

UVA GCRC Investigator/Staff Handbook

I. Administration Information

A. Administration

The GCRC Administrative Offices are located in University Hospital, on 8 West, in Room 8701 beside the West Staff elevators. The office hours are 8:00 a.m.-- 5:00 p.m. Contact Pam Sprouse (4-2073), GCRC Administrator, Karen Dorsey (2-3160), GCRC Program Support Tech, Sr., or Charlotte Bailey (4-2685), GCRC Executive Secretary with any questions related to the GCRC.

B. How to Submit a Protocol

1. Complete the Human Investigation Committee (HIC) application found at <http://www.med.virginia.edu/medcntr/committees/human-investigation/>, and the GCRC application found at <http://gcr.med.virginia.edu/>.
2. Email the applications and the consent form(s) to Helena Estes-Johnson, HIC Coordinator at hve5r@virginia.edu, and Lynne Simpson, GCRC Protocol Nurse Manager at lss2f@virginia.edu.
3. Charlotte Bailey, GCRC Executive Secretary, will notify you of the date of the GCRC Advisory Committee review.

C. How to Revise a GCRC Protocol

Contact Lynne Simpson at lss2f@virginia.edu to receive the revision form.

D. Special Issues for Industry-Sponsored Studies (“D” Category)

1. The sponsor is responsible for all costs related to “D” category studies. The costs include inpatient rooms, use of outpatient space, nursing time, supplies and processing lab time. You will need the same approvals for these protocols as for investigator-initiated studies. For information on these costs, contact Pam Sprouse. The GCRC charges a one-time administrative fee of \$291.11. PI's must pay this cost before admitting subjects.
2. Before beginning an industry category study, you will need to give the GCRC Administrator a copy of the industry-approved budget and a University PTAO for all charges. You will also need to provide Admissions with the PTAO and the name of a contact person to whom Admissions will send the inpatient bills. Be

sure to notify Admissions of impending admissions so they will send the bills to you.

E. Special Issues for Cancer Center Protocols

The GCRC Advisory Committee will give expedited approval to Cancer Center protocols that have received Cancer Center Review Committee approval. Please provide copies of the Cancer Center Review Committee critiques when you submit your protocol.

F. Expectations of PI

1. If any subject on your protocol suffers a serious adverse event, contact the GCRC Research Subject Advocates, Walter Davis, MD at (434) 924-5492 and Karen Parks, RN, at (434) 982-4311.
2. Please remember to credit the GCRC grant on ALL publications which relate to your GCRC research or use of our facilities. The NIH uses your publications to justify GCRC funding to Congress. We recommend the following language to credit the GCRC: "This work was supported in part by a grant from the National Institutes of Health to the University of Virginia General Clinical Research Center, number M01RR00847."
3. Twice a year (for the budget and the annual report), we will request information relating to your protocol and reprints of publications related to your GCRC work. When submitting reprints, please be sure to indicate the protocol number to which the publication relates.
4. Please remember to mention the GCRC in any press releases that relate to your research. We send copies of all newspaper and magazine articles that mention our GCRC to the NIH.

G. Frequently Asked Questions

1. *Who can be a PI on a GCRC protocol?*
PIs are UVA faculty members. PIs do not have to be MDs, but a MD with "attending" privileges at University Hospital must at least be a co-investigator.
2. *Why do you ask for so much information in the application?*
The National Institutes of Health (NIH) provides the funding for the GCRC. We are required to report all of this information to the NIH.
3. *How do you determine individual industry study charges?*

The NIH requires all GCRC's to recover the costs related to industry studies. We base our charges on the time the subject will be in GCRC space and the nursing and administrative time spent on the protocol by GCRC staff.

4. *How can I find out how much an industry study will cost?*
Contact Pam Sprouse at 4-2073 to discuss the requirements of your protocol. We charge by the hour, but we do not charge the full hourly charge for lengthy protocols if the nurse is not required to remain with the subject at all times.
5. *Do I have to obtain a cost for each individual industry study or can I just estimate the cost based on my previous protocols?*
The hourly cost changes each year based on staff salaries and space costs. We suggest checking with the Administrator before submitting budgets for each protocol.
6. *What about supplies for industry studies?*
The PI must obtain his/her own supplies for all out patient industry studies and bring them to the GCRC. For inpatient studies, the GCRC provides standard floor stock supplies and the PI provides non-floor stock supplies.