



COLLEGE of AMERICAN PATHOLOGISTS

February 23, 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 (CAP) appreciates the opportunity to comment on the research priorities for the All of Us Research Program (the Program). 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.

The CAP applauds the All of Us Research Program efforts to create a national large scale research program to help better understand what factors contribute to individual health and disease. A crucial element of the program is the collection of a limited set of standardized data from sources that will include biospecimens (ie, blood and urine samples). The program will collect biospecimens by two means through direct volunteers or health care provider organizations. We share with the All of Us Research Programs' focus on the importance of advancing precision medicine in order to develop breakthrough therapies for better treatment and prevention options. As such, the CAP began the Biorepository Accreditation Program (BAP), the only program of its type in the USA. The Biorepository Accreditation program provides the means for biorepositories to attain and maintain standardization and confidence by following best practices, resulting in high quality specimens obtained under proper regulatory guidelines used to support research, drug discovery, and personalized medicine.

The All of Us Program does not include requirements or guidelines on how the biospecimens should be collected. Since the biospecimens are intended to inform many research studies on a wide variety of health conditions, we are concerned that the lack of guidance may result in poor quality biospecimens, which will jeopardize the goals of the Program. It is important to have well-qualified and trained personnel adhere to applicable standards and guidelines. Studies show that the pre-analytical phase accounts for 46% to 68.2% of errors observed during the total testing process¹ and are associated with biospecimen collection and preparation. The CAP has long recognized these errors as a critical issue and thus developed and implemented a myriad of

¹ Plebani M. Errors in clinical laboratories or errors in laboratory medicine? Clin Chem Lab Med. 2006;44(6):750-759.



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practices and programs (eg, Accreditation program standards) to address the issue. Therefore, the CAP believes that pathologist's input on biospecimen issues is both appropriate and important.

To that end, the CAP believes it important to have best practices for personnel that collect non-cancer biospecimens and recommend the Program incorporate best practices for non-cancer biospecimen collection. **We believe this can be accomplished by (1) requiring the use of best practice guidelines that the CAP is offering to develop for the program and (2) including biospecimen collection as part of the institutional review board (IRB) application.**

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 if you have any questions on these comments.

Closing,

The College of American Pathologists

Sent via All of Us Research Priorities.com