How to use the **newly enacted policy** for storage on the **CCTSI REDCap Instance** of **data collected on veteran subjects*** who were enrolled into multisite studies at the Denver VA Medical Center

*Veteran’s data that can be stored on the CCTSI REDCap following this policy can include any PHI and/or PII approved for collection by COMIRB
Events occurring during the last decade involving the loss of Veteran’s Personal Health Information have led to an increased scrutiny and stringency regarding use of veterans’ data, which is considered to be owned by the VA, outside of the VA.

Such “VA Data” is protected by numerous VHA Information Security Requirements.

Data is considered “VA Data” if it is collected during the performance of research approved by the VA Research and Development Committee, or is collected, managed or analyzed by VA personnel working on “VA time”.
“VA Data” Security Requirements have served as an impediment to the performance of multisite studies, coordinated by an outside affiliate and which desire to use the VA as a performance site.

The National Institutes of Health, Association of American Medical Colleges, and the Veterans Health Administration recognized this was the case, and in 2010 they convened a working group to discuss and propose policies which would allow for collaborative efforts to progress between VA’s and their affiliated academic institutions.
Collaborative efforts between the Denver VA Medical Center and the University of Colorado, Anschutz Medical Campus, led by the UC-VA Research Liaison, resulted in the formulation of a policy, based upon the ORO Guidance Document, to allow investigators to place “disclosed” VA data on the CCTSI REDCap Instance.
The purpose of this presentation is to...

Outline the process for adding the VA as performance site to an existing COMIRB study (requires identifying a VA PI or obtaining a VA appointment).

Detail the new policy relating to necessary documents for “disclosure” of veterans’ data to projects on the CCTSI REDCap.

Describe VA Research Data Storage Requirements and how they relate to disclosure of veterans’ data to the CCTSI REDCap.

Discuss policies relating to VA requirements for time allocation during the collection, disclosure and subsequent manipulation of veterans’ data relating to CCTSI REDCap storage.
New or Existing Applications Adding VA as a Site

VA Submission Process: Effective 10/1/13

PI/Coordinator e-mails all documents to VA: Connie in Research Office
Connie.Steinbrunn@va.gov

VA pre-review
Coordinated by VA Research Office

VA Clearance
Letter sent to PI/Coord

PI /Coordinator Receives VA Clearance Letter; sends submission packet (including VA Clearance Letter) to COMIRB

COMIRB receives Paperwork and Conducts review

COMIRB Approval Sent to PI without Consent document

R&D Approval letter & VA Consent sent to COMIRB for file

R&D Committee/ Final Approval

Stamp Consent And R&D Approval Letter Sent to PI and Coordinator

PI can begin research

VA Research Office

VA recommends obtaining Required Research Impact Statement Signatures as soon as possible, but Required prior to R&D Approval

Receipt of RIS Signatures

If necessary, Identify a VA PI

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VA Research Office
Review and Sign Policy Document with the VA Privacy Officer

Execute VA Consent Form with Veteran Subject containing the REDCap “disclosure” language

Execute HIPAAB Form with Veteran Subject with REDCap “disclosure” language
Pete Watson PhD, Research Liaison
Denver VA Medical Center/University of Colorado,
Anschutz Medical Campus/COMIRB

“Owned” by VA

Collected or Generated on “VA time”

Copied of Disclosed Data

Kept by VA

“Owned” by CCTSI

Collected or Generated on “Affiliate time”

Disclosed Data

Placed in Project on CCTSI REDCap
Collection of Primary Data from Veterans
Preparation of Copy of “Disclosed” Data
Storage of Primary and Copy of Disclosed Data

Placement of “Disclosed” Data on CCTSI REDCap
Management of mixed VA “Disclosed” data and “other” Performance Site Data on CCTSI REDCap

Data Disclosure
Add the VA as a Performance Site

- Support of Research Liaison and Research Administrative Staff is available when preparing documents
- Include REDCap language in VA Consent and HIPAA B
- If necessary, identify a VA PI

The VA PI must sign the REDCap Policy Document with the Privacy Officer.

Enroll veterans at the Denver VA Medical Center using the VA Consent and HIPAA B containing the “REDCap disclosure language”

The “VA PI” or “VA coordinator” collects Data and prepares a copy of data for “disclosure” on “VA time”

Disclose Data to REDCap by placing it in your project on “affiliate time”.

Manage and analyze “disclosed” VA Data and Mixed “Affiliate Data” on REDCap during “affiliate time”.
Questions?

Need more information?

Guidance or Contacts?

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RC-1 South, Room 7123