Department of Veterans Affairs

Memorandum

Date: May 18, 2009

From: Chief Officer, Office of Research Oversight (ORO)(10R)

Subj: Remedial Actions Related to Research Compliance Officer Audit Findings

To: VHA Facility Directors
Associate Chiefs of Staff for Research (ACOS/Rs)
Research Compliance Officers (RCOs)

1. ORO has received a number of inquiries concerning the appropriate mechanism for remediation of noncompliance identified during RCO informed consent and regulatory audits.

2. As always, authority to require remedial actions and to approve proposed remedial actions in response to identified noncompliance rests with the Institutional Review Board (IRB).

3. RCOs have an obligation to share their expertise with the IRBs on which they serve (as non-voting members) and should make recommendations to the IRB regarding appropriate remediation of noncompliance. However, RCOs have (a) no independent authority to require or approve modifications to the IRB-approved protocol or informed consent, and (b) no authority to require or approve specific remedial actions, such as requiring investigators to revise informed consent documents, requiring investigators to obtain missing signatures or dates, or requiring investigators to seek "renewed" consent or "re-consent" from subjects.

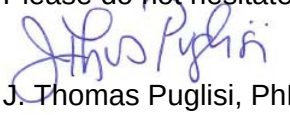
4. As the attached decision chart indicates, an RCO identifying apparently serious or continuing noncompliance during an informed consent or regulatory audit must notify the Facility Director, ACOS/R, IRB, and Research and Development Committee as soon as possible, but no later that 5 business days after discovery. The Facility Director must then notify the relevant ORO Regional Office (as well as the Network Office and the Office of Research and Development) within an additional 5 business days.

5. Upon receiving notification from the RCO of apparently serious or continuing noncompliance, the ACOS/R and IRB Chairperson should invoke the applicable local procedures for resolving such apparent noncompliance. Ultimately, the IRB must determine (a) whether serious or continuing noncompliance actually did occur and (b) the nature of required remedial actions.

6. The Facility Director must provide progress reports as directed by the relevant ORO Regional Office.

7. A copy of ORO's statement on the May 1 VHA national call regarding mandatory compliance audits is also attached.

Please do not hesitate to contact me should you have any questions.



J. Thomas Puglisi, PhD

Attachments

cc: Deputy Under Secretary for Health for Operations and Management (DUSHOM)(12)
Chief Research and Development Officer (CRADO)(12)

RCO REPORTING OF NONCOMPLIANCE IN VA HUMAN RESEARCH

A Research Compliance Officer (RCO) finds that a VA research project or VA researcher fails to comply with the laws, regulations, or policies governing VA research or with IRB requirements or determinations.[1]

Does/did the failure result in substantive harm, or risk of harm, to safety, rights, or welfare of subjects, research staff, or others?

NO

Does/did the failure substantively compromise the integrity or effectiveness of research protections (systemically or for an individual project)?

NO

Does/did the failure reflect a pervasive or persistent pattern of continuing noncompliance with research requirements?

YES (from first question)

YES (from second question)

YES (from third question)

NO (from third question)

Was the noncompliance IDENTIFIED and CONFIRMED by an RCO performing an informed consent[2] or regulatory[3] audit? (If RCO is uncertain about a "YES/NO" decision above, RCO should answer "NO")

YES

NO

USE SPECIAL RCO REPORTING PROCEDURE:

- RCO must report to Facility Director, IRB, ACOS/R, and R&D Committee as soon as possible, but no later than 5 business days after discovery.
- Facility Director must report to ORO Regional Office (RO), Network Office, and Office of Research and Development (ORD) as soon as possible, but no later than 5 business days after being notified by RCO.
- Facility Director must provide follow-up reports as directed by ORO RO, including subsequent IRB determinations.
- If the IRB ultimately determines that serious or continuing noncompliance actually did occur, Facility Director must report promptly to OHRP and/or FDA.

USE LOCAL REPORTING PROCEDURES:

- Noncompliance (or apparent noncompliance) must be reported as soon as possible, but no later than 5 business days after discovery, to IRB Chair and ACOS/R for review and possible substantiation per local SOPs.
- Did the IRB ultimately determine that serious or continuing noncompliance actually did occur?

YES

- IRB must notify Facility Director within 5 business days after its determination.
- Facility Director must report to ORO RO as soon as possible, but no later than 5 business days after IRB notification.
- Facility Director must report promptly to OHRP and/or FDA.

NO

If minor noncompliance occurred, IRB may require remedial action.

Do not report to ORO, OHRP, or FDA.

[1] See VHA Handbook 1058.01 §§4e, 4t, and 6a(4).

[2] Examples of noncompliance identified during an RCO informed consent audit that require 5-day reporting to Facility Director:

- Lack of a signed informed consent document or HIPAA privacy rule authorization for one or more subjects.
- Use of a consent document that lacks VA-required information on loss of benefits or treatment in case of injury.
- Pervasive or persistent use of an unapproved, unstamped, or outdated consent document (refer isolated uses to IRB).
- Pervasive or persistent failure to obtain dates of subject signatures (refer isolated cases to IRB)
- Pervasive or persistent failure to obtain signatures or dates for witnesses or persons obtaining consent (refer isolated cases to IRB).
- Pervasive or persistent failure to document informed consent as required by applicable VA policy (refer isolated cases to IRB).

[3] Examples of noncompliance identified during an RCO regulatory audit that require 5-day reporting to Facility Director:

- Lack of IRB approval or lack of VA approval before initiating research.
- Initiating research procedures before obtaining required informed consent.
- Initiating changes in research without IRB approval, unless necessary to prevent immediate hazards to the subject.
- Implementing substantive protocol amendments without IRB approval.
- Failure of one or more members of research team to satisfy research credentialing, privileging, or scope of practice requirements.
- Pervasive or persistent failure to comply with IRB determinations or requirements (refer isolated cases to IRB)..
- Pervasive or persistent failure to report AEs or problems in research per IRB or VA requirements (refer isolated cases to IRB).
- Pervasive or persistent failure to maintain required study documentation; e.g., case report forms (refer isolated cases to IRB).

VHA NATIONAL CALL

FRIDAY, MAY 1, 2009

Research Compliance Officer and Research Audit Requirements
Read by Tom Puglisi, PhD, ORO Chief Officer

The Office of Research Oversight (ORO)(10R) has received many questions about the new requirements for Research Compliance Officers (RCOs) and mandatory compliance audits. We invite everyone to explore ORO's expanded website for information on these topics.

1. ORO will continue to monitor implementation of the requirement that each VHA research facility appoint at least one RCO. Requests for approval to appoint a part-time (rather than a full-time) RCO must be sent to ORO and the Office of Research and Development (ORD)(12) for review. ORO and ORD will forward finalized requests to VHA leadership for final action. Approximately 15-20 such requests are currently in process.

2. The primary function of RCOs is to conduct mandatory informed consent and regulatory audits of VHA research. Every VHA research study must receive a 100% audit of informed consent documentation each year, as well as a regulatory audit approximately every 3 years. Audit tools are posted on the ORO website. RCOs also serve as local resources on research compliance requirements and as non-voting members of the Institutional Review Board (IRB) and other research oversight committees.

3. The lead RCO at each facility MUST report directly to the Facility Director. It is critical that the RCO function independently of the Research Service. Please note that RCO activities MAY NOT be directed or prioritized by Research Service leadership or personnel. Each Facility Director has a responsibility to ensure the functional independence of the facility's RCO(s).

4. Completion of the required informed consent and regulatory audits is an element of Facility Director and RCO performance plans. Thus far, however, ORO has concentrated on training RCOs to conduct informed consent audits and has advised RCOs to complete all of their required consent audits before beginning their regulatory audits. ORO and the Deputy Under Secretary for Health for Operations and Management (DUSHOM)(10N) recognize that because many RCOs were not in place until January 1, 2009, or later, some research facilities will not be able to meet the regulatory audit goal in Facility Director and RCO performance plans (i.e., regulatory audits of 1/3 of the facility's research studies). The DUSHOM has indicated that individual Facility Director and RCO performance evaluations should take such constraints into account.