IRB AND IBC SERVICES

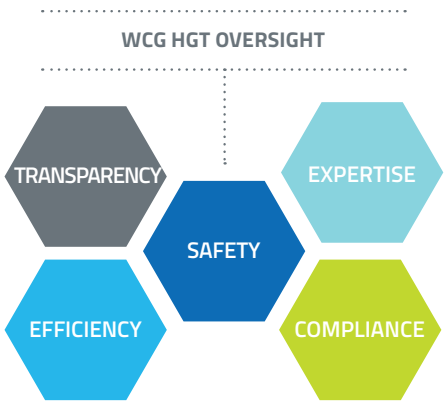
Partnering with Universities and Academic Medical Centers

Unparalled Expertise in Oversight of Human Gene Transfer Research at Academic Centers

Research institutions must oversee a broad range of activities subject to the *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules*. Depending on research under review, Institutional Biosafety Committees (IBCs) must oversee activities involving transgenic plants and animals, recombinant microbes, toxins, animal gene transfer studies, and preclinical drug development.

In addition, clinical trials subject to Section III-C of the *NIH Guidelines*-- also known as **Human Gene Transfer (HGT) research**—require special attention and expertise from IBCs. Review of HGT research poses numerous extra challenges for IBCs, even at institutions with large clinical trials programs. That's why so many institutions have chosen to partner with WCG for HGT review.

Since 2000, WIRB and WCG have provided IBC services to nearly 800 institutions, with hundreds of active sites around the world, and almost 400 protocols reviewed. Academic institutions that already have self-administered IBCs can still benefit from partnering with WCG for IBC review of HGT clinical trials. There are usually no costs to the institution for IBC services involving commercially-sponsored research.



WCG IBC and IRB services can provide integrated, coordinated, simultaneous review of clinical trials for sites that choose to use both.

IBCS@wcgclinical.com

WCG IBC SERVICES DELIVERS:

EXPERTISE: Our analysts and review teams are experts in biosafety risk assessment, site preparation, best practices, and compliance. Our team members come from diverse backgrounds in academic science, biotech/pharma, and clinical operations.

VALUE: In most cases, IBC services relating to commercially-sponsored clinical trials incur **NO COST** to the institution.

TRANSPARENCY: Each IBC administered by WCG includes at least one rostered member who is an employee of the institution, ensuring that WCG and the institution are active partners at every step of the process

CHOICE: Institutions that partner with WCG choose which projects to submit for review.

EFFICIENCY: We are experts in bridging the communication gaps among commercial sponsors, CROs, SMOs, institutions, and investigators. We provide our partner sites with vetted biosafety standard operating procedure (SOP) templates customized to each clinical trial.

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