Ralph H. Johnson VA Health Care System

What to Look for When Reviewing VA Research:
Helpful Tips and Considerations
https://gov.irbnet.org/

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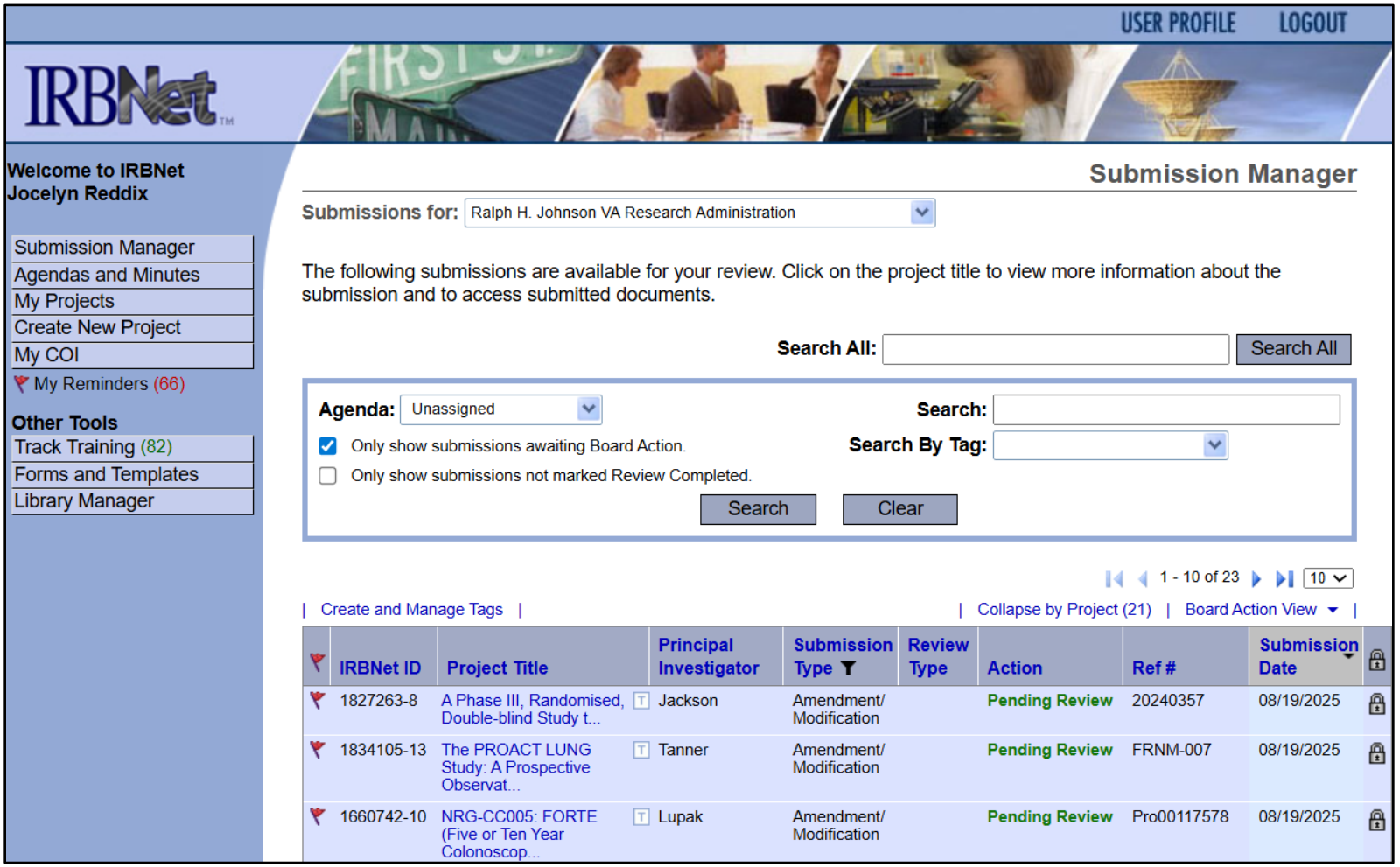
VAIRRS/IRBNet

- VA's internal IRB application system



VA's Research and Development Committee (R&DC) Review Process

(IN-PROGRESS)

Pre-Review in IRBNet

- Review of initial documents
  - Protocol, ICD(s), HIPAA, VA Form 10-250, ERDSP, etc.
- Financial Conflict of Interest(s)

Submission to IRB + Approval

After pre-review has been completed, study teams are authorized to submit to their respective IRB(s).

R&DC + SRS Review

After IRB approval, study teams will submit approval documents to IRBNet (study application, stamped/signed documents, recruitment materials, etc.) for review.

R&D Committee Submission

Following R&D and SRS review by Administrators, the study will be submitted to, and reviewed by, the R&D Committee for deliberation and (potential) approval.

R&DC Review + Approval

After R&DC deliberation, the study will be denied, approved with contingencies, or granted full approval to execute their research.

Initial VA Study Reviews (ICDs)

- **VA Treatment for Research-Related Injuries**
  - A statement that VA will provide treatment for research related injury in accordance with 38 CFR 17.85.
- **Costs for Study Participation**
  - When appropriate, a statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research.
- **Consent for Photographs, Video, or Audio Recordings**
  - The informed consent for research must include information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes; how the photographs, video, and/or audio recordings will be used for the research; and whether the photographs, video, and/or audio recordings will be disclosed outside VA.
- **Certificates of Confidentiality (CoCs)**
  - For studies in which information about the subject's participation will be included in the subject's VHA medical record, information must be given to the prospective subjects as part of the informed consent process that information regarding study participation will be included in the medical record.
  - For studies in which the IRB requires a written informed consent, the informed consent document approved by the IRB must include a statement that the study has a Certificate of Confidentiality.
- **Additional Elements of Informed Consent**
  - For studies subject to the 2018 Requirements, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
  - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
  - When appropriate, a statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research.

Additional Reviews

- The **Privacy Officer (PO)** and the **Information System Security Officer (ISSO)** serve in an advisory capacity to the IRB as either non-voting members or as consultants.
- **Privacy Officer (PO) – *Departmental Review***
  - Reviews HIPAA Authorization, HIPAA Waiver, and release/access to PHI/PII/III information
  - Completes the VA Form 10-250 (VHA Research Protocol Privacy Review Checklist)
    - The protocol, addendum, and/or IRB of Record application must describe the data to be disclosed to collaborators, the entities to which the data are to be disclosed, how the data are to be transmitted, and how the transmitted data will be stored, retained, destroyed, and/or further disclosed and to whom.
- **Information Safety Security Officer (ISSO)**
  - Reviews the Enterprise Research Data Security Plan (ERDSP) for data usage and storage

FAQs

- **What is VA's Electronic Health/Medical Record system?**
  - The Computerized Patient Record System (CPRS) is VA's EHR/EMR.
- **What program does VA use for electronic consent?**
  - DocuSign is VA's approved program for electronic consent.
    - Study teams should consider the use of iMedConsentTM for inpatient studies.
    - Requires approval from the Office of Research and Development (ORD)
- **Does the VA allow proactive calling (cold-calling)?**
  - *"Calling potential VA subjects without first sending a notification in person or through mail or email for the purpose of VA research recruitment is NOT permitted outside of [an] ORD approval process."*
    - Requires approval from the Office of Research and Development (ORD)

HIPAA Authorization Updates (VA Form 10-0493)

- Administrative changes
- Provides additional examples of the data types to be used by the VA
- Updated instructions on required (conditional) or optional (unconditional) banking of data and/or specimens
- Added required witness signature blocks for research subjects that cannot physically sign or “mark”

(Tentative) Roll-out required by 11/3/2025

* Please await additional information from Research Service before implementation

RHJ VAHCS Research Department Contacts

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  - Howard C. Becker, PhD (Howard.Becker2@va.gov)
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- **R&DC Program Manager**
  - Judy Stine (Judy.Stine@va.gov)

References

- VHA Directive 1200.05(4), Requirements for the Protection of Human Subjects in Research, dated January 27, 2019.
- VHA Directive 1605.01, Privacy and Release of Information, dated July 24, 2023.
- VHA Directive 1907.06, Health Care Information Security Policy and Requirements, dated April 30, 2019.