

# GCRC Protocol Expedited Revision Request

**Protocol Number:** \_\_\_\_\_

Protocol revisions require approval by the Advisory Committee before changes can be made to a protocol. A GCRC Associate Director can give expedited approval to simple changes to a protocol that do not add cost or make significant changes to the methodology. Changes to the subject consent form or methodology require approval from the Human Investigation Committee (HIC). If HIC review is required, please submit a copy of the revised consent form with your request for expedited review.

**Steps:**

- 1) Update your TURBO Protocol File including the revision section. Print one copy of the protocol and a copy of the revision summary. You must also bring a copy of the protocol file on disk.
- 2) Receive approval for the revision from a GCRC Associate Director. A Director should be available in the hospital during business hours. Call 982-3160 for assistance in locating an available director. A Director's signature is required.
- 3) Meet with the Nursing Manager who will update the GCRC Nursing Documents and print a new copy for your approval. The Nursing Manager will then sign this form.
- 4) If your protocol includes meal service, meet with the Dietician who will update the GCRC Diet Flowsheets and print a new copy for your approval. The Dietician will then sign this form.
- 5) Meet with the Exercise Physiology Laboratory Director and/or the Sleep Laboratory Director, if necessary
- 6) Bring the disk, the printed protocol copy, and the signed form to the GCRC Administrative Office for the Administrator's signature. Once we load the protocol into our database system, the expedited approval is complete. You must either submit the required 28 copies of the protocol when you submit the expedited revision request or bring the 28 copies by the normal submission deadline for the next GCRC Advisory Committee meeting. The GCRC Advisory Committee will review your revision at the next full GCRC Advisory Committee meeting to allow formal action on the revision.

_____ Principal Investigator Signature	_____ Date
_____ GCRC Associate Director Signature	_____ Date
_____ GCRC Nursing Manager Signature	_____ Date
_____ GCRC Dietician Signature	_____ Date
_____ GCRC Ex. Physiology Director Signature	_____ Date
_____ GCRC Sleep Lab Director Signature	_____ Date
_____ GCRC Administrator Signature	_____ Date