



R&D COMMITTEE

Worksheet for Submitting a Human Subjects Research Project

- | | |
|---|--|
| <input type="checkbox"/> NEW PROTOCOL
<input type="checkbox"/> ANNUAL UPDATE
<input type="checkbox"/> STUDY CLOSEOUT | <input type="checkbox"/> AMENDMENT (office determines type)
<input type="checkbox"/> Administrative review
<input type="checkbox"/> Full review |
|---|--|

GENERAL INFORMATION

Principal Investigator	
E-mail Address	
Study Coordinator(s)	
Contact person/info	
IRB Protocol Number	
Study Title	
Date of IRB Initial Approval	
Amendments	This is Amendment # _____. Approved by the IRB: _____ Short description:
Annual Update (AU)	Study is still enrolling? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A #Screened to date 444 #Enrolled to date 444 Have any SAEs occurred since last AU? <input type="checkbox"/> Yes <input type="checkbox"/> No
Date of Closure	

For OFFICE USE ONLY:

Amendments (modifications) do not need to be voted on individually by a convened R&D Committee UNLESS any of the following apply:

Answer the following questions to determine eligibility for Administrative review:

1. Yes No Does the amendment require review by the Radiation Safety Officer?
2. Yes No Does the amendment require review by the Subcommittee on Research Safety?
3. Yes No Does the amendment change the risk level of the study?
4. Yes No Is there is a change in data management that would require review by the Privacy and/or Information Security Officers?
5. Yes No Does the amendment involves the decisionally impaired or other vulnerable populations.

6. Yes No Was the study suspended?

7. Yes No Was the amendment a result a full R&D committee requirement?

A no answer to all the questions means the amendments are eligible but not guaranteed administrative approval by the RDC. Depending on the nature of the modification, some amendments may need further review, the RDC Chair makes the final decision on administrative review eligibility.

If #1-7 do not apply, the amendment and supporting documents must still be reviewed (including Checklist B), an approval letter produced, and placed in the R&D files. It is listed on the R&D agenda as “For Information Purposes” section.

Module Name of Form	Required for:				Submitted
	New Submissions	Amend ment	Ann. Up- date	Close- Out	
Protocol (as submitted to IRB)					
Investigator’s Brochure (if applicable, as submitted to IRB)					
Printed copy of BRAAN protocol					
Printed copy of Modification Request (from BRAAN)					
Printed copy of Annual Report (from BRAAN)					
HIPAA authorization form and/or waiver [Request waiver letter from IRB]		[if applicable]			
IRB Approval letter					
Approved IRB VA Form 10-1086 consent form, <i>with VA contact, VA phone number and VA injury statement on consent form</i>		[if applicable]			
Study Activity Schedule with “research purpose only” (R) v. “clinical care” (C) clearly <u>identified</u> ; copy of the BRAAN study schedule is OK		[if applicable]			
Confirmation of Required Trainings for PI Y <input type="checkbox"/> N <input type="checkbox"/> CITI Y <input type="checkbox"/> N <input type="checkbox"/> GCP modules in CITI Y <input type="checkbox"/> N <input type="checkbox"/> VHA Privacy Policy Y <input type="checkbox"/> N <input type="checkbox"/> VA Cyber Security Awareness		[[for added staff only]			

Module Name of Form	Required for:				Submitted
	New Submi ssions	Amend ment	Ann. Up- date	Close- Out	
Y <input type="checkbox"/> N <input type="checkbox"/> Information Security 201 (PI is responsible for research staff adherence to required research training. Training adherence will be audited)					
If PI is a physician, (s)he is credentialed at the VAMHCS Y <input type="checkbox"/> N <input type="checkbox"/>		[[for added staff only]			
Research Staff are WOC or VA employees Y <input type="checkbox"/> N <input type="checkbox"/>		[[for added staff only]			
ISO Data Security Checklist for Principal Investigators (needs to be completed, even if a consent waiver or privacy waiver has been obtained)		[if change affects data handling]			
Outpatient Clinic: What is the name of the clinic you will be using? _____					
Will ANY drug (<i>investigational or not</i>) be used for the purposes of this study? ¹ Y <input type="checkbox"/> N <input type="checkbox"/> If “Y”, VA Form 10-9012 is required for <i>each</i> study-related drug,		[if applicable]			
Investigator must meet with Investigational Drug Pharmacist (IDP) (x7113) and must provide a hard copy of the research protocol to the IDP					
Copy of IDS agreement signed by PI and IDP (discussions on the agreement occurs during the meeting above.)		[if applicable]			
Will ANY device, equipment or procedure be used/done specifically for the purpose of this study, <i>even if the device/procedure is not in/of itself investigational?</i> Y <input type="checkbox"/> N <input type="checkbox"/> If “Y”, the following, <i>as applicable</i> , are required;		[if applicable]			
Attestation for the Use of <i>Investigational Devices</i> in the Conduct of a Research Study	[if applicable]	[if applicable]			

¹ OFFICE USE: If yes, notify the Investigational Drug Pharmacist; send materials for IDS review. Notified: _____

Module Name of Form	Required for:				Submitted
	New Submi ssions	Amend ment	Ann. Up- date	Close- Out	
Attestation for the Use of <u>Equipment</u> in the Conduct of a Research Study	[if applicable]	[if applicable]			
Attestation for the <u>Performance of Procedures</u> in the Conduct of a Research Study	[if applicable]	[if applicable]			
VA Form 10-0398 “Research Protocol Safety Survey” (RPSS)		[if applicable]			
Was Question 7 on the RPSS answered “Yes”? Y <input type="checkbox"/> N <input type="checkbox"/> If “Y”, VA Form 10-0398 Appendix A ‘Use of Radioactive Materials’ is required		[if applicable]			
Clinical Trials Data Sheet		[if applicable]			
Other: Project Data Sheet (from Promise)	N	N	Y	Y	
Other: Abstract	N	N	Y	Y	
Other:					