

VAMHCS RESEARCH SERVICE HOT TOPIC

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Reminders on How to Conduct VAMHCS Research

The VAMHCS Office of Research Compliance (ORC) conducts routine informed consent and regulatory audits. An annual compilation of the ORC's audit findings is submitted to VHA Office of Research Oversight every July.

Based on analysis of audit findings from the 2014-2015 audit year, the VAMHCS R&D Service has the following reminders for the conduct of VA research:

1. **Do not let your approval lapse with the IRB¹, IACUC², SRS³, IBC⁴ and/or RDC⁵.** Submit your Continuing Reviews/Annual Updates in enough time to obtain Committee approval, including time for issues to be settled if necessary. A protocol expiration of even one day counts against VAMHCS in the national statistics.
2. As soon as a new (modified or renewed) informed consent form has been approved by the IRB and posted in CICERO, **stop using the old version!** Destroy any remaining unsigned hard copies so that they are not used by mistake. If your study requires having multiple pre-printed blank hard-copies of an ICF on hand, assign a team member to be a 'document manager' who is responsible for ensuring that only current documents are available for use.
3. Always **keep original signed documents** (informed consent, HIPAA authorizations, etc.). **DO NOT** give original documents to participants, the ORC, or others. **Give them copies.** Securely store the original documents in an organized fashion in your study files.
4. Ensure that your staff is aware of even very basic research requirements. This applies particularly to mentoring of students, trainees or new staff, but even experienced staff make these mistakes:
 - Obtain informed consent documents that are **properly signed and dated by the participant (or legally authorized representative [LAR]) and the person obtaining consent.**

¹ Institutional Review Board (IRB): the oversight committee for human research

² Institutional Animal Care and Use Committee (IACUC): the oversight committee for animal use in research

³ Subcommittee on Research Safety (SRS): the oversight subcommittee for safety of research laboratory practices

⁴ Institutional Biosafety Committee (IBC): the oversight subcommittee for the use of recombinant or synthetic DNA in research.

⁵ R&D Committee (RDC): the oversight committee for protocols not under the oversight of the IRB, IACUC or SRS. For example: IRB-exempt studies, "not human subjects research" (NHRS) studies, "data analysis only" (DAO) studies, etc.

- Obtain properly signed and dated HIPAA authorizations ([VA Form 10-0493's](#)) from participants. For 10-0493's that [contain a page 5](#), **be sure that page 4 is signed!** Page 5 must also be signed IF the participant authorizes the optional storage of data or specimens for future research.
 - Before the participant leaves the consent visit, **double check that all pages of the original signed documents are present and all blanks are filled in.**
 - **Follow the protocol.** Do no more, and no less than what has been approved by the IRB (for human research), IACUC (for use of animals), and/or SRS/IBC (for laboratory safety). Submit a protocol modification if you need to change your protocol in any way.
 - **Maintain source document files** for validation of participants' entry criteria and of study data points. This is crucial for scientific integrity and for audits.
5. Follow the rules for **annual reviews for your protocols:**
 - a. The IRB, the IACUC, the SRS, and the RDC all have requirements for annual reviews of protocols. Depending on your research project, **you may have annual reporting requirements for multiple committees.**
 - b. It is the PI's responsibility to ensure that annual reviews are submitted in a timely manner to assure uninterrupted approval of the project. The committee and subcommittee **reviews will probably be due throughout the year, based upon the committees' initial approval dates for your protocol.** You must keep track of the various due dates to avoid lapses in approval.
 - c. Send **IRB approvals of CRs and modifications** to the **VAMHCS R&D Committee (RDC) within 30 days of IRB approval using the RDC Worksheet.**
 - d. **Follow the IACUC's process for annual reporting.** At this time, the IACUC administrative staff automatically notifies the VAMHCS R&D Committee when a VAMHCS transaction is approved.
 - e. **Follow the SRS' process for annual reporting.** Submit the **"SRS Annual Update" form and "Amendment Request" form.** *Remember that many human research studies require SRS annual review!* At this time, the SRS administrative staff automatically notifies the R&D Committee when an SRS Annual Update is approved.
 - f. For **IRB-exempt studies, "not human subjects research" (NHSR) studies, and "data analysis only" (DAO) studies,** submit annual review **to the RDC using the RDC Worksheet.**
 6. Ensure that all members of the research team are **current in all applicable training requirements and documentation of the training is present/retrievable.**
 7. Ensure that all members of the research team have a **documented Research Scope of Practice.**

For questions concerning this or other Research Service Bulletins or Hot Topics,
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