

May 4, 2019

Norman E. Sharpless, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

Subject: Request for Comment on Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable [Docket No. FDA-2012-N-0560]

Dear Dr. Sharpless:

We, the undersigned, are pleased to comment on the informed consent for *in vitro* diagnostic device studies using leftover human specimens that are not individually identifiable [Docket No. FDA-2012-N-0560]. The 2006 FDA Guidance stated FDA's intention to use enforcement discretion, noting that FDA "does not intend to object to the use, without informed consent, of leftover human specimens." **The 2006 Guidance represented a substantial, positive step toward reducing administrative burden for investigators, streamlining effectiveness, and harmonizing FDA requirements with the requirements of the Common Rule. We continue to support the FDA's 2006 Guidance and strongly support further harmonization between the updated Common Rule and FDA regulations.**

Under the previous and now updated Common Rule, de-identified specimens are generally outside of the purview of Common Rule requirements. While we support the FDA's 2006 Guidance and discretionary enforcement, scientists would welcome further efforts to remove investigations using de-identified human tissues from FDA's human subject regulations. We see little practical utility of FDA's maintaining de-identified specimens as part of FDA's human subject investigations. Removing de-identified specimens from these requirements allows for safety and ethical considerations while reducing administrative burden for investigators, ensuring consistency with the Common Rule and streamlining effectiveness.

If you have questions about this letter, please contact Jennifer Dreyfus, Consultant, American Society for Investigative Pathology at jdreyfus@asip.org or 301-908-0843.

Sincerely,

Academy of Clinical Laboratory Physicians and Scientists
American Academy of Oral and Maxillofacial Pathology
American Physiological Society
American Society for Clinical Pathology
American Society for Investigative Pathology
American Society of Cytopathology
Association for Molecular Pathology
Association of Clinical Scientists
Association of Pathology Chairs
College of American Pathologists
North American Vascular Biology Organization