

NIH Biosafety Modernization Initiative Engagement Summary
Sabai Global
January 27, 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 Sabai Global, a commercial firm that provides Institutional Biosafety Committee (IBC) review services, specifically for protocols involving human gene transfer.

Event Summary

The discussion focused on how Sabai Global conducts its risk assessments and IBC approvals for human gene transfer protocols. Sabai Global staff spoke about a continuum of specific human gene transfer trials that pose minimal biosafety risks to those that may pose more significant biosafety risks.

The meeting also involved a discussion of how other regulations and standards fit in with the IBCs' review of human gene transfer protocols. This would include Food and Drug Administration (FDA) and Occupational Safety and Health Administration (OSHA) oversight, among others.

Specifically, regarding a new NIH biosafety policy, attendees provided individual feedback that included some of the following comments and input:

- A potential reduction in IBC oversight of human gene transfers trials already under the purview of the FDA might create a gap since biosafety oversight is not part of FDA's oversight of these trials.
- Trends show that human gene transfer trials are more often moving away from large biomedical institutions to smaller clinics, especially as trials move into later phases. These smaller, less experienced clinical sites would benefit from the expertise of the IBC and its review.



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.