

The Human Side of Human Subjects Research

NCRC Research Forum

VA Ann Arbor Healthcare System

October 20, 2015

What is Research?

- * Federal Regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102(d)).

Human Subjects Research

- * Research projects involving human subjects require review and approval by an Institutional Review Board (IRB) BEFORE any work is initiated...

What is a Human Subject?

- * A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR46.102(f)(1),(2))

IDENTIFYING HUMAN RESEARCH STUDIES

- * Certain studies may have the characteristics of human subjects research but may not meet the regulatory definition. Studies which meet the definition require IRB review. There are three categories to be considered:
 - studies that are human subjects research
 - studies that may be considered human subjects research (gray area)
 - studies that do not qualify as human subjects research

So Where Do YOU Begin?



Always Start HERE:

* Leonard Cooke – 845-5602
[R&D Coordinator]

* Catherine Kaczmarek – 845-3439
* Terry Robinson – 845-3440
[IRB Coordinators]

* Tabitha Metreger – 845-3624
[HSRD IRB Representative]

Scott Sample or Sheena Bruton – 845-4013
[Research Compliance Office]

Visit the Ann Arbor VA Research Website EVERY time you submit...

* <http://www.annarbor.research.va.gov/ANNARBORRESEARCH/forms.asp>

* Research Application Forms

1. R&D Application
2. Human Studies Application
3. Research Safety Application (if applicable)

Ann Arbor VA Research Deadlines:

New Project Submission Deadlines	IRB Amendment Submission Deadline	R&D Meeting (1st Wed)	IRB Meeting (2nd Thurs)	IACUC Meeting (2nd Fri)	RSC Meeting (3rd Thurs)
Jul 20	Jul 31	Aug 5	Aug 13	Aug 14	Aug 20
Aug 17	Aug 28	Sept 2	Sept 10	Sept 11	Sept 17
Sept 21	Sept 25	Oct 7	Oct 8	Oct 9	Oct 15
Oct 19	Oct 30	Nov 4	Nov 12	Nov 13	Nov 19
Nov 16	Nov 27	Dec 2	Dec 10	Dec 11	Dec 17
Dec 21	Dec 31	Jan 6	Jan 14	Jan 15	Jan 21
Jan 18	Jan 29	Feb 3	Feb 10	Feb 12	Feb 18
Feb 15	Feb 26	Mar 2	Mar 10	Mar 11	Mar 17
Mar 21	Apr 1	Apr 6	Apr 14	Mar 15	Mar 21
Apr 18	Apr 29	May 4	May 12	May 13	May 19
May 16	May 27	Jun 1	Jun 9	Jun 10	Jun 16
Jun 20	Jul 1	Jul 6	Jul 14	July 15	Jul 21
Jul 18	Jul 29	Aug 3	Aug 11	Aug 12	Aug 18

Tracking your Progress...

1. R&D Committee (1st Review) meets the 1st Wednesday of the month
2. IRB Committee meets the 2nd Thursday of the month
3. Safety Committee meets the 3rd Thursday of the month
4. Information Security/Privacy Review (after IRB Final Approval)
5. R&D Committee (Final Review & Approval)
6. ACOS Approval Letter is Provided by email
7. Research May Now BEGIN...

New VHA Handbook 1200.05

- * NEW VHA Handbook 1200.05 – Protection of Human Subjects Research (Dated November 12, 2014) was released by VA Central Office.
- * Can be found on our Website under the Research Policies Tab on the left... or this link:
- * http://www.annarbor.research.va.gov/ANNARBORRESEARCH/docs/IRB/VHA_Handbook_1200_05_111214.pdf

Summary of Important Changes:

- * **Advertisements:** VA facilities may now post/distribute advertisements and recruitment documents for other federally-funded research that is not taking place at a VA facility. Use of the local form “**Request to Post Non-VA Research at VAAHS**” is required.
- * **Certificates of Confidentiality:** are allowed with proper NIH and VA IRB approval.
- * **Emergency Use of a Test Article:** VA does not consider this a research activity.

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- * **HIPAA Authorization Form:** VA Form 10-0493 must be used for HIPAA authorizations. (New form dated October 2015 is currently on the website...)
- * **VA Consent Form:** The approved consent form must indicate the date of IRB approval on it, however **there will no longer be an expiration date listed on the Consent Form.**
- * **VA Form 10-3203:** “CONSENT FOR PRODUCTION AND USE OF VERBAL OR WRITTEN STATEMENTS, PHOTOGRAPHS, DIGITAL IMAGES, AND/OR VIDEO OR AUDIO RECORDINGS BY VA” is no longer required. However, the consent form must include information describing any photographs, video, and/or audio recordings that will be obtained for research purposes.

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- * **Subject Outreach:** Investigators are no longer required to perform subject outreach nor distribute the brochure, “volunteering in research.”
- * **Notice of Privacy Practices:** Investigators must provide notice of privacy practices to any non-veteran enrolled in an approved VA protocol (VHA Handbook 1605.04).
- * **Master List of Subjects:** Investigators are no longer required to maintain a master list of subjects enrolled in their research studies.

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- * **Flagging Health Records:** Investigators are no longer required to flag health records of subjects enrolled in VA research (unless determined to be appropriate by IRB).
- * **Scanning VA Consent Forms into CPRS:** As of October 1, 2015, the Ann Arbor VA IRB will not require routine scanning of informed consent documents into the health record or entering of a research study enrollment note into the health record except for research drug studies, investigational device studies, high risk studies, or any determined to be appropriate by the IRB. The Ann Arbor VA IRB will evaluate and determine, for each project, whether scanning of informed consent documents or entering a research study enrollment note will be required. If you have stated that you will scan the document into the medical record on your current approved consent form, then you must continue to scan until an amendment is reviewed and approved by the VA IRB.

Other Important Changes...

- * **NEW Serious Adverse Event Reporting Form (Local Policy)**

An updated Serious Adverse Event Reporting Form has been released (dated - 09/10/2015). This form aligns with the new VHA Handbook 1058.01 - Research Compliance Reporting Requirements (dated June 15, 2015). Please read the form carefully as it includes important updates to reporting regulations, including the following: Local SAEs - VA personnel, including WOC and IPA appointees, must ensure written notification of the IRB within 5 business days after becoming aware of any local SAE that is both **UNANTICIPATED** and **RELATED** to the research. You should continue to keep track of all SAEs for annual reporting through your continuing review... Please be familiar with the full policy!

- * **Financial Conflict of Interest Form - October 2015**

A **NEW** Annual Certification Form of a previously reviewed Financial Conflict of Interest Statement has been released. This form may be used at your next Continuing Review. If there are changes to disclose, or you are being added to the study, please submit a new OGE Form 450-A, Research Financial Conflict of Interest Statement. A certification is required for every approved study annually.

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* **NEW Scope of Practice Form – October 2015**

In accordance with VA Directive 1200, Veterans Health Administration Research and Development Program, the Ann Arbor VA Healthcare System Research Service has developed and introduced a NEW Research Scope of Practice form.

- 1) The new SOP defines the duties an employee is allowed to perform for research purposes. Thus, it is person-specific, not study-specific and each employee will ultimately have one SOP.
- 2) It requires the signature of the employee's direct supervisor, defined for these purposes as whoever conducts and signs the annual evaluation. This person may or may not be the PI of a study for which the employee is working. The signature of the ACOS/R&D is also required.
- 3) If research personnel are involved in more than one study, the SOP should be written to cover all of them.
- 4) When the employee is working on multiple research protocols, the PI for each protocol must also agree that the SOP includes all activities required of the employee. In some cases, the SOP may need to be modified by the supervisor, the PI and the employee to accommodate new responsibilities.

New Records Control Schedule 10-1

- * Unless otherwise obligated by contract or sponsor stipulations, research records may be destroyed 6 years after the end of the fiscal year in which study termination occurred. Appropriate documentation of destruction **MUST** be provided to the Records Liaisons (Terry Robinson/Catherine Kaczmarek) **PRIOR** to destruction. The following outlines the Disposal of Temporary Research Records in accordance with Disposition Authority - DAA-0015-004-0032 Section 7.6 - Investigator Files:

Disposal of Temporary Research Records

- * Research records that have met their Records Control Schedule (RCS), by the approved NARA schedule or other contractual obligation (whichever retention schedule is longest), may be disposed of. Any temporary research records created as part of VAAAHS approved research are subject to the approved NARA schedule for disposition, and must remain VAAAHS property even if an investigator transfers to another facility. Inventory of destroyed records is required to be maintained by a Research Service Records Liaison (RL). Temporary records may not be disposed of until the retention period in the RCS has been met.
- * **Paper Records.** Paper records may be destroyed using approved shred bins. Prior to destruction, the RL must complete VA Form 7468 (Request for Disposition of Records). This form is to be completed by the Service Records Liaison (Catherine Kaczmarek/Terry Robinson), signed by the Records Officer and a file copy is to be kept by both, the RL and the RO. Please contact the Research Office **BEFORE** the disposition of research records.
- * **Compact Discs/DVDs.** CD/DVD's are collected and boxed by the Research Service RL, prior to having another contractor pick them up, taking them to their facility, shredding them, and providing us a certified copy of that destruction. A VA Form 7468 will need to be completed to prove that VA was the owner of those files. The current contractor we use to destroy CD/DVDs is: Rapid Shred, LLC. Please contact the Research Office if you have CD/DVDs that have past their retention period.
- * **Electronic records Stored on VA Servers.** At study completion, all investigator files should transfer to a file maintained by the research RL. The research RL utilizes a naming convention to track the study and disposition date for the files. Files stored on VA servers, when they have met their retention requirement, can be destroyed by deleting the file. It will be over-written and it will be no longer retrievable. The RL will maintain record of what was deleted and when.
- * **Electronic records Stored on Non-VA servers.** The mechanism for storage and deletion of VA records stored on non-VA servers must be detailed in contractual agreement. Issues such as third-party back-up servers and encryption are typical issues dealt with in these arrangements; use of VA servers wherever possible is strongly preferred.
- * **Electronic Records Stored on Portable Media.** Portable media used to store VA records, such as external hard-drives, or thumb-drives must be handled in accordance with current information security guidelines. The Information Security Officer must perform a sanitization of the portable media device and provide documentation of having completed the sanitization. A copy of that documentation must be provided to the Research Service RL for record-keeping.

Other Significant Things to be **AWARE** of:

- * If using Non-Veterans as Research Subjects, it should always be well justified in your application.
- * **Approved VA Research needs to benefit Veterans!**
- * Information should be consistent between the R&D Application, IRB Application, and the Protocol. (Number of participants being recruited, etc...)
- * Use of Email as a means of communication with Research Subjects is strictly **PROHIBITED!**
- * Training should be current and noted in your submission documents as well as your Regulatory Binder.
- * Revisions should always include new signatures and dates so that the IRB staff as well as outside auditors can keep track of current updates to your protocol/documents...
- * Always submit a “Tracked Changes” version of your documents when requesting a modification, as well as clean versions for easy review!

And Finally...

***Please, Please, Please... Make sure that the IRB Application ONLY reflects those activities that are occurring under the purview of the VA!**

Any Questions?

