



ASSOCIATION FOR MOLECULAR PATHOLOGY
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January 6, 2016

Jerry Menikoff, MD, JD
Office for Human Research Protections
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville MD 20852

Subject: Common Rule NPRM Comment Letter [Docket ID HHS-OPHS-2015-0008](#)

Dear Dr. Menikoff:

Thank you for the opportunity to submit these comments to the Notice of Proposed Rulemaking (NPRM) to update the Federal Policy for the Protection of Human Subjects promulgated as the Common Rule. The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, clinical testing laboratories, and the in vitro diagnostics (IVD) industry.

In 2011, AMP submitted comments to the Advance Notice of the Proposed Rulemaking (ANPRM) which can be found here:

http://www.amp.org/publications_resources/position_statements_letters/documents/ANPRM_ResearchProtections_Oct2011.pdf.

As we stated in 2011, AMP continues to be pleased with the efforts to streamline the regulations governing human research protections and believes that many of the proposed changes will help facilitate participation in research while maintaining the high level of protections patients deserve and expect. In particular, AMP commends the agency with changes that allow the use of a single IRB for multi-center research protocols and the exemption of low risk clinical trials. Further, AMP also supports changes that would simplify consent forms to better assure participant understanding of the specifics of the trial that are of greatest interest to them and to allow for broad consent.

Additionally, in our previous comments, we requested that the ANPRM be modified to allow the practice of using samples for validation, verification, etc. for quality control and quality assessment activities as laboratories validate tests for clinical use. We are very pleased that the NPRM proposes that a subset of secondary research on stored biospecimens would be allowed without consent when used for the development and validation of certain tests, quality assurance and control activities, and

proficiency testing. AMP strongly encourages the Agency to include this exclusion in future rulemaking activities.

However, AMP also has significant concerns with the NPRM's expansion of the definition of human subject to include biospecimens. Both Alternative Proposal A (expand the definition to include whole genome sequencing) and the even more stringent Alternative Proposal B (expand the definition to include any biospecimen with bio-unique information) are unnecessary and would have many negative consequences for research. The administrative hurdles and barriers this would create outweigh the almost nonexistent risk to privacy when conducting secondary research on de-identified biospecimens. Therefore, AMP opposes this expansion of the human subject definition in the NPRM.

As we stated in our 2011 comments, linking extracted DNA from a biospecimen to an individual is practically impossible with current technologies. In the few instances when this has occurred, investigators had access to samples from family members and/or the phenotypic information described a clinical presentation so extremely rare in prevalence that an assumption could be made regarding the identity of the affected family. These instances are very limited; the effort it would take to link an individual to his or her DNA without any identifying information is almost insurmountable. As such, AMP considers NPRM's view that biospecimens cannot be de-identified to be far reaching and believes that the current policy of exempting de-identified biospecimens (i.e. removal of identifiers as defined under HIPAA) from human research protections is reasonable and should be maintained.

AMP is aware that the American Society of Investigative Pathology (ASIP) submitted extensive comments to the docket in response to specific questions in the NPRM and we write today endorsing ASIP's position and rationale as they relate to expanding the definition of human subject to include biospecimens. AMP strongly urges the Administration not to finalize this policy as written.

Thank you in advance for your consideration of these comments and please do not hesitate to contact Tara Burke, AMP Policy Analyst, at tburke@amp.org if we may be of further assistance.

Sincerely,

Charles E. Hill, MD, PhD
AMP President