Sustainability of Biobanks in the Future

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Abstract

Human biorepositories are essential in providing high quality specimens that are well characterized. Biospecimens are used in basic, clinical, and translational research. However, as regulatory requirements and scientific demands increase the complexity of the daily operations of a biorepository, the cost of maintaining a biobank will increase. How can biobanks today maintain sustainability during the current economic climate and changing landscape of operating a biorepository? This is a brief review of how different biobanks have approached sustainability.

Keywords

Biobank • Biorepository • Cost recovery • Fee-for-service • Sustainability • Workflow

3.1 Introduction

The focus of this paper will be on the future sustainability of human biobanks/biorepositories. Human biobanks have evolved over the past decades. The majority of biobanks started as small academic biorepositories that were developed for specific or unique research projects. Over time biobanks evolved to larger institutional, government supported biorepositories, commercial biorepositories (for profit), population based biobanks, and virtual biobanks. Their basic mission is to collect, process, store, and disseminate human specimens and data that are used for basic science and biomedical studies. These specimens play an important role in the development of new therapeutics, pharmaceuticals, diagnostics, population genomics, etc.

The field of biorepository and biospecimen science keeps evolving due to changing needs of researchers, regulatory requirements, ethical and legal issues, and the rapidly changing face of science [1]. The disciplines of proteomics,

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genomics, and personalized medicine all demand high quality specimens associated with well characterized data. Today there is discussion among funding agencies that biorepositories should obtain accreditation [2, 3] in order to demonstrate consistency in quality assurance and quality control programs.

However, as regulatory requirements and scientific demands increase the complexity of daily operations of a biorepository, the cost of processing and maintenance will increase. How will biobanks of the future sustain themselves? The economic down turn of 2008 has affected non-profit and for profit biorepositories. Today large pharmaceutical companies have reduced staffing as well as research and development programs, and academic biobanks are experiencing reduced funding from institutional and government agencies. As market forces change the business structure, the character, and morphology of a biobank will have to change, to meet the ever increasing need for biobank innovation and services.

3.2 Economics of a Biorepository

Biorepositories are costly in regards to staffing, equipment, service contracts, consumables, and expertise [4–6]. For many biorepositories a pre-eminent expense is that of maintaining a collection of specimens (long term storage) that are under-utilized. In order to maintain sustainability, biobanks must run as business units as well as scientific laboratories [7]. Some academic biobanks outsource their storage of collections. To maintain sustainability some biobanks leverage the financial potential of their specimens and data. However this may lead to ethical and legal issues in regards to HIPAA, consent forms, and the public trust in biorepositories [8].

Some recently published works have described various operational models that may provide insight as how to sustain a biorepository. Vaught et al. [4] reviewed 16 of the largest international biobanks and networks in their management of processing and storing biospecimens while recovering their operating costs. The biobanks reviewed have agreed that the specimens they store cannot be used for commercial purposes. The majority of biobanks implemented a cost recovery system by charging investigators access to specimens and data. However, all of the biobanks reviewed did not fully recover their costs. They relied on governmental and charitable support. The approaches to cost recovery varied among the many biobanks. Some defrayed the cost of a portion of the price of biobanking in order to make their services affordable to the investigator. Other biorepositories had different cost recovery rates for non-profit versus private companies. Additional sample processing services were offered by some biobanks in which the full cost was paid by the requestor.

3.3 Academic Biorepositories

For an academic biobank, a fee for service [7] model is one approach to recover a biobank's expenses. Federal funding is shrinking and charitable donations are few and far between. At the University of California, San Francisco (UCSF), core facilities are encouraged to develop a recharge methodology in order to recover their costs. A recharge will recover nonsubsidized direct costs for a core's services. A recharge proposal is submitted to UCSF Budget Office for review and approval. The UCSF AIDS Specimen Bank (ASB) has developed a recharge methodology to recover its costs associated with staffing, processing, consumables, equipment depreciation, service contracts, software and hardware maintenance, data management, storage, and dissemination. In the development of this recharge the workflow of ASB had to be taken into consideration in determining a fee-for-service schedule.

Figure 3.1 depicts the work flow of receiving, processing, and storing specimens. Figure 3.2 depicts the dissemination process in which specimens are selected, removed from storage, and shipped to their final destination. Each step in the process has a related cost.

At the Washington University Medical Center, St. Louis, Missouri's Tissue Procurement Core a fee- for- service business model [7] was developed

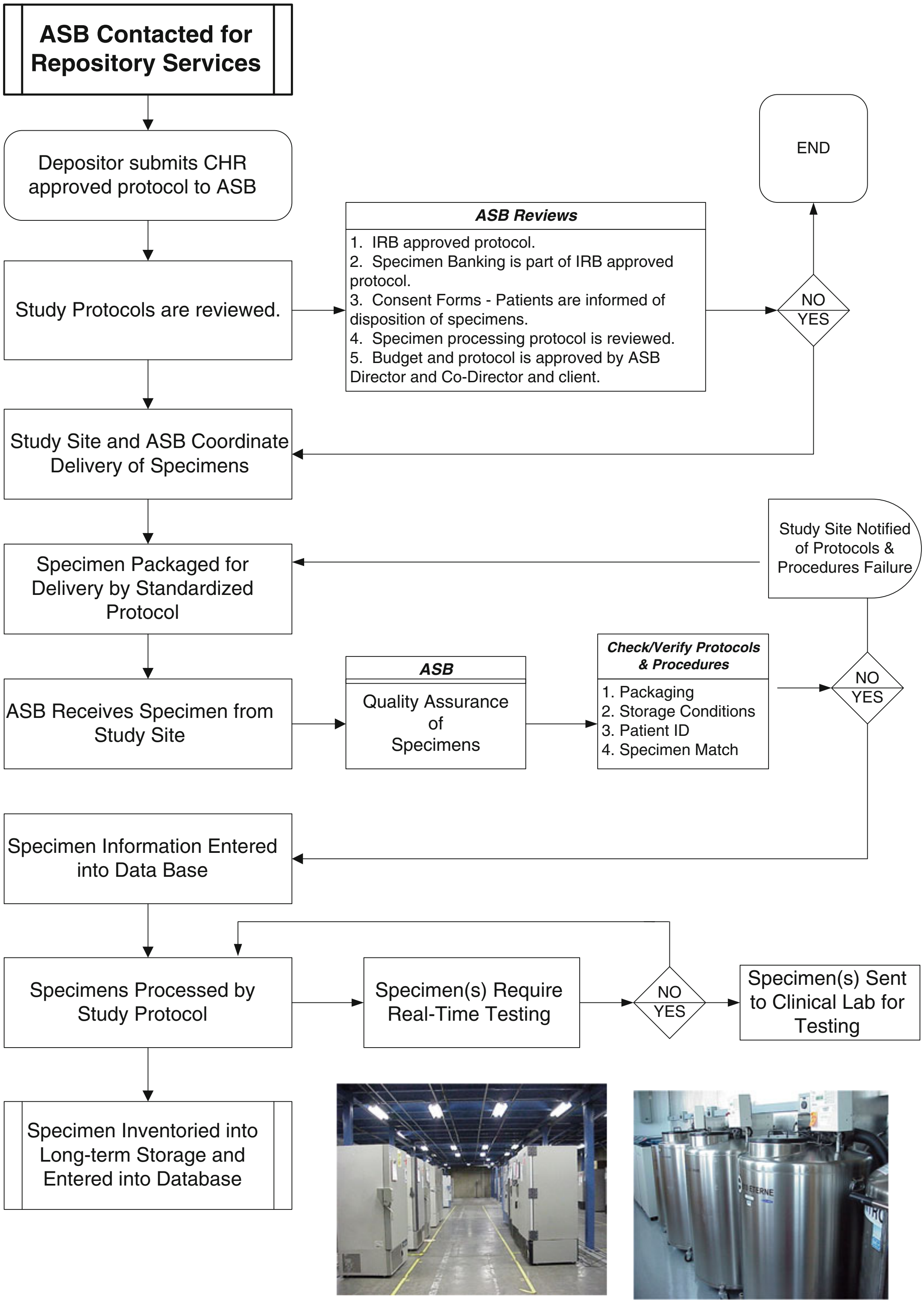

Fig. 3.1 UCSF AIDS specimen bank – specimen accessioning, processing and storage workflow

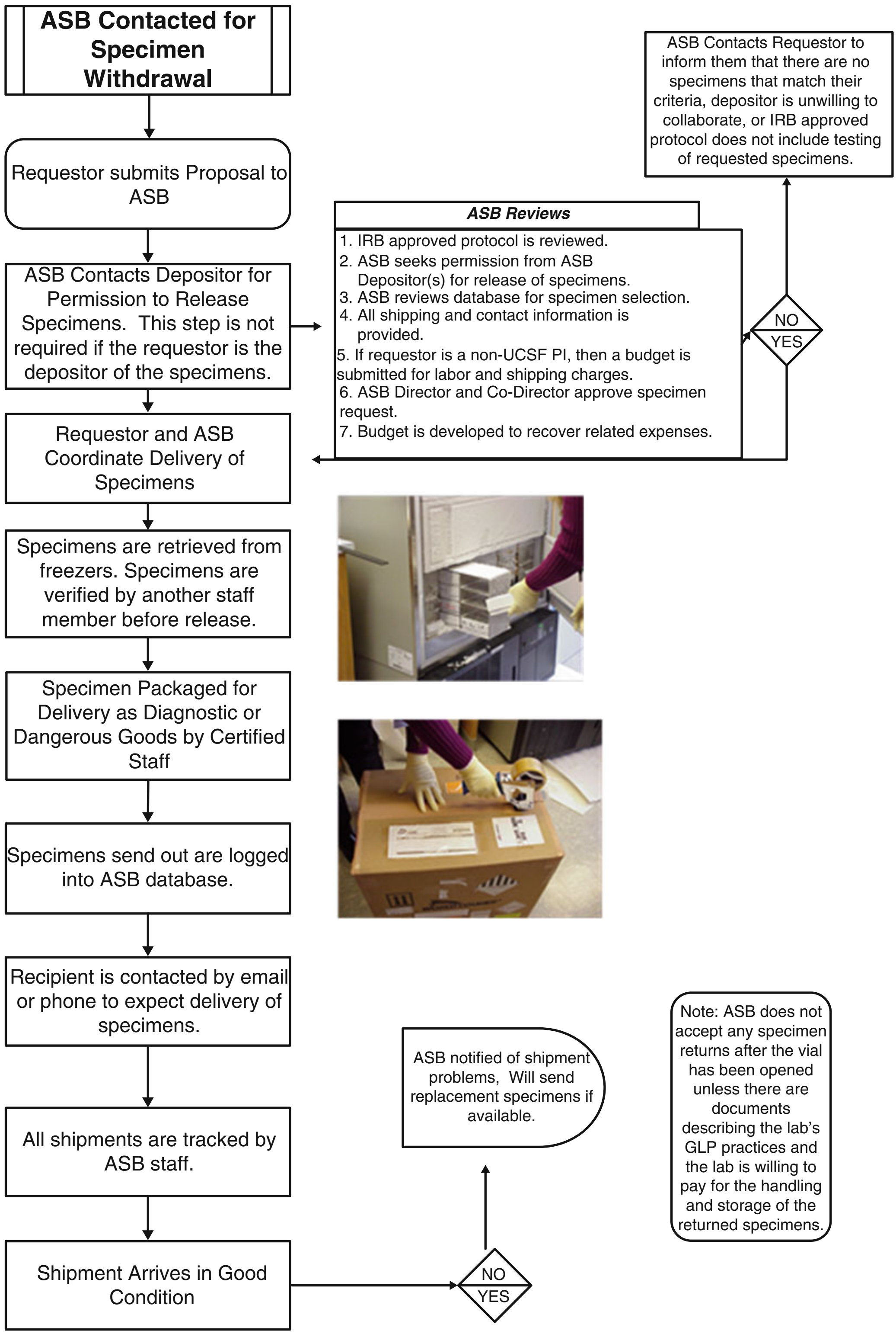

Fig. 3.2 UCSF AIDS specimen bank – specimen withdrawal/request workflow

in order to recover operational costs while still offering competitive value to its users. They do not charge researchers for the use of biospecimens, but rather the services associated with the specimens. They developed a financial model taking into consideration labor, consumables, pathology review, storage, and infrastructure.

McQueen et al. [9] describes the challenges that arise when managing and sustaining a large biobank and their Clinical Research Trials Laboratory (CRTL) at the Hamilton General Hospital in Hamilton, Ontario, Canada. Their biggest challenge was obtaining space for freezers and laboratory space. Their bank grew from 500 ft^2 in the 1990s to about 12,000 ft^2 in 2013. The Hamilton Health Sciences provided the space, and there is support from industry due to the high quality of the clinical studies being developed by the CRTL. The Population Health Research Institute (PHRI) also provided support as well as grants. This paper describes how collaboration, the implementation of best practices as published by the International Society of Biological and Environmental Repositories (ISBER) [10] and the National Cancer Institute (NCI) [11] help them to achieve accreditation of their biobank and CRTL by the International Standards Organization (ISO). By achieving accreditation and producing high quality specimens, this biobank continues to sustain itself.

Development of a centralized and well-coordinated biorepository within an academic institution may be an approach to reduce costs and improve the quality of specimens and its associated data. A centralized biobank may help to promote collaboration among investigators [12]. A common informatics system will help to direct or manage the collection, processing, and dissemination of biospecimens within an institution.

The centralization of an academic biorepository does not necessarily mean that one biorepository will serve the needs of an academic institution. The process of centralization could be that an institution would invest in a common informatics system that will link biobanks and researchers. This would improve the coordination between researchers and access to biospecimens. Standard operating procedures would be shared and best practices would be developed for quality control and quality assurance. This could help to improve the sustainability of an institution's biorepositories by insuring that the specimens processed are of high quality and are well characterized.

3.4 Other Economic Models

Several publications from the NCI [13–15] describe key considerations in the development of a cost recovery model for a biorepository. Factors such as size of the biobank, inventory turnover, market price, and other potential revenue sources are discussed.

The Infectious Diseases Biobank (IDB) at King's College London [16] developed an interesting economic model in order to sustain their extensive tissue collections. In addition to their core funding the IDB developed three strategies to increase their funding. The first was to charge investigators for samples and associated labor, or an investigator could donate specimens to the IDB. The next step was to identify 'emerging markets' outside the original scope of the IDB. Their third step was the most successful, was the offering of contract services.

Watson et al. [17] published a paper in which they proposed that sustainability of a biobank must take into consideration a framework which includes financial, operational, and social. Financial would include developing a business model defining user fees based on operational costs, identify stakeholder needs, measure value and monitor its impact on the biorepository. Operational decisions would involve reviewing and improving the biobanking process. This includes specimen collection and processing, data annotation, and assessing if a biobank needs to offer more products and services. The social aspect refers to the impact of a biobank to the community, its participants, patients that donate specimens, and finally the funding agencies.

The British Columbia BioLibrary [18] (BC) was created to connect specimen donors, biobanks, and researchers. It is not a biorepository but more of a conduit that has enhanced the value and accessibility of high quality biospecimens to investigators and has gained the public's trust. This has contributed to the sustainability of biobanking in British Columbia.

The University of British Columbia Office of Biobank Education and Research [19] developed a biospecimen user fee calculator that could help biobanks develop a more accurate and transparent costing tool. They enrolled several members of the Canadian Tumour Registry Network (CTRNet) to test the tool. The authors commented that many biobanks keep their prices low in order to increase business and investigators that request services from a biorepository may have not planned to pay for these services in their grant proposals or had inadequately budgeted for these services. These inadequate planning issues will not financially sustain a biorepository. The authors this tool available on line at www.biobanking.org. This tool is designed to give a biobank the ability to develop a realistic fee for their services. There will be additional releases of this tool in the future.

3.5 Conclusion

During these challenging economic times it is essential that biobanks develop an efficient cost recovery mechanism in order to remain sustainable. The NCI's Biorepositories and Biospecimen Research Branch has developed a financial sustainability survey to collect data on direct and indirect costs associated with biobanks, technology challenges associated with the operations of the biobank, demographic data of biobanks, and techniques that biobanks have used to successfully maintain financial sustainability.

In order to remain sustainable a biobank must communicate with their customers and stakeholders to gain support for their methodology of cost recovery. In addition, biobanks must develop viable business models and marketing strategies. These methods must be reviewed annually to adjust to changes in client needs. There is no one perfect solution in maintaining sustainability. It is imperative biobank managers must understand the complexities of science and business in operating a biorepository.

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