

New Protocol Flow for studies submitted to the GCRC and IRB

Email the study documents to Lynne Simpson, GCRC protocol manager and Helena Estes-Johnson, GCRC IRB coordinator or gcreprotocols@virginia.edu

Protocol goes to GCRC Biostatistician, RSA and as applicable to exercise physiology, and the dietician.

Helena does administrative review

Based on findings by the above group the protocol and consent are returned to the study coordinator or PI for clarification and changes

Once the changes are completed, the protocol is submitted to the GCRC Advisory Committee.

Helena sends it to the IRB for pre-review.

Pre-review changes are highlighted and incorporated into the final document following the GCRC Advisory Committee

The GCRC Advisory Committee meets. A letter from the GCRC Administrative Director is emailed to the PI detailing the findings of the committee. The study documents to which the corrections should be made is emailed (contains highlighted changes from IRB pre-review).

Corrections should be emailed to gcreprotocols@virginia.edu , or Lynne Simpson. The corrections are forwarded to the reviewers.

After receiving approval from the reviewer, an email giving GCRC approval is sent to Helena and the

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study coordinator. Helena submits to the IRB

The IRB Committee reviews. Recommendation from IRB committee sent to Helena. Helena may begin modifications, and sends to PI and SC for review and completion. Final documents should be returned to Helena for review and submission to the IRB. IRB approval form and consent received by Helena, copies made for GCRC files, originals sent to PI or study coordinator

Helena notifies Lynne that the study is approved and opened to enrollment. All IRB changes incorporated into the GCRC protocol. Lynne meets with study coordinator or PI to develop Drs orders and flow sheets, protocol packet is signed by PI. Study is ready to begin

Process for Submission of Status Reports for GCRC Studies

Email re: continuation notice sent to PI, study coordinator and GCRC IRB Coordinator.

Study coordinator or PI to complete the Status Report form electronically and email to Helena Estes-Johnson GCRC IRB coordinator for review.

Helena reviews status report to determine if it is complete and makes comments or suggestions.

If modification contained with the submission, the modification is sent to Lynne Simpson for GCRC processing.

Once complete, PI signs the form and Helena submits the status report form to the IRB..

Per agreed arrangement Helena or the study coordinator emails the current study documents (protocol, consents) to the IRB.

IRB reviews, Helena receives the approval and consents, copies for GCRC file, original to PI or study coordinator.

Process for Modifications to GCRC Studies

Email study document with tracked changes and request for modification form for GCRC studies to Lynne Simpson GCRC protocol manager and Helena Estes-Johnson GCRC IRB coordinator or to gcrprotocols@virginia.edu.

Lynne reviews to determine if the modification may receive GCRC Administrative approval, expedited approval or full committee review.

Expedited review requires a GCRC assistant Director to review and give preliminary approval. May be submitted to the IRB following preliminary approval, but the full Advisory Board will ultimately review.

Full committee review requires that the full Advisory Board reviews prior to IRB submission

Helena reviews for IRB specific requirements in tandem with the above and submits to the IRB following GCRC approval.

If additional clarifications or changes required, Helena assists with the process as needed.

IRB approval and stamped consents received by Helena. Copies to the GCRC file, originals sent to the study coordinator or PI.