

General Clinical Research Center

Section 1 General Administrative	01/15/09 Originated
1.1 Protocols	00/00/00 Reviewed w changes
SOP for Expedited Review of GCRC Protocols	00/00/00 Reviewed w/o changes
	GCRC Author

SOP for Expedited Review of GCRC Protocols:

Protocols that Qualify for an Expedited Review: Protocols that propose limited use of GCRC resources that do not involve research subject safety, such as only dietary recall support, use of the core lab, use of the biorepository resources, etc. may be considered for expedited approval at the request of the PI. Such protocols must have IRB approval before any use of GCRC resources.

Steps Involved in an Expedited Review:

1. The PI submits to Liz Ruiz electronic copies of all documents submitted to the IRB as part of the original IRB application package, as well as copies of any subsequent IRB correspondence.
2. Animesh Chandra, in consultation with the PI, fills out the GCRC Resource Request Form. Consultation with the GCRC resource involved may be necessary to assess feasibility of the proposed utilization.
3. The protocol and other documents are reviewed by two Program Directors, who are assigned to expedited review of protocols on a rotating basis.
4. If the two Program Directors determine that additional expertise is needed to review the protocol, they may request additional advice from members of the GAC, or decide that the protocol must be submitted for the usual full GAC review.
5. If the two Program Directors recommend approval, Animesh Chandra prepares an expedited approval memo to the PI to be signed by the Program Director.
6. The protocol is presented, discussed and voted on for final approval at the next GAC meeting.