SUBJECT RECORDS CHECKLIST
VAMHCS Research Compliance Office

SELF-ASSESSMENT TOOL

GENERAL INFORMATION

Principal Investigator		
E-mail Address		
Sub-Investigator(s)		
Key Personnel/Function	**Personnel**	**Function**
IRB Panel		
IRB Protocol Number		
Study Title		
School/Center/Institution ***Please check one:***	☐ SOM ☐ Dental ☐ Pharm ☐ Nursing ☐ SW ☐ CVD ☐ MPRC ☐ IHV ☐ GCC ☐ GCRC	
Subject Population ***Please check all that apply:***	☐ Geriatric ☐ Pregnant Women ☐ Pediatric ☐ Prisoner ☐ Psychiatric ☐ Mentally Disabled ☐ Handicapped ☐ Veteran ☐ Employee/Student ☐ Community	
Sponsor ***Please check one:***	☐ Industry ☐ Government ☐ Internal/Department ☐ Foundation ☐ Other: _____	
Funding Source ***Please check one:***	☐ Industry ☐ Government ☐ Internal/Department ☐ Foundation ☐ Other: _____	
Person Completing Checklist		
Date Checklist Completed		

1. INFORMED CONSENT PROCESS

1.1 100% Review of Informed Consent Forms Signed by All Subjects Enrolled in the Study

(copy this page as many times as necessary to accommodate the number of subjects enrolled)

#	Subject ID Screen # Initials Rand. #	Version Signed *(key p.3)*	ID on all pages of ICF? *(Required by VAMC)*		Subject or Legal Rep. Signed		Date Signed	Date of 1st Res. Proc. (or drug admin)	PI or Study Rep Signed *(key p.3)*	Date Signed	Witness Signed and Dated		PI/SubI Review *(key p.3)* Signed and Dated
			Y	N	Y	N					Y	N	
1		a1	☐	☐	☐	☐					☐	☐	
2		a2	☐	☐	☐	☐					☐	☐	
3		a3	☐	☐	☐	☐					☐	☐	
4		a1	☐	☐	☐	☐					☐	☐	
5		a2	☐	☐	☐	☐					☐	☐	
6		a3	☐	☐	☐	☐					☐	☐	
7		a1	☐	☐	☐	☐					☐	☐	
8		a2	☐	☐	☐	☐					☐	☐	
9		a3	☐	☐	☐	☐					☐	☐	
10		a1	☐	☐	☐	☐					☐	☐	
11		a2	☐	☐	☐	☐					☐	☐	
12		a3	☐	☐	☐	☐					☐	☐	
13		a1	☐	☐	☐	☐					☐	☐	
14		a2	☐	☐	☐	☐					☐	☐	
15		a3	☐	☐	☐	☐					☐	☐	
16		a1	☐	☐	☐	☐					☐	☐	
17		a2	☐	☐	☐	☐					☐	☐	
18		a3	☐	☐	☐	☐					☐	☐	
19		a1	☐	☐	☐	☐					☐	☐	
20		a2	☐	☐	☐	☐					☐	☐	
21		a3	☐	☐	☐	☐					☐	☐	

1. INFORMED CONSENT PROCESS, continued

1.1 100% Review of Informed Consent Forms Signed by All Subjects Enrolled in the Study, continued

#	Subject ID Screen # Initials Rand. #	Version Signed *(key p.3)*	ID on all pages of ICF? *(Required by VAMC)*		Subject or Legal Rep. Signed		Date Signed	Date of 1st Res. Proc. (or drug admin)	PI or Study Rep Signed *(key p.3)*	Date Signed	Witness Signed and Dated		PI/SubI Review *(key p.3)* Signed and Dated
			Y	N	Y	N					Y	N	
22		A1	☐	☐	☐	☐					☐	☐	
23		A2	☐	☐	☐	☐					☐	☐	
24		A3	☐	☐	☐	☐					☐	☐	
25		A1	☐	☐	☐	☐					☐	☐	
26		A2	☐	☐	☐	☐					☐	☐	
27		A3	☐	☐	☐	☐					☐	☐	

Key: ICF Version	Key: PI/SubI/Study Representative
a1 = (list effective dates)	ID = Name (list initials in table, list name here)
a2 = (list effective dates)	ID = Name (list initials in table, list name here)
a3 = (list effective dates)	ID = Name (list initials in table, list name here)

		YES	NO	N/A	Reference:
1.2	Are all original signed ICFs available? Location: _____	☐	☐	☐	
1.3	Were any invalid consent forms used: Unapproved? Outdated?	☐ ☐	☐ ☐	☐ ☐	
1.3.a	If yes, was a protocol violation submitted to the IRB?	☐	☐	☐	
1.4	Did each subject sign his/her own consent form?	☐	☐	☐	21 CFR 50.27(a) ICH GCP 4.8.8
1.5	Did each subject date his/her own consent form?	☐	☐	☐	21 CFR 50.27(a) ICH GCP 4.8.8
1.6	Was the consent form signed and dated by all parties before any research procedures were performed or study drug administered?	☐	☐	☐	
1.6.a	If no, was a protocol violation submitted to the IRB?	☐	☐	☐	
1.7	Has the IRB requested that subjects be re-consented?	☐	☐	☐	
1.7.a	If yes, were re-consents obtained?	☐	☐	☐	

1. INFORMED CONSENT PROCESS, continued

1.8 Audit Sample – List Subject Numbers or IDs: _____

Subject # or ID: _____

		YES	NO	N/A	References:
1.8.a	Is the consent process documented in an Enrollment Note in CPRS?	☐	☐	☐	
1.8.b	Did each subject receive a copy of the signed consent form?	☐	☐	☐	21 CFR 50.27(a) ICH GCP 4.8.11
1.8.c	Is subject's receipt of a copy of the signed consent form documented?	☐	☐	☐	*Quality Improvement Recommendation*
1.8.d	Are copies of all signed ICFs and HIPAA Authorizations included in: Research Record? CPRS (scanned)?	 ☐ ☐	 ☐ ☐	 ☐ ☐	
1.8.e	Is there a Research Subject Clinical Warning in CPRS for this subject (if the study is interventional or if the subject is seen more than once at the VAMHCS or is followed up for a period of time)?	☐	☐	☐	Research Service requirement

Subject # or ID: _____

		YES	NO	N/A	References:
1.8.a	Is the consent process documented in an Enrollment Note in CPRS?	☐	☐	☐	
1.8.b	Did each subject receive a copy of the signed consent form?	☐	☐	☐	21 CFR 50.27(a) ICH GCP 4.8.11
1.8.c	Is subject's receipt of a copy of the signed consent form documented?	☐	☐	☐	*Quality Improvement Recommendation*
1.8.d	Are copies of all signed ICFs and HIPAA Authorizations included in: Research Record? CPRS (scanned)?	 ☐ ☐	 ☐ ☐	 ☐ ☐	
1.8.e	Is there a Research Subject Clinical Warning in CPRS for this subject (if the study is interventional or if the subject is seen more than once at the VAMHCS or is followed up for a period of time)?	☐	☐	☐	Research Service requirement

1. INFORMED CONSENT PROCESS, continued

1.8 Audit Sample, continued

Subject # or ID: _____

		YES	NO	N/A	References:
1.8.a	Is the consent process documented in an Enrollment Note in CPRS?	☐	☐	☐	
1.8.b	Did each subject receive a copy of the signed consent form?	☐	☐	☐	21 CFR 50.27(a) ICH GCP 4.8.11
1.8.c	Is subject's receipt of a copy of the signed consent form documented?	☐	☐	☐	*Quality Improvement Recommendation*
1.8.d	Are copies of all signed ICFs and HIPAA Authorizations included in: Research Record? CPRS (scanned)?	 ☐ ☐	 ☐ ☐	 ☐ ☐	
1.8.e	Is there a Research Subject Clinical Warning in CPRS for this subject (if the study is interventional or if the subject is seen more than once at the VAMHCS or is followed up for a period of time)?	☐	☐	☐	Research Service requirement

Subject # or ID: _____

		YES	NO	N/A	References:
1.8.a	Is the consent process documented in an Enrollment Note in CPRS?	☐	☐	☐	
1.8.b	Did each subject receive a copy of the signed consent form?	☐	☐	☐	21 CFR 50.27(a) ICH GCP 4.8.11
1.8.c	Is subject's receipt of a copy of the signed consent form documented?	☐	☐	☐	*Quality Improvement Recommendation*
1.8.d	Are copies of all signed ICFs and HIPAA Authorizations included in: Research Record? CPRS (scanned)?	 ☐ ☐	 ☐ ☐	 ☐ ☐	
1.8.e	Is there a Research Subject Clinical Warning in CPRS for this subject (if the study is interventional or if the subject is seen more than once at the VAMHCS or is followed up for a period of time)?	☐	☐	☐	Research Service requirement

1. INFORMED CONSENT PROCESS, continued

1.8 Audit Sample, continued

Subject # or ID: _____

		YES	NO	N/A	References:
1.8.a	Is the consent process documented in an Enrollment Note in CPRS?	☐	☐	☐	
1.8.b	Did each subject receive a copy of the signed consent form?	☐	☐	☐	21 CFR 50.27(a) ICH GCP 4.8.11
1.8.c	Is subject's receipt of a copy of the signed consent form documented?	☐	☐	☐	*Quality Improvement Recommendation*
1.8.d	Are copies of all signed ICFs and HIPAA Authorizations included in: Research Record? CPRS (scanned)?	 ☐ ☐	 ☐ ☐	 ☐ ☐	
1.8.e	Is there a Research Subject Clinical Warning in CPRS for this subject (if the study is interventional or if the subject is seen more than once at the VAMHCS or is followed up for a period of time)?	☐	☐	☐	Research Service requirement

Subject # or ID: _____

		YES	NO	N/A	References:
1.8.a	Is the consent process documented in an Enrollment Note in CPRS?	☐	☐	☐	
1.8.b	Did each subject receive a copy of the signed consent form?	☐	☐	☐	21 CFR 50.27(a) ICH GCP 4.8.11
1.8.c	Is subject's receipt of a copy of the signed consent form documented?	☐	☐	☐	*Quality Improvement Recommendation*
1.8.d	Are copies of all signed ICFs and HIPAA Authorizations included in: Research Record? CPRS (scanned)?	 ☐ ☐	 ☐ ☐	 ☐ ☐	
1.8.e	Is there a Research Subject Clinical Warning in CPRS for this subject (if the study is interventional or if the subject is seen more than once at the VAMHCS or is followed up for a period of time)?	☐	☐	☐	Research Service requirement

2. SUBJECT SELECTION CRITERIA

Review the study files for the subjects you have chosen for inspection and complete the following. Add additional space as necessary to accommodate the number of chosen subjects.

		YES	NO	N/A	References:
2.1	Is there an inclusion/exclusion criteria checklist?				*IRB requirement*
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
		YES	NO	N/A	References:
2.2	Was the subject was included/excluded appropriately?				
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
2.2a	If **NO,** was a protocol deviation submitted to the IRB?	☐	☐	☐	ICH GCP 4.5.2 ICH GCP 4.5.3
		YES	NO	N/A	Reference:
2.3	Does the inclusion/exclusion criteria checklist for each subject include dated signature/initials of the person obtaining the information?				ICH GCP 8.3.14
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	

Please use this space to explain any discrepancies found in the Subject Selection Criteria section:

3. SERIOUS ADVERSE EVENT (SAE) REPORTING

Review the study files for the subjects you have chosen for inspection and complete the following. Add additional space as necessary to accommodate the number of chosen subjects.

		YES	NO	N/A	References:
3.1	Has the subject experienced any serious adverse events (SAEs)?				
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
3.1.a	If so, have they been reported to the IRB?				
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	

3.1.a.1	If **NOT,** please list unreported SAEs and reason(s) for not reporting				
	Subject # or ID	Date of SAE	Description of SAE	Reason(s) for Not Reporting *Summarize events in progress report for continuing review*	

General comments about adverse event reporting:

4. DRUG/DEVICE DISPENSING ACCOUNTABILITY

4.1 Review the study files for the subjects you have chosen for inspection and complete the following. Add additional space as necessary to accommodate the number of chosen subjects.

Subject #: _____

		YES	NO	N/A	References:
4.1.a	Is drug/device administration documented in the: Research chart? Hospital/Medical chart? Clinic/Outpatient chart? Special Service chart (e.g. radiation oncology)? Specify: _____	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	
4.1.b	Is drug/device administration documented in the pharmacy record?	☐	☐	☐	
4.1.c	List treatment dosage/regimen, dates, and reasons for changes:				

Drug/Device	Dosage/Regimen	Date Start	Date End	Pharm Record	Reason for change

Subject #: _____

		YES	NO	N/A	References:
4.1.a	Is drug/device administration documented in the: Research chart? Hospital/Medical chart? Clinic/Outpatient chart? Special Service chart (e.g. radiation oncology)? Specify: _____	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	
4.1.b	Is drug/device administration documented in the pharmacy record?	☐	☐	☐	
4.1.c	List treatment dosage/regimen, dates, and reasons for changes:				

Drug/Device	Dosage/Regimen	Date Start	Date End	Pharm Record	Reason for change

4. DRUG/DEVICE DISPENSING ACCOUNTABILITY, continued

Subject #: _____

		YES	NO	N/A	References:
4.1.a	Is drug/device administration documented in the: Research chart? Hospital/Medical chart? Clinic/Outpatient chart? Special Service chart (e.g. radiation oncology)? Specify: _____	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	
4.1.b	Is drug/device administration documented in the pharmacy record?	☐	☐	☐	
4.1.c	List treatment dosage/regimen, dates, and reasons for changes:				

	Drug/Device	Dosage/Regimen	Date Start	Date End	Pharm Record	Reason for change

Subject #: _____

		YES	NO	N/A	References:
4.1.a	Is drug/device administration documented in the: Research chart? Hospital/Medical chart? Clinic/Outpatient chart? Special Service chart (e.g. radiation oncology)? Specify: _____	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	
4.1.b	Is drug/device administration documented in the pharmacy record?	☐	☐	☐	
4.1.c	List treatment dosage/regimen, dates, and reasons for changes:				

	Drug/Device	Dosage/Regimen	Date Start	Date End	Pharm Record	Reason for change

4. DRUG/DEVICE DISPENSING ACCOUNTABILITY, continued

Subject #: _____

		YES	NO	N/A	References:
4.1.a	Is drug/device administration documented in the: Research chart? Hospital/Medical chart? Clinic/Outpatient chart? Special Service chart (e.g. radiation oncology)? Specify: _____	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	
4.1.b	Is drug/device administration documented in the pharmacy record?	☐	☐	☐	
4.1.c	List treatment dosage/regimen, dates, and reasons for changes:				

	Drug/Device	Dosage/Regimen	Date Start	Date End	Pharm Record	Reason for change

Subject #: _____

		YES	NO	N/A	References:
4.1.a	Is drug/device administration documented in the: Research chart? Hospital/Medical chart? Clinic/Outpatient chart? Special Service chart (e.g. radiation oncology)? Specify: _____	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	 ☐ ☐ ☐ ☐	
4.1.b	Is drug/device administration documented in the pharmacy record?	☐	☐	☐	
4.1.c	List treatment dosage/regimen, dates, and reasons for changes:				

	Drug/Device	Dosage/Regimen	Date Start	Date End	Pharm Record	Reason for change

Please use this space for any necessary explanations regarding drug/device administration/accountability:

5. CASE REPORT FORM (CRF) / SOURCE DOCUMENTS

References:
21 CFR 312.62(b)
ICH GCP 1.51
ICH GCP 1.52
ICH GCP 8.3.13

Review CRF documentation for the subjects you have chosen for inspection and complete the following. Add additional space as necessary to accommodate the number of chosen subjects.

		YES	NO	N/A	References:
5.1	Are there CRFs for this study?	☐	☐	☐	ICH GCP 4.9.1 ICH GCP 4.9.2
5.1.a	If not, how are study data compiled (recorded and reported)?				
5.2	List all source documents:				
5.3	Are all protocol-required procedures performed and captured in the CRF/source documents for each subject?				ICH GCP 4.9.1 ICH GCP 4.9.2
		YES	NO	N/A	Comments
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
5.4	Does the source documentation for each subject include dated signature/initials of the person obtaining the information for each subject?				ICH GCP 8.3.14
		YES	NO	N/A	Comments
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
	Subject # or ID:	☐	☐	☐	
5.4	Are changes/cross-outs (if any) routinely initialed and dated in subject file?	☐	☐	☐	ICH GCP 4.9.3

6. INCIDENTS AND DEVIATIONS

Review CRF documentation for the subjects you have chosen for inspection and complete the following. Add additional space as necessary to accommodate the number of chosen subjects.

6.1	Were there any incidents or protocol deviations?					Reference:
	Subject # or ID	Description	YES	NO	N/A	
			☐	☐	☐	
			☐	☐	☐	
			☐	☐	☐	
			☐	☐	☐	
			☐	☐	☐	
			☐	☐	☐	
6.2	Have these incidents been reported to the IRB?		☐	☐	☐	
6.2.a	If not, please give explanation:					
6.3	General comments regarding incidents or protocol deviations:					

APPENDIX A

SUBJECT ENROLLMENT

Compliance with eligibility criteria will be evaluated for each subject included in the audit sample.

As of April 2005, all new submissions to BRAAN must have eligibility checklists which are to be completed for all subjects that are screened. If checklists have been completed, use those copies for this portion of the audit. If there is no checklist (pre-4/05), use the format below to make your own version. In either case, the "Yes" and "No" columns should be used to indicate whether or not a candidate fits criteria. Use the margin to indicate whether or not source documentation validates the eligibility decisions.

Subject # or ID: _____

Yes	No	Inclusion Criteria

Yes	No	Inclusion Criteria

	YES	NO	Comments
Is it documented that the subject met inclusion criteria?	☐	☐	
Is it documented that the subject did not meet exclusion criteria?	☐	☐	
General comments about the enrollment process:			

SUMMARY

	YES	NO	Comments
Is it documented that all enrolled subjects met inclusion criteria?	☐	☐	If not, which subjects and which criteria did not have source documentation to support the decision?
Is it documented that all enrolled subjects did not meet exclusion criteria?	☐	☐	If not, which subjects and which criteria did not have source documentation to support the decision?
General comments about the enrollment process:			

APPENDIX B

RESEARCH PROCEDURES

Protocol adherence will be evaluated for each subject included in the audit sample. Copies of the flow chart from the study RPN, or copies of this appendix, may be used to facilitate this process.

Subject # or ID: _____

Protocol-Specific Research Procedures				
Procedure	**Yes**	**No**	**Date**	**Comments**
	☐	☐		
	☐	☐		
	☐	☐		
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