May 17, 2018

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

Re: Docket No. HHS-OPHS-2018-0007

Comments submitted electronically to the docket at www.regulations.gov

Dear Dr. Menikoff,

Thank you for the opportunity to provide these written comments on behalf of the American Society for Investigative Pathology to the request for comments in Docket No. HHS-OPHS-2018-0007. The American Society for Investigative Pathology (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. Many ASIP members serve in leadership positions providing oversight to clinical laboratory services and conducting biomedical research utilizing human biospecimens. Our society represents approximately 1,000 physicians and doctoral scientists who perform or are involved with pathology research in academic medicine, government, and private industry.

ASIP has reviewed the Notice of Proposed Rulemaking and agrees with the proposal as set forth. The six-month extension until January 21, 2019 will provide researchers with additional time to comply with the updated provisions in the revised Common Rule. In addition, the Office of Human Research Protections will have further opportunity to release additional guidance assisting the research community in understanding, training and implementing the updated regulations.

ASIP appreciates the option allowing researchers and institutions to voluntarily implement the three burden-reducing 2018 Requirements [§.102(l); §.103(d); and §.109(f)(1)(i) and (iii)] during the transition period from July 19, 2018 to January 21, 2019. Should OHRP find it necessary to further define the institutional requirements for documenting a “decision to transition” to these requirements, such clarification should be provided prior to the July 19, 2018 implementation date. We appreciate the flexibility that this option offers, allowing institutions to determine which, if any, research study should adopt the burden-reducing 2018 Requirements.

The American Society for Investigative Pathology supports the proposals set forth in the Notice of Proposed Rulemaking. Thank you for the opportunity to submit these comments. If ASIP may be of further assistance, please contact Dr. William B. Coleman at wbcoleman@asip.org.

Sincerely,

William B. Coleman, PhD
Executive Officer