Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Review of Informed Consent in the Department of Veterans Affairs Human Subjects Research

Report No. 08-02725-127

May 15, 2009

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations

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Introduction

Representative Steve Buyer, Ranking Member of the House Committee on Veterans' Affairs, requested VA Office of Inspector General, conduct a review to determine whether VA research involving human subjects had on file either the informed consent forms or a waiver for this requirement from the institutional review board (IRB), and to determine for consent forms on file whether they comply with the Federal and VA regulations and Veterans Health Administration (VHA) policies.

The study population consisted of all enrollees of human subjects research projects conducted under VA auspices that were active and required informed consent, and had at least one enrollee as of August 20, 2008. The study used a complex, three-stage sample design that included stratification, clustering, and unequal probabilities of selection. From the 102 facilities that had at least one applicable protocol, we statistically randomly selected 30 (29.4 percent) facilities where we conducted onsite inspections. There were 5,993 sampled participants.

Results

The Common Rule and VA regulations authorize IRBs to waive the required informed consent if they find and document specific criteria when approving the waiver. We found insufficient IRB documentation for the waiver for 2 of the 33 sampled research protocols that were waived from the required informed consent process.

We estimated that 1.7 percent of the 367,103 VA research subject consent forms could not be located, and we are 95 percent confident that the true percent value is somewhere from 0.6 percent to 4.5 percent. It appears that some investigators utilized consent procedure as "deferred consent" or "ratification" since research subjects were added to the enrollee list before completing the informed consent. The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided for under the Common Rule. Any informed consent procedures, other than the required prospectively obtained consent, fail to constitute informed consent under the regulations for the protection of human research subjects. Subjects should not be added to the enrollee list or counted as enrollees in the annual progress report to the IRB for continuing review until their informed consents are prospectively executed.

Thirty-one percent (110,231) of the 361,042 VA research subject consent forms on file were estimated to be noncompliant; most (97 percent) lacked witness signature. We found that (annual) IRB-approved consent forms for particular protocols did not consistently include witness blocks over the course of the research, which likely

contributed to the high percent of missing witnesses. In addition, investigators may have mistakenly taken the required witness as an option.

We estimated that nearly 1 percent (1,023) of the 110,231 VA noncompliant forms lacked subject or subject's authorized representative signature. As mandated by the Common Rule and VA regulations, consent forms without subject signature are not "legally effective."

Recommendations

Recommendation 1: We recommended that the Under Secretary for Health require that facility Directors ensure sufficient IRB written documentation of waiver from informed consent.

Recommendation 2: We recommended that the Under Secretary for Health establish procedures requiring facility Directors to ensure signed informed consent forms are on file.

Recommendation 3: We recommended that the Under Secretary for Health establish procedures requiring facility Directors to ensure that informed consents are prospectively obtained, which includes adding subjects to enrollee lists and/or to annual research progress reports only after obtaining the informed consent.

Recommendation 4: We recommended that the Under Secretary for Health require facility Directors to ensure that witnesses are obtained for all VA consent forms as required.

Recommendation 5: We recommended that the Under Secretary for Health establish procedures requiring facility Directors to ensure that IRB-approved informed consent forms consistently contain witness blocks or ensure sufficient IRB written documentation of waiver from the witness requirement.

Comments

The Under Secretary agreed with the findings and recommendations and provided an appropriate improvement plan. See Appendix B (pages 24–30) for the full text of his comments. We will follow up on all recommendations until they are completed.

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Introduction

Purpose

In a letter dated July 3, 2008, Representative Steve Buyer, Ranking Member of the House Committee on Veterans' Affairs, requested that the Department of Veterans Affairs, Office of Inspector General, Office of Healthcare Inspections, conduct a review of human subject protection in VA research, particularly in the area of informed consent. The objectives for the review were (1) to determine whether VA research involving human subjects had on file either the informed consent forms or a waiver for this requirement from the institutional review board (IRB), and (2) for consent forms on file, determine whether they comply with the Federal and VA regulations and VHA policies.

Background

In accordance with Title 38 U.S.C., section 7303, the VA conducts medical research with a focus on areas that most directly address the diseases and conditions affecting veterans. Non-veterans may be enrolled in VA medical research only when there are insufficient numbers of veterans available.

The Office of Research and Development (ORD) of the Veterans Health Administration (VHA) administers all VA research conducted at VA medical facilities nationwide. The VA Research and Development (R&D) program is an intramural program and allocates appropriated Medical and Prosthetic Research funds to VA medical facilities through its four services: (1) Laboratory Biomedical R&D, (2) Clinical Sciences R&D, (3) Rehabilitative R&D, and (4) Health Services R&D.

The ORD allocates appropriated research funds to VA medical facilities for scientifically meritorious research related to the high priority health care needs of veterans. In addition to the appropriated Medical and Prosthetic Research funds, VA investigators may also obtain funding support for their research from extramural sources, such as other Federal agencies, private health organizations and foundations, and commercial entities. Unlike agencies such as the National Institutes of Health and the Department of Defense, VA does not have the statutory authority to make research grants to non-VA entities. However, contracts may be utilized to obtain special services not available in VA. VA medical R&D spending in 2008 was approximately $1,805 million and involved 3,250 full-time employee equivalents (FTE). VA is anticipating $1,845 million and 3,201 FTE in 2009.[1]

VA is one of the 17 Federal departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects, known as the Common Rule, effective June 18, 1991 (56 Federal Register (FR) 28001). VA regulations pertaining to

[1] Department of Veterans Affairs, FY 2009 Budget Submission, Vol. 2, Pg. 2A-7.

implementation of the Common Rule are incorporated in Title 38 Code of Federal Regulations Part 16 (38 CFR 16). In 1999, VA established an independent office of research compliance and assurance. In 2003, this office was succeeded by the Office of Research Oversight (ORO). The ORO is the primary office responsible for overseeing research compliance and assurance for human subjects protections, animal welfare, research safety, and research misconduct throughout the VA system. VHA Handbook 1200.05, *Requirements for the Protection of Human Subjects in Research*, details the procedures all VA research facilities must use to implement 38 CFR 16. Food and Drug Administration (FDA) regulations at 21 CFR 50 may also apply if the research involves a clinical investigation regulated by the FDA.

Federalwide Assurance and Institutional Review Board for the Protection of Human Subjects.

The Common Rule defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge (38 CFR 16.102(d)). All research conducted under VA auspices is considered to be Federally supported. Thus, each VA facility conducting or engaged in research involving human subjects must obtain an Assurance in accordance with 38 CFR 16.103. This Assurance, when granted, is called a Federalwide Assurance (FWA). It is a written commitment by research facilities that complies with the Common Rule and other applicable Federal and VA requirements for the protection of human subjects. Under 38 CFR 16.102(f), a facility is engaged in human subjects research whenever its employees or agents (1) intervene or interact with living individuals for research purposes or (2) obtain individually identifiable, private information for research purposes. FWAs for VA facilities are filed with the Department of Health and Human Services' (HHS) Office for Human Research Protections (OHRP) through the VA ORO. FWAs must be approved by both the ORO and the OHRP before any human subjects research is initiated.

Each VA facility engaged in research involving human subjects or human biological specimens must hold an effective FWA approved by the OHRP with an effective VA FWA Addendum approved by the ORO. In rare cases and with the ORD's concurrence, the ORO may negotiate special Assurances or recognize Assurances issued by other Common Rule departments and agencies in lieu of FWAs.[2] FWAs must be renewed at least every 3 years in order to remain active. FWAs are inactivated if a renewal has not been approved by both the ORO and the OHRP prior to the end of the FWA's approval period.

The institutional review board (IRB) designated under the FWA at each research facility is the committee charged with the oversight of all research activities involving human subjects for compliance with regulations within the facility. Every VA facility conducting

[2] VHA Handbook 1058.03, *Assurance of Protection for Human Subjects In Research*, May 10, 2007, 5a(11).

research involving human subjects must establish an IRB or must secure the services of an IRB, as described in VHA Handbook 1200.05. The use of a commercial IRB is prohibited. IRBs must have at least five members with varied backgrounds to promote complete and adequate review of research activities. At least one member's primary expertise must be scientific and at least one member's must be non-scientific. Also, at least one member must not otherwise be affiliated with the VA medical center. No IRB may consist entirely of members of one profession. The IRB is a subcommittee of the R&D Committee at VA research facilities, which is the local committee charged with oversight of all R&D activities within a facility. The IRB must approve a research protocol before the R&D Committee considers its approval.

All VA-covered human subjects research activities must be reviewed and prospectively approved and are subject to continuing review at least annually by the designated IRB(s). IRBs must approve, require modifications to (in order to secure approval), or disapprove the proposed human subjects research. Before approval, the IRB must review the full research proposal, the consent form, and all supplemental information to determine that the following requirements are satisfied: (1) risk must be minimized; (2) there must be a reasonable risk to benefit ratio; (3) subjects must be equitably selected; (4) informed consent forms must be valid; (5) the informed consent process for patients must be documented; (6) safety must be monitored; (7) privacy and confidentiality must be maintained; (8) vulnerable subjects must be protected; (9) conflicts of interest must be managed, reduced, or eliminated; and (10) investigators must meet education requirements for the protection of human subjects in research and for conducting the research.

Research activities may be exempt from review by the IRB if the only involvement of human subjects is in one or more of the categories specified in 38 CFR 16.101(b) (or in Appendix A of VHA Handbook 1200.05). Investigators must submit the proposed research and the request for exemption to the IRB. Exemption status must be approved by the IRB Chair or an IRB member designated by the Chair, and the decision must be communicated in writing to the investigator and the IRB.

VA Requirements for Obtaining Signed Informed Consent Forms from Research Subjects.

Unless waived by the IRB under criteria at 38 CFR 16.116(c) or 16.116(d), Federal regulations and both VA regulations and VHA policies require that written informed consent be obtained from every subject participating in human research conducted under the auspices of the VA, and the consent form must be the most recent IRB-approved consent form. Regulations at 38 CFR 16.117(c) require specific findings on the part of the IRB for waiver of the requirement for the investigator to obtain a signed consent form from any subject. VHA Handbook 1200.05 further stipulates that only VA Form 10-1086, "Research Consent Form," be used as the consent form. Unless the IRB waives the requirement for the investigator to obtain a signed consent form from some or all subjects

in the research, the final page of each consent form must be signed and dated by the following three individuals:

- The subject or the subject's legally authorized representative.
- A witness whose role is to witness the subject's or the subject's legally authorized representative's signature.
- The person obtaining the informed consent.

The original signed consent form must be filed in the subject's research case history as a part of the requirements for documentation of the informed consent. VHA Handbook 1200.05 further requires a written progress note in the subject's medical record describing the consent process. Additionally, VHA Handbook 1907.01, *Health Information Management and Health Records*, August 25, 2006, requests that the signed and dated consent form be scanned into the medical record.

Scope and Methodology

We reviewed applicable laws, regulations, policies, procedures, and guidelines. Each of the 15 two-inspector teams visited 2 of the 30 statistically randomly selected VA research facilities to examine and retrieve pertinent documentation. Facility Directors were notified 2 business days prior to our visits.

Study Populations.

The study population consists of all enrollees of human subjects research projects conducted under VA auspices that were active and required informed consent, and had at least one enrollee as of August 20, 2008.

To identify the study population, we first obtained a list from the HHS's OHRP of all VA facilities holding an active FWA with the assistance of the ORO. As discussed in the Background section, each VA facility engaged in research involving human subjects or human biological specimens must hold an effective FWA registered with the OHRP. There were 114 VA facilities with current FWAs.

We then requested from all 114 facilities a list of all human subjects research protocols that were active at their facilities as of August 20, 2008, which was the day our request was sent. We also requested identification of any protocols that had not enrolled any human subjects (no enrollees) as of August 20, 2008, and any that had obtained IRB approval of waiver from informed consent (waivers). We asked facilities to exclude protocols that were exempted from IRB review because an exemption preempts the requirement for an informed consent process.

After receiving facility-specific protocol listings, we excluded 12 facilities that did not have any active protocols which required informed consent and had at least one enrollee.

Thus, 102 VA facilities had at least one applicable protocol for this review. The study population constitutes all subjects from whom informed consent was required for these active protocols at the 102 facilities.

To estimate the extent of no enrollee and waiver protocols on facility-specific protocol listings, we statistically randomly sampled 15 protocols from each facility listing (if the listing included more than 15 protocols). We then sent the facility-specific list of 15 protocols to the corresponding facility and asked for numbers of enrollees within each protocol. For facilities with 15 protocols or fewer, we sent the list of all protocols and asked for the numbers.

Sample Design.

The sample design consisted of three stages for selecting the probability-based random sample of subjects. With probability sampling, each subject in the study population has a known, positive probability of selection. This property of probability sampling avoids selection bias and enabled us to use statistical theory to make valid inferences from the sample to the study population.

In the first stage, we statistically randomly selected 30 VA facilities from the universe of 102 facilities, stratified by numbers of protocols within facilities. The stratification was used to ensure the inclusion of a spectrum of facilities with fewer and more protocols in our sample. The first stage of sampling resulted in 4 facilities with 10 or fewer protocols within each of them and 26 facilities with more than 10 protocols within each of them.

For the second stage of sampling, we statistically randomly selected 10 protocols from each of the 26 sample facilities with more than 10 protocols. We included all protocols from the four sample facilities with 10 or fewer protocols.

In the third stage, we statistically randomly selected 50 subjects from each of the sample protocols that had enrolled more than 50 subjects. We included all of the subjects if the protocol enrolled 50 subjects or fewer. All consent forms from an individual subject were collected for examination. This third stage of sampling was conducted by our inspectors onsite during their visits to the 30 sample facilities.

This was a complex, multistage sample design that included stratification, clustering, and unequal probabilities of selection.

Site Visits for Document Examination and Retrieval.

Each of the 15 two-inspector teams visited 2 of the 30 randomly selected facilities during the week of September 29, 2008, (and the following week, if necessary) to examine and retrieve the pertinent documentation for the selected sample protocols within each facility. One facility was visited during the week of October 6, 2008. We notified facility Directors 2 business days prior to our inspectors' visits. Facility Directors were

informed which of the 10 protocols were selected (all were selected if the facility had 10 or fewer) and were requested to provide pertinent documentation for review.

Onsite, the inspectors asked for the enrollee lists for the selected sample protocols, all consent forms for each subject on the protocol enrollee list, the IRB waiver document if the requirement to obtain an informed consent was waived for the protocol, and the most recent investigator progress report dated within the past year. If the selected protocol was granted a waiver for the requirement to obtain an informed consent under 38 CFR 16.116(c) or 16.116(d), the IRB's documentation of the waiver was examined for confirmation. These confirmed waivers were then excluded from consent form inspection.

For the remaining protocols that required informed consent, the enrollee lists were checked against the number of subjects listed in the most current investigator progress report. For examination of consent forms, inspectors then used random number generation software to select a sample of 50 subjects from each of the protocols that had more than 50 subjects. For protocols with 50 subjects or fewer, all subject consent forms were included for review.

Presence or Absence of Informed Consent Forms.

We first verified whether there was at least one research consent form for each of the sample subjects. If no consent forms were located for any of the sample subjects during our site visit, the facility was notified to provide the opportunity to locate the forms and/or provide an explanation. If the facility was unable to provide the forms to our inspectors, we counted the forms as absent.

Review of Executed Informed Consent Forms.

We examined all the consent forms that were located to check for the existence of the following four elements:

- Subject or the subject's legally authorized representative signature.
- Date of subject or subject's legally authorized representative signature.
- Witness signature.
- Date of witness signature.

Note that for this review, we examined only for the existence of signatures and their dates; we did not verify the authenticity of signatures.

Since more than one consent form might be executed by an individual subject during the course of the research, we examined each of the consent forms from the same subject for the same study.

Statistical Analysis.

We classified an executed research consent form as "compliant" for the purpose of this review if the form had all the following:

- Subject or the subject's legally authorized representative signature.
- Date of subject or subject's legally authorized representative signature.
- Witness signature.
- Date of witness signature.
- Identical signature dates.

If any of the above elements was missing from a consent form, the form was deemed noncompliant. A subject may have had more than one consent form for a given protocol. We defined a subject's form as compliant if any of his/her multiple forms were compliant. Thus, a subject would be judged as not having a compliant form for a protocol only if all of the subject's consent forms pertaining to that protocol were noncompliant. If more than one compliant form was located for a subject, we used the one with the earliest consent date in our data analyses. The consent date was defined as the date of the subject or subject's legally authorized representative signature. If all consent forms for a subject of a given protocol were noncompliant, we also used the form with the earliest consent date in the analyses.

It is possible for a veteran to participate in more than one VA research protocol. Because ensuring proper informed consent is the obligation of the investigators and not the responsibility of the subjects, we did not attempt to identify same subjects across different protocols. Therefore, we treat same subjects in different protocols, if any, as different subjects.

We estimated the number and the percentage of research subjects whose consent forms were on file for all active research protocols in VA that required informed consent; and from among those subjects with research consent forms, we estimated the number and the percentage of subjects whose forms were compliant. Horvitz-Thompson sampling weights, which are the reciprocal of sampling probabilities, were used to account for our unequal probability sampling. To take into account the complexity of our multistage sample design, the jackknife replicate-based method was employed to obtain the sampling errors for the estimates.

We also presented a 95 percent confidence interval for the true value (parameter) of the study population. A confidence interval gives an estimated range of values (being calculated from a given set of sample data) that is likely to include an unknown population parameter. The 95 percent confidence interval indicates that among all possible samples we could have selected of the same size and design, 95 percent of the time the population parameter would have been included in the computed intervals.

Percentages can take only positive values from zero to 100, but their logits can have unrestricted range; hence, the normal approximation can be used to estimate the parameters. Thus, we calculated the confidence intervals for percentages on the logit scale and then transformed them back to the original scale to ensure that the calculated confidence intervals contained only the proper range of zero to 100 percent.

All data analyses were performed using SAS statistical software (SAS Institute, Inc., Cary, NC), version 9.2 (TS1M0). Maps were produced using ArcGIS software (Environmental Systems Research Institute, Redlands, CA), version 9.2.

This inspection was performed in accordance with *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Results and Conclusions

As of August 20, 2008, 102 out of the 114 VA facilities holding active FWAs had active protocols that required informed consent and had at least one subject. From the 102 facilities, we statistically randomly selected 30 (29.4 percent) facilities for our review. Appendix A lists the 30 sample facilities where we conducted onsite inspections. Figure 1 depicts geographically the 114 VHA facilities with active FWAs and the 30 facilities we inspected. It shows that we visited 19 of the 21 Veterans Integrated Service Networks.

Ten research protocols were statistically randomly selected from each of the 26 sample facilities with more than 10 protocols, and all protocols from each of the 4 sample facilities with 10 or fewer protocols were included in our protocol sample. In total, we obtained 289 sample protocols from the 30 sample facilities (Figure 2). One protocol was for a serum repository that was an auxiliary study of a treatment protocol initiated in 1991. Originally, the informed consent for the auxiliary study was incorporated into the approved treatment protocol consent. In 1996, the informed consent document for the repository was separated from the treatment protocol. Since these two protocol titles were different, our inspectors did not accept copies of these treatment consent forms. The copies were shredded as they contained confidential information. Also, because these subjects were non-veterans at a university affiliate and it would take considerable effort for the facility to get copies of these treatment consent forms, we excluded this protocol from our data analysis.

Of the remaining 288 sample protocols, 24 did not have any subjects. Hence, a total of 264 protocols were included in our protocol sample for further review. Of these 264 protocols, 33 were waived from informed consent, leaving a total of 231 protocols that had at least one subject and required informed consent.

Figure 1. 114 VA Research Facilities with an Active Federalwide Assurance as of August 20, 2008

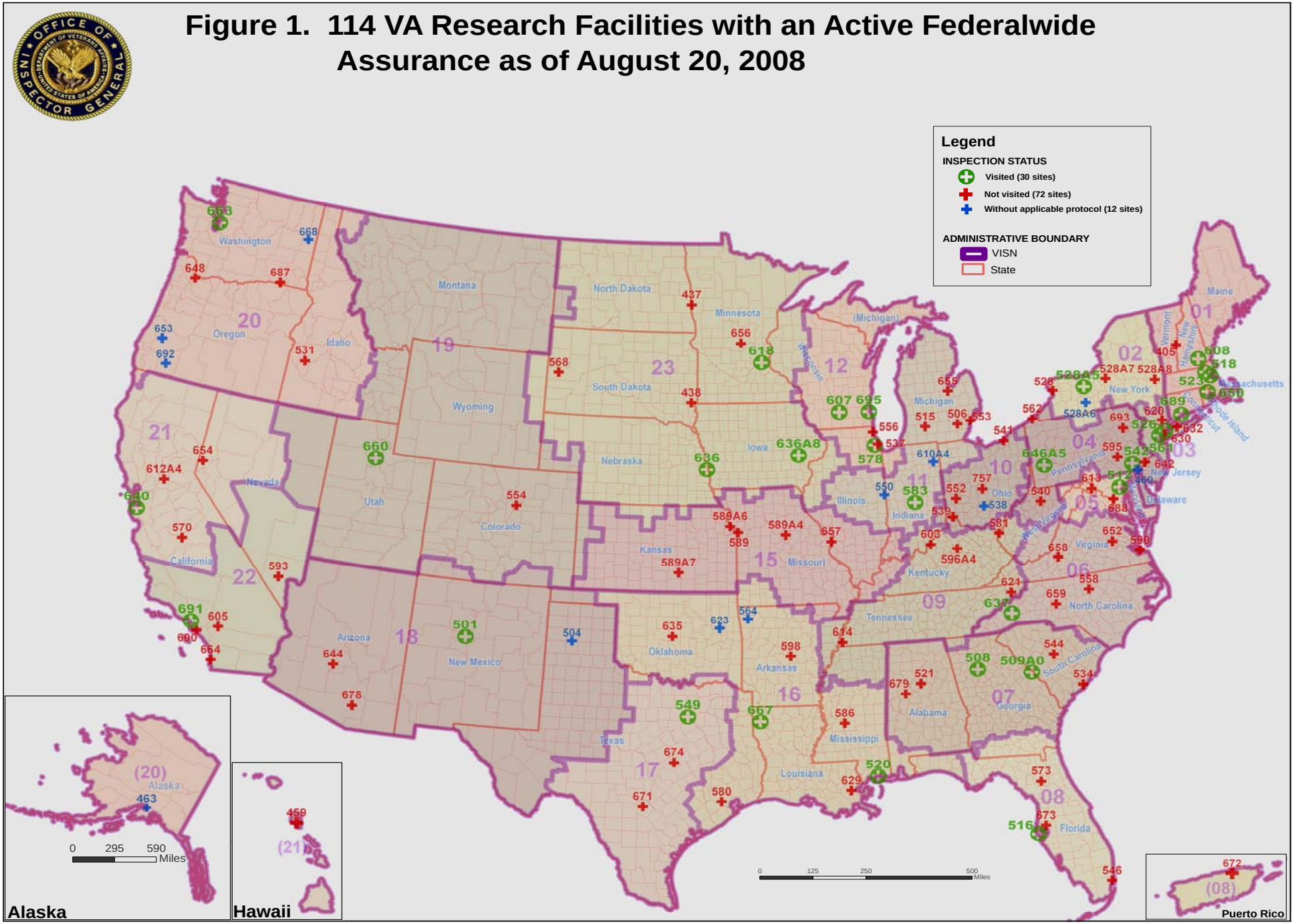
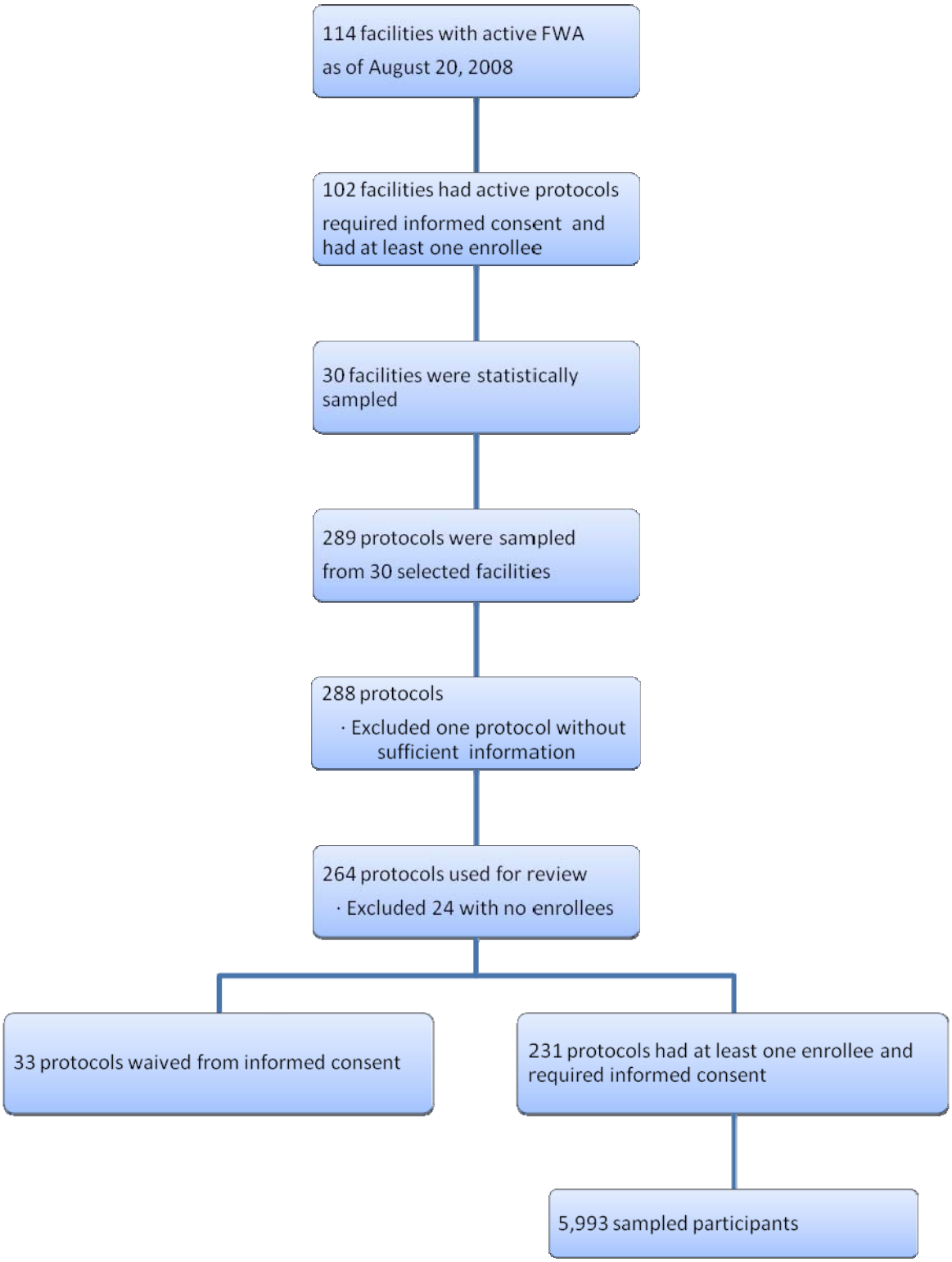


Figure 2. Sampling flowchart.



Findings

Part I. Protocols Exempt from Informed Consent

Issue 1: Insufficient Institutional Review Board Waiver Documentation

The Common Rule and VA regulations at 38 CFR 16.116 mandate that no investigator may involve a human being as a subject in research covered by the regulations unless (a) the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative, or (b) the IRB has waived the requirements to obtain informed consent in accordance with 38 CFR 16.116(c) or (d).

The regulations give IRBs authority to waive the required research consent under two circumstances. The first waiver authority is applicable only to research activities designed to study certain aspects of public benefit or service programs, which cannot be carried out without a waiver. The conditions under which this waiver may be authorized by an IRB are detailed at 38 CFR 16.116(c). The second waiver authority is described at 38 CFR 16.116(d) as follows:

> An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
>
> (1) The research involves no more than minimal risk to the subjects;
> (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
> (3) The research could not practicably be carried out without the waiver or alteration; and
> (4) Whenever appropriate, the subjects will be provided with additional information after participation.

The waiving of informed consent using a method other than that requiring the IRB findings and IRB documentation specified at 38 CFR 16.116(c) or (d), is not in compliance with the regulations. VHA Handbook 1200.05, Appendix C 2, stipulates the same requirement of "the IRB finds and documents" for waiving the requirement to obtain an informed consent.

We examined IRB documentation for each of the 33 waivers. All but two waivers had the IRB written decision of the waiver. One facility was unable to provide our inspectors with the IRB waiver documentation. Rather, they supplied the IRB meeting minutes for the initial approval of the research. The "new research registration" section of the

minutes contained "ADMINISTRATIVELY APPROVED (data collection)" for the protocol. This fails to satisfy the regulations at 38 CFR 16.116(c) and (d) requiring that the IRB find and document specific criteria when approving waiver or alteration of some or all of the required elements of informed consent.

Another facility was also unable to provide us with the IRB written decision to the investigator approving a waiver of informed consent for the study subjects. Instead, we were offered a printed copy of the computerized Project Summary and the IRB-approved consent form effective from July 17, 2008 to July 17, 2009. The Project Summary shows that the investigator asked for a waiver of consent for some subjects in the Description of Subject Population section. However, the investigator's answer was "*No*" to the question "*Are you requesting a waiver of documentation of consent (either no subject signature or no written document*)?" In the section "*Provide a description of the enrollment and consent process for adult subjects*," the investigator detailed the procedure and included the sentence "*The subject will be instructed to keep a copy of the consent document and to send the other to me using the included stamped addressed envelope*." Thus, it seems that the investigator only asked for a waiver of consent for some special subjects. However, the Administrative Codes section of the Project Summary indicates that the IRB approved waiver of documentation of consent. Without IRB written documentation to the investigator, it is uncertain exactly what the IRB approved the waiver for since the IRB contradictorily approved the consent form for the informed consent documentation.

Part II. Protocols That Required Informed Consent

Table 1 shows the distribution of informed consent forms per subject of the sampled subjects (Table 1). A total of 5,993 subjects were sampled from the 231 protocols that required informed consent and had at least one subject. Consent forms could not be located for 43 (0.7 percent) subjects. Of the remaining 5,950 subjects with at least one consent form located, 90 percent had one consent form, 6 percent had two forms, and 2 percent had three forms; and 15 subjects had six forms in a protocol.

Table 1: Distribution of number of forms per subject (including those with no forms) in sampled research protocols.

Forms Per Subject	# of Subjects	Percent
0	43	0.7
1	5,394	90.0
2	352	5.9
3	107	1.8
4	55	0.9
5	27	0.5
6	15	0.3
Total	*5,993*	*100.0*

The consent dates ranged from March 24, 1987, to September 30, 2008. In our following data analyses, for subjects with more than one consent form for a same protocol, we used the earliest compliant consent form if more than one compliant form existed or the earliest noncompliant form if all a subject's forms were noncompliant. Table 2 gives the year distribution of these 5,950 forms (one form per subject). The consent date was missing for 20 forms. Over 55 percent of the consent forms had a consent date in 2006 or later. The median consent date was April 30, 2006 (not shown in Table 2), which means that half of our sampled forms were signed before May 1, 2006, and half were signed on or after that date.

Table 2: Yearly distribution of consent dates for the sampled consent forms.

Consent Year	Sampled Forms	Percent
.	20	0.34
1987	1	0.02
1990	1	0.02
1992	1	0.02
1993	1	0.02
1994	3	0.05
1995	5	0.08
1996	17	0.29
1997	48	0.81
1998	32	0.54
1999	75	1.3
2000	159	2.7
2001	282	4.7
2002	397	6.7
2003	453	7.6
2004	490	8.2
2005	675	11.3
2006	916	15.4
2007	1,226	20.6
2008	1,148	19.3
Total	*5,950*	*100.0*

Issue 2: Absence of Informed Consent Forms

Table 3 reports the presence/absence of consent forms for the 5,993 sampled subjects. It also gives the estimated number (and the percent) of VA subjects whose consent forms were present/absent, based on our sample data. Of the 5,993 sampled subjects from the enrollee lists, 43 subjects' consent forms could not be located. After taking into account the complexity of our sample design, we estimated that 367,103 subjects were under VA

active research protocols as of August 20, 2008; and that 98 percent (361,042) of their forms were able to be located, and we are 95 percent confident that the true percent value is somewhere from 95.5 percent to 99.4 percent.

Table 3: Presence/absence research consent forms for the 5,993 sampled and the estimated VA subjects.

Form Located	Sampled	VA Estimates			
	Subjects	# of Subjects	(95% Confidence Interval)	Percent	(95% Confidence Interval)
No	43	6,061	(2,169.9, 16,613.8)	1.7	(0.6, 4.5)
Yes	5,950	361,042	(350,489.1, 364,933.0)	98.3	(95.5, 99.4)
Total	*5,993*	*367,103*		*100.0*	

Forty-three sampled consent forms could not be located. Regulations at 38 CFR 16.117(c) require specific findings on the part of the IRB for waiver of the requirement for the investigator to obtain a signed consent form from any subject. As a part of the requirements for informed consent documentation, the original signed consent form must be filed in the subject's research case history. VHA Handbook 1200.05 further demands that a written progress note be placed in the subject's medical record describing the consent process, and in addition, VHA Handbook 1907.01 requests that the signed and dated consent form be scanned into the medical record.

Explanations provided to us for the missing forms indicated that none of these forms were from protocols that obtained the IRB waiver of obtaining a signed consent form. Based on these explanations, it seems that some investigators utilized consent procedure as "deferred consent" or "ratification" rather than the required prospectively obtained consent. Subjects should not be added to the enrollee list or counted as enrollees in the annual progress report for IRB continuing review until after the informed consent. Below are some of the explanations provided to us for the missing forms.

- Explanation: A patient on the enrollee list was offered entry into the study but never returned to sign an informed consent document and thus, never officially enrolled.

  However, based on further information we requested from the facility, we found out that this patient was a screen failure and that all screen failures we sampled from the enrollee list had signed a consent form except for this particular patient.

- Explanation: Consent forms have been found for all subjects who entered the protocol and received clinical treatment. The missing forms for subjects on the enrollee list and listed in progress reports to the IRB were believed not to have been saved by the prior investigator because the subjects volunteered to be screened but did not actually enter treatment.

- Explanation: A patient was deemed ineligible to participate in the study after review of his medical record. The patient was not invited to participate in the

study and never signed the consent form. The patient's name was placed on the annual report in error.

- Explanation: The number of enrollees in annual progress reports to the VA IRB was over-reported due to the inclusion of non-veteran subjects.

  We requested consent forms for these non-veteran subjects because all regulations pertaining to veteran research subjects also apply to non-veteran subjects enrolled in VA-approved research (VHA Handbook 1200.05). The facility reported later that the investigator was unable to locate these remaining consent forms.

- Explanation: The investigator mixed up subjects in different protocols, and these subjects were incorrectly included on the enrollee list.

  However, we found that the investigator could not locate another consent form for one of the remaining three subjects in the study even though it was confirmed that he/she should be on the enrollee list.

Issue 3: Noncompliance of Consent Forms

Table 4 shows the distribution of compliant consent forms among the located forms. Of the 5,950 sampled subjects with a located consent form, 4,887 subjects' forms were compliant. We estimated that throughout VA, about 69 percent of the 361,042 subjects' located forms were compliant, and we are 95 percent confident that the actual compliant form percent is somewhere from 39.9 to 88.6.

Table 4: Compliance of research consent forms for the 5,950 sampled and the estimated VA subjects whose forms were on file.

Compliance of Form	Sampled	VA Estimates			
	Subjects	# of Subjects	(95% Confidence Interval)	Percent	(95% Confidence Interval)
Compliant	4,887	250,811	(144,123.7, 319,976.3)	69.5	(39.9, 88.6)
Noncompliant	1,063	110,231	(41,065.2, 216,917.8)	30.5	(11.4, 60.1)
Total	*5,950*	*361,042*		*100.0*	

We further looked into the categories for classifying these forms as noncompliant. The five noncompliant categories were defined as follows:

1. No signature of the subject or the subject's legally authorized representative.
2. No date of subject (or the subject's legally authorized representative) signature but subject or the subject's legally authorized representative signature present.
3. No witness signature but form signed and dated by subject or the subject's legally authorized representative.
4. No date of witness signature but witness signature and subject (or the subject's legally authorized representative) signature and date present.

5. Different dates of subject (or the subject's legally authorized representative) and witness signatures.

These categories are listed in the hierarchical order. Thus, each noncompliant form was sorted into only one category although some noncompliant forms may have contained more than one noncompliant element. For example, if a form lacked both subject (or the subject's legally authorized representative) signature and date of witness signature, the form was placed only into the category "no subject signature" and was not counted in the category "no witness date."

Table 5 shows the distribution of the categories for classifying these forms as noncompliant. It indicates that most noncompliant forms were due to no witness signature. The estimated percent attributable to "no witness signature" from among the 110,231 noncompliant VA forms is 97.2 percent, and we are 95 percent confident that the actual percent of "no witness signature" is somewhere from 84.8 percent to 99.5 percent.

We observed that more than 60 percent of the noncompliant consent forms in our sample did not contain a witness signature and date block. Three out of four of these with no witness block consent forms had a consent date after July 15, 2003. Thus, the witness part of the consent could easily be missed during the informed consent process. It is unclear why IRBs approved consent forms without a witness block. We also found that during annual continuing reviews for a same protocol in different years, IRBs approved consent forms that did not consistently contain witness blocks. It is perplexing that consent forms used in an earlier year contained witness blocks while those in a later year did not.

Table 5: Distribution of Noncompliance research consent forms for the 1,063 sampled and the estimated VA subjects whose forms were noncompliant.

	Sampled	VA Estimates			
Noncompliance Category	Subjects	# of Subjects[3]	(95% Confidence Interval)	Percent	(95% Confidence Interval)
No subject signature	16	1,023	(96.2, 10,062.9)	0.9	(0.1, 9.1)
Subject signature, but no date	20	1,350	(243.8, 7,151.3)	1.2	(0.2, 6.5)
No witness signature	994	107,178	(93,480.8, 109,734.2)	97.2	(84.8, 99.5)
Witness signature, but no witness Date	20	507	(77.7, 3,241.8)	0.5	(0.1, 2.9)
Dates different	13	172	(25.2, 1,162.4)	0.2	(0.02, 1.1)
Total	*1,063*	*110,230*		*100.0*	

[3] Total is different from 110,231 in Table 4 due to rounding errors.

The following are some examples illustrating the inconsistency of excluding witness blocks in IRB-approved consent forms.

- The IRB-approved consent form used in 2003 had a witness block, but the block was omitted in the approved form used in 2005. All these consent forms are not the VA Form 10-1086, *VA Research Consent Form*.

- The IRB approved the VA consent form (Form 10-1086) used in 2000 with no witness block; the approved VA consent form used in 2001 had a witness block.

- The IRB approved the consent form (in lieu of VA Form 10-1086) used in 2005 without a witness block; the approved consent form (in lieu of VA Form 10-1086) used in 2006 had a witness block.

- The IRB-approved non-VA consent form used from June 14, 2007, through February 21, 2008, did not have a witness block; the approved VA consent form on July 26, 2007 had a witness block.

- The IRB-approved VA consent form (Form 10-1086) used in 1999 had a witness block; the approved VA consent form used in 2006 did not have a witness block.

- The IRB-approved consent form (in lieu of VA Form 10-1086) used from August 1, 2005, through April 3, 2006, did not contain a witness block; the one used from March 5, 2007, through March 4, 2008, had a witness block. However, these forms showed the same form version number and the same revision date even though they were clearly different versions.

- Both versions of consent forms approved by the IRB in March 2002 and in January 2003 did not have a witness block. However, the later version of the executed forms contained witness signatures and dates even though the forms did not have witness blocks.

Another explanation for the high percent of no witness signature is the likelihood that investigators mistakenly thought the witness was an option rather than a requirement. For example, an investigator sent a memo to the IRB to clarify the consenting procedure after our inspector examined the consent forms for his/her research project. In the memo, the investigator noted that he/she mistakenly understood that witnesses were not absolutely necessary and that the only instance in which a witness was necessary was if the subject was somehow compromised.

38 CFR 16.117(a) stipulates that informed consent be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. Sixteen sampled subject consent forms were unsigned. Four (25 percent) of these unsigned forms were incomplete or had missing pages. From

among the rest of the sampled consent forms, an additional 20 were undated by the subjects, an extra 20 were undated by the witnesses, and 13 more had different subject and witness signature dates.

Figure 3 shows the estimated percent of compliance forms for each facility sorted by the percent compliant. The percent of facility compliance ranged from 15 to 100, with half of the facilities having a compliant percent of over 93 percent and the other half having a compliant percent below that.

Figure 4 charts the estimated percent of compliance for each sampled protocol within a facility. It shows that some facilities performed much better than others.

Figure 3. Estimated percent of compliant forms for each facility.

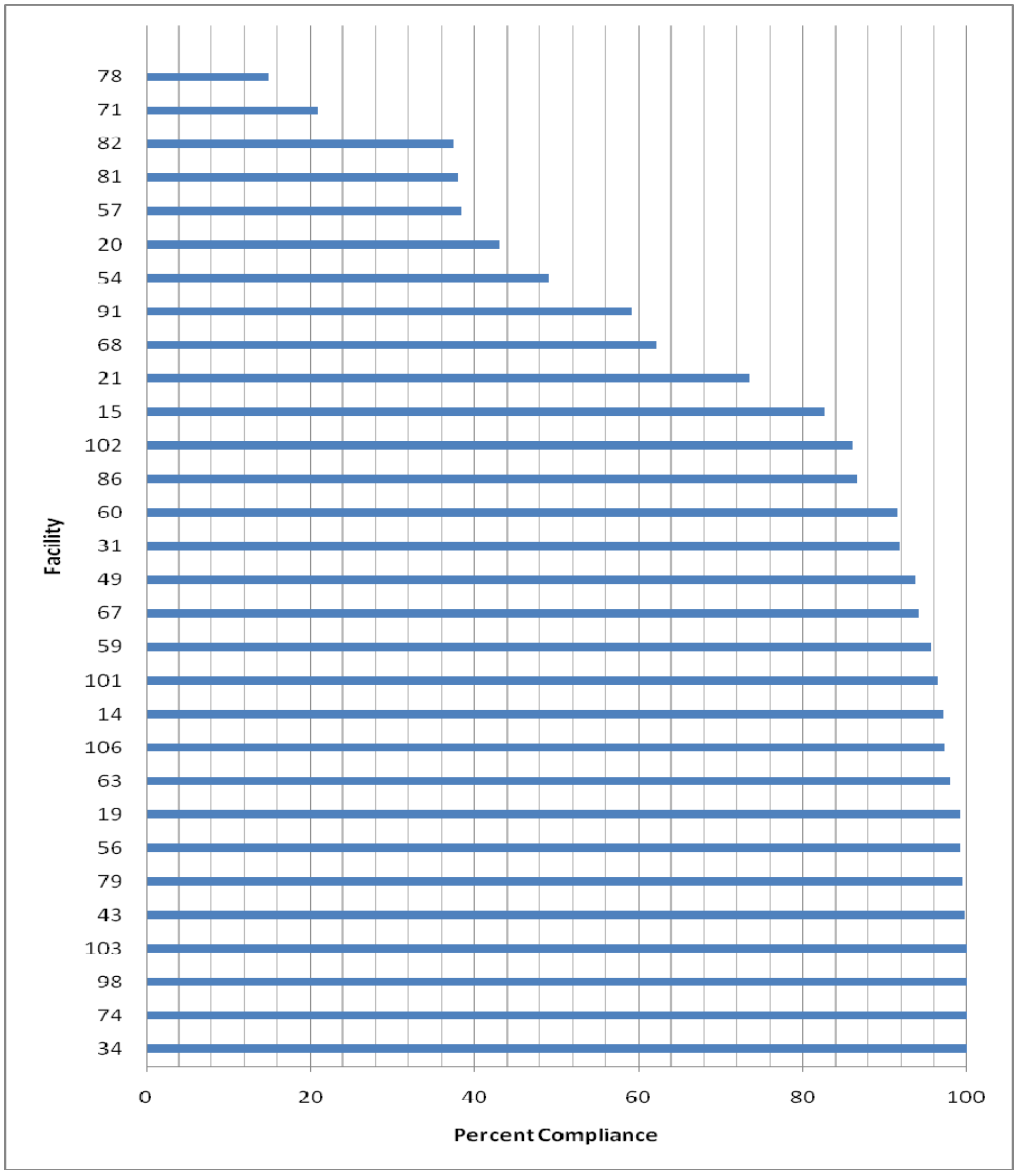
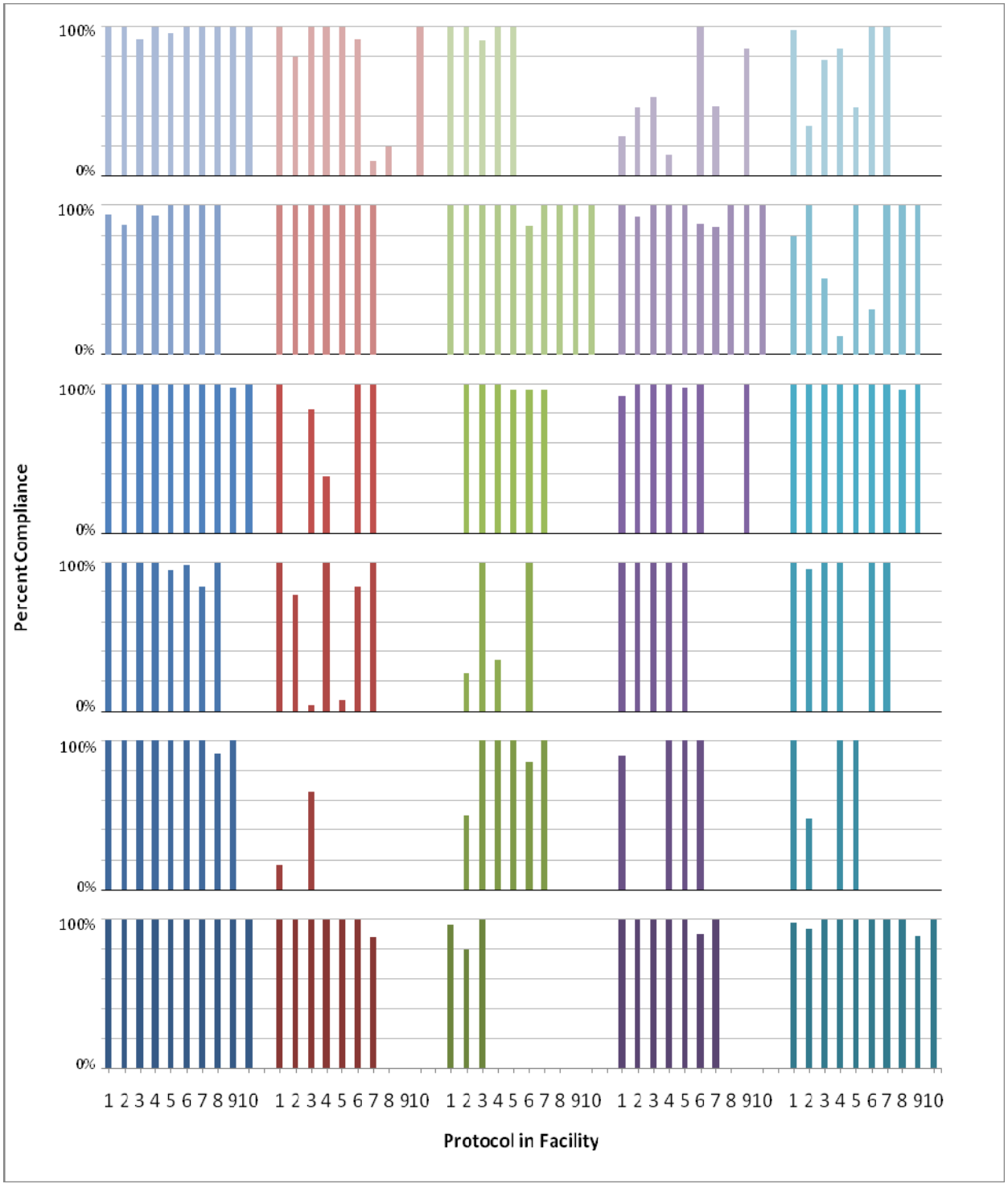


Figure 4. Estimated percent of compliant forms for each sampled protocol within a facility.



Conclusions

The Common Rule and VA regulations authorize IRBs to waive the required informed consent if they find and document specific criteria when approving the waiver. We found insufficient IRB documentation for the waiver of informed consent for two of the 33 sampled research protocols that were waived from the required informed consent process.

We estimated that 1.7 percent of the 367,103 VA research subject consent forms could not be located, and we are 95 percent confident that the true percent value is somewhere from 0.6 percent to 4.5 percent. It appears that some investigators utilized consent procedure as "deferred consent" or "ratification" since research subjects were added to the enrollee list before completing the informed consent. The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided for under the Common Rule. Any informed consent procedures other than the required prospectively obtained consent, fail to constitute informed consent under the regulations for the protection of human research subjects. Subjects should not be added to the enrollee list or counted as enrollees in the annual progress report to the IRB for continuing review until their informed consents are prospectively executed.

Thirty-one percent (110,231) of the 361,042 VA research subject consent forms on file were estimated to be noncompliant; most (97 percent) lacked witness signature. We found that (annual) IRB-approved consent forms for particular protocols did not consistently include witness blocks over the course of the research, which likely contributed to the high percent of missing witnesses. In addition, investigators may have mistakenly taken the required witness as an option.

We estimated that nearly 1 percent (1,023) of the 110,231 VA noncompliant forms lacked subject or subject's authorized representative signature. As mandated by the Common Rule and VA regulations, consent forms without subject signature are not "legally effective."

Recommendations

Recommendation 1: We recommended that the Under Secretary for Health require that facility Directors ensure sufficient IRB written documentation of waiver from informed consent.

Recommendation 2: We recommended that the Under Secretary for Health establish procedures requiring facility Directors to ensure signed informed consent forms are on file.

Recommendation 3: We recommended that the Under Secretary for Health establish procedures requiring facility Directors to ensure that informed consents are prospectively obtained, which includes adding subjects to enrollee lists and/or to annual research progress reports only after obtaining the informed consent.

Recommendation 4: We recommended that the Under Secretary for Health require facility Directors to ensure that witnesses are obtained for all VA consent forms as required.

Recommendation 5: We recommended that the Under Secretary for Health establish procedures requiring facility Directors to ensure that IRB-approved informed consent forms consistently contain witness blocks or ensure sufficient IRB written documentation of waiver from the witness requirement.

Appendix A

Thirty Sampled VA Research Facilities Visited by Inspectors

VA New Jersey Health Care System – East Orange Campus
James J. Peters VA Medical Center – Bronx, NY
Edward Hines Jr. VA Hospital – Hines, IL
Clement J. Zablocki Veterans Affairs Medical Center – Madison, WI
Edith Nourse Rogers Memorial Veterans Hospital – Bedford, MA
Overton Brooks VA Medical Center – Shreveport, LA
VA Medical Center – Canandaigua, NY
VA Connecticut Healthcare System – West Haven Campus
Manchester VA Medical Center – Manchester, NH
VA North Texas Health Care System – Dallas VA Medical Center
VA Nebraska Western Iowa Health Care System – Omaha Division
VA Boston Healthcare System – Boston, MA
VA Medical Center – Providence, RI
VA Health Care System – Albuquerque, NM
VA Pittsburgh Healthcare System – University Drive Division
Richard L. Roudebush VA Medical Center – Indianapolis VA Medical Center
VA Maryland Health Care System – Baltimore VA Medical Center
VA Medical Center – Iowa City, IA
William S. Middleton Memorial Veterans Hospital – Milwaukee, WI
VA Puget Sound Health Care System – Seattle, WA
VA Medical Center – Asheville, NC
VA Palo Alto Health Care System – Palo Alto, CA
VA Greater Los Angeles Healthcare System – Los Angeles, CA
VA Medical Center – Atlanta, GA
VA Medical Center – Coatesville, PA
Charlie Norwood VA Medical Center – Augusta, GA
VA Healthcare System – Bay Pines, FL
VA Gulf Coast Veterans Health Care System – Biloxi, MS
VA Medical Center – Minneapolis, MN
VA Salt Lake City Health Care System – Salt Lake City, UT

Appendix B

Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: May 7, 2009

From: Under Secretary for Health

Subject: **Healthcare Inspection – Review of Informed Consent in the Department of Veterans Affairs Human Subjects Research, (WebCIMS 427012)**

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have reviewed the draft report, and I concur with the report and its recommendations. While I am pleased that VHA requires additional human subject protections beyond those afforded under the Common Rule, it is disturbing that some of our institutional review boards (IRBs) and investigators are not implementing the additional protections that VHA requires. These protections include requiring a witness signature on the informed consent form and specific IRB responsibilities in approving and documenting waivers related to the informed consent process.

2. VHA Directive 2008-064, "Research Compliance Officers and the Auditing of VHA Human Subjects Research to Determine Compliance with Applicable Laws, Regulations, and Policies," requires Research Compliance Officers (RCOs) to conduct annual audits of informed consent forms for all active research protocols. These audits include verifying that prospective informed consent was obtained and that the informed consent form contains the dated signatures of the subject and a witness. The requirement for a witness signature is one of the additional safeguards for VHA research subjects.

3. It is extremely disappointing that some of our IRBs were unaware of the responsibility to approve and document waivers related to the informed consent process. The VHA Office of Research Oversight (ORO) will, therefore, immediately require that the annual informed consent audits conducted by each facility's RCO include a review of the justifications and IRB documentation of such waivers.

4. To strengthen IRB understanding of VA requirements concerning the roles and responsibilities of IRBs and investigators, the Office of Research and

Page 2

OIG Draft Report, Healthcare Inspection, Review of Informed Consent in the Department of Veterans Affairs Human Subjects Research, (WebCIMS 427012)

Development (ORD) will develop training for IRB chairs and members. This training will address requirements for waivers related to the informed consent process, the requirement for a witness signature on the consent form, and IRB assessment of investigator compliance at the time of continuing review. This assessment will include verifying that investigators are obtaining informed consent prospectively, prior to initiating screening procedures or research interventions, and that the signatures of both the subject and the witness are being obtained properly. In addition, ORO is developing mechanisms to assist facility RCOs in conducting effective audits, in reporting findings related to informed consent deficiencies, and in helping investigators develop and implement responsive remedial action plans. RCOs will continue to report annual audit findings to the facility Director and the IRB with recommendations for corrective actions where noncompliance is identified. The combination of new training and the new procedures for annual RCO informed consent audits of all VA studies will help to ensure compliance with both VHA policy and Common Rule regulations concerning informed consent in human subject research.

5. Thank you for the opportunity to review the draft report and for incorporating our technical comments in the final report. A detailed action plan to implement all report recommendations is attached. If you have any questions, please contact Margaret M. Seleski, Director, Management Review Service (10B5) at (202) 461-8470.

(original signed by:)

Michael J. Kussman, MD, MS, MACP

Attachment

Under Secretary for Health's Comments to Office of Inspector General's Report

The following comments are submitted in response to recommendations in the Office of Inspector General's report:

OIG Recommendations

Recommendations/ Actions	Status	Completion Date

Recommendation 1: We recommended that the Under Secretary for Health establish procedures requiring facility Directors to ensure sufficient IRB written documentation of waiver from informed consent.

Concur

a. The Office of Research and Development (ORD) will strengthen its policies on the IRB's responsibility related to the requirements for waiver of the requirement to obtain informed consent as found in 38 CFR 16.116(c) and (d) and the IRB's requirement to appropriately document its findings.

b. The Office of Research Oversight (ORO) will require that the mandatory annual informed consent audits conducted by each facility's Research Compliance Officer (RCO) include a review of (i) the justifications for such waivers relative to applicable regulatory criteria, and (ii) the adequacy of IRB documentation that all such criteria were satisfied.

c. Per VHA Directive 2008-064 *"Research Compliance Officers and the Auditing of VHA Human Subjects Research to Determine Compliance with Applicable Laws, Regulations, and Policies,*" dated October 16, 2008, the RCO is required to report the finding of audits to the facility Director with a recommendation for corrective actions if the audits reveal any noncompliance. Audit results related to waivers of informed consent, the justifications for such waivers relative to applicable regulatory criteria, and the adequacy of the IRB's documentation of its determinations regarding such criteria will be reported to the facility Director and others as required by the policy.

d. The new policy requirements, the RCO audits, and the reporting to the facility Director will assist the facility Director in ensuring that the IRB appropriately documents the approval of a waiver to obtain the informed consent.

In process November 2009

Recommendation 2: We recommended that the Under Secretary for Health establish procedures requiring facility Directors to ensure signed informed consent forms are on file.

Concur

a. The Office of Research and Development (ORD) will strengthen its policies in the new version of VHA Handbook 1200.05 on the investigator's responsibility to maintain signed informed consent forms for all subjects entered into the investigator's protocol if the IRB has not waived the requirement for obtaining informed consent or to obtain a signed informed consent. ORD will also strengthen its policies related to the role of the facility Research Compliance Officer (RCO) as a non-voting member of the IRB related to assessing the investigator's compliance with the requirement to ensure signed informed consent forms are on file when the investigator submits his or her research protocols for continuing review.

b. ORD will develop a training program for IRB chairs and members that will include the IRB's role in ensuring that the investigator's records contain all signed informed consents when the IRB conducts continuing review of the protocol.

c. The Office of Research Oversight (ORO) is currently developing procedures for facility RCOs related to the auditing process, developing corrective action plans, and the reporting of all findings related to failure of investigators to maintain signed informed consents in the investigator's protocol files.

d. The new policy requirements, the RCO audits, and the reporting to the facility Director will assist the facility Director in ensuring that signed informed consent forms are found in the investigators' records.

In process December 2009

Recommendation 3: We recommended that the Under Secretary for Health establish procedures requiring facility Directors to ensure that informed consent forms are prospectively obtained, which includes adding subjects to participant lists and/or to annual research progress reports only after obtaining the informed consent.

Concur

a. The Office of Research and Development (ORD) will develop a training program for IRB chairs and members that will include the IRB's responsibilities in ensuring that informed consent forms are prospectively obtained prior to screening procedures or before research procedures are begun. It will also address:

- The use of participant lists and when it is appropriate to add names of subjects to such lists.

- The IRB's role in ensuring that the annual research report submitted at the time of continuing review only includes subjects who have provided prospective informed consent. The IRB may review the list or require materials from the investigator to document that the participant list is in compliance with all requirements.

b. The Office of Research Oversight (ORO) will assist all facility Research Compliance Officers (RCOs) in developing procedures to audit and reconcile participant lists with signed informed consent documents and procedures for reporting any noncompliance with recommendations for corrective actions to the facility Director.

Note: Under VHA Directive 2008-064, dated October 16, 2008, facility RCOs are already required to audit the consent forms for all active research protocols each year and to develop procedures for notifying the facility Director, the IRB, and the investigator. ORO has developed audit criteria and audit tools for use in satisfying this requirement. One of the elements for such audits is determining if informed consent has been prospectively obtained.

c. The combination of the new educational program, the RCO audits, and the reporting to the facility Director will assist the facility Director in ensuring that informed consent is prospectively obtained, which includes adding subjects to participant lists and annual research progress reports only after obtaining the subjects' informed consent.

In process December 2009

Recommendation 4: We recommended that the Under Secretary for Health require facility Directors to ensure that witnesses are obtained for all VA consent forms as required.

Concur

Note: The Federal Policy for the Protection of Human Subjects (the Common Rule) does not require there be a witness to the subjects or the subject's Legally Authorized Representative's signature. This is an added protection that VHA implemented to ensure that the informed consent is prospectively obtained.

a. The Office of Research and Development (ORD) will develop a training program for IRB chairs and members that will include the IRB's responsibilities in ensuring that the informed consent form contains the appropriate signature block for a witness' signature and that at the time of continuing review of all protocols ensuring that all informed consent forms obtained by the investigator contain the signature of a witness as required by policy. The IRB or the Research Compliance Officer (RCO) may conduct the audits to ensure the witness' signatures have been obtained as required by policy.

b. Under a directive developed by ORD (VHA Directive 2008-064, *"Research Compliance Officers and the Auditing of VHA Human Subjects Research to Determine Compliance with Applicable Laws, Regulations, and Policies,*" dated October 16, 2008) facility RCOs are required to audit informed consent forms for all active research protocols each year and to develop procedures for notifying the facility Director, the IRB, and the investigator. Auditing of informed consent forms includes documenting that the signature of the witness was obtained. The signature of the witness is one of the elements in the audit tool developed by the Office of Research Oversight (ORO).

c. These audit processes, the reporting of the audit results, and the development of corrective action plans have been put in place to allow the facility Director to ensure that the signature is obtained as required.

In process December 2009

Recommendation 5: We recommended that the Under Secretary for Health establish procedures requiring facility Directors to ensure that IRB-approved informed consent forms consistently contain witness blocks or ensure sufficient IRB written documentation of waiver from the witness requirement.

Concur

a. The Office of Research and Development (ORD) will develop new policy requirements that will allow the IRB to waive the signature of a witness if specific criteria are met and that the IRB documents that the criteria are met in its minutes. The new policy requirement will be found in a revised version of VHA Handbook 1200.05.

b. ORD will develop a training program for IRB chairs and members that will address this new policy including the criteria for waiver and the required documentation.

c. The Office of Research Oversight (ORO) will require that the annual informed consent form audits conducted by facility Research Compliance Officers (RCO) will include elements related to the IRB's documentation of:

- Its review of the informed consent forms including documentation that the IRB found that all required criteria for an informed consent were met including the block for the signature of a witness

- Its determination that all required criteria for waiver of the signature of a witness to the subject's signature have been met.

These audit processes, the reporting of the audit results, and the development of corrective action plans have been put in place to allow the facility Director to ensure that the IRB approved informed consent form contains the signature block for a witness or, if the IRB waived the requirement, that the IRB appropriately documented this requirement.

In process November 2009

Appendix C

OIG Contact and Staff Acknowledgments

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Appendix D

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