During the Forum:

✓ **Webinar Housekeeping** – Mute your mics to avoid echoing or background noise. Avoid activating your camera to preserve bandwidth.

✓ **Q&A** – In lieu of voicing your questions, use the chat function, a moderator will respond to your question.

✓ **Recording** - This session is being recorded and the full presentation and slides will be available on the VPR website. [https://www.uthscsa.edu/vpr/services/](https://www.uthscsa.edu/vpr/services/)
Overview:

- VA Human Research Program Overview / VA Staff Changes
- Process Improvements
- Coming Soon
- VPR Staff Changes for RAQ, IRB and CTO
Human Subject Protocol Managers (functions for VA institutional reviews have now been assumed by UTHSA OCR staff under contract to the STVHCS for all human-focused submissions, regardless studies’ IRB of record)
VA facilities engaged in research must ensure:

- Human Subjects Protections as overseen by Institutional Review Board (IRB)
  - UTHSA IRB, VA CIRB, NCI IRB, ADVARRA, WCG, etc
- Institutional requirements mandated by VA ORD monitored and verified by Research & Development (R&D) Service and overseen by R&D Committee
  - Personnel, Privacy, Information Security, Safety, Clinical Resources

All VA Human-focused research requires both: IRB approval/determination and R&D Committee approval
VA Innovation Research Review System (VAIRRS)

VA ORD-mandated implementation of VAIRRS March 2021 to standardize the institutional review and approval process:

1) VA-approved version of IRBNet web-based research management review system
2) New Submission Pathway
3) New Standardized Forms / Templates
## IRBs and IRBNet

Processes differ slightly based on whether or not IRB uses IRBNet

<table>
<thead>
<tr>
<th>IRB</th>
<th>Commercial?</th>
<th>Uses IRBNet?</th>
</tr>
</thead>
<tbody>
<tr>
<td>UT Health SA</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>VA CIRB</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>NCI IRB</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>WIRB</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>ADVARRA</td>
<td>Yes</td>
<td>No</td>
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</tbody>
</table>
Process Improvements & Coming Soon

Brandie Otten
Research Compliance Manager
Office of Clinical Research

• Supports the submission and management of all applicable institutional components and approvals for human research at UT Health

• Effective May 15, 2022 – Supports the submission and management of VA human subject protocols
VA Preliminary Review

• VHA Directive 1605.03, Privacy Compliance Assurance Program requires that a preliminary research privacy review is completed prior to IRB approval

• IRBNet submission required prior to IRB submission
IRBNet Submission Process – New Studies

- Submit to IRBNet
- VA preliminary review
- VA preliminary review complete
- Submit to IRB
- Receive IRB approval
- Submit IRB approval letter/documents in IRBNet
- Final Privacy Officer review
- R&DC review/approval
- Approval letter from ACOS for R&D
How can OCR help?

- VA dedicated webpage
- Same OCR Analyst for IRBNet and UT IRB tracking
- Initial review of IRB application in IRBNet
- Assistance submitting IRB application
- On demand concierge service
- Consistently monitored e-mail: VAHumanResearch@uthscsa.edu
Updated/Added New Study Checklists

- Posted in IRBNet under Forms and Templates and on VA Human Research Website
- Includes Statement of Commitment and Understanding by PI
- PDF fillable for electronic signature
- No longer requires additional Readme document
Revised Privacy Checklist Instructions

➢ Removed Privacy Checklist “Cheat Sheets”
➢ Added VA 10-250 Fillable form
Form and Template Updates

- R&DC Continuing Review Application
- R&DC Institutional Update Form
- R&DC Amendment Form

No longer requires personnel list

- UTHSA Personnel Form (Inst M)

No longer contains VA personnel

- VA – Project Cover Sheet

Personnel list in a single consistent location

Removed PI Signature Requirement
Accessing VA Electronic Health Record data nationally

• Data information page for VA Human Research website on accessing VA Electronic Health Record data

• Example information:
  • Electronic application (DART) to request national data for research purposes
  • Preparatory to research
  • QI projects

STVHCS Research Service Contact Information:
Michael Mader
Research Statistician
Email: Michael.Mader2@va.gov
Phone: (210) 617-5300 ext 17325
“My COI” – IRBNet module for Investigators

• The purpose of the “My COI” Module is to serve as the smart form version of the OGE 450 Alternative VA (“OGE 450 alt-VA”) COI disclosure form and support the COI review process

• Allows for Investigator and FCOI administrator signature within IRBNet

• FCOI acknowledgement form no longer required

• Implementation pending:
  • FCOI Administrator and support staff training from IRBNet
  • Updated forms, checklists and IRBNet reminder notices
  • Investigator Instructions
  • Distribution of instructions via listservs and website
Questions?
Research Administration & Quality (RAQ)

Melanie Zuñiga Rapp, Director

Danielle “Dani” Gordon, Research Compliance Coordinator - Sr

Krista Kilpadi Research Compliance Coordinator - Sr

Cheryl Blalock, Research Compliance Coordinator - Sr

Ann “Kat” Gonzales, Administrative Assistant
Clinical Trials Office (CTO)

Vacant Position: Manager, Clinical Research Finance
Concierge appointments are now “On Demand”

Register online for virtual concierge:
https://redcap.uthscsa.edu/REDCap/surveys/?s=4TKCEP74J347ML83

Questions?

Thank you for attending the Research Forum