Association for Molecular Pathology comments on proposed changes to the common rule

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Yesterday, the Association for Molecular Pathology (AMP) submitted comments on the Advanced Notice of Proposed Rulemaking (ANPRM) called, Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators. AMP commends the agency for its efforts to streamline the regulations to facilitate participation in research while maintaining the high level of protections research subjects deserve and expect. The Association also supports the creation of an excused category of studies and modifies the rule to allow a multi-site study to rely on a single institutional review board (IRB). However, AMP believes that this should not be mandatory and asks that the final rule deem this change to be optional.

Despite these positive changes in the proposed rule, AMP is very concerned about the sections addressing biospecimens and calls on the Department of Health and Human Services (DHHS) to modify the rule prior to being implemented. In medical practice, molecular pathologists and laboratory directors develop and validate testing for clinical use. Generally, laboratories use samples collected outside of a research study, e.g., leftover tissue following surgery, or share samples with other laboratories to use as controls. In these instances, all identifiers have been removed from the samples to protect the patient's confidentiality. "These practices are instrumental to molecular pathology and are necessary to ensure high quality, safe testing for patients," said Dr.

Elaine Lyon, chair of AMP's Professional Relations Committee. Dr. Lyon stressed that, "the practice of using samples for validation and verification are part of conducting quality control and quality assessment activities, and are not research."

As such, AMP calls on the DHHS to include language that identifies these activities to be part of clinical care and the practice of medicine, and not considered to be research, to clarify any confusion and prevent possible future misinterpretations.

AMP also believes the proposed rule oversimplifies the ability to link a de-identified biospecimen back to an individual based on the sample's extracted DNA. "This is practically impossible with current technologies," explained Dr. Lyon, "In fact, the few instances when this has occurred, investigators had access to samples from family members or information about a clinical presentation so rare that it was easy to identify who gave the sample." AMP views the proposed rule's reaction to this concern to be disproportionate to the risk and the conclusion that biospecimens cannot be de-identified to be far reaching. To address this remote concern, AMP shares the American Society for Investigative Pathology's view that enforcement of the current policy of the use and misuse of biospecimens coupled with stricter penalties for violations is the best way to ensure the best protection of human subjects who are involved in research.

Last, in regards to obtaining broad consent from research participants, AMP encourages the agency to address ways to obtain consent without needlessly creating mistrust or fear as potential participants review the consent form.

Provided by Association for Molecular Pathology