Informed Consent Form Audit Tool

Auditing Period June 1, 2013-May 31, 2014
Atlanta VA Medical Center

Auditor: **Audit Date:** **Protocol Status:** ☐Open ☐Closed to enrollment ☐Closed/Terminated **IRB Protocol Number:**

PI: **Protocol Name:**

IRB Approval Date: **R&D Approval Date:**

Informed Consent (check one):

- ☐ Full Informed Consent Document (ICD) with Signatures
- ☐ Short Form ICD per 38 CFR 16.117(b)(2)
- ☐ Witness Signature Required by IRB

- ☐ Includes Research-Related Injury Language (each ICD ver.)
- ☐ If FDA regulated, contains statement on clinical trials.gov (each ICD ver.)

HIPAA Document:

- ☐ No HIPAA required (No PHI)
- ☐ Waiver of Authorization
- ☐ Partial HIPAA Waiver
- ☐ HIPAA Authorization

Consents not audited because (check one):

- ☐ Protocol exempt from IRB review
- ☐ Informed consent waived per 38 CFR 16.116(c) or (d)
- ☐ ICD signature waived per 38 CFR 16.117(c)
- ☐ No ICDs signed in the 12 months prior to audit
- ☐ Other reason for not auditing consent:

- ☐ Continuing Review occurred as required?
- ☐ Lapse occurred (check for consenting during lapse)

SC:

Subject Last Name/	Last 4 or ID Number	ICD or Copy able to be Located Y/N	Date Subject Signed ICD	Version of ICD Signed	ICD IRB Approval Stamp Date	Correct ICD Used Y/N	Subject Signature Present Y/N	Date of Subject Signature Present Y/N	Date & Signature of POC Y/N	Authorized POC Y/N	HIPAA Auth Obtained If Required Y/N/NA	Consent Process Noted in CPRS Y/N/NA	Contains Required Sponsor Info Y/N/NA	Consent prior to study procedures Y/N	Inc/Excl confirmed Y/N	Comments