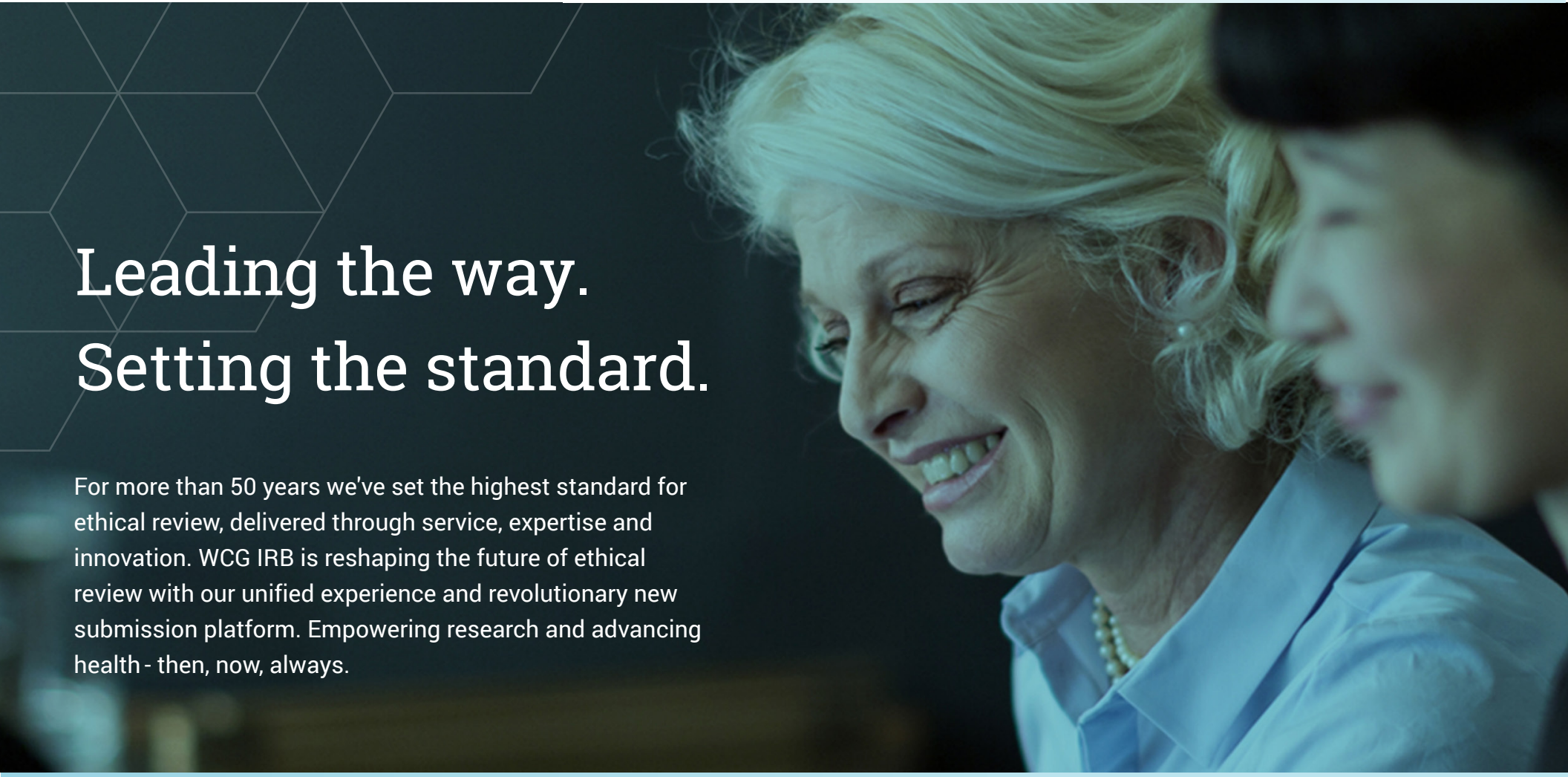
wcg™ IRB



Leading the way.
Setting the standard.

For more than 50 years we've set the highest standard for ethical review, delivered through service, expertise and innovation. WCG IRB is reshaping the future of ethical review with our unified experience and revolutionary new submission platform. Empowering research and advancing health - then, now, always.

www.WCGIRB.com

No other independent IRB has the depth and breadth of expertise and experience protecting human research participants

For more than 50 years—with the founding of our landmark IRB, Western IRB (WIRB)—we have been the gold standard IRB for the protection of the rights and welfare of human research participants.

The world's leading biopharmaceutical companies, CROs, academic medical centers, and research institutions rely on WCG IRB to maintain the highest standards of quality, efficiency, and timeliness in all activities.

EXPERIENCE WITH VIRTUALLY ALL SPONSORS, CROS AND RESEARCH SITES

12,000 Clinical Trials per year

40,000 US-based Investigators

16,000 Global Research Sites

3,100 Academic Medical Centers & Institutions

UNMATCHED EXPERTISE

200+ Board Members

56 Physicians

18 Reg Attorneys

20+ IRB meetings weekly

THE HIGHEST STANDARDS IN ETHICAL REVIEW

Longest AAHRPP accreditation of any central IRB

Only ISO-certified IRBs

The WCG IRB Difference

For Research Sponsors & CROs

WCG IRB has contracts with more than 3,100 US hospitals and academic centers, in addition to relationships with 99% of all independent and community practice sites. As such, we bring more predictability in site activation through our expertise in site-specific requirements. This leads to improved study time lines.

- Full board determination within 5-6 business days of a complete submission
- Site approvals within 1-2 days of complete site submission
- WCG IRB reviews your site lists and provides insights on each institution
- WCG IRB contacts key institutional players when there are questions about IRB reliance
- Dedicated client-specific point of contact

For Research Sites & Institutions

WCG IRB is the chosen IRB partner to hundreds of research institutions and academic medical centers. We customize our submission and communication process to each and every participating site, and coordinate with participating investigators and local IRB offices.

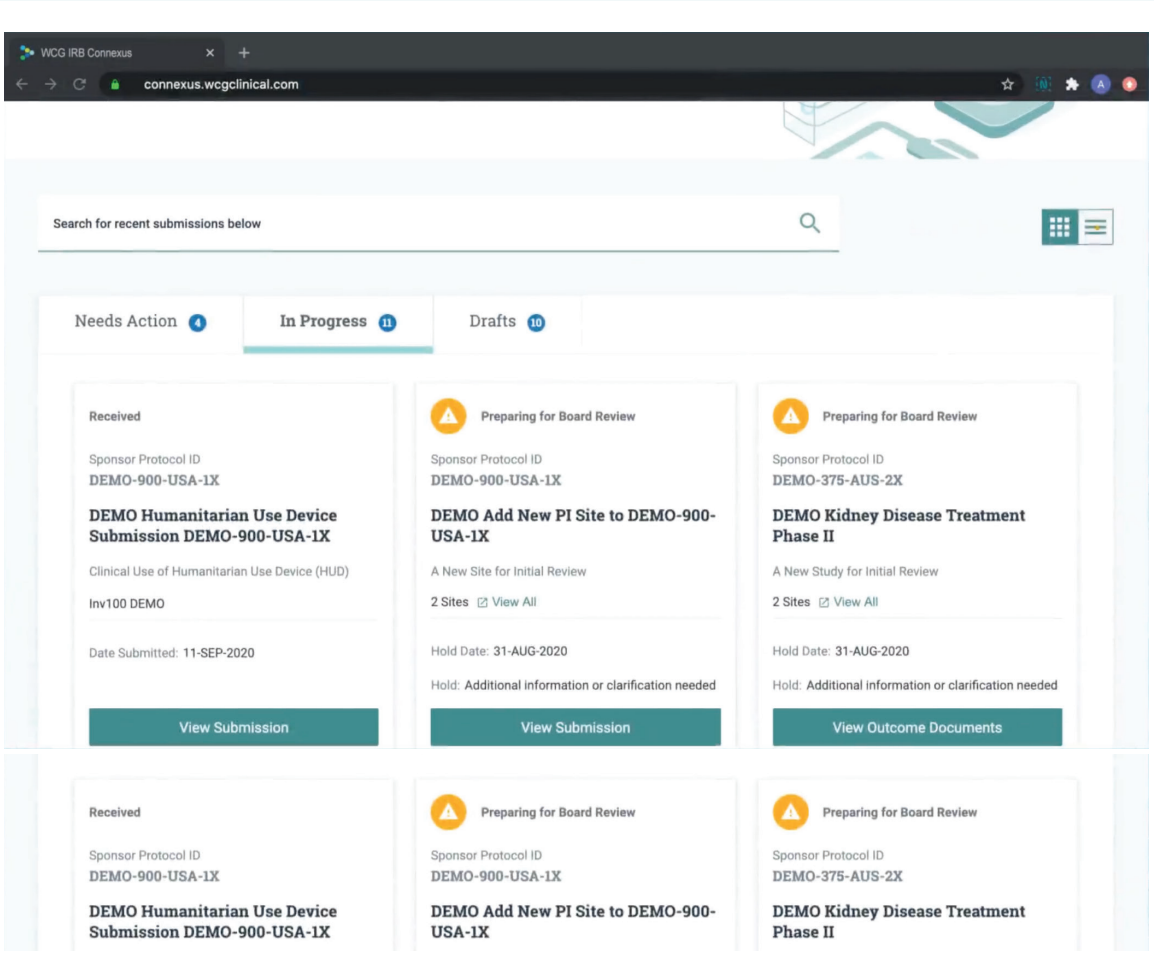
Our single IRB process is 100% compliant with NIH requirements. WCG IRB makes it easy for academic medical centers and investigators to comply with NIH's single IRB policy.

- Budgets prepared at cost
- Customized institutional workflow
- Fast turnaround time for grant submission quotes
- Project management support for the entire study and for research sites
- Single IRB plan template for submissions

wcg IRB Connexus

WCG IRB Connexus is a revolutionary IRB submission and review portal built from the ground up based on feedback from users like you. The result? Dramatic improvements to the things that matter most:

- speed of submission
- ease of use
- real-time visibility of submission review status
- immediate access to approval documents



Submit in 3 Easy Steps

STEP 1

Log in to WCG IRB Connexus (or set up an account if you don't have one)

STEP 2

Follow the prompts to input the necessary information to get your study review started.

STEP 3

Easily upload supporting docs including protocol, informed consent, and investigators brochure.

www.WCGIRB.com

Your Partner in Gene Transfer Research

Since 2000, WCG IBC Services has provided Institutional Biosafety Committee (IBC) services to **more than 800 institutions** comprising hundreds of active sites around the world. WCG IBC Services is by far the most experienced and knowledgeable provider of IBC administration and review. Our team has evaluated **more than 400 human gene transfer protocols** - more than any organization outside the FDA and NIH.

By coordinating the IRB and IBC review of gene transfer studies, we eliminate the duplicative reviews that are characteristic of unaffiliated IRBs and IBCs, ensuring an efficient and thorough turnaround for each review.

IBC SERVICES FOR RESEARCH INSTITUTIONS

Our IBC review teams work closely with clinical coordinators and investigators at each site to learn about their needs and concerns and advise on best practices for safety and compliance. We provide a customized biosafety standard operating procedure (SOP) and walk you through the steps required to get to IBC approval. IBC operations are transparent and interactive and allow sites to fully understand and direct compliance activities related to gene transfer research.

To learn how WCG IBC Services can help with your IBC set up and administration, contact: ibcservices@wcgirb.com

IBC SERVICES FOR SPONSORS AND CROS

Most drug products that incorporate engineered DNA or RNA qualify as human gene transfer products. Our experts can help you determine whether your clinical trial requires IBC review and we'll review with you prospective site lists to advise on the best startup approach for each site requiring IBC review. We can also walk you through the IRB/IBC review coordination process to reduce duplicative and redundant reviews.

For support with the project planning phase of your upcoming gene transfer trial, contact: ibcservices@wcgirb.com

855-818-2289 **info@wcgirb.com** **www.WCGIRB.com**