# Why Biorepositories Have an Important Role in Supporting Medical Research

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**Julie McDowell:**

Pathologists play an important role in assisting biorepositories in obtaining and setting standards for quality samples for research. In this CAPcast, Dr. Rebecca Obeng discusses the range of services and resources that biorepositories can provide researchers, as well as the benefits and value of accreditation for biorepository. Dr. Obeng is a pathologist at Northwestern Medicine and the CEO of the Sub-Saharan Africa Healthcare Initiative, a nonprofit organization working to improve pathology services in Africa. Dr. Obeng, biorepositories often have human and animal tissue and fluid biospecimens from a variety of diseases and conditions that can be made available to research investigators. Can you give us an overview on the types of samples and conditions that biorepositories usually store?

**Dr. Rebecca Obeng:**

Yes, I can. Biorepositories store human samples and some mouse or other animal types of samples, and this is mainly dependent on the biorepository, and these may be made available to researchers. Microbial specimens may also be stored by biorepositories. The type of specimens that are available in biorepositories include tissues, blood, cerebral fluid, urine, sweat, and stool. Even whole organs and organisms may be stored by biorepositories. Some biorepositories collect and store specific biospecimens like brain biobanks. Others have a myriad of tissues and sample types available.

There are also a wide variety of diseases and conditions for which samples are collected and stored in biorepositories. For example, there are specialized biorepositories that collect and store samples for specific diseases like Alzheimer's disease, neuromuscular diseases, inflammatory bowel disease, and cancer. Biorepositories may also collect and store samples from patients prior to treatment, while they're receiving treatment or some form of medical intervention, and after treatment or intervention has been completed.

The types of diseases and conditions as well as the types of samples collected by a biorepository depends on a number of factors, and this includes the goals and purpose of the biorepository, stipulations based on who is funding the biorepository and specific tasks and purposes that instituted the biorepository.

**Julie McDowell:**

Now, in what forms are these samples and specimens stored?

**Dr. Rebecca Obeng:**

Yeah, so biospecimens can be procured in a number of different ways. Depending on the capabilities of the biorepository and the type of studies that are to be done, investigators may receive fresh, snap-frozen, cryopreserved, formalin-fixed and paraffin-embedded, specimens embedded and fixed in other preservatives or process samples. Process samples include those in which nucleic acids, including RNA and DNA, proteins or metabolites have been isolated from the tissues and blood fluids. At institutions that have comprehensive biorepositories, all of these options are likely available to researchers.

**Julie McDowell:**

What is the value in going through biorepositories for research samples?

**Dr. Rebecca Obeng:**

That's a great question. There are several advantages to procuring research specimens from biorepositories. One of the advantages is sample size. Biorepositories may have multiple samples of tissues, diseases specific and anatomic sites or specific interventions that researchers can't access. Samples may be rare or difficult to get. Biorepositories can be good sources of such rare and hard to come by samples of research. The biorepositories may also have samples stored in different states such as fresh, frozen, alcohol-fixed or formalin-fixed samples. Researchers can request these samples that have been appropriately preserved to suit the studies that are to be done.

Biorepositories may also offer services to screen, consent and collect samples for the researchers. This may be especially attractive to researchers who do not have the opportunity to interact directly with patients or who may not have collaborations to receive such samples. Since biorepositories collect and store samples, there will be documentations related to the chain of custody for samples. With the appropriate institutional review board approved protocols, clinical information for samples can be obtained through the biorepository. In cases where the investigators do not have the necessary equipment and instruments to collect certain process samples such as RNA and DNA, they may obtain those samples from biorepositories.

**Julie McDowell:**

How can investigators identify a good biorepository? And what are some things that investigators should think about when identifying a biorepository for research?

**Dr. Rebecca Obeng:**

Yeah, I'm sure a lot of people think about this. So before investigators identify a biorepository, it is important to clearly define the research project and identify the types of biospecimens that are most appropriate for the planned studies. After these factors have been identified, investigators can then begin to identify biorepositories that procure the types of samples that are needed.

Oftentimes, biorepositories will provide an initial consultation to assess project feasibility and provide recommendations on sample procurement. Now, this initial consultation may be very helpful because challenges and nuances related to specimen collection, authentication and validation may be identified in the process. The biorepositories may be able to offer solutions and alternatives for researchers.

It may also be beneficial to think about the breadth of services that different biorepositories provide. Depending on the needs of the research team, it may also be important to work with a biorepository that can provide chain of custody documentation for samples or to be able to access clinically relevant information about the samples from the biorepository. Access to protected health information will require approval from an institutional review board or a waiver. Procuring tissues and fluids from biorepository that can then be further processed to extract nucleic acids or proteins within the same repository would reduce the workload and also help reduce variability in sample handling and results.

Lastly, biorepositories that adhere to evidence-based best practices are good repositories to use. Many biorepositories will have information about what guidelines and best practices they adhere to. If that information is not readily available, the investigators should call to obtain information about that. Ideally, investigators should use biorepositories that are accredited, and there are national and international accreditation organizations that ensure that biorepositories follow evidence-based and strict guidelines to maintain specimen integrity and quality.

**Julie McDowell:**

Who are the accrediting bodies that ensure that biorepositories adhere to best practices and standards?

**Dr. Rebecca Obeng:**

Yeah, so there are two main biorepository accreditation programs. Biorepositories can be accredited through the Biorepository Accreditation Program of the College of American Pathologists and the ISO 20387 guidelines from the International Standards Organization.

**Julie McDowell:**

Now, is it necessary to obtain biospecimens for research purposes from an accredited biorepository?

**Dr. Rebecca Obeng:**

No, it's not necessary for researchers to obtain samples from an accredited biorepository. Many biorepositories will independently adhere to best practice guidelines such as the National Cancer Institutes' Best Practices for Biorepositories or the International Society for Biological and Environmental Repositories or ISBER Best Practices.

However, investigators want fit-for-purpose biospecimens, and investigators can be assured that the sample integrity and quality are not compromised when the samples are provided by an accredited biorepository. Biorepositories that participate in external or third-party accreditation programs are inspected regularly and are required to adhere to specific guidelines and best practices in all aspects related to samples in the biorepositories.

Feeling confident about how samples were collected, stored and transported reduces the probability that planned experiments fail due to improper procurement and handling of specimens. Suboptimal and poor-quality samples may end up being costly for investigators, not to mention the lost time and effort that would result from low quality samples. Additionally, incorrect conclusions may be drawn from experiments conducted in samples that have not had the proper and adequate handling and verification.

Pathologists routinely review and confirm that samples collected by accredited biorepositories are what were intended to be collected. For example, an investigator may want to conduct experiments using colorectal adenocarcinoma samples. If the samples collected by the biorepository are not verified by a pathologist to be colorectal adenocarcinomas, the investigator may receive samples that contain other types of tumors or no tumor at all. That would significantly impact the data collected and the conclusions drawn from the experiments using those samples. Also, some funding agencies may require the specimens used in proposed research projects be obtained from an accredited biorepository. So for all of these reasons, getting samples from an accredited biorepository is extremely important.

**Julie McDowell:**

What is the value of obtaining samples specifically from biorepositories that are accredited by the CAP's Biorepository Accreditation Program?

**Dr. Rebecca Obeng:**

Yeah, so the CAP's Biorepository Accreditation Program pioneered the first accreditation program designed to improve the quality and consistency of biorepositories. The program was developed based on best practices from a number of established institutions, including ISBER, the National Cancer Institute, and the Organization for Economic Cooperation and Development, the Centers for Medicare and Medicaid Services and CAP's own Laboratory Accreditation Program.

The CAP's Biorepository Accreditation Program provides requirements for standardization of processes to ensure high quality biospecimens that can be used for research purposes. Some of the experts who established the CAP's Biorepository Accreditation Program were also involved in developing the ISO 20387 standards for biobanking. Biorepositories that receive accreditation through the Biorepository Accreditation Program or BAP all follow clear evidence-based processes to ensure specimen integrity and quality.

An added value to the Biorepository Accreditation Program is that the checklist requirements used by the program is consistent with clear regulations. This ensures confidence in specimen providence and in pre-analytic variable tracking and controls of samples. The program also ensures appropriate and legal frameworks for the use of biospecimens in institutional review board approved research, robust chain of custody tracking with reduced risk of misinformation, misidentification, and appropriate storage conditions and temperature monitoring. Also, histologic quality assurance for samples for further studies and confidence in long-term quality of biospecimens as well as best practices, policies and procedures for sample release are all ensured through this program.

**Julie McDowell:**

Are there other services besides the provision of samples that biorepositories offer to research investigators?

**Dr. Rebecca Obeng:**

Yes. Aside from collecting samples, some biorepositories offer additional services that include screening and consenting patients for investigative specific projects. Some biorepositories may assist with the study design and logistics of sample collection and preservation. Pathologists review and confirm the diseases and conditions of samples collected in many biorepositories. Some biorepositories may offer these services as well as authentication of tissues and cell lines on samples that were independently collected by investigators. Biorepositories can also perform some of the pre-analytical testings, including nucleic acid and protein extractions, quality checks from sample investigators as well. Sample storage, maintenance and specimen transfers are other services that can be provided by biorepositories if investigators need them.

**Julie McDowell:**

Finally, Dr. Obeng, are there databases that provide a list and contact information of biorepositories?

**Dr. Rebecca Obeng:**

Yes, so there are several online databases that list biorepositories all over the world. These databases can be found using search engines. It may be easiest for investigators to contact biorepositories within their institutions first. Many academic and commercial institutions have biorepositories that may fulfill the research needs of the investigators and might provide additional support if needed.

**Julie McDowell:**

Great. Well, thank you so much Dr. Obeng for highlighting the value of biorepositories to researchers who may be interested in obtaining biospecimens for research. For more information on the CAP'S Biorepository Accreditation Program, please visit the accreditation section of cap.org.

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