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◆ **"As a steward of the nation's biomedical research enterprise, NIH is dedicated to ensuring that when data and biospecimens are shared, that it is done ethically and securely, and with respect for the privacy, autonomy, and well-being of research participants and the communities to which they belong," the agency said in a recent notice**. "As part of this commitment, NIH is working with stakeholders to identify best practices for developing and implementing effective consent practices to inform prospective research participants about potential risks and benefits of data and biospecimen sharing for future research."

NIH provided sample language it said could be used even for studies in which "data and biospecimens are completely delinked from identifiers and cannot be linked back to the participant." Sections address the need to give participants "the option to agree to, or opt out of, having their data and biospecimens stored and shared for future research." NIH noted that mandating "storage and sharing may be considered coercive if the participant does not want to agree to sharing of data and biospecimens but feels compelled to agree anyway in order to join a possibly beneficial clinical trial." NIH stressed that "any use of the sample informed consent language is completely voluntary and shall not be required." Feedback on the sample language and points to consider "will be essential in ensuring this resource is maximally useful to the community," the NIH Office of Science and Technology Policy said in a July 7 email announcing the notice. Comments are due by Sept. 29 and will be accepted via a web portal. Developing informed consent procedures has generally been undertaken by the HHS Secretary's Advisory Committee on Human Research Protections; it is not clear whether SACHRP has been involved with NIH on this project. The Common Rule does not require consent for use of unidentified biospecimens or data as studies involving them are not considered human subjects research. (7/15/21)