

NIH Biosafety Modernization Initiative Engagement Summary
Advarra
February 5, 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 Advarra, a commercial firm that provides Institutional Biosafety Committee (IBC) review services, mainly for protocols involving human gene transfer.

Event Summary

NIH met with Advarra staff to get individual input on the mechanisms and utility of IBC review of human gene transfer protocols. Advarra staff provided a quick presentation on how they register and review human gene transfer protocols. This presentation also included details of the risks they are specifically trying to mitigate.

During the conversation, attendees at the meeting provided individual feedback on a new biosafety policy that included some of the following comments and input:

- Consideration should be given to alignment with U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA) so that potential gaps do not arise in biosafety oversight.
- There is an increase in clinical trials involving human gene transfer taking place in smaller, and sometimes rural, locations. These locations often do not have biosafety expertise on hand like major medical schools or research-intensive institutions.
- The IBC registration system could be streamlined to make it easier and quicker to register clinical trial sites.

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