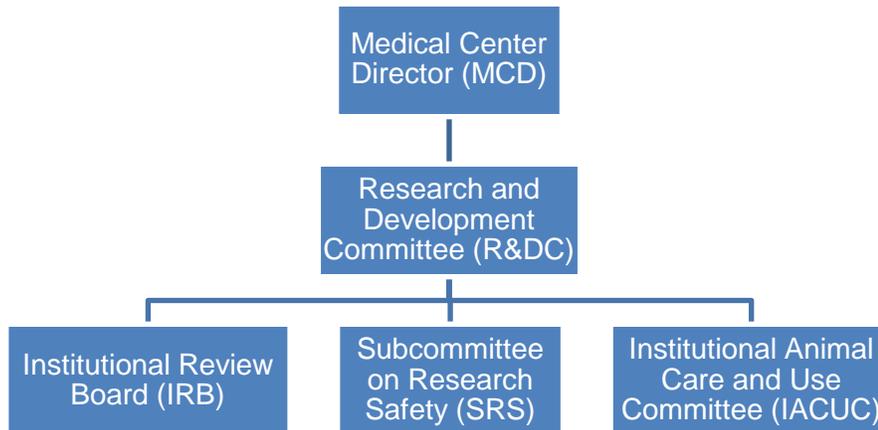


DURHAM VAMC RESEARCH PROGRAM INFORMATION SHEET



RESEARCH OFFICE CONTACTS:

Name	Point of Contact	Contact Information
John Whited, MD	Associate Chief of Staff, Research and Development	X6926 John.Whited@va.gov
Brad Olson	Administrative Officer	
Nancy Dixon	Research Secretary	X6926 / Nancy.Dixon5@va.gov
Hayley White	Human Research Protections Program (HRPP) Coordinator	X4726 / Hayley.White2@va.gov
Kelvin Pleasant	Program Administrator	X5170 / Kelvin.Pleasant@va.gov
Kim Clark	Budget / Participant Payments / Research Scope of Practice	X5671 Kimberly.Clark5@va.gov
Jamece Petteway	Supervisory Budget Analyst / project funding	X6544 Jamece.Petteway@va.gov
Lester Nichols	Safety and Occupational Health Specialist / archiving records / inventory	X7341 / 919-880-6917 Lester.Nichols@va.gov
Margaret Jones	Research Compliance Officer / Annual Informed Consent Audits / Triennial Research Audits	X7616 Margaret.Jones@va.gov
Virginia Rhodes	Research Compliance Officer / Annual Informed Consent Audits / Triennial Research Audits	X7616 Virginia.Rhodes@va.gov

INFORMATION SECURITY OFFICER / PRIVACY OFFICER

Jeffrey (Scott) Gardiner	VHADURISOSUPPORT@va.gov
Pauline (Michelle) Denison	
Thomas Delaney	VHADURPOSUPPORT@va.gov
Rita Davison	

DURHAM VAMC RESEARCH PROGRAM INFORMATION SHEET

IRB submission items that need ISO/PO review *PRIOR* to IRB review:

1. All Initial Review Submission
2. Amendments that require a change in the collection, transmission/storage or management of data or changes to HIPAA authorization or waiver status. Contact ISO/PO if you are unsure.

IRB SUBMISSIONS:

- All IRB submission and reporting forms are found here:
<http://www.durham.va.gov/research/research.asp>
- IRB submissions must have an accompanying memo signed by investigator describing the reason for submission and providing a rationale for any modifications made (e.g., rationale for the change in inclusion or exclusion criteria). The memo should also detail each change made and where it can be found in the submission packet (e.g., document title and page number).
- Included tracked changes version and clean version in the submission

DURHAM IRB REPORTING REQUIREMENTS:

- Immediate (*within 1 hour*)
 - Local Research Deaths--oral notification of the Institutional Review Board (IRB) immediately upon becoming aware of any local research death that is ***both unanticipated*** and ***related*** to the research.
 - Call the research office using the contact numbers listed above
- Immediate (*within 5 business days of learning of the event*)
 - Local Serious adverse event that is ***both*** unanticipated and related to the research
 - Local Serious Problem that is ***both*** unanticipated and related to research
 - For local serious problems or serious adverse events that are both unanticipated and related, submit the ***Serious Unanticipated Adverse Event or Problem Related to Research Report Form*** to IRB/Research Office.
 - Privacy and/or Information Security incidents in VA research—inappropriate access, loss or theft of PHI; noncompliant storage, transmission, removal, or destruction of PHI; theft, loss or nonprompt description of equipment containing PHI.
- Immediate (*within one hour*):
 - Report potential privacy and information security incidents, regardless of whether it is serious or not, immediately (within one hour) to VHADURResearchEventReport@va.gov. Second, submit to the IRB using the ***Report Form for Privacy and/or Information Security Incidents in VA Research*** within 5 business days of learning of the event (see above).
- All other local adverse events or protocol deviations will be reported at the time of continuing review.

DURHAM VAMC RESEARCH PROGRAM INFORMATION SHEET

PARTICIPANT RECRUITMENT/CONTACT:

- First contact must be made via face-to-face contact or mailed letter, unless subject has agreed to be re-contacted for future research via another study.
- When returning phone calls to potential subjects or enrolled subjects: Leave a HIPAA compliant message that gives your name, telephone number and institutional affiliation (Durham VAMC)

CPRS:

- Set up a non-billable research clinic in CPRS. E.g, DUR-RESEARCH-[PI Name]
- clinic activation: (*right click, select 'open link'*)

Clinic Build/Modification/Deactivation Request

- Primary Stop Code: 474
- Appointment type: Research
- Select 'NO' for appointment / cancellation letters
- Contact Jonathan.Bunting@va.gov or Theresa.Holloway@va.gov for assistance in setting up the non-billable research clinic.
- All research related procedures (e.g., labs, EKG) must be ordered through the research clinic.
- Research Consent Note must be entered within 24 hours of subject providing informed consent. Entered by individual who administered the consent.
 - CPRS Note title: RESEARCH-CONSENT NOTE
- If a Clinical Warning is required (IRB makes the determination): enter CPRS note titled, RESEARCH-STUDY PARTICIPANT NOTE
 - Clinical warning must be removed via VistA after subject has completed or withdrawn from the study.
- VA Form 10-9012 Investigational Drug Record—must be scanned into the medical record within 14 days of subject signing consent (attach to the RESEARCH-STUDY PARTICIPANT NOTE)
- Research progress notes / follow-up notes: should be entered within 48 hours of follow-up visit.
 - Certificate of Confidentiality—no annotation in medical record is required.

DURHAM VAMC RESEARCH PROGRAM INFORMATION SHEET

REMOVE CLINICAL WARNING (Research Study Participant Note) IN CPRS

Select icon on desktop:



Log in information is the same as CPRS

Select Division: type DURHAM VA MEDICAL CENTER, then *enter* command → next screen says “Select Basic Menu Option:” → Type “Progress Notes”, then *enter* command → type “1”, then *enter* command → type “2b”, then *enter* command → Type last name initial and last 4, *enter* → type note number (type ‘+’ and enter to see more notes or search by author) → type “Change Title”, *enter* → Type “RESEARCH-PRIOR STUDY PARTICIPANT” → press enter → type “^” and *enter* to exit VISTA.

GOOD CLINICAL PRACTICE TIPS:

- Never whiteout or erase mistakes on research documents
- To correct mistakes—draw a single line through the text, initial and date beside the edit
- The participant must sign and date the ICF and HIPAA Authorization
- Ensure the correct spelling of the participant’s name is included on all pages of the Informed Consent.
- Create a Note-To-File and for any discrepancies that do not require reporting to IRB.

TRAINING, CERTIFICATES, and COMPETENCY EVALUATIONS:

- Required Training: *VA Human Subjects Protection and Good Clinical Practices*
- <https://www.citiprogram.org/>



CITI Training
Instructions.pdf

- Valid for 3 years
- Research Scope of Practice: All new Research employees/WOCs/IPAs, etc. must submit an initial Scope of Practice.
 - A new Research Scope of Practice must be submitted if there are any changes in his/her responsibilities
 - Research Scope of Practice must be updated if supervising Investigators has changed

DURHAM VAMC RESEARCH PROGRAM INFORMATION SHEET

- Blood Collection Competency Evaluation
 - Required annually, unless exempt, for research staff performing blood draws for research purposes.
- Vital Signs Competency Evaluation
 - Required annually, unless exempt, for research staff collecting vital signs for research purposes.

MONITORING AND AUDITING

- DVHACS Monitoring and Auditing
 - Annual Informed Consent Audit--DVAHCS Research Compliance Officer(s) (RCO) will conduct an annual informed consent audit on all studies, including studies that have a waiver of informed consent process or waiver of informed consent documentation.
 - Triennial audit—RCO(s) will conduct a regulatory audit for all protocols every three years, or when the study is closed.
 - For cause Audit—For cause audits may be authorized/requested by the IRB for various reasons. If your research is selected for a for-cause audit, you will be notified and given instructions as to what documentation will be reviewed.
- Other VA monitors (e.g., SMART monitors / CSP studies)
 - VA monitors who have a VA issued PIV card do not need to check into the research office to obtain a visitor's badge.
 - Complete the CRA Monitoring Visit Entrance and Exit forms and email to Courtney.Taylor@va.gov
 - Forms are available here: https://www.durham.va.gov/research/amendments/Amendments_Miscellaneous_Forms.asp
- Non-VA monitors (e.g., industry sponsored trials)
 - On the first day of the visit, the monitor must check-in with the Research Office, Nancy Dixon (room 119A) to obtain a visitors badge.
 - Complete the CRA Monitoring Visit Entrance and Exit forms and email to Courtney.Taylor@va.gov
 - Forms are available here: https://www.durham.va.gov/research/amendments/Amendments_Miscellaneous_Forms.asp

DURHAM VAMC RESEARCH PROGRAM INFORMATION SHEET

STUDY CLOSURE

- When to close a study:
 - Individually identifiable data are no longer being collected
 - All approved data analyses (and manuscript preparations) and data cleaning are complete
 - The sponsor closes a study or, if multi-site industry-sponsored research, the PI submits a final report to the sponsor, or
 - Multi-site non-industry studies where Durham is not the lead site may be closed with the Durham PI is no longer collecting data
- Studies can be closed at the time of continuing Review our outside continuing review. If the study is closed outside the time of continuing review, submit a memo to IRB requesting study closure, along with a progress report since the last continuing review.
- Record retention and storage:
 - Investigator files must be maintained for 6 years, in most cases, after study closure.
 - Contact Lester.Nichols@va.gov for archiving and storage.