Association for Molecular Pathology
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October 24, 2011

Department of Health and Human Services
Office of the Secretary
C/O Jerry Menikoff, M.D., J.D.
Office of Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Submitted electronically to http://www.regulations.gov

Re: Docket # HHS-OPHS-2011-0005

To Whom It May Concern:

Thank you for the opportunity to submit 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." The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,000 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 and the *in vitro* diagnostics industry.

AMP commends the agency on its 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 is pleased to see that the proposed rule creates an "excused" category of studies and changes the regulation to allow a multi-site study to rely on a single IRB; however, we do not believe that this should be mandatory.

Questions #47-50:

AMP is concerned about the proposed changes to research using pre-existing data or biospecimens. 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. This practice of using samples for

validation, verification, etc. are quality control and quality assessment activities, and are not research. As such, **AMP requests that the rule 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.**

In addition, the proposed rule would require written general consent for research using pre-existing data or biospecimens, even when all identifiers have been removed. Participants would need to sign a standard, brief general consent form allowing for broad, future research. The ANPRM states the reason for this change to be that regardless of what information is removed from the sample, extracted DNA from a biospecimen can potentially identify individuals. Hence, you are considering categorizing secondary analysis of existing biospecimens as research using identifiable information.

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 views the ANPRM reaction to this concern as disproportionate and the conclusion that biospecimens cannot be de-identified to be far reaching. **To address this remote concern, AMP encourages the regulators to consider more reasonable and practical actions instead of categorizing all biospecimens as identifiable research.**

Additionally, AMP is concerned that a broad general consent for future research may confuse participants and discourage them from engaging in research. The ANPRM needs to address ways to obtain consent without needlessly creating mistrust or fear as potential participants review the consent form.

Finally, AMP is aware of the comments submitted by the American Society for Investigative Pathology (ASIP) and agrees with their view that "the enforcement of current policies regarding the use or misuse of biospecimens coupled with stricter penalties for violations will best ensure protection of human subjects who are involved in research. Required informed consent for the use of all biospecimens, including de-identified specimens, is an ideal that may prove impracticable to achieve…and represents a disproportionate concern relative to realistic risk." Thank you very much for your consideration of our comments and requests. Please do not hesitate to contact AMP if we may be of assistance as you work to finalize this rulemaking process.

Sincerely,
Elaine Lyon, PhD
Chair, AMP Professional Relations Committee