



IRB Newsletter:

Review of Policy and Procedure Changes January 2010

Multiple policy revisions have been made and approved by both IRBs at the January 2010 meeting. Almost all the revisions were based on changes requested by the VA oversight organization, the Office of Research Oversight.

Here's the Highlights (see Attached Summary and January 2010 policies for all the details)

VA Only: VA initial approval letters will be sent to the

VA Research and Development Office (VA R&D) rather than the PI. The VA R&D Office will forward approvals to the PI when appropriate VA approvals are also obtained.

VA Only: references to Appendix C and D have been deleted (no longer required) and requirement for VA form 10-3203 added (for studies that are obtaining picture or video information from subjects).

VA Only: Modification requests and continuing review must be reviewed by the VA R&D office prior to IRB submission.

VA only: Clarifications were added regarding conflict of interest standards, VA-approved tissue banks, and UPIRSTO reporting.

VA only: Prohibition of planned emergency research subject to VA regulations was added.

ETSU, VA and MSHA:

Other minor revisions, including changing the number of copies required for full sub-

missions (HUDS included) in accordance with current procedures, were also made.

In addition, the case study policy

was revised to include information regarding case studies involving more than a single patient.

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Policy Revisions December 2009

A. Policy 3 Roles and Responsibilities for the Protection of Human Research Participants, revision date 11/11/2009, section VII,

Change Summary: (VA studies only) VA initial approval letters will be sent to the VA R&D rather than the PI.

Rationale for change: Two active studies were recently identified to have IRB approval but lack VA R&D approval.

Change Specifics: addition of "non-VA" in the following sentence: "The Coordinator will notify non-VA investigators in writing of board actions related to their protocols"; and the addition of "For VA studies, letters for initial approval of exempt, expedited and full studies will be forwarded to the VA R&D . The VA R&D will distribute to the PI" to item 2.

Also, the addition of "non-VA" to the following sentence : "The Coordinator will inform non-VA investigator in writing of the approval/denial of a research project by the IRB and/or required modifications to the application."; and addition of "For VA studies, approval pending letters that list required modifications will be forwarded to the PI and copied to the VA R&D. For VA studies, letters for initial approval of exempt, expedited and full studies will be forwarded to the VA R&D . The VA R&D will distribute to the PI" to item 3.

B. Policy 7 Exempt Studies, revision date 10/7/2009 section II,

Change Summary: (VA studies only) The ACOS/R cannot make exemption determinations.

Rationale for change: VHA Handbook 1200.05 Appendix A.1 stipulates that "The exemption status must be approved by the IRB Chair or an IRB member designated by the Chair."

Change Specifics: Addition of "for non-VA studies" to the following sentence: "If the research is submitted by the IRB Chair, for non-VA studies, either the Vice Chair or the Vice Provost for Research at East Tennessee State University will review this determination."; and addition of "For VA studies, the Vice Chair will review this determination."

Also, addition of "For non-VA studies and deletion of reference to the ACOS/R in this sentence: "For non-VA studies, in the absence of the Chair or Vice Chair, the Vice Provost for Research, will review the determination."; and addition of "For VA studies, the exemption status must be approved by the IRB Chair or an IRB member designed by the Chair."

C. Procedures 7 Exempt Studies, revision date 11/11/2009, Section II.A.6 and Section II.B.1

Change Summary: (VA studies only) VA initial approval letters will be sent to the VA R&D rather than the PI and references to Appendix C and D have been deleted.

Rationale for change: Two active studies were recently identified to have IRB approval but lack VA R&D approval. Appendix C and D are no longer required by the VA.

Change Specifics: Addition of "for non-VA studies" and changing the "copy" to "the approval" to the following sentence: "Within 2 weeks of submission of the request for exemption, for non-VA studies, the IRB Coordinator will forward correspondence to the PI, and for VA studies, the approval letter(s) and, if applicable, a Form 1223 will be forwarded to the VA R&D AO." Also addition of "The VA R&D will release the letter to the PI."

Also, section II.B.1, deletion of sentence referencing Appendix C and D

D. Policy 8, Expedited Studies, 11/11/2009, Section VI

Change Summary: (VA studies only) References to Appendix C and D have been deleted and requirement for VA Form 10-3203 was added.

Rationale for change: Appendix C and D are no longer required by the VA. Submission of VA Form 10-3203 is required for VA studies that are obtaining picture or video information from participants.

Change Specifics: Deletion of items 14 and 15, "For VA studies, Appendix C and D" And addition of item 16, "For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects."

E. Procedures 8a, Expedited Studies, 11/11/2009, Section II.A.7, II.A.13 and 14, Section B.2

Change Summary: (VA studies only) References to Appendix C and D have been deleted and requirement for VA Form 10-3203 was added. VA initial approval letters will be sent to the VA R&D rather than the PI

Rationale for change: Appendix C and D are no longer required by the VA. Submission of VA Form 10-3203 is required for VA studies that are obtaining picture or video information from participants. Two active studies were recently identified to have IRB approval but lack VA R&D approval.

Change Specifics: Section II.A.7- Deletion of items q and r, "For VA studies, Appendix C and D"

And addition of item s, " For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects."

Section II.A. 13, addition of "For non-VA studies to this sentence: "For non-VA studies, the approval letter(s) with the Chair's signature is forwarded to the PI in a timely manner."; and addition of " For VA studies, initial approval documents are forwarded to the VA R&D Office. The VA R&D Office forwards the documents to the PI." Also deletion of "database generated" on item 13b

Section II.A. 14, addition of "For non-VA studies: to this sentence: Upon study approval (except in cases of waiver), the IRB Coordinator is responsible for returning an approved copy of the Informed Consent document to the investigator for non-VA studies."; and addition of "For VA studies, the document will be returned to the VA R&D who will forward to the PI."

Section II.BA.2- Deletion of items k and l, "For VA studies, Appendix C and D"

And addition of item m, " For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects."

F. IRB Policy 9, Full Studies, 11/11/2009, Section III.D

Change Summary: (VA studies only) References to Appendix C and D have been deleted and requirement for VA Form 10-3203 was added. VA initial approval letters will be sent to the VA R&D rather than the PI

Rationale for change: Appendix C and D are no longer required by the VA. Submission of VA Form 10-3203 is required for VA studies that are obtaining picture or video information from participants. Two active studies were recently identified to have IRB approval but lack VA R&D approval.

Change Specifics: Section III.D.- Deletion of items k and l, "For VA studies, Appendix C and D" and addition of item n, " For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects."

Section III.E, Deletion of items h and i, "For VA studies, Appendix C and D"

And addition of item j, " For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects."

Section J, Addition of "For VA studies, letters for initial approval of full studies will be forwarded to the VA R&D . The VA R&D will distribute to the PI." And with regard to ICD, addition of "(for VA studies, through the VA R&D)."

G. IRB Procedures 9, Full Studies, 11/11/2009, Section II.A.6, 7, 9;

Change Summary: (VA studies only) References to Appendix C and D have been deleted and requirement for VA Form 10-3203 was added. VA initial approval letters will be sent to the VA R&D rather than the PI

All full studies: change in number of copies required (30 to 3 plus CD; 1 to 3 protocols/Investigator Brochure, etc)

Rationale for change: Appendix C and D are no longer required by the VA. Submission of VA Form 10-3203 is required for VA studies that are obtaining picture or video information from participants. Two active studies were recently identified to have IRB approval but lack VA R&D approval.

Change Specifics: Section II.A.6, 7 and 9, Deletion of items , “For VA studies, Appendix C and D” and addition of item, “ For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects.”

Section II.A. 12, addition of “For non-VA studies to this sentence: “For non-VA studies, the approval letter(s) with the Chair’s signature is forwarded to the PI in a timely manner.”; and addition of “ For VA studies, initial approval documents are forwarded to the VA R&D Office. The VA R&D Office forwards the documents to the PI.”

Section II.A. 15, addition of “for non-VA studies” to following sentence: “Appropriate approval letter(s) will be drafted for the Chair’s signature and forwarded to the PI for non-VA studies.”; and addition of “For VA studies, initial approval documents are forwarded to the VA R&D Office. The VA R&D Office forwards the documents to the PI.”

Section II.A. 16, addition of “For non-VA studies: to this sentence: Upon study approval (except in cases of waiver), the IRB Coordinator is responsible for returning an approved copy of the Informed Consent document to the investigator for non-VA studies.”; and addition of “For VA studies, the document will be returned to the VA R&D who will forward to the PI.”

Section B.2., Deletion of items , “For VA studies, Appendix C and D” and addition of item, “ For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects.”

Also, change in number of submission copies required

H. IRB Policy 10, Modifications, 11/11/2009, Section VIII

Change Summary: (VA studies only) Modifications must be reviewed by the R&D Office prior to IRB submission.

Rationale for change: To enable VA R&D to ensure appropriate training of study personnel, and review other relevant issues prior to IRB review

Change Specifics: Section VIII, addition of “Prior to IRB submission” in the following sentence: “ Prior to IRB submission, modifications must be submitted to the VA R&D

Office, if the study involves VA patients, VA staff, VA resources, time or equipment.”
And addition of “The VA R&D Office initials the modification request to document their review.”

Section II.A. 12, addition of “For non-VA studies to this sentence: “For non-VA studies, the approval letter(s) with the Chair’s signature is forwarded to the PI in a timely manner.”; and addition of “ For VA studies, initial approval documents are forwarded to the VA R&D Office. The VA R&D Office forwards the documents to the PI.”

Section II.A. 15, addition of “for non-VA studies” to following sentence: “Appropriate approval letter(s) will be drafted for the Chair’s signature and forwarded to the PI for non-VA studies.”; and addition of “For VA studies, initial approval documents are forwarded to the VA R&D Office. The VA R&D Office forwards the documents to the PI.”

Section II.A. 16, addition of “For non-VA studies: to this sentence: Upon study approval (except in cases of waiver), the IRB Coordinator is responsible for returning an approved copy of the Informed Consent document to the investigator for non-VA studies.”; and addition of “For VA studies, the document will be returned to the VA R&D who will forward to the PI.”

Section B.2., Deletion of items , “For VA studies, Appendix C and D” and addition of item, “ For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects.”

Also, change in number of submission copies required

I. IRB Procedures 10, Modifications, 11/11/2009, Section II.A.1

Change Summary: (VA studies only) Modifications must be reviewed by the R&D Office prior to IRB submission.

Rationale for change: To enable VA R&D to ensure appropriate training of study personnel, and review other relevant issues prior to IRB review

Change Specifics: Section II.A.1., the following sentence was added: “ For VA studies, the IRB Coordinator will verify that the VA R&D has initialed or signed the modification request.”

J. IRB Policy 11, Continuing Review, 11/11/2009, Section III.A and B

Change Summary: (VA studies only) References to Appendix C and D have been deleted and requirement for VA Form 10-3203 was added.

Rationale for change: Appendix C and D are no longer required by the VA. Submission of VA Form 10-3203 is required for VA studies that are obtaining picture or video information from participants.

Change Specifics: Section III.A and B, Deletion of items , “For VA studies, Appendix C and D” and addition of item, “ For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects” for both expedited and full lists

K. IRB Procedure 11, Continuing Review, 11/11/2009, Section II.A 3, 10, 12, B

Change Summary: (VA studies only) addition of reference that IRB verifies documentation of VA R&D review prior to IRB continuing review. References to Appendix C and D have been deleted and requirement for VA Form 10-3203 was added.

Rationale for change: The VA has changed their submission process to so that the R&D office will review the continuing review application and then will forward the application, along with any R&D or SRS requests for changes, to the IRB. Appendix C and D are no longer required by the VA. Submission of VA Form 10-3203 is required for VA studies that are obtaining picture or video information from participants.

Change Specifics: Section II.A. 3, addition of: “The IRB Secretary and IRB Coordinator will ensure that VA continuing reviews have documentation of R&D Office processing prior to IRB review.”

Section II.A 10 and 12, Deletion of items , “For VA studies, Appendix C and D” and addition of item, “ For VA studies, Form 10-3203 for studies that are obtaining picture or video information from subjects.”

Section II.B., addition of “VA investigators submit their continuing review application to the VA R&D office. (see James H Quillen VA Medical Center (JHQVAMC) Guideline for Submitting Applications to Conduct Human Subject Research for documents required)”

L. IRB Policy 17a, Conflict of Interest Review, 10/28/2009, Section B

Change Summary: (VA studies only) addition of ORO required language

Rationale for change: policy cited VHA Handbook 1200.13 which was rescinded when the CRADO issued a memo entitled “Financial Conflict of Interest in Research.”

Change Specifics: Section II.A. 3, addition of: “Like all VA employees, VHA employees conducting VA research approved by the Research and Development Committee, must comply with the Federal criminal code and the Standards of Ethical Conduct for Executive Branch Employees.”

M. IRB Policy 22, Repository, 10/28/2009

Change Summary: (VA studies only) addition of ORO required language

Rationale for change: revision in policy required by ORO to be consistent with ORB tissue banking requirements

Change Specifics: revised language to state: "Only the NCI-sponsored Cooperative Groups tissue banks listed on the ORD tissue banking website (http://vaww.reserach.va.gov/programs/tissue_banking/default.cfm) can be used for the specified protocols without ORD approval."

N. IRB Policy 32, Planned Emergency Research, 10/7/2009

Change Summary: (VA studies only) Addition of prohibition of planned emergency research that is subject to VA regulations

Rationale for change: ORO states VA has no authority to conduct Planned Emergency Research

Change Specifics: Section III, addition of "In addition, the IRB must determine whether the research is subject to VA regulations. If it is subject to VA regulations, the IRB cannot approve the study as VA policy prohibits the conduct of planned emergency research."

O. IRB Policy 30, Record Keeping , 11/19/2009

Change Summary: (VA studies only) addition of requirement to list waiver determinations for expedited studies in the minutes

Rationale for change: ORO requirement

Change Specifics: Section B, addition of "For VA studies only, the minutes will include documentation of required determinations and justification for each for each of the criteria based on protocol-specific findings when a waiver of informed consent or waiver of documentation of informed consent is granted for initial expedited studies. In addition, for VA studies only, the minutes will include documentation of required determinations when a HIPAA Waiver of Authorization is granted on initial expedited studies."

P. IRB Policy 18, UPIRTSOS , 11/19/2009

Change Summary: (VA studies only) addition of clarification regarding safety problems and deletion of 24 hour VA reporting of death requirement

Rationale for change: ORO requirement re clarification, revision of reporting requirement

Change Specifics: Section IV, addition of "In general, offsite SAE reports lacking specifics for a meaningful analysis do not need to be reported to the IRB. However when an offsite SAE leads to the DMC/sponsor to describe a safety problem in its report, the investigator should report the problem to the ACOS/R and IRB (VHA Handbook 1058.01 §6a(1)(d) & (e))" and Section VI, deletion of "The VA AO is responsible for submitting the report to ORO within 24 hours of the Chair's determination that the death was unanticipated."

Q. IRB Policy 35, HUDS , 11/19/2009

Change Summary: revision of number of copies needed

Rationale for change: IRB no longer requires submission of 30+ copies

Change Specifics: Section III, revise number of documents needed from 30 to 3, and addition of CD with electronic documents

S. IRB Policy 5 Case Studies, 1/5/2010

Change Summary: addition of information regarding multiple case studies

Rationale for change: ORO requested addition of first sentence and ETSU/VA IRB added second sentence for clarification regarding multiple case studies

Change Specifics: Section IV, table, addition of word "single" to "Case Studies" section, and addition of "For case reports involving more than one patient, IRB should be consulted (by submitting a Form 129) to determine whether the case report is research. If the proposed case report activity involves 4 or more patients, it must be submitted as human subject research."