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How to Manage Research Data in "Collaborative" Studies between the VA and the Affiliates

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Challenges & Opportunities Related to "Collaborative" Research with Affiliates

- Challenges
  - Federal Records Retention Requirements
  - Privacy/Confidentiality Requirements
    - Privacy Act, HIPAA Privacy Rule, etc
  - Data Ownership Issues
  - VA Data Security Requirements
  - Dual Appointment Investigator Issues

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Challenges & Opportunities Related to "Collaborative" Research with Affiliates

- Opportunities
  - *AAMC Working Group on Information Technology Security and Privacy in VA and NIH-Sponsored Research*
- The *Working Group* report describes:
  - Disclosure of PHI
  - Pursuant to a request from the affiliate
  - For use in non-VA research conducted by the affiliate
- ORO's *Interim Guidance*
  - Assumes (pending clarification in VA policy) that the *Working Group* report also applies to "collaborative" research in which VA data are combined with affiliate data

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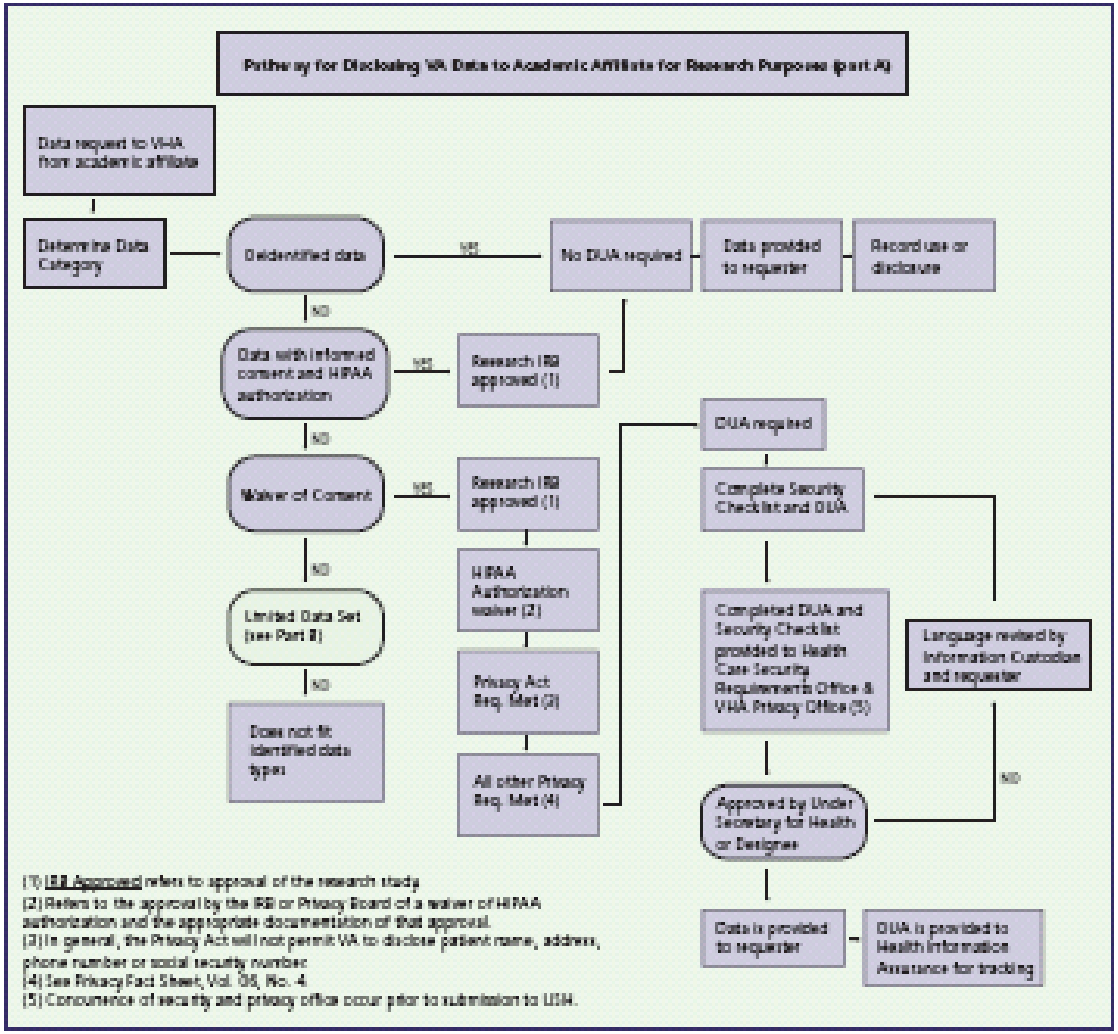
Working Group Report



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Record Retention Requirements

- VA research data must be maintained per Federal records retention and other requirements
- A Records Control Schedule approved by National Archives and Records Administration (NARA) is required to destroy Federal records
- Records Control Schedule for VA facility-level research records is currently under development
- VA facilities must retain data from VA research pending approval of an applicable Records Control Schedule

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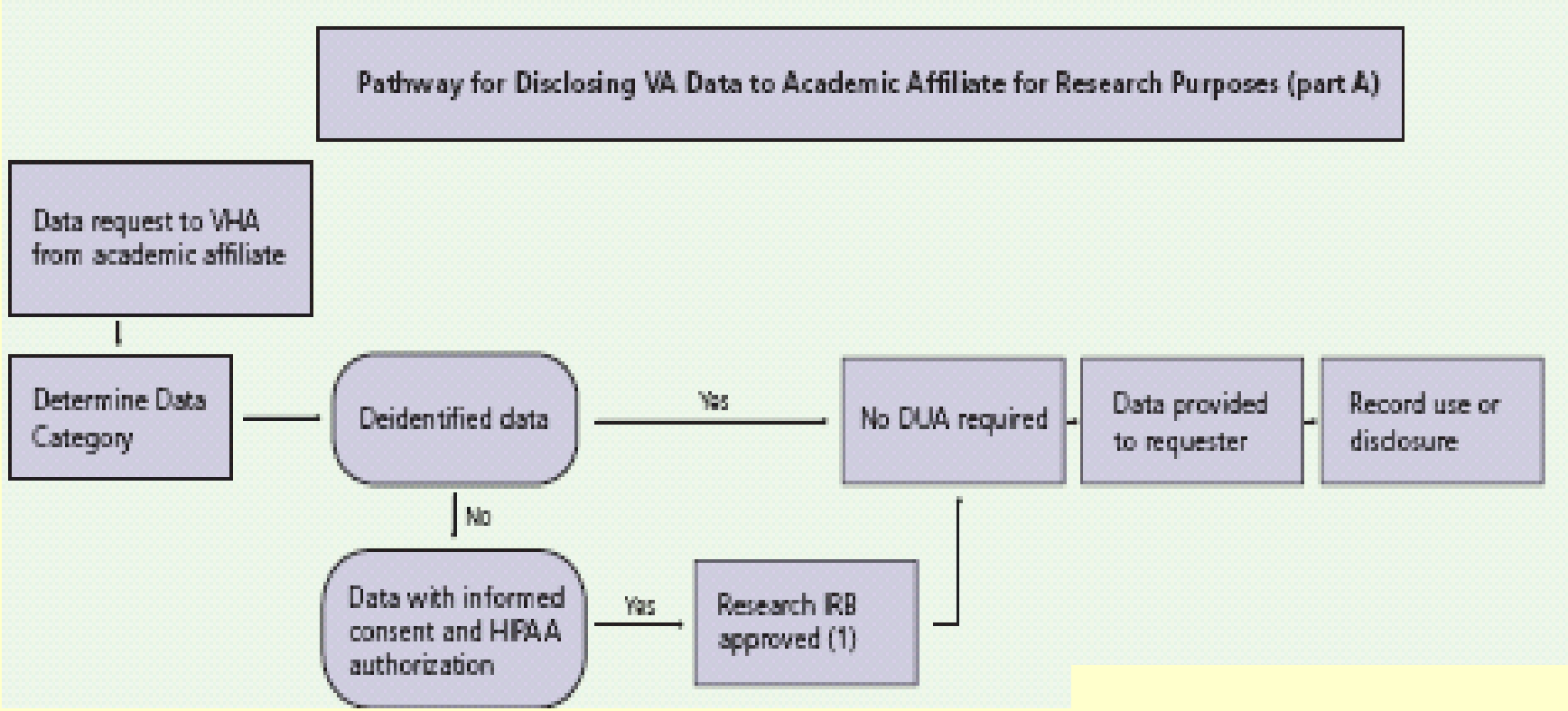
Working Group Report – Disclosure Under HIPAA Authorization

(Appendix A)



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Disclosure Under HIPAA Authorization

- Subject's HIPAA authorization permits VA to disclose subject's data for research as described in the authorization
- No Data Use Agreement required per *Working Group*
- Authorization, informed consent document, study protocol, and CRADA (where applicable) must be consistent as to data and purpose
- Authorization and consent must include all required elements and permit informed decision by subject
- Research data repository (per VHA Handbook 1200.12) must be established if use or disclosure by VA for future research (ie, outside study for which the data were collected) is anticipated

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Disclosure Under HIPAA Authorization – Data Ownership & Information Security

- Valid informed consent and HIPAA authorization are required
  - Informed consent and HIPAA authorization requirements apply to all VA PHI and individually identifiable private information that are used/disclosed for research
  - Includes clinical data used in research for “control” or “comparison” groups
- VA must retain a complete record (original or copy) of the disclosed data

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Disclosure Under HIPAA Authorization – Data Ownership & Information Security

- The record retained by VA is:
  - Owned by VA
  - Subject to VA information security requirements
- Once the disclosed copy is held by the Affiliate, VA may no longer be able to:
  - Control the disclosed copy
  - Enforce VA information security requirements

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Disclosure Under HIPAA Authorization – Policy Clarification Desirable

- *Working Group* describes disclosure pursuant to a request from the affiliate *vs* "collaborative research"
- Not clear that disclosure under a HIPAA authorization necessarily transfers ownership
- Without a DUA or other legal agreement, it would seem problematic, for VA to exert ownership of the disclosed copy of any data provided to the affiliate/collaborator
- A DUA or other legal agreement would seem to be advisable if VA wishes to exercise ownership or control of disclosed data

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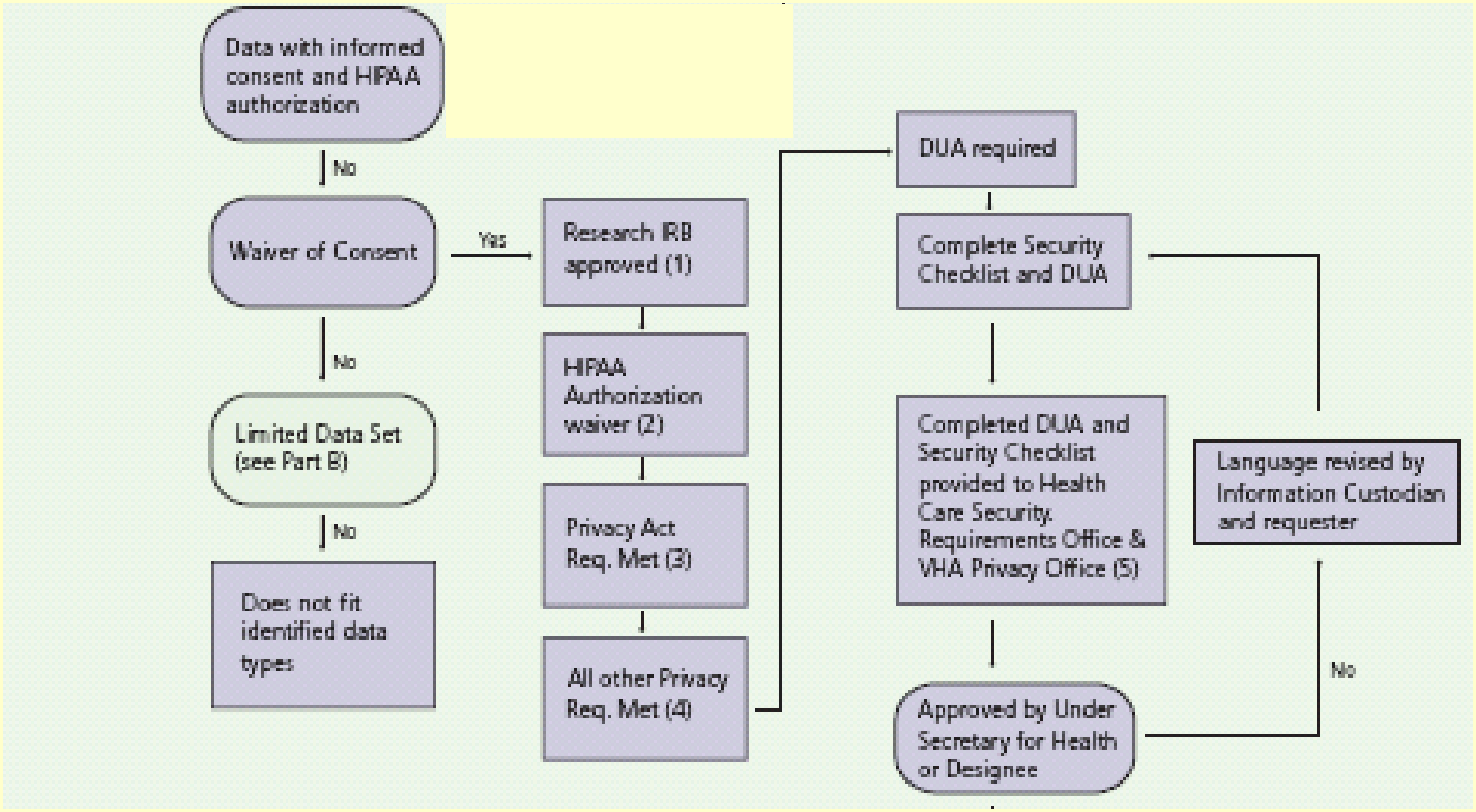
Working Group Report –

Disclosure without Authorization and Consent

(Appendix A)



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"Working Group" Report

Disclosure Without HIPAA Authorization and/or Informed Consent

- Requirements are fact-specific
- ORO strongly recommends consulting ORD, the VHA Privacy Office, and Regional Counsel prior to such disclosures

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VA Information Security Requirements

- Apply to all research data owned by VA
- If maintained electronically and containing VA Sensitive Information (VASI) must reside on VA-owned equipment unless:
  - A waiver has been approved by the VA CIO ***or***
  - A valid Memorandum of Understanding / System Interconnection Agreement (MUA/SIA) has been approved ***or***
  - Where appropriate, a valid contract with VA's security clause and security requirements has been established to permit alternate arrangements.

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Investigators Holding Dual Appointments

- Critical to separate and document:
  - VA activities on VA time *vs*
  - Affiliate activities on affiliate time
- Documentation should clarify:
  - VA duties
  - VA duty locations
  - VA tours of duty or time allocations
  - Data ownership issues
  - Data security requirements
- Separation of VA activities/research from affiliate activities/research is critical for studies combining VA data with affiliate data

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Combining VA Data with Affiliate Data for "Collaborative" Studies

- VA data are data collected:
  - By a VA investigator
  - On VA time
  - Under a protocol approved by the VA IRB of Record and the VA R&D Committee
- Affiliate data are data collected:
  - By an Affiliate investigator
  - On affiliate time
  - Under a protocol approved by the affiliate IRB

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Combining VA Data with Affiliate Data for "Collaborative" Studies -- Separate Activities Defined for Each Site

- The "collaborative" study should be implemented as a multi-site study with activities clearly defined for each site
- Critical factors:
  - Data collection should typically take place at the VA site on VA time and at the affiliate/collaborator site on affiliate/collaborator time as separate activities that can be clearly distinguished by the IRB and the R&DC
  - The status "off-site" VA research taking place at an affiliate site on VA time should be clarified through a written agreement with the affiliate addressing data ownership and responsibility for research-related injury
  - The R&D Committee must only approve the VA research

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Combining VA Data with Affiliate Data for "Collaborative" Studies When Affiliate IRB is VA IRB of Record

- Each facility exercises latitude in administrative management of its research projects
- If the Affiliate IRB serves as the VA IRB of Record, the IRB may ***either***:
  - Approve two separate "protocols" – one for the VA research and one for the Affiliate research

    or

  - Approve a single "protocol" under which the VA research activities are clearly separated from the affiliate research activities

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Combining VA Data with Affiliate Data for "Collaborative" Studies When Affiliate IRB is VA IRB of Record

- For existing "collaborative" studies with a single "protocol," ORO suggests:
  - Separation of VA vs Affiliate research at applicable continuing reviews occurring after December 31, 2011
  - By appropriately amending the informed consent documents and HIPAA authorizations

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Combining VA Data with Affiliate Data for "Collaborative" Studies When Affiliate IRB is VA IRB of Record

- For new "collaborative" studies with a single "protocol," ORO suggests:
  - Separation of VA vs Affiliate research at initial reviews occurring after December 31, 2011
  - In addition to informed consent documents and HIPAA authorizations, relevant areas of separation may include:
    - Recruitment procedures/strategies/advertisements
    - Research related procedures
    - Data collection/storage/uses/disclosures
    - VA researchers/personnel/staff
    - VA Clinics/Units/Labs/Locations involved
    - Results of VA ISO and PO reviews

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Combining VA Data with Affiliate Data for "Collaborative" Studies

- Protocols, consent documents, and authorizations for both sites must include:
  - Use of data in a multi-site study combining VA data and affiliate data
  - Data will be disclosed to study Coordinating Center
  - Location of Coordinating Center

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Combining VA Data with Affiliate Data for "Collaborative" Studies

- If Coordinating Center is at the VA site, the VA research described in the "protocol" must include:
  - Interaction/intervention and data collection activities at VA
  - Activities of the Coordinating Center

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Combining VA Data with Affiliate Data for "Collaborative" Studies

- If Coordinating Center is at the Affiliate Site :
  - A dual appointment investigator should not conduct research using the combined data set while on VA time unless data ownership issues have been clarified in writing
  - ORO strongly recommends consultation with ORD and Regional Counsel regarding data ownership clarifications

Office of Research Oversight
Combining VA Data with Affiliate Data for "Collaborative" Studies
Related Documents

- *ORO Interim Guidance on Research Data Disclosures for "Collaborative" Studies (July 27, 2011)*

- *AAMC Working Group on Information Technology Security and Privacy in VA and NIH-Sponsored Research*

Available at:
http://vaww.vha.vaco.portal.va.gov/sites/ORO/RCO/default.aspx
(click on: Memoranda, Clarifications, and Guidance)

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VA Funding Available:

- Career Development – Intended to attract, develop and retain talented researchers working in areas of particular importance to improve the health and care of our nation's Veterans.
- VA Merit Grants – Funding of the merit is capped at $150,000 annually. The first year may contain an additional $50,000 in equipment or start-up funds. Studies are funded between three to five years
- VA Cooperative Studies Program (CSP)
- RIPS (Research Initiative Programs) – A one-time $10,000 grant. Typically for newer investigators.
- NIH/DOD – Funding varies (Administered through CERV)
- Industry Sponsored (Administered through CERV)

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Merit Review Qualifications:

- To be eligible to submit Merit Review proposals to BLR&D or CSR&D Services, the PI must have at least a 5/8ths time VA appointment at the time the Merit Review award is funded.
- In addition, all new non-clinician PIs must be accepted into the BLR&D and CSR&D intramural research program. For purposes of eligibility, a clinician is defined as a licensed practitioner with a doctoral degree (MD, DO, DDS, etc.), who treats patients at a VA Medical Center (VAMC). All others are considered as non-clinicians.
- An applicant must be a current U.S. citizen in order to submit an application for acceptance into non-clinician eligibility program or have a firm date for being sworn in as a U.S. citizen and submit documentation from the Immigration and Naturalization Service.
- This eligibility criteria is only for non-clinician investigators with doctoral degree (Ph.D. or equivalent).
- A junior investigator must be within 10 years of obtaining doctoral degree and is an independent PI.

Note: If you are a non-clinician interested in submitting grants, please contact the Cincinnati VA Research Service

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Clinical Research Unit

- TBN, Director
- Colleen Rogge, RN, Nurse Manager (475-6478)
- 3 Study Coordinators
- VA and non-VA funded studies
- Planned overnight housing
- Part of CCTST with CCHMC, UC
- Seed grants (RIP, Rehn)

Cincinnati Education and Research for Veterans Foundation (CERV)

- Used for the submission of NIH/DOD or Industry Sponsored grants at the VA
- Ron Hakes, Executive Director of CERV 513-474-6403
- http://www.cervf.org/

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