1 PURPOSE
1.1 This procedure establishes the process to maintain HRRC records.
1.2 The process begins when records are received or created.
1.3 The process ends when records have been filed.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Removed VA requirements no longer in VA Handbook

3 POLICY
3.1 HRRC records are to include:
  3.1.1 Protocol files.
  3.1.2 Minutes of HRRC meetings.
  3.1.3 Copies of all correspondence between the HRRC and the investigators.
  3.1.4 Current and all previous HRRC member rosters.
  3.1.5 Current and all previous HRRC member files.
  3.1.6 Current and all previous policies and procedures.

3.2 Protocol files are to include, as applicable:
  3.2.1 All submitted materials.
  3.2.2 Protocols.
  3.2.3 Investigator brochures.
  3.2.4 Scientific evaluations.
  3.2.5 Recruitment materials.
  3.2.6 Consent documents.
  3.2.7 DHHS-approved sample consent document and protocol, when they exist.
  3.2.8 Progress reports submitted by investigators.
  3.2.9 Reports of injuries to subjects.
  3.2.10 Records of continuing review activities.
  3.2.11 Data and safety monitoring board reports.
  3.2.12 Amendments.
  3.2.13 Reports of unanticipated problems involving risks to subjects or others.
  3.2.14 Documentation of non-compliance.
  3.2.15 Correspondence between the HRRC and investigator related to the
          protocol.
  3.2.16 Significant new findings and statements about them provided to subjects.
  3.2.17 For initial and continuing review of research by the expedited procedure:
          3.2.17.1 The specific permissible category.
          3.2.17.2 Description of action taken by the reviewer.
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3.2.17.3 Any findings required under the regulations.
3.2.18 For exemption determinations the specific category of exemption.
3.2.19 Unless documented in the HRRC minutes determinations required by the
regulations and protocol-specific findings supporting those determinations for.
3.2.19.1 Waiver or alteration of the consent process.
3.2.19.2 Research involving pregnant women, fetuses, and neonates.
3.2.19.3 Research involving Prisoners.
3.2.19.4 Research involving children.
3.2.19.5 Research involving adults unable to consent.
3.2.19.6 Significant/non-significant device determinations.
3.2.20 For each protocol's initial and continuing review, the frequency for the next
continuing review.
3.2.21 For Veterans Administration (VA) research:
3.2.21.1 Correspondence between the IRB/HRRC and the Veterans
Administration (VA) Research and Development Committee.
3.2.21.2 Internal or local serious adverse events.
3.2.21.3 Audit results and documentation of compliance with remediation
requirements

3.3 Policies and procedures include:
3.3.1 Checklists.
3.3.2 Forms.
3.3.3 SOPs.
3.3.4 Template letters.
3.3.5 Template minutes.
3.3.6 Worksheets.

3.4 HRRC member files include a resume for each HRRC member.

4 RESPONSIBILITIES
4.1 HRPO staff members are responsible to carry out these procedures.

5 PROCEDURE
5.1 Minutes of HRRC meetings: File electronically. File correspondence related to a
specific protocol in the electronic study file.
5.2 File correspondence NOT related to a specific protocol in a file related to that
person or topic.
5.3 HRRC member rosters: File electronically.
5.4 HRRC membership records (e.g., curricula vita and resumes): File in HRRC
member files.
5.5 Policies and procedures:
5.5.1 File current policies and procedures electronically and in a Master SOP
binder.
5.5.2 File replaced policies and procedures in an electronic policies and
procedures history file.

6 MATERIALS
6.1 None

7 REFERENCES
7.1 None