NIH Releases Draft Resources and Launches Policy Engagement Efforts to Support Clinical Research

NIH views clinical research participants as vital partners in turning discovery into health. Ensuring participant safety, rigorous research, and public trust are NIH's highest priorities. With this in mind, NIH is excited to announce:

- The availability of two draft resources aimed at supporting participants in implantable device clinical trials. These two resources provide guidance on post-trial considerations for participants along with points to consider and sample informed consent language. Comments will be accepted on these two resources until **May 25, 2026**. More information, including how to comment can be found here.

- Two stakeholder engagement campaigns to develop NIH policies relating to:

    - Sharing of Summary Level Study Results with Participants in NIH-Supported Clinical Research (event co-hosted with the MRCT Center of Brigham and Womens Hospital and Harvard); and
    - Modernizing NIH's Data and Safety Monitoring Policy

The above stakeholder engagement campaigns will include webinars, the ability to provide on-demand comments through the OSP website, and numerous other opportunities to provide feedback to help inform the development of draft policies.

More information about stakeholder engagement for developing a policy for the sharing of summary level study results can be found here.

Information about how to get involved with the modernizing of NIH's Data and Safety Monitoring Policy can be found here.

To learn more about how this suite of efforts ties into the NIH mission, please see the most recent Under the Poliscope blog by Dr. Lyric Jorgenson, NIH Associate Director for Science Policy.

Questions may be sent to SciencePolicy@od.nih.gov