Research Subject Advocates

Redefining the role in the transition from GCRC to CTSA (Version 2)

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Since their introduction to the General Clinical Research Centers (GCRCs), Research Subject Advocates (RSAs) have been physicians, nurses, pharmacists, ethicists and other highly trained professionals with relevant research backgrounds charged with ensuring the safety of subjects participating in research in GCRC studies. Initial areas of key focus, as guided by NCRR and NIH guidelines in 2001 were to:

1. Guide and assist research staff in creating protocol-specific "Data and Safety Monitoring Plans" (DSMPs) for safety monitoring, AE tracking, and execution of reporting requirements and ensuring that they are implemented;
2. Ensure that the research study is carried out in compliance with the IRB-approved protocol;
3. Ensure that serious adverse events are reported in a timely fashion to the IRB and appropriate federal agencies;
4. Interact with research participants to assess informed consent process and comprehension;
5. If requested by the PI of the GCRC, monitor all GCRC-based research studies.

Over time NCRR guidelines evolved to more global goals, namely “ensuring that research studies are designed and conducted safely and ethically with protection of human subjects the highest priority.” Most RSAs created a program including education of investigators and research teams as to their ethical and regulatory responsibilities, and provided tools to conduct research optimized to protect human subjects. Some assumed additional roles ranging from review of study design, IRB liaison, membership on IRBs or ethics boards, development of independent safety monitoring programs or committees, direct observation of informed consent, and integration of communication and data sharing across the IRB, the compliance office, GCRCs, Cancer Centers, and satellite research sites. Many RSAs collaborated with information technology departments to create central databases to reduce obstacles to research, enhance patient safety, improve reporting timeliness, reduce duplication of effort, make databases transparent, and collect safety and productivity metrics. Some RSAs worked within programs wherein their reach extended beyond the GCRC and included the whole institution.

RSAs, by the integrative nature of their work, cross the silos of IRB, institutional compliance office, research support services, human subject protection programs, ethics programs, research teams, and research subjects. The large and complex structures of the expanding group of NIH Clinical Translational Science Awards (CTSA) recipients will require extraordinary coordination and integration of policy and function to sustain the highest standards of safe and ethical conduct of science of the highest caliber. Extending the RSA model to include entire academic medical institutions in the clinical research enterprise affords an important opportunity to enhance the ethics and safety of the conduct of human subjects’ research.

Recommendation of the Working Group:

The functions of an RSA program should be fulfilled at every CTSA funded center. The implementation of the functions of the RSA program can be tailored to the strengths, needs, and resources of the individual institution; however, in fulfilling this charge consideration should be given to inclusion of the following core characteristics and functions:

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