



NF/SGVHS STANDARD OPERATING PROCEDURES FOR SEPARATING VA RESEARCH FROM NON-VA RESEARCH

Beginning January 1, 2012, per direction from the VA Office of Research Oversight, VA research facilities must ensure that VA research activities and data are clearly separated from non-VA research activities and data, and to ensure that the VA R&D Committee only approves the VA research activities.

1. VA research is research conducted by VA investigators (serving on compensated, without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded. (VHA Handbook 1200.01 §3.b)
2. The protocol(s) for research studies must clearly separate VA research activities and data from non-VA research activities and data, including for example where applicable, recruitment procedures, strategies, and advertisements; procedures, interactions, and interventions related to the research; data collection, storage, access, use, disclosure, and analysis; uses and disclosures of Protected Health Information (PHI); researchers and study team members roles and responsibilities; use of VA clinics, units, and laboratory locations; and VA Information Security and Privacy reviews.
3. “Off-site” VA research activities, including data collection and use, occurring at non-VA locations (i.e., locations not owned or leased by VA) must be clearly identified.
4. If VA data will be combined with non-VA data for “collaborative” studies, the protocol(s) must specify when and how this will occur and where the combined data will be stored.
5. A copy of any memorandum of understanding (MOU), or Cooperative Research and Development Agreement (CRADA) with the non-VA entity describing data ownership or data security arrangements for the “collaborative” study must be provided to the VA IRB and the VA R&D Committee.
6. For existing protocols in which VA data have already been combined with non-VA data at the time of continuing review, the continuing review materials must specify where the combined data are located, and separation of VA and non-VA research activities must be clearly defined.
7. The informed consent document and HIPAA authorization from both VA and non-VA sites must clearly separate VA research activities from non-VA research activities, and clearly state that:
 - (i) Resultant data are to be used in a multi-site (“collaborative”) study that combines VA data with non-VA data; **and**
 - (ii) The data are to be disclosed to the Coordinating Center site (located at either the VA site or the non-VA site) where the data will be combined and analyzed for the study.

NF/SGVHS PROTOCOL ADDENDUM FOR SEPARATING VA RESEARCH FROM NON-VA RESEARCH

Protocols for “collaborative” research studies must clearly separate VA research activities and VA data from non-VA research activities and non-VA data. Investigators with dual appointments at a VA facility and a non-VA (affiliate) institution must separate and document their activities as VA employees on VA time versus their activities as affiliate/collaborator employees on affiliate/collaborator time. The documentation must clarify (i) VA duties, (ii) VA duty locations, (iii) VA tours of duty or time allocations, (iv) issues related to data ownership, and (v) research information protection and data security requirements. The protocol submission form below is designed to help investigators separate VA research activities from non-VA research activities. Please complete sections 1-4 as applicable and include this document as an addendum to the study protocol.

Protocol Title:

Principal Investigator:

IRB Study Number:

1. Will ALL research related activities, including data storage take place at the VA?

a. If yes, please check here:

STOP: Because all research activities will be conducted at the VA, you do not need to complete the rest of this form.

By checking the box above you are indicating that ALL research related activities will be conducted by VA investigators (serving on compensated, without compensation (WOC), or Intergovernmental Personnel Agreement (IPA) appointments) while on VA time, utilizing VA resources (e.g. equipment), or on VA property including space leased to, or used by VA. The research may be funded by VA, by other sponsors, or be unfunded. If any of the research related activities will be conducted at a non-VA site, or if VA data will be combined with non-VA data, you will need to check “no” below and complete the remainder of this form.

b. If no, please check here: Complete sections 2-4 below. Please include detailed explanations. References to other study documents only will not be accepted.

2. Data Collection Activities:

- a. Describe in detail all data collection activities for the VA research¹ and non-VA research to be included in the “collaborative” study (including location of collection and storage, access and use, statistical analyses, and security measures).

VA Data Collection Activities:

Non-VA Data Collection Activities:

- b. If VA data will be combined with non-VA data, describe in detail when and how this will occur and where the combined data will be stored²:
- c. Identify any VA research activities occurring at non-VA sites (i.e., at non-VA properties).
- d. **CONTINUING REVIEW SUBMISSION ONLY:** For existing protocols in which VA data have already been combined with non-VA data at the time of continuing review, describe where the combined data are located.
- e. Provide a copy of any memorandum of understanding (MOU), or Cooperative Research and Development Agreement (CRADA) with the non-VA entity describing data ownership or data security arrangements for the “collaborative” study.
NOTE: Items “a” thru “e” **must** be reviewed and approved by the VA R&D Committee.
- f. If the protocol involves data collected in non-VA research (i.e., not collected by VA investigators serving on compensated, WOC, or IPA appointments while on VA time,

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² If the combined data are located at the non-VA site, investigators with dual appointments should not use the combined data while on VA time unless approved as an “off-site” VA research activity in consultation with ORD and Regional Counsel. Data collection must take place at the VA site and non-VA site as separate activities that can be clearly distinguished. HIPAA authorizations and informed consent forms must make clear that VA data will be combined with non-VA data, and where it will be combined, analyzed and stored. **IMPORTANT:** Until VHA issues a record retention policy, ALL VA data must be maintained indefinitely.

utilizing VA resources, or on VA property including space leased to, or used by VA), explain how non-VA activities and data are separated from VA activities and data. These are activities that would be considered non-VA research.

NOTE: *The non-VA activities above must not be approved by the VA R&D Committee.*

3. Describe how the informed consent document and the HIPAA authorization inform the subject that:

- a. This is a “collaborative” study that will combine VA research activities and VA data with non-VA research activities and non-VA data.
- b. The data are to be disclosed to the Coordinating Center site located at (either the VA site or the non-VA site) where the data will be combined and analyzed for the “collaborative” study. (Describe where data will be combined and analyzed)

4. Summary of Activities for “Collaborative” Research

Briefly summarize below all research activities separating VA and non-VA research.

You must also clearly define how dual-appointed personnel are separating VA from non-VA activities. For example: If a dually appointed investigator is only participating in the study under their affiliate appointment, it must be clearly defined what activities are being done under the affiliate appointment.

RESEARCH ACTIVITIES	ACTIVITIES FOR VA RESEARCH These activities MUST be approved by the VA R&D Committee		ACTIVITIES FOR NON-VA RESEARCH These activities MUST NOT be approved by the VA R&D Committee	Explain how VA and NON-VA activities of Dual-Appointment personnel are distinguished
	VA Research Activities Conducted at VA Site	VA Research Activities Conducted at Non-VA Site		
Advertising				
Recruitment				
Research-related medical procedures to be performed (LIST)				
Other interventions or interactions with living individuals to be performed (LIST)				

RESEARCH ACTIVITIES	ACTIVITIES FOR VA RESEARCH These activities MUST be approved by the VA R&D Committee		ACTIVITIES FOR NON-VA RESEARCH These activities MUST NOT be approved by the VA R&D Committee	Explain how VA and NON-VA activities of Dual-Appointment personnel are distinguished
	VA Research Activities Conducted at VA Site	VA Research Activities Conducted at Non-VA Site		
Clinics, labs, other units to be used (LIST)				
PHI Use: (Who will collect, use and disclose)				
PHI Disclosure (Who will PHI be disclosed to)				
Data Coordinating Center				
Members of Research Team (List all from Addendum A)				