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The University of Rochester Research Subject Advocacy Program

By Nancy A. Needler and Norman M. Goldfarb

The National Institutes of Health (NIH) funds General Clinical Research Center (GCRC) research facilities to provide clinical investigators with resources to conduct inpatient and outpatient studies.[1] Per NIH requirements, the University of Rochester Medical Center (URMC) GCRC created a Research Subject Advocate (RSA) program in 2003 to add an extra measure of protection for CRC research participants.

As shown in Table 1, research subject advocacy has many variations and goes by many names. This article emphasizes the NIH terminology (RSA) and approach. The primary function of the URMC RSA Program, as outlined in the CRC model, is "to ensure that studies on the CRC are designed and conducted safely and ethically with protection of human subjects accorded the highest priority."[4]

Table 1. RSA Names[2,3]

Clinical Advocate
Nurse Advocate
Ombudsman
Organizational Advocate
Patient Advocate
Research Advocate
Research Intermediary
Research Subject Advocate
Research Participant Advocate
Witness

In 2006, the NIH awarded the URMC a Clinical & Translational Science Award (CTSA).[5] The existing GCRC became a component within the CTSA: the Clinical Research Center (CRC). In this article, the CRC acronym will be used. The RSA program is advancing further under the newly adopted 2008 best practices defined by the CTSA Consortium Oversight Committee of Principal Investigators (now called the CTSA Consortium Steering Committee), in collaboration with the NIH. These best practices state that the research subject advocacy function:[6]

- Should include a reporting pathway to institutional officials of appropriate authority and should be free of conflict of interest.
- Should be complementary to and integrative with existing entities at the institution to promote and facilitate safe and ethical conduct of human research.
- Should have, or have direct access to, an authority that can temporarily suspend a research activity based on ethical and safety concerns so that problems can be explored or resolved through proper procedures. This capacity enables preliminary intervention into problems that might not necessarily invoke an institutional review board (IRB) suspension.
- Should be a resource to the research community and to participants; have a voice in policy regarding research ethics, participant rights, and research safety; and play a role in the protection of human subjects and responsible conduct of research educational programs at the institution.

Organizational Structure

Until recently, the URMC RSA Program reported directly to the Principal Investigator (PI) of the CRC. The CRC Program Director, responsible for day-to-day CRC operations, also reports to the PI. This reporting model prevents undue influence on RSAs by the Program Director and clinical investigators, although collaboration with CRC personnel, clinical investigators, study coordinators, nurses, the Institutional Review Board (IRB), the URMC Office for Human Subject Protection (OHSP), and HIPAA Compliance Office is at the heart of the RSA Program. The CRC RSA Program employs two part-time RSAs.

The RSA Program recently transferred to the University's CTSA Office of Regulatory Support, with institution-wide responsibilities. Duplication of effort, e.g., reviewing protocol amendments, has been eliminated. Safety monitoring and other CRC policies and procedures will be adapted and implemented throughout the URMC.

RSA Activities

The RSA Program operates in two modes: proactive and reactive. In proactive mode, RSAs consult with investigators, study nurses, and coordinators; review protocols; and work to prevent issues from occurring. However, if an issue does arise, RSAs respond as quickly and effectively as possible. Inpatient studies require RSA support 24 hours per day, seven days per week, although calls at night are rare. In the absence of both RSAs, other trained personnel are available to cover safety issues.

To accomplish the Program's objectives, RSAs:

- Serve as the research participant's advocate, both individually and collectively.
- Meet with individual participants to identify and address concerns.
- Liaise between CRC personnel and research study teams on human subject protection issues.
- Help investigators develop Data and Safety Monitoring Plans (DSMPs).[7]
- Coordinate data monitoring and safety training.
- Review the human subjects protection aspects of protocols and amendments.
- Assist investigators with adverse event and protocol deviation reporting.
- Serve as an impartial informed consent witness.

RSAs observe some informed consent discussions. Selection is based on the risk and complexity of the study, experience level of the investigator and study coordinator, and requests by participants and investigators. Observation reports are submitted to the study principal investigator and reviewed with appropriate personnel. Training in the informed consent process is also a component of the RSA Program.

In addition to day-to-day responsibilities, RSAs work to raise the general level of clinical research expertise, practices and communications.[8-10] They help develop policies and guidelines, train investigators and other study personnel on topics relating to human subjects protection, and review safety-related trends for improvement opportunities.

For the RSA program to be effective, clinical investigators, other study personnel, and study participants must know that RSAs are available to assist them. We therefore contact new investigators and study coordinators, and distribute informational documents to them. Web pages specific to research participants explain how to contact the RSA office.[11] RSA brochures are available in areas accessed by research participants.

Collaboration across Institutions

NIH CTSA grants include a requirement for RSA programs to disseminate best practices and participate in inter-institutional collaborations.[12] One such collaboration is led by the RSA at The Rockefeller University. In this project, RSAs are developing a validated instrument to measure research participants' perceptions of their clinical research experience. The objectives are to improve the participants' experience and the conduct of clinical research.[13]

NIH RSAs also formed the Society for Research Subject Advocates, which holds an annual meeting, operates a listserv, and makes other resources available.[14]

Challenges and Solutions

Table 3 presents challenges that the URMC RSA Program is currently addressing:

Table 3. Challenges and Solutions

Challenges	Solutions
RSA Program has been available only to CRC investigators.	Expand services to other URMC researchers.
RSA Program location in CRC offices is somewhat inaccessible to the rest of the institution.	Move RSA Program office to the future CTSA building, which will centrally house other internal regulatory groups that assist investigators.
Overlaps exist between IRB, RSA Program, and other institutional department responsibilities.	Review overlaps and recommend changes.
Continued identification and integration of best practice models for RSA functions across institutions is warranted to help assure consistency and higher standards.	Participate in RSA professional-focused organization, as well as in CTSA consortium-driven activities

Conclusion

The URMC RSA Program has made substantial progress in meeting the human subjects protection goals set forth by the NIH. The success of our proactive work has minimized the call for reactive work. Nevertheless, substantial opportunities remain to expand our role across the institution and to collaborate with RSA programs at other institutions. The NIH's GCRC, CRC, and CTSA initiatives have been and continue to be instrumental in supporting this work.

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