Managing the Scientific and Ethical COMPLEXITIES OF MEDICAL INNOVATION

Today, advances in science and medicine are occurring at an unprecedented pace. These exciting changes broaden the ethical implications of medical innovation and expand the need to protect clinical research subjects. Often, Institutional Review Boards (IRBs) find themselves on the frontline of these emerging issues, and must embrace their role as both arbiter and guide. The role of the IRB is to protect the welfare, rights and autonomy of research participants, while helping to facilitate exciting, ground-breaking, and innovative medical research. But to fulfill this role in an era of rapid discovery, the IRBs must continually innovate, helping sponsors to navigate the ethical complexities that new discovery brings to clinical research.

Research in the field of human gene transfer is an excellent example of this new paradigm. As gene transfer research programs progress into late-stage clinical development, clinical research teams find themselves in uncharted territory. Traditionally, we thought of biosafety as a concept that applied only to research laboratories. But now, new therapeutic technologies are bringing biosafety considerations into the clinic. Studies involving human gene transfer products that include recombinant or synthetic DNA — and that may include viral vectors and other components — are not only increasing in numbers, they are being conducted at sites that have never participated in this type of research before.

The Role of the IBC

Although the role of the IRB is well known to most of the clinical research community, the role of the Institutional Biosafety Committee (IBC) has been far less prominent. Through oversight of the facility and research team, the IBC protects everyone who might come in contact with investigational product — from the lab to the pharmacy and the subject's family. Considering their overlapping yet separate missions, it's not merely possible for the IRB and IBC to work together: it is imperative that they do. IRB and IBC collaboration will result in a synergistic improvement in the efficiency, rigor and quality of the proposed research review.

Keeping Pace with Innovation

In clinical research, we recognize that all trials involve a certain level of complexity. But in no specialty is this truer than in oncology. Oncology research has opened new and promising avenues of investigation thanks to significant advances in the areas of personalized medicine, immunotherapy, and human gene transfer research. To accommodate these scientific advances, newer, more complex forms of clinical trial design have emerged.

THE KEY TO MANAGING THE GROWING COMPLEXITY OF CLINICAL RESEARCH IS NOT LESS INNOVATION, BUT MORE. WE ARE AT A CLEAR INFLECTION POINT IN THE FUTURE OF HEALTHCARE; THE PROSPECTS FOR IMPROVING HUMAN HEALTH ARE MORE PROFOUND NOW THAN EVER.

Moving away from the traditional phased model of study design, sponsors are exploring concepts like the basket trial, efficacy assessments in translational and early-phase studies, adaptive designs, and other novel methods intended to speed the drug development process.

To minimize risk and accelerate start up, sponsors must select IRB partners that can keep pace with the speed of innovation.

An IRB partner must understand the underlying scientific principles of the protocols, even in complex and rapidly evolving specialties, such as oncology.

The IRB must also appreciate the biosafety implications, as well as the ethical considerations of new and promising forms of study design.

In addition to research reviews, sponsors should rely on their IRB partner to assist in the evaluation of potential study sites, to ensure that those sites are equipped to manage not just the usual clinical trial operations, but also the storage, handling and disposal of new types of biological products.

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Lastly, but perhaps most importantly, sponsors should elect to work only with institutions that are willing to centralize the management and administration of their IRB and IBC functions. Then, they can be confident that they've selected sites that truly prioritize quality in human subject protection, and efficiency in research operations.

In our experience, the key to managing the growing complexity of clinical research is not less innovation, but more. We are at a clear inflection point in the future of healthcare; the prospects for improving human health are more profound now than ever. By partnering with change-driven organizations such as the WIRB-Copernicus Group, sponsors can be sure that they've got a partner that can keep them safe — today, tomorrow, and well into the future. PV

WIRB-Copernicus Group (WCG) *is the world's leading provider of ethical and regulatory solutions for clinical research, which include IRB and IBC review services, as well as consulting in the fields of Human Research Protection, Good Clinical Practice and Biosafety.*

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