



## COLLEGE of AMERICAN PATHOLOGISTS

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August 2, 2018

Eric Dishman, Director  
All of Us Research Program  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, Maryland 20892

Dear Mr. Dishman:

The College of American Pathologists congratulates the All of Us Research Program for the enormous undertaking in overseeing a research project of this magnitude. However, in order to realize the vision of the All of Us Research Program it is critical that specimen integrity of the biospecimens collected from the cohort of 1 million study subjects is optimized. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

In our previous letter dated February 23, 2018, we addressed the issue of establishing requirements or guidelines for the collection and processing of the biospecimens. Since the biospecimens are intended to inform many of the planned research studies, we expressed concern that the lack of best practice guidelines for personnel and biospecimen collection may result in poor quality biospecimens which, in turn, will jeopardize the goals of the Program. We put forward the idea of framing best practices for the training of personnel and handling of the specimens and offered to assist the All of Us program in development of these guidelines.

To that end, we wish to share with you that our members have developed recommendations in a white paper entitled, "Preanalytics and Precision Pathology: Pathology Practice to Ensure Molecular Integrity of Patient Biospecimens for Precision Medicine". Outlined in this paper are recommendations for the collection and processing of blood and tissue specimens. We believe that compliance with these data-driven practice metrics is a first and essential step towards achieving a quality continuum for patient biospecimens. Further, the CAP believes that pathologist's input on biospecimen issues is both appropriate and important and would welcome the opportunity to incorporate specimen pre-analytic standards in the All of Us research program.

Thank you for your serious consideration of our comments as we all strive to provide the best care for our patients. Please feel free to contact Helena Duncan, CAP Assistant Director, Economic and Regulatory Affairs at [hduncan@cap.org](mailto:hduncan@cap.org) if you have any questions on these comments.

Sincerely,

The College of American Pathologists

Cc: Francis S. Collins, M.D., Ph.D., NIH Director  
Gail Habegger Vance, M.D., CAP Personalized Health Care Committee Member