

Human Studies (IRB): Initial Submission Checklist

Protocol:

Investigator:

Date:

This form should be completed by the Investigator prior to submitting a study for initial review. All items must be addressed.

ITEMS PRESENT FOR INITIAL REVIEW	Yes	No	N/A	Comments
1. Page 18/Investigator Data: Page 18 is required for new Principal Investigators (PIs) or Co-Investigators only. If the PI has submitted a Page 18 for a prior study, do not re-submit. PIs must be VA faculty (full time, part time, or WOC). Medical residents, fellow, pharmacy students, and nursing students must contact the Research Office prior to a protocol submission. <i>Note: New Investigators must also submit a CV.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Initial Request to Review: Funding source must be included (write 4 digit number and sponsor name). If unfunded, use code 0000 and identify as none or pending sources. Once funded, you must notify the Research Office. This form must be signed by the Section/Service Chief or it will not be submitted to the IRB for review. Complete all applicable items.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Abstract: The abstract is mandatory and must be submitted on paper and electronically to the Research Office. Abstract should only be one page long with no special characters. The abstract should include the Purpose, Methodology, and Objectives.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Protocol: The protocol must contain all elements as required in the Research SOP RI 802, Research Protocol. Note: Two protocols may need to be submitted—the main protocol and a local protocol that is Durham specific for the procedures/research that will be done at the Durham VAMC as part of the study.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. Grant Application: If applicable, a copy of the grant must be submitted regardless of funding source.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Informed Consent: If applicable, the informed consent form be drafted using the VA Form 10-1086 template and must contain elements of informed consent as required in the Research SOP IC 701, General Requirements and Documentation of Informed Consent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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7. Waiver or Alteration of Informed Consent Process: Include if you are requesting a waiver or alteration of the required elements of informed consent (or if you want to screen and recruit prior to obtaining informed consent and HIPAA authorization).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Waiver of Informed Consent Documentation: Include if you are requesting a waiver of documented informed consent (e.g., consent process occurs but no signed ICF).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9. HIPAA Authorization: Must be included if you are obtaining written informed consent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10. Waiver or Alteration of HIPAA Authorization: Submit if you are requesting to waive or alter elements of HIPAA Authorization (or if you want to screen and recruit prior to obtaining informed consent and HIPAA authorization).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Include the following, as applicable:				
11. Investigator's Brochure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12. Package Insert	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13. Form 10-9012 (required for drug studies)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14. All surveys/questionnaires that will be given to subjects for completion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15. Typed telephone script	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16. Recruitment letters (no drafts)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17. Advertisements: Flyers, radio or newspaper adds, etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
18. VA Form 10-0398 Research Protocol Safety Survey (RPSS): <i>(Formerly Appendix G)</i> This form concerns safety issues for the research team and is required when the study involves biological, chemical, physical, or radiation hazards. If the study involves any sample collection, transport, or processing by the VA clinical laboratory, the form is not required, as there are no concerns for the research team.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19. Privacy, Confidentiality, and Information Security Checklist: The Privacy Officer (PO) and Information Security Officer (ISO) reviews should occur prior to IRB submission. The Checklist and supporting documentation should be completed, signed by the PI, and submitted electronically to the PO and ISO at the same time. Do not submit your application to the IRB until you have made all corrections and have signed PO and ISO approval.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20. Staff Listing: A completed Staff Listing must be submitted for initial review.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
21. Conflict of Interest Survey: All Investigators (including co-Investigators, sub-Investigators, etc.) must complete this form.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
22. Exemption Application: Required if the project is exempt from IRB review (not human subject research).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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23. Declaration of HIPAA De-Identification: Required if you are using de-identified data to conduct analyses.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
24. Packing and/or Shipping of Biological Specimens: If research personnel package or ship biological samples, they must receive specific training and provide documentation with this submission.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
25. Standard Operating Procedure (SOP) for Using Human Blood or Tissue: Required if human samples are collected or transported by the research staff, or if they are processed and or analyzed in a research laboratory.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
26. Recombinant DNA Form: This form is required if the protocol includes the generation of recombinant DNA.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
27. Viral Vector Form: Required if the protocol includes the use of viral vectors for recombinant DNA purposes.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
28. Application to Establish a Research Data Repository: Include if you are establishing a new research data repository.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
29. Research Data Repository Written Procedures for Operations: Include if you are submitting a protocol that will establish a research data repository. <i>Note: The written procedures for operations (SOPs) must also be reviewed by the ISO and PO.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
30. Application to Use Data from a Data Repository: Include if you are requesting to use data from a VA data repository.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
31. Department of Defense (DoD)-funded Research: DoD-funded research is subject to additional review requirements. Complete and submit the "Durham VAMC Supplemental Information, Application, and Review of Human Subjects Research Involving the DoD" form. Additional documentation may also be required. Contact the Research Office for more information and education.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
32. Department of Education (ED)-funded Research: ED-funded research is subject to additional review requirements. Complete and submit the "Durham VAMC Supplemental Information, Application, and Review of Human Subjects Research Funded by the ED" form. Additional documentation may also be required. Contact the Research Office for more information and education.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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33. Data Management and Access Plan (DMAP): This document supports policy requiring VA investigators include in their research proposals, a data management plan that describes how, where, and to the extent to which they will make the data and results of their research available to the public and specifying what data will be available in machine readable formats.	<input type="checkbox"/>	<input type="checkbox"/>		

Comments:

Principal Investigator Signature	Date