REGULATORY DOCUMENTS POLICY

1. RESPONSIBILITIES:

The Principal Investigator (PI) and/or designee is responsible for:

Maintaining Investigator's Research Records. This means maintaining written documentation on file that the protocol is being implemented as approved by IRB and in accordance with other required approvals (R&D Committee, Subcommittee for Research Safety, etc). Binders are available in the Clinical Studies Center.

(1) Research records include the following when relevant to the study:
- (a) Copies of all IRB-approved versions of the protocol and amendments.
- (b) Case report forms and supporting data, including, but not limited to, signed and dated informed consent forms and HIPAA authorizations.
- (c) Documentation on each subject including, but not limited to:
  1. Informed consent,
  2. Interactions with subjects by telephone or in person,
  3. Observations,
  4. Interventions,
  5. Other data relevant to the research study, including, but not limited to:
     - a. Progress notes,
     - b. Research study forms,
     - c. Surveys, and
     - d. Questionnaires.
- (d) Reports of adverse events.
- (e) Data analyses.
- (f) Reports including, but not limited to, abstracts and other publications.
- (g) All correspondence including, but not limited to, that with the funding source or sponsor, and with applicable oversight entities including, but not limited to, IRB, R&D Committee, ORO, and FDA.
- (h) A master list of all subjects for whom informed consent has been obtained in the study

(2) Documents must be maintained so that they may be audited by the facility RCO or other entities according to applicable sponsor, local, VA and other Federal requirements

(3) An Accounting of Disclosure must be maintained for each and every disclosure of information from this study to a non-VA entity. ***NOTE:*** *The facility Privacy Officer can assist in providing a mechanism to account for this disclosure.*

(4) At the end of the study, send the study binder, along with all study documents, to long-term storage. Please see the *Long Term Storage of Research Records Policy* for instructions.

SEE APPENDIX (1) FOR SUGGESTED REGULATORY DOCUMENTS CHECKLIST

REGULATORY DOCUMENTS CHECKLIST (Appendix 1)

Regulatory documents include but are not limited to the following documents:

1.	Principal Investigator's CV*	On file	Pending to file	Comments
2.	Delegation of Authority Log*			
3.	Research staff Resume/CV*			
4.	Research staff certification			
5.	Final signed 1572/ All amended FDA 1572s			
6.	Research Protocol*			
7.	Investigator's Brochure*			
8.	IRB & R&D Committee applications and approval letters*			
9.	Financial Disclosure Form			
10.	Approved Informed Consent Forms, HIPAA Authorizations, & HIPAA Revocation Letters *			
11.	Approval documentation of Protocol Amendments and copies of applications *			
12.	Approved advertisements			
13.	Continuing Review approval documentation and copies of applications *			
14.	Unanticipated Problem(s) reports*			
15.	IRB and R&D Committee correspondence*			
16.	Internal/external communications (e.g. letters, memos, phone contacts)*			
17.	Laboratory certification and lab normal values (if applicable)			
18.	Investigational article log and copies of drug/device shipment/retrieval			
19.	Copies of any document related to the investigational article			
20.	Master List/Subject Enrollment log*			
21.	Sponsor's correspondence*			
22.	Copy of randomization codes			
23.	Monitoring visit reports and Privacy Training Certifications			
24.	Protocol Termination Documentation*			

* Required

Revised: 07/01/11