Scientific Merit and Scholarly Validity Review

What's new with the Scientific Merit and Scholarly Validity Review at Palmetto Health?

As of October 1, 2015, Palmetto Health will no longer utilize a Scientific Review Committee (SRC) to perform the scientific merit and scholarly validity review (scientific review, for short) for any types of human subject research. The responsibility of the scientific review will now reside with the departments performing the research in association with qualified individuals.

Why are you making this change?

Piloting of the original Attestation form (dated May 2014) with retrospective chart reviews and qualitative research, which was begun on May 1, 2014, was well received and offered faster review times. This new, improved scientific review process is expected to continue to shorten overall Palmetto Health research review times once a study is submitted into the eIRB system. This will also drive collaboration among the principal investigator, their associated department, and a qualified individual to ensure appropriate protocol preparation prior to submission.

How will the new scientific review work?

The process will require a new, modified “Scientific Merit and Scholarly Validity Attestation” form (Attestation form, for short) to be completed. The new form is dated October 2015. It will be the responsibility of the Department Chair/Director and/or the Department’s appointed Vice Chair/Director of Research to ensure that an individual with appropriate qualifications has thoroughly reviewed the study to ensure that the following five (5) statements are true:

1. The rationale for the study is clearly stated and supported by an adequate literature review.
2. The hypothesis and corresponding aims are clearly stated.
3. The primary outcome (and secondary outcomes, as appropriate) is clearly defined.
4. The study design and subject population are appropriate for the questions posed.
5. The sample size and justification, and statistical analysis are clearly described and adequate to meet the study objectives.
What are the qualifications of the individual that should be utilized by the department to perform the scientific review?

An individual, other than the principal investigator, that has at least a Masters in statistics or biostatistics or equivalent training/experience. The equivalent training/experience must include at least 12 hours of graduate level statistics, biostatistics, and/or research design courses.

Is there someone at Palmetto Health who can provide study design and analysis services?

Yes. Martin Durkin, MD, MPH is available to assist with protocol development and to ensure that the study is appropriately constructed per the five statements listed above. He may be contacted at 803-434-6963 or Martin.Durkin@PalmettoHealth.org. His services are free of charge for individuals conducting research at Palmetto Health. We strongly encourage your use of Dr. Durkin or another qualified individual prior to your submission to the IRB. Also, it is recommended to use the same individual assisting in the study design to perform and/or direct the analysis of the data once collected.

Are there any exclusions to this Attestation process?

Yes. An Attestation form is not required if there is documentation the study has been (1) reviewed by the Food and Drug Administration (FDA) and received designation, such as Investigational New Drugs (INDs) or Investigational Device Exemptions (IDEs) or (2) peer reviewed by an outside (non-Palmetto Health and/or non-University of South Carolina) entity and is being funded by that entity.

Once the Attestation form is completed, what do I do with it?

The completed, signed Attestation form must be uploaded into the eIRB system (Section 9, Other Study Specifics – Scientific Review, #2.0) prior to submitting the study to the IRB.

What happens if I submit an Attestation form and the five (5) statements are not all answered “Yes“?

The Institutional Review Board (IRB) will not review your study, and the study will be returned to you. Once the protocol is sufficiently modified so a qualified individual can answer the five statements of the Attestation form with “Yes”, you may re-submit the study for IRB review.
I have already submitted a study for review within eIRB. It has not received SRC approval yet. What should I do?

If you have a study that was submitted prior to the initiation of the new Attestation form (October 1, 2015), please contact Dr. Durkin (contact information above) or another qualified individual to ensure that your protocol is re-worked so that the five statements of the Attestation form can be answered with “Yes”. Then, have your Department Chair/Director and/or the Department’s appointed Vice Chair/Director of Research complete/sign the new Attestation form. Upload the completed Attestation form (Section 9, Other Study Specifics – Scientific Review, #2.0) into the eIRB system, and re-submit the study for IRB review. If you currently do not have access to your eIRB application, please contact Mary Prather (contact information below) to gain access.

I have a study that has received SRC approval but it has not received IRB approval yet. Do I need to complete the new Attestation form and re-submit?

No, you will not need to complete the new Attestation form if you have already received SRC approval.

I have a study that I submitted prior to October 1, 2015 with the original Attestation form, but it has not received IRB approval yet. Do I need to complete the new Attestation form and re-submit?

No, you will not need to complete the new Attestation form if you have submitted prior to October 1, 2015. The original Attestation form will be sufficient.

I have a study that has a completed and signed, original Attestation form. It is October 1, 2015 (or later), but I haven’t submitted the study yet through eIRB. Do I need to complete the new Attestation form before I submit?

Yes. Please take your completed original Attestation form to your Department Chair and/or the Department’s appointed Vice Chair of Research so that they can complete the new form and sign. Upload the completed, new Attestation form (Section 9, Other Study Specifics – Scientific Review, #2.0) into the eIRB system, and submit the study for IRB review.

Why is scientific review even required?

IRBs must ensure that risks to subjects are minimized and are reasonable. 45 CFR 46.111(a) states that the IRB shall determine that the following requirements are satisfied:
• Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic and treatment purposes.
• Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.

In addition, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) sets forth elements to achieve rigorous standards for ethics, quality, and protections for human research which require scientific review:

• Element I.1.F. The Organization has and follows written policies and procedures for reviewing the scientific or scholarly validity of a proposed research study. Such procedures are coordinated with the ethics review process
• Element II.1.E. The IRB or EC has and follows written policies and procedures requiring research protocols or plans to be reviewed by individuals with appropriate scientific or scholarly expertise and other expertise or knowledge as required to review the research protocol or plan

**What if I have questions related to the scientific review process?**

You may contact Mary Prather, Manager IRB, at 803-296-6089 or Mary.Prather@palmettohealth.org with questions related to the scientific review process.