

**NIH Biosafety Modernization Initiative Engagement Summary**  
**WCG Clinical**  
**February 10, 2026**

**Background**

NIH announced its Biosafety Modernization Initiative in Fall 2025 and began an expansive plan for engaging stakeholders. In addition to holding six regional listening sessions, NIH also participated in smaller engagements to gather individual input to help inform a new NIH biosafety policy.

NIH met with staff from WCG Clinical, a commercial firm that provides Institutional Biosafety Committee (IBC) review services, mainly for protocols involving human gene transfer.

**Event Summary**

WCG Clinical provided an overview that included how they conduct biosafety reviews, laboratory inspections, and risk assessments specific to the products being administered in the clinical trial under review. The purview of WCG Clinical is mainly small clinics, surgical centers, and doctors' offices. WCG Clinical also described the risks of research involving human gene transfer and how risk assessment is used to protect the pharmacy staff mixing the product as well as the staff administering it.

WCG Clinical outlined the intersection of its review with Food and Drug Administration (FDA) regulations, as well as Occupational Safety and Health Administration (OSHA) standards. There was also discussion of the gradations of risk within certain classes of human gene transfer clinical trials.

Attendees also provided individual feedback on several topics, including some of the following comments and input:

- Expanding the scope to include wild-type organisms is appropriate from a risk-based perspective.
- A delegated or expedited approval process where a biosafety officer or a subset of IBC members could approve research on the committee's behalf would reduce burden.

NIH thanked individuals for their comments and encouraged attendees to continue providing feedback through the mechanisms listed on the NIH Office of Science Policy website.