

The GCRC, IRB and Subject Safety

The GCRC has certain “statutory” responsibility for subject safety that is separate from the responsibility of the Principal Investigator and his/her team (PI), and separate from the responsibility of the IRB. This “statutory” responsibility is given by our funding agency, the NIH through the NCCR and is expressed in the general [GCRC Guidelines](#) as well as in a separate document titled “[Recommendations to GCRCs for Patient Safety in Clinical Research.](#)”

A specific component of this responsibility is that the GCRC staff has to be certain that all GCRC protocols and modifications thereof are approved by the IRB before implementation. To facilitate this process the IRB and the GCRC copy each other on their approval letters (by bringing a study to the GCRC the PI agrees to this exchange of information).

Another component of the human subject safety responsibility of the GCRC is the Research Subject Advocate. The NIH specifically funds this position with the responsibility to ensure that GAC-approved data and safety monitoring plans are fully implemented, that the research carried out on the GCRC is in compliance with the IRB-approved protocol, and that serious adverse events are reported in a timely fashion to the IRB and appropriate Federal agencies. The RSA will have direct access to and responsibility to the Dean of the College of Health and Human Development.

An important part of the responsibility that the GCRC has for subject safety is a more general attentiveness to safety matters and PIs will find that the theme of subject safety is something that the GCRC staff pays particular attention to during the collaborative process of research in the GCRC.

The GCRC staff has significant expertise in human subject research and for this reason the IRB has appointed several members of the GCRC staff as members of the IRB. Because of the collaborative nature of the relationship between PIs and the GCRC staff, whenever a GCRC protocol is brought to the IRB, the GCRC staff either excuse themselves or physically move to the side of the PI or PIs representative in order to support the PI in his/her presentation to the IRB. GCRC staff excuse themselves from all IRB deliberations about GCRC protocols.