Research Subject Advocates
at General Clinical Research Centers

General Clinical Research Centers

The National Center for Research Resources (NCRR) supports 79 General Clinical Research Centers (GCRCs) that are distributed across the US, mostly in academic institutions. GCRCs and their satellites provide clinical investigators specialized environments with the infrastructure necessary to conduct sophisticated patient-oriented research. They are staffed by nurses experienced in clinical research and have inpatient and outpatient facilities. Most GCRCs also have a core laboratory, a bioinformatics system, and a metabolic kitchen. Their position at the forefront of patient-based research makes GCRCs the ideal environment to develop an important new position in the research team: the Research Subject Advocate (RSA).

Research Subject Advocate

Federal regulations and policies protect subjects in clinical research protocols, ensuring that their safety is given the highest priority. These regulations complement the policies of academic institutions that host the GCRCs. Proper performance of research consent and oversight procedures makes demands on the time of already-busy clinician researchers. It is to address these demands that the NCRR has created a Research Subject Advocate (RSA) position within each GCRC. The purpose of this position is to assure that all steps are taken to maximize patient safety as detailed in the protocols approved by the Institutional Review Board (IRB).

The RSA (or some other title–each GCRC may select its own title) must understand the research protocols and have sufficient stature with the institutional community to achieve the goals of the program. To date, over 90% of GCRCs have appointed an RSA. Their backgrounds are in medicine, research nursing, pharmacy, and ethics. Individuals trained in other relevant areas may also assume the RSA responsibilities. The position may be divided among more than one qualified individual. When a GCRC has a satellite or other significant outreach activities, one or more additional individuals may be appointed at those sites to share the responsibilities.

The Principal Investigator (PI) of the GCRC grant will determine the RSA responsibilities and position with the institution's organizational structure. The RSA at each GCRC must report directly to the PI of the GCRC grant, but work closely with the Program Director and GCRC Advisory Committee (GAC), assisting in the interpretation of the clinical and scientific aspects of the protocols to facilitate both regulatory compliance and patient safety. The effort of the RSA funded through the GCRC grant must be dedicated exclusively to the GCRC activities.

RSA Responsibilities

Since the intensity of clinical research and associated risks vary widely among the GCRCs and satellites, the level of effort and responsibilities of the RSA will also vary. Examples of RSA responsibilities may include but are not limited to:

- Serve as an unbiased observer during the consent process when requested by the either the patient/volunteer or investigator.

- Provide information to patients/volunteers participating in Phase I or II clinical trials and other research that is above minimal risk.

- Assist the GCRC investigators in formulating, and the GAC in reviewing, data and safety monitoring plans.

- Assure that the GCRC studies are performed in accordance with IRB-approved protocol and monitoring plan.

- Facilitate the reporting of Serious Adverse Events and Conflicts of Interest to appropriate local committees and Federal agencies.

- Provide access to minutes of GAC meetings that relate to the review of monitoring plans upon request of NCRR staff and site visit team members during the GCRC competitive renewal process.

- Assure that the GCRC investigators are appropriately trained to remain current on their regulatory and patient safety responsibilities.

- Participant in other relevant activities, such as GAC and IRB meetings, as determined by the Principal Investigator of the GCRC grant.

NCRR anticipates that the RSA program will quickly become a highly valued resource within institutions that have GCRCs: NIH-funded researchers will very likely want their human subject research protocols to take place on their GCRC so that their efforts to protect their patients can be facilitated by the RSA. The first national meeting of RSAs at the GCRC Program Directors' Meeting in April 2002 should help to identify the qualities common to optimal consent and compliance procedures.