission and approval, to include required IO training certifications, are kept on file by date of approval or update. Hard copies of all IO delegation of authority letters are also kept in this folder. A separate file is made for each renewal or resubmission of the VHA HRPP FWA.

4.6.2 When the IRB registration for the VA Central IRB is updated, a hard copy is filed with the updated registration notice received from OHRP. The registration information is filed chronologically with the most recent information on top.


4.6.3 A hard, signed copy of each MOU entered into with a local facility, along with associated site documentation, is kept in an "MOU" folder with a separate file folder being maintained for each VA facility and associated Non-Profit Corporation (NPC) if applicable.

4.6.4 Electronic copies are also kept of all FWA updates and IRB registration notices, as well as or MOUs in appropriately labeled electronic folders the VA Central IRB shared drive. See VA Central IRB Work Instruction 201, Maintenance of Federalwide Assurance (FWA), Memoranda of Understanding (MOUs), and IRB Registration Files for internal filing formats and procedures.

4.7 Standard Operating Procedures. The VA Central IRB Administrator maintains current and obsolete copies of the VA Central IRB SOPs as follows:

4.7.1 Current copies of all SOPs are kept in a notebook in the VA Central IRB Administrator's Office. All current VA Central IRB SOPs are maintained on the VA Central IRB website for reference by investigators, local sites, VA Central IRB members, and the general public.

4.7.2 All VA Central IRB SOPs will conform to VA ORD's ISO 9001 SOP format. In addition, a separate table listing the current SOPs and approval dates is kept on the PRIDE or VA Central IRB shared drive, as is a table for the associated VA Central IRB work instructions and VA Central IRB forms. The SOPs on the website are listed in chronological order while the forms are grouped by category, i.e., investigator, IRB members, and local sites for ease of reference.

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4.7.3 The VHA Central Office HPA has been delegated the authority to review and approve all VA Central IRB SOPs. No VA Central IRB SOP may be posted to the VA Central IRB website without final approval of the VHA Central Office HPA.

4.7.4 SOPs are revised and updated as changes occur. If changes are minor, changes may be made by pen and ink on the copy of the SOP maintained by the VA Central IRB Administrator until an official revision can be processed and published.

4.7.5 Form revisions are tracked by date and are made and approved by the VA Central IRB Administrator. Changes in VA Central IRB forms are posted to the website upon the change being made by the VA Central IRB Administrator. The SOP does not need to be updated due to a change in the form unless an associated procedure detailed in the SOP is also changed. Copies of obsolete forms are kept electronically in an archived file.

4.7.6 SOPs are updated by the VA Central IRB administrative staff on an ongoing basis and are reviewed on at least annually for currency during the annual review of the VHA Central Office HRPP and documented in the report .

4.7.7 VA Central IRB members are notified at meetings when changes are made to the SOPs or VA Central IRB forms, while VA Central IRB Site Liaisons are notified via e-mail on a monthly basis if there was a change in a given month.

4.7.8 The VA Central IRB Administrator maintains hard copies of both the current and obsolete SOPs in accordance with the VHA Records Control Schedule. SOPs do not have to be kept in locked storage when not in use.

4.8 Access Database. The VA Central IRB maintains, on a real-time basis, an Access database on the internal PRIDE drive with controlled access limited to PRIDE staff. Non-PRIDE staff are granted access on an “as needed” basis for a limited periods of time. This database is backed up on a daily basis and is mainly used for tracking study site contacts, local site MOU and FWA updates, and project tracking information by date. It is also used to generate reports and to generate routine notices via-email. E-mails that must be maintained as part of the study file, such as routine reportable event determinations, will be captured and filed in the applicable project folder on the shared drive.

4.9 Exempt Project Files. The VA Central IRB Administrative Office maintains a project folder on all exempt projects that were reviewed and exempted by the VA Central IRB. These files are kept in electronic format only. See VA Central IRB Work Instruction 200, Maintenance of VA Central IRB Project Files, which includes the format and procedures for maintaining the exempt files as well as the non-exempt files.

5 DOCUMENTATION REQUIREMENTS

5.1 This SOP describes processes for maintenance of required VA Central IRB documentation and does not mandate any new documentation.

5.2 This SOP references associated VA Central IRB work instructions that provide more detail in regard to internal file formats, filing procedures, and document retention requirements.



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6 REFERENCES

- 6.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects
- 6.2 VHA Handbook 1200.5, Requirements for the Protection of Human Subjects in Research
- 6.3 Department of Veterans Affairs, Veterans Health Administration Records Control Schedule 10-1
- 6.4 VHA Handbook 6500, Information Security Program
- 6.5 VHA Handbook 1058.03, Assurance of Protection for Human Subjects in Research
- 6.6 VHA Handbook 1605.1, Privacy and Release of Information

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00	Original	4/18/14
01	Incorporates changes in filing methodology from paper files to electronic files for all non-FDA regulated studies. Also incorporates changes based on policy changes in the most recent update to VHA Handbook 1200.05	2/9/2015
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Attachment 1: VA Central IRB SOP 116 Process Chart

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