

Anticipating New Directions in Human Subjects Research

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Human subjects research, highly regulated and overseen through the Institutional Review Board, is still viewed by many as a barrier to research. The question is, how we can as institutions, move from being the barrier to research to aiding in creating a culture of compliance?

Challenges

Today, research and academia face an ever-growing number of challenges. The changing funding environment is at the top of most lists. With decreased federal funding there is increased competition for research dollars and increased look to industry to remain competitive.

Institutions face challenges in dealing with the increasing number and complexity of regulations. These unfunded mandates provide both fiscal challenges and challenges in implementation in an environment where investigators are already feeling the burdens. Even potential changes to the regulations, such as has been suggested by the Advanced Notice of Public Rulemaking (ANPRM) proposing to revise the human subjects regulations, creates an unknown which may benefit the research environment but might also bring increased burdens to the institution as well as the investigator.

Increased complexity of contracts creates challenges, extending timelines for study implementation in an already competitive environment. Contracts may have to go through countless sets of ne-

gotiations over items ultimately inconsequential to the institution. Integrated systems of contract review with timely weigh-in need to be developed to cut down the turnaround time and move contracts on in a timely fashion.

Difficulty recruiting subjects poses another challenge. Adequate feasibility analysis needs to be conducted to determine that the population is available to be recruited. Investigators need to take into account for the amount of work that is involved in recruiting subjects – “build it and they will come” rarely works in the research enterprise. You need to create relationships, revisit those relationships and put a significant amount of elbow grease into the recruitment and retention of research subjects. In addition, if you do not have a strong culture of research you have to educate the community you are recruiting from. The community needs to understand the value and availability of research.

Inadequate research training, poor mentoring of new researchers, research coordinators without appropriate skills to carry out a research protocols and lack of professional compliance staff, all cause

inefficiency in the research enterprise and leads to dissatisfaction and frustration.

How do we respond?

We must be proactive not reactive, balance accountability and risk management and understand the needs of the investigator. We need to rethink the way we do business. Many times we get stuck in the mindset that we have to do it this way because we have always done it this way. We have forgotten why or if there ever was good justification for doing it that way. Times have changed, we need to rethink and reanalyze our interpretations - are they still good, or do we need to adjust? Many in human subjects protections are currently rethinking several areas, one is the reliance on a single IRB in multicenter trials. In some places this has been off limits, either it was reviewed at the institution it was being conducted at or it was not done. Today, many are rethinking this position and facilitating multicenter research through a single IRB. Another area being explored is the option for equivalent protections in human subjects protections. Federal regulation dictates the regulations applied to federally funded research but flexibility is possible in non-federally funded research, provided it provides equivalent protections. This may lead to a lessening of the burden for some types of research i.e. research in schools. Metrics are another way to show the value of what we do in human research protections, today's electronic systems allow us to track

and quantify the many activities that go into human subject protections. Metrics allow us to calculate time from submission to approval and identify where delays occur. We can determine the portfolio of studies by funding type, type of subject, or regulatory status - giving a much better picture of what a human subjects protection program does.

How do we help investigators?

We need to help investigators understand what the rules are, when the rules apply, whom they apply to, and what the consequences are. Investigators often do not have the toolbox that would allow access to pertinent information directly related to their research needs. A toolbox would allow investigators to access information needed for IRB submission, forms and templates, FDA regulations, and guidelines on how to navigate the human subjects research experience. There is generally no one-stop shop for regulatory compliance, but today with technology available to us, the ability to create a more centralized place for investigators and compliance staff to interact is possible. Technology can allow submission of a protocol for IRB review, access to conflict of interest disclosures and reviews by biosafety and radiation safety all within the same system. We need to make the most effective and efficient use of time and effort in order to meet the needs of both the institution and the investigator.