wcg Biosafety™

A Division of the WIRB-Copernicus Group

Learn More About Clinical & Gene Therapy Research Services

WCG BIOSAFETY™ PROVIDES COMPREHENSIVE biosafety review services to sponsors and institutions who conduct clinical and human gene therapy research.

Externally-administered Institutional Biosafety Committees (IBC)

Research institutions are seeing a proliferation of new studies involving deliberate transfer into human subjects of recombinant or synthetic DNA and RNA. For any product or site subject to NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), each study protocol must be reviewed by a local Institutional Biosafety Committee (IBC) registered with the NIH Office of Science Policy before subjects can be enrolled. When choosing clinical trial sites, sponsors place high value on IBCs that return compliant and consistent reviews, with a responsive turn-around time.

Many institutions with IBCs focused on basic science and bench work find that they are not prepared to efficiently review Human Gene Transfer clinical trials. Many other institutions face challenges in identifying appropriate experts, rostering, registering, and administering an IBC at all.

WCG Biosafety provides externally-administered IBC services to institutions, hospitals, and Academic Medical Centers (AMCs) engaged in human gene transfer research. WCG IBC Services division has reviewed over 250 human gene transfer protocols to date and has over 15 years of experience in the management and administration of local IBCs from single investigator clinics to large AMCs. Our service not only guarantees access to unparalleled expertise, but allows you to become a part of our network that connects sponsors with institutions. Through our unique partnering process, we can help you achieve faster turnaround times in as little as 4-6 weeks. Importantly, we administer IBCs for clients not only conducting clinical research, but to those institutions conducting any research with recombinant or synthetic DNA.

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Human Gene Therapy Expert Consultation

WCG Biosafety provides experts to help clients conduct research or clinical studies involving human gene therapy without delays or interruption. Our team:

Evaluates the Necessity for Recombinant DNA Advisory Committee (NIH-RAC) Review

The NIH Guidelines require that an IBC and IRB pre-review a protocol and make a recommendation if RAC review is needed. Expertise in human gene therapy is critical for an accurate pre-RAC review assessment. We provide experts to conduct the assessment and help create the letter to the RAC on behalf of the institution.

Serves as Human Gene Therapy Experts on Local IBCs

WCG Biosafety provides experts in human gene therapy to serve as non-voting members of a local IBC. In this capacity, our experts are able to assist the IBC with completing an accurate and reliable risk assessment on the protocol. This allows the IBC to make an appropriate determination on the proposed research.