**Background**

ORO’s *Interim Guidance on Research Data Disclosures for “Collaborative” Studies*, dated July 27, 2011, recommends that when a study will combine data collected at both a VA site and an affiliate/collaborator site, the study should be implemented as a multi-site study with one of the sites serving as the “Coordinating Center.” The Coordinating Center site will receive the data disclosed by the other site and combine the data as needed for analysis.

1. Data collection for such “collaborative” studies must take place at the VA site and at the affiliate/collaborator site as separate activities that can be clearly distinguished.
2. If the affiliate/collaborator’s Institutional Review Board (IRB) serves as the VA’s IRB of Record, the IRB must either:
3. Approve two separate “protocols” (one VA “protocol” and one affiliate/collaborator “protocol”), ***or***
4. Approve a single “protocol” in which the activities constituting VA research can be clearly separated from the activities constituting the affiliate/collaborator research. In either case, the VA Research and Development (R&D) Committee may only approve the VA research activities (see definition at VHA Handbook 1200.01 §3.b).
5. Health Insurance Portability and Accountability Act (HIPAA) authorizations, informed consent documents, and study protocols for both sites must make clear that (i) resultant data are to be used in a multi-site study that combines VA data with affiliate/collaborator data; and (ii) the data are to be disclosed to the Coordinating Center site where the data will be combined and analyzed for the “collaborative” study.

After December 31, 2011, ORO will seek evidence of a good faith effort by VA research facilities to separate for “collaborative” studies the VA research activities and data from the non-VA (affiliate) research activities and data in a clear and systematic manner (as described in ORO’s *Interim Guidance* and *Implementation Update,* dated December 12, 2011). Such evidence may consist of one or both of the following:

* 1. Revised Standard Operating Procedures (SOPs) that describe the content and review procedures for protocols, informed consent documents, and HIPAA authorizations that clearly separate VA research activities from non-VA (affiliate) research activities.
  2. Revised protocol applications and templates that incorporate the content and review procedures for protocols, informed consent documents, and HIPAA authorizations that clearly separate VA research activities from non-VA (affiliate) research activities.

ORO provides the attached **sample documents** to assist facilities in their efforts to separate VA research from non-VA research. **Use of these sample documents is entirely optional.** Each facility should develop materials that are specific to its own research program.

**SAMPLE FACILITY STANDARD OPERATING PROCEDURES (SOPs)**

**FOR SEPARATING VA RESEARCH FROM NON-VA RESEARCH**

Beginning January 1, 2012, the VA research facilities must ensure that their R&D Committee SOPs and IRB SOPs have incorporated the following criteria for the initial and continuing reviews of each “collaborative” research project to 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 “collaborative” 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; VA clinics, units, and laboratory locations; and VA Information Security Officer (ISO) and Privacy Officer (PO) 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) 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.
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:
8. Resultant data are to be used in a multi-site (“collaborative”) study that combines VA data with non‑VA data; ***and***
9. 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.

**SAMPLE FACILITY PROTOCOL APPLICATION FORM**

**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.

**Protocol Title:**

**Principal Investigator:**

**IRB Protocol ID:**

1. **Data Collection Activities:**
2. Describe all data collection activities for the VA research[[1]](#footnote-1) to be included in the “collaborative” study (including location of collection and storage, access and use, statistical analyses, and security measures)

1. If VA data will be combined with non-VA data, describe when and how this will occur and where the combined data will be stored[[2]](#footnote-2)

1. Identify any VA research activities occurring at non-VA sites (i.e., at non-VA properties).

1. 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.

1. Provide a copy of any memorandum of understanding (MOU) 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.*

1. 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, 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.

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

1. **Describe how the informed consent document and the HIPAA authorization inform the subject that:**
2. This is a “collaborative” study that will combine VA research activities and VA data with non‑VA research activities and non-VA data.

1. 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.

1. **Summary of Activities for “Collaborative” Research**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 Site** | **Non-VA Site** |
| Advertising |  |  |  |  |
| Recruitment |  |  |  |  |
| Research-related medical procedures to be performed  **(LIST)** |  |  |  |  |
| Other  interventions or interactions with living individuals to be performed **(LIST)** |  |  |  |  |
| Clinics, labs, other units to be used **(LIST)** |  |  |  |  |
| PHI Use |  |  |  |  |
| PHI Disclosure |  |  |  |  |
| Data Coordinating Center |  |  |  |  |
| Members of Research Team **(LIST)** |  |  |  |  |

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) [↑](#footnote-ref-1)
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.* [↑](#footnote-ref-2)