American Society for Investigative Pathology
Investigating the Pathogenesis of Disease

MARK E. SOBEL, MD, PHD
EXECUTIVE OFFICER
9650 Rockville Pike, Bethesda, MD 20814-3993 (USA)
Tel: 301-634-7130 • Fax: 301-634-7990 • Email: mesobel@asip.org • www.asip.org

September 11, 2014

Margaret Hamburg, M.D., Commissioner
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

Dear Dr. Hamburg:

The American Society for Investigative Pathology (ASIP) is pleased to comment on the Draft Informed Consent Information Sheet – Guidance for IRBs, Clinical Investigators, and Sponsors (June 2014). ASIP is a nonprofit educational 501(c)(3) organization primarily representing the academic pathology research community. We are a society of biomedical scientists who investigate disease, linking the presentation of disease in the whole organism to its fundamental cellular and molecular mechanisms. Our members use a variety of structural, functional, and genetic techniques, seeking to ultimately apply research findings to the diagnosis and treatment of patients. ASIP advocates for the practice of investigative pathology and fosters the professional career development and education of its members.

ASIP believes that the draft Guidance on Informed Consent is a significant improvement and represents current thinking on informed consent concerns in the biomedical research community. ASIP understands and supports the need for informed consent as a key component of respecting research subjects' autonomy and their contributions to clinical research. In particular, ASIP is pleased with the expanded policy and the inclusion of the following:

- examples and discussions of the practical concerns that arise in gathering informed consent;
- extensive guidance on working with research participants that have diminished capacity and those research participants that are non-English speakers; and
- new technologies as vehicles for gathering informed consent.

After reviewing this document, ASIP notes that the Guidance does not address unique issues related to biospecimen research. Research utilizing biospecimens may increasingly provide key data and support for FDA applications.

As background, ASIP believes that there are unique concerns raised by utilization of biospecimens in FDA-relevant research that require a modified approach to gathering informed consent. Research utilizing archived retrospective collections of biospecimens does not involve active intervention with a research participant. The biospecimen has already been collected along with relevant phenotype information, and therefore no further need for interaction between the research participant and the researcher exists unless it is determined that the previous informed consent for collection of the biospecimen requires revision or update. In addition, many research participants

consent to use of biospecimens in secondary research projects and/or to donate their biospecimen to a biorepository, allowing for yet unspecified research to be conducted in the future. ASIP suggests that a biospecimen section within the Guidance would serve to further clarify relevant concerns related to secondary use of archived biospecimen collections.

Therefore, ASIP recommends the following modifications of the FDA Guidance:

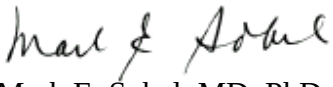
1. Biospecimens can safely be used in more than one clinical investigation simultaneously. In the current draft guidance, FDA strongly discourages subjects from participating in more than one clinical investigation simultaneously.[1] As no ongoing, active intervention occurs with the research participant in retrospective use of archived biospecimens, there should be no concern regarding subjects' participation in more than one clinical investigation.

2. FDA should explicitly state that it will allow secondary use of biospecimens gathered under an informed consent allowing for such secondary research. Increasingly, consents include language allowing for the secondary use of a biospecimen. With the growing use of biorepositories and databanks, researchers may utilize specimens and information far beyond what was envisioned in the original research study. The Havasupai Indian Tribe case[2] illustrates that appropriate informed consent for secondary use is important to allow future studies. Furthermore, data gathered from biospecimens are increasingly digitized, used to populate large databanks, and support additional research. This movement has been fostered by the federal government through initiatives such as NIH's Genomic Data Sharing Policy.[3] FDA should encourage data sharing initiatives and clearly state its support for such data use when consistent with the donor's consent. ASIP believes that the informed consent should clearly articulate that secondary use is granted and allow the donor the ability to opt out.

ASIP appreciates the opportunity to raise our concerns with FDA. We commend FDA for the draft Guidance and hope that our comments may further refine the Guidance. Should you have questions or concerns, please feel free to contact Mark E Sobel, M.D., Ph.D. at (301) 634-7130 or mesobel@asip.org.

Thank you for your consideration.

Sincerely,



Mark E. Sobel, MD, PhD
Executive Officer

CC: Alonza Cruse, (Acting) Director, Office of Medical Products and Tobacco (OMPT)
Joanne Less, Ph.D., Director, Office of Good Clinical Practice (OGCP)
Karen Midthun, M.D., Director, Center for Biologics Evaluation and Research (CBER)
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research (CDER)

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[1] Draft Guidance, Informed Consent Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors, July 2014. p. 39.

[2] Mello MM and Wolfle: The Havasupai Indian Tribe Case – Lessons for Research Involving Stored Biologic Specimens, NEJM (363) 15 Jul 2010, p204

[3] NIH Genomic Data Sharing Policy Notice Number: NOT-OD-14-124