



IRB Policy Revision: Records

The IRB Policies and Procedures have recently been revised by the ETSU and ETSU/VA IRB.

One of our goals in the recent revision was to implement improvements in response to input from our researchers.

One major change is especially welcome:

Until now, the IRB required investigators to retain study records for a period of 10 years following completion of the study.

Now, the IRB has decreased that required retention period from 10 years to 5 years!

Please keep in mind that study records must be retained for



longer periods if required by other entities, such as sponsors or the FDA.

As always, records must be stored securely with access limited to IRB-approved personnel for that project.

In addition, records that are no longer required to be retained must only be destroyed securely in accordance with a plan detailed in the IRB narrative.



IRB Policies and Procedures

This newsletter focuses on a few major policy revisions. Please refer to the revised Policies and the Summary of Changes for more detailed information.

The revised Policies and a Summary of the Changes are posted on our website (<http://www.etsu.edu/irb/irb.html>).



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Special points of interest:

- *Record Retention*
- *Student Research*
- *UPIRTSO Policy Revision*
- *Recruiting at the VA*

IRB Policy Revision: Student Research (Policy 3)

One of the federal requirements for review of research is that each research study undergoes periodic review (continuing review). One of the difficulties that the IRB has addressed is that student investigators often graduate with active studies, and then are not reachable at the time of the next continuing review.

Both the ETSU and the ETSU/VA IRB want to ensure that expectations for student principal investigators (PIs) and their Thesis/Dissertation Chairs or Non-



Thesis Faculty Advisors are clearly communicated.

Therefore, the IRBs have developed a form called an Assurance Statement. This form clearly itemizes the responsibilities of faculty members who are working with student researchers. For example, one of the statements is "I have advised the

student that regulations require that a change in study status, **including study completion**, be communicated to the IRB (form 107)."

This form, signed by both the student principal investigator and the Thesis/Dissertation Chair/Non-Thesis Faculty Advisor, is required for all new student research submissions. The form is available on our website, www.etsu.edu/irb.

IRB Policy Revision: Responsibilities

Another of the IRB's goals is to ensure consistency in our policies and procedures. Therefore, the responsibilities outlined in the Assurance Statement discussed above have been added to IRB Policy 3.

Responsibilities for Thesis/

Dissertation Chairs and Non-Thesis Faculty Advisors have been incorporated as Section IV of this policy.



Student researchers acting as principal investigators are additionally attesting that they have read and understand their responsibilities as PI (Policy 3) by their signature on the Assurance Statement.

IRB Form 103 Revision

In an effort to streamline the IRB process for this new Assurance Statement, the signature currently required as attestation on the Form 103 for Thesis/Dissertation Chairs and Non-Thesis Faculty Advisors has been moved to the new Faculty Assurance. This means only 1 faculty signature is required.

The signature of Thesis/Dissertation Chairs and Non-Thesis Faculty Advisors on the Assurance Statement attests the following:

1. Certification that the student is knowledgeable about the regulations and policies governing research with human

participants

2. Certification that the proposal has been reviewed for scientific merit and that adequate resources are available to protect participant rights and welfare
3. Agreement to the listed responsibilities

IRB Policy Revision: UPIRTSOs (Policy 18)

Federal regulations require that the IRB review unanticipated problems involving risks to subjects or others.

Often in multi-site clinical trials, an adverse event report generates an initial report and then multiple follow-up reports.

With a desire to streamline this reporting process and the IRB reviewing process, the IRBs have made the following addition to Policy 18:

“Follow-up reports of an off-site event may be submitted on a

tracking log without an accompanying Form 109 if the following are true:

1. the initial report of the event was submitted as a UPIRTSO on a Form 109.
2. the local PI has determined that the follow-up information does not contribute meaningful new information”

Call the IRB at 439-6053 for questions.



IRB Policy Revision: VA Recruiting (Policy 16)

In VA studies, during the recruitment process, researchers must make initial contacts with veterans in person and/or by letter prior to any telephone contact and provide a telephone number or other means that veterans can use to verify the validity of the study (One source of infor-

mation about clinical trials is <http://www.clinicaltrials.gov>). After recruitment and during the follow-up phase, VA researchers should begin phone calls by referring to previous contacts and the information provided on the informed consent document .

In addition, for VA studies, researchers must restrict their telephone and other contacts with veterans to only those procedures and data elements outlined in IRB-approved protocols. **In these contacts, researchers must not request social security numbers.**

IRB Policy Revision: VA Data Security and Privacy

As part of a concentrated focus on the safety of research data, the VA has developed new rules regarding VA data security and privacy.

In order to ensure that PIs understand the importance of the data security issues and the ne-

cessity of compliance with all the relevant rules and policies, the VA is requiring that PIs submit a completed [Appendix C](#) and [Appendix D](#).

These completed forms must be submitted with new VA initial submissions to both the ETSU/

VA IRB and the VA R&D. Refer to IRB Review Volume 3, Issue 2 for detailed information.





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