Building Blocks of a Successful Biospecimen Repository

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BACKGROUND

Developing a biospecimen repository for use in translational research presents unique planning challenges for the research administrator. A viable specimen must meet the qualitative and quantitative needs of current and future research scientists—specimens that exhibit physical integrity, regulatory compliance, and ethical responsibility. To be successful, administrators must have a basic understanding of ethics, management, science, and technology—the building blocks of a successful biospecimen repository.

Science is the core of the relationship between pre-analytical variables found during sample handling and the accuracy and reproducibility of data for research. Advancements in biospecimen science facilitate understanding of the environmental, technological, and biological influences that impact the short-term and long-term viability and utility of scientifically-relevant specimens. Research administrators can influence the adoption and implementation of scientific innovation by engaging the research team with consistent and timely communication and professional development opportunities.

Ethical Practices should be infused into every aspect of the planning & implementation process of the repository:
- responsible custodianship based on transparent policies;
- informed consent, privacy, & confidentiality aligned with regulations and “best practices”;
- material transfer agreements, intellectual property rights, equitable access to biospecimens & data;
- cost-recovery, self-sustainability, and commercial use;
- harmonization of ethical standards across national & international organizations; and
- blending of stewardship into every aspect of the program.

Technology permeates every aspect of a repository, supporting the collection, tracking, storage, analysis, and distribution of specimens. The research administrator must be aware of the need for cost efficient, reliable, long-term preservation that includes:
- cryostorage systems and ultra-low temperature freezers;
- selection, customization and/or standardization of specimen inventory tracking systems;
- interoperability and validation of clinical data management informatics;
- automated sample processing;
- capabilities for continuous monitoring and auditing throughout the specimen’s life; and
- new technology that will drive innovation and further discoveries in biospecimen science.

Management supports the business perspective of a successful repository from start-up, through collection, maintenance, and disbursement of specimens. Planning should include key stakeholders such as institutional officials, patient advocates, fundraisers, investigators, and technologists and should include provision for:
- budgetary and operational constraints;
- long-term funding & change in management;
- hiring and training of appropriate personnel;
- technology support and oversight; and
- quality control, risk management & safety implementation.

Quality Data & Specimens

CONCLUSION

To meet the needs of current and future research scientists, the successful biospecimen repository must exhibit specimen integrity, regulatory compliance, and ethical responsibility. The research administrator who has an understanding of the importance of ethics, management, science and technology, will have the tools to build a successful biospecimen repository.

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