Background and Hypothesis

The Duke Human Vaccine Institute (DHVI) Accessioning Unit and Biorepository (AUB) is a multipurpose unit that has two functions: 1) receipt/accessioning, processing, request/retrieval, and shipping of fresh and frozen clinical and research study specimens and samples (Accessioning Unit) and 2) storage/maintenance of over 1,500,000 samples stored in multiple cold storage units (Biorepository). Since 2012, DHVI AUB support of the clinical and research studies has operated under Good Clinical Laboratory Practice (GCLP) guidelines and has quality oversight by the Quality Assurance for Duke Vaccine Immunogenicity Programs (QADVIP). Seeking ISO 20387 accreditation would provide investigators with added assurance in accessioning and biobanking in the DHVI AUB.

Methods

To prepare for the accreditation process the AUB worked with QADVIP to outline accreditation expectations and then interviewed two accreditation bodies (American Association of Laboratory Accreditation (A2LA) and ANSI National Accreditation Board (ANAB)) to better understand requirements and expectations of each institution. A2LA was selected as the accrediting body and the application process began. The application packet contained the ISO 20387 Biobanking Accreditation Program General Checklist, Technical Staff Matrix for Accreditation, and the Biobanking Scope Document. The application was submitted in the Spring of 2023. An initial on-site assessment of the AUB was performed in August 2023. One month after the initial on-site assessment, the A2LA assessor provided a report outlining deficiencies in the AUB based on ISO 20387 Standards. The AUB had three months to respond to the deficiencies and implement corrective actions. Responses were submitted in December 2023.

Results

The DHVI AUB became an A2LA accredited biobank under the ISO 20387:2018 standard in January 2024, becoming one of ten A2LA ISO 20387 accredited biobanks in the world.

Objective

International Organization of Standardizations (ISO) 20387 Biobank Accreditation is the gold standard for biobanking which promotes confidence in the biobanking field. Obtaining such international accreditation was the main goal of the DHVI AUB efforts.

Conclusions

The DHVI AUB processes and stores over 40,000 samples from human and non-human primate clinical and research study specimens yearly, including whole blood, lymph node biopsies, nasal swabs, and oral swabs.

Biobanks are critical for clinical and research studies conducted at Duke and outside of Duke and ISO 20387 Biobanking accreditation provides investigators with confidence when using the DHVI AUB.

Acknowledgements

Thanks to the members of the Accessioning Unit and Biorepository: Cindy Kuykendall, Anthony Tritz, Russell Zoeller, and Katrina O’Kelley. Thanks to Jonathan Harden for Data Management assistance.