



IRB Newsletter:

Review of Policy and Procedure Changes October 2008

VA investigators:

IRB Policy 3 was revised to include the requirement that for VA research, investigators are required to prepare and maintain adequate and accurate case histories.

What is a case history?

A case history is a record of all observations and other data pertinent to the investigation on each research subject.

What do case histories include?

Case histories include the case report forms and supporting data including signed and dated consent forms, any medical records including, but are not limited to: progress notes of the physician, the individual's hospital chart(s), and nurses' notes. The case history for each individual must document that informed consent was obtained prior to participation in the study.

This requirement is found in VHA Handbook 1200.5.



For MSHA Investigators who are not employed by ETSU or the VA:

In the past, the Form 103 used for initial submission has only required a departmental signature for ETSU and VA applications. Now, a signature on the form 103

from the Corporate Director of Research at MSHA will be required to document that the proposal has been reviewed for scientific merit. The attestation of review

for scientific validity documented by this signature must be obtained prior to submission to the IRB. See IRB Policy 3 for more information.

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Observation of consent process



Per federal regulations, the IRB has the authority to observe or have a third party observe the consent process.

IRB Policy 13 on Informed Consent was revised to include the following situations in which the IRB might consider observing the consent process.

- situations where capacity of the participant to provide informed consent may be questionable
- Previous investigator serious or continuing non-compliance
- High risk studies, such as Phase I trials
- Complaint(s) received about the informed consent process
- Any others as determined necessary by the IRB

If the IRB determines that the consent process of your study will be observed, you will be notified and a time for the observation will be scheduled.



Studies With an Associated Contract

Verification of the consistency for provisions of medical care or other care and services for research-related injury between the consent document and the contract is required.

In order for this process to be

followed, the IRB Policies 7a, 8, 8a, 9, and 9a were revised to require Principal investigators to submit a copy of the contract or, at minimum, a copy of any contract pages referencing provisions for medical care or other care and services for research-related injury.

Policy 13 has been revised to note that ETSU Sponsored Programs will review to ensure that the contractual language regarding medical care or other care or services for research-related injury in the consent.

Studies With an Associated Contract continued

If there is an associated contract with an IRB submission, please include when you submit your project to the IRB.

States Health Alliance.



This applies to all studies with an associated contract, including studies conducted at Mountain

Please contact the IRB Office if you have any questions about this policy change.

Importance of complete submissions to the IRB

If a study requiring review by the convened board requires changes before a final approval can be issued, the IRB must consider whether the changes are substantive modifications or clarifications directly relevant to the regulatory criteria for approval.

If so, then the study must be deferred and the information obtained and subsequently reviewed by the convened board.

This requirement is one mandated by the federal govern-

ment.

For PIs, a deferral because of missing information causes a delay in obtaining study approval.

To minimize the likelihood of this scenario, be sure that your submission documents are complete and provide all the relevant information to the IRB.

For more help achieving this goal, see the next column.



Helpful information for narrative completion

Question marks have been inserted in the narrative for relevant questions (those more difficult questions that often require revisions). These question marks indicate to the researcher that detailed information/clarification is available on the IRB website.

The additional information provided contains information about



what the question means, why the IRB is asking for the information and samples of complete and not-so-complete responses.

We have designed this document to help you answer the more difficult narrative questions in a more complete manner.

More helpful information for narrative completion

This will help ensure that the IRB has all the information needed to evaluate your study.

Please note that the answers

for your submission will be protocol specific. The example answers are provided to enhance understanding of the type of information the IRB is

requesting.



December 2008

Sun	Mon	Tue	Wed	Thu	Fri	Sat
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

January 2009

Sun	Mon	Tue	Wed	Thu	Fri	Sat
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

2– Medical IRB Meeting
4– Campus IRB Meeting
8– Deadline for Initial Full Submissions for January 2009 IRB Meetings
24– Last Day ETSU (reopens Jan 5, 2009)
25– Jan 2 Holidays (ETSU Closed)

1-2 ETSU Closed
6- Medical IRB Meeting
8– Campus IRB Meeting
12– Deadline for Initial Full Submissions for February 2009 IRB Meetings
19– ETSU Closed

We're on the Web!
www.etsu.edu/irb

ETSU
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