EDITORIAL REVIEW

Biobanking past, present and future: responsibilities and benefits

Yvonne G. De Souza and John S. Greenspan

The review explores the field of biobanking as it has evolved from a simple collection of frozen specimens to the virtual biobank. Biorepository and biospecimen science has evolved in response to the changing landscape of external regulatory pressures, the advances made in the biological sciences, and the advent of the computer chip. Biospecimen banking is a growing enterprise crucial to health science research and other biological sciences. In this review we discuss the history of biobanking, highlight current and emerging issues, discuss demands and responses, and describe an example of a biobank, the University of California, San Francisco AIDS Specimen Bank that has functioned for 30 years. © 2013 Wolters Kluwer Health | Lippincott Williams & Wilkins

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Introduction

The term biobank covers collections of plant and animal, including human specimens. For the purposes of this discussion, we focus on human biobanks. A biobank is a biorepository that accepts, processes, stores, and distributes biospecimens and associated data for use in research and clinical care. The field of biobanking has changed tremendously over the past 30 years. It started with small, predominantly university-based repositories that were developed for the research needs of specific projects. There gradually evolved institutional and government-supported repositories, commercial (for profit) biorepositories, population-based biobanks, and most recently, virtual biobanks. The data associated with stored biospecimens have increased in complexity from basics, such as date of collection and the diagnosis, to extensive information sets encompassing many aspects of participant or patient phenotype, now rapidly extending into genetic, proteomic, and other 'omics' information. Population-wide biobanks have been developed in several countries, including Iceland, UK, Sweden, Denmark, Lativa, Estonia, Canada, South Korea, Japan, Singapore, and USA. These large-scale repositories have been created in order to collect, analyze, and store phenotypic and genetic information on representative samples of their source populations. Virtual biobanks are developed to assist investigators locate biospecimens for testing and data mining from multiple biobanks in dispersed locations. Such virtual biobanks are accessed using specialized software or web portals designed to connect biobanks and investigators throughout the world.

The field of biorepository and biospecimen science has evolved in response to the changing needs of investigators and projects using specimen banking, as well as to external regulatory and related pressures. This changing environment can be attributed in part to emerging fields such as proteomics, genomics, and personalized medicine as well as to the increasing precision of the associated fields of

Department of Orofacial Sciences and the AIDS Research Institute, University of California San Francisco, San Francisco, California, USA.

Correspondence to Yvonne De Souza, Department of Orofacial Sciences, UCSF, 513 Parnassus Ave., Box 0422, San Francisco, CA 94143-0422, USA.

E-mail: yvonne.desouza@ucsf.edu
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science. This process has increased the demand for high-quality specimens with accurate, reliable, standardized clinical and laboratory data. Thus, optimum collection, processing, storage, tracking, and shipment of biospecimens are key to the outcome of a multitude of studies. The field of Biorepository and Biospecimen Science has emerged [1]. The journal, *Cancer Epidemiology, Biomarkers & Prevention* is based on this emerging field. Further issues that have affected the field of biobanking include regulatory requirements, such as Health Insurance Portability and Accountability Act (HIPAA), Institutional Review Board (IRB), and consent documentation, whereas the area of genetics and biobanking has addressed serious ethical and legal issues [2].

Biobank taxonomy

There are several types of biobanks, including those that are disease-centric, population-based, genetic or DNA/RNA, project-driven, tissue versus multiple specimen type, commercial, and virtual biobanks. Watson and Barnes [3] emphasized the importance of properly classifying biobanks. Table 1 lists some examples of biobank types with their websites. Upon review of these websites one can appreciate the complexity of these biobanks and the amount of support they provide their research base.

Evolution of the biobank and its diverse activities

Human specimens have been collected and stored at institutions in the US and elsewhere for over 100 years [4]. Specimen banks have advanced in their activities from small operations based on the needs of a specific study, in which record keeping was confined to a laboratory notebook and specimen storage was in one or a few freezers. This modest style of banking has become a far more complex enterprise. Technological advances, notably procedure automation, computerization, and the Web, have revolutionized the management of biobanks. Specimen annotation and location can now be maintained in a computerized database and biobanks that have sufficient funding are able to invest in robotics to expedite specimen processing and sampling. The internet has expanded communication with clients and also facilitates the establishment of virtual biobanks. Software companies are developing packages that support biobanks in tracking inventory, expenses, consent documentation, and the handling of clinical and laboratory data.

Biorepositories encompass collections including those from epidemiological cohorts, clinical trials, diagnostic and etiopathogenesis studies. Large-population biobanks have become common over the past two decades. In these, robotic devices handle the processing of specimens,

Table 1. Examples of biobank types and their websites.

Name of bank	Biobank type	Website and/or reference
Adolescent and Young Adult Biorepository	Disease-specific biobank	http://www.ohsu.edu/xd/health/services/cancer/outreach-programs/programmatic-outreach/how-is-young-adult-cancer-uniq.cfm
Australia – Breast Cancer Bank	Disease-specific biobank	http://www.abctb.org.au/abctbNew2/AboutUs.aspx
Cancer Human Biobank – caHUB	NCI-sponsored national biobank	http://cahub.cancer.gov/ [9]
Cincinnati Biobank	Pediatric biobank	http://www.cincinnatichildrens.org/research/cores/biobank/default/
Coriell Cell Repositories	Cell culture biobank	http://ccr.coriell.org
Danish National Biobank	Population-based biobank	http://www.biobankdenmark.dk/
Duke Institute for Genome Sciences & Policy Biospecimen Repository	Centralized biobank for Duke University Investigators	http://www.genome.duke.edu/cores/biorepository
Estonian Biobank	Population-based biobank	http://www.itfom.eu/partners/associate-partners/18-associate-partners/198-estonian-genome-center-university-of-tartu-estonia
Kaiser Permanente Research Program on Genes, Environment, and Health (RPGEH)	Kaiser member-based biobank	http://www.dor.kaiser.org/external/DORExternal/rpgeh/index.aspx
Northwest Biobank at Kaiser Permanente	Partnership between Oregon Health & Science University and the Kaiser Permanente Center	http://www.ohsu.edu/xd/research/centers-institutes/octri/funding/nw-biobank.cfm
SeraCare Life Sciences	Commercial biobank	http://www.seracarecatalog.com/default.aspx
Specimen Central	Virtual biobank	http://specimencentral.com/about-us.aspx
Thyroid Biobank Pasteur Hospital, Nice, France	Organ-specific biobank	[12]
Tissue Solutions	Virtual biobank	http://www.tissue-solutions.com/
Tumour Tissue Repository	Cancer biobank	http://www.bccrc.ca/dept/ttr
UCSF AIDS and Cancer Resource	Disease-specific biobank	http://acsr.ucsf.edu/
UCSF AIDS Specimen Bank	Disease-specific biobank	http://ari.ucsf.edu/programs/asb.aspx [8]
UK Biobank	Population-based biobank	http://www.ukbiobank.ac.uk/ [6,27]
Univ. of Minnesota Tissue Procurement Facility	Centralized biobank for Univ. of Minn. investigators	http://www.bionet.umn.edu/tpf/hone.html

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whereas terabytes of data are collected and stored. In 2012, the Danish National Biobank [5] opened as a collaboration between the public and private sectors. Such national biorepositories make it possible to study populations throughout the lifespan and in this example plan to provide more than 15 million biospecimens to investigators. The UK biobank [6,7] was created after a decade of careful planning with the goal of improving the prevention, diagnosis, and treatment of a wide range of serious and life-threatening illnesses, including cancer, cardiovascular disease, diabetes, osteoporosis, depression, and forms of dementia. UK Biobank has reported recruiting 500 000 people aged 40–69 years during 2006–2010.

An example of a disease-centric biobank is the University of California, San Francisco (UCSF) AIDS Specimen Bank (ASB). The ASB was started in December 1982 in response to the early challenges of the AIDS epidemic [8]. At the time, the causative agent for AIDS was not known. Investigators from disciplines such as infectious diseases, epidemiology, oncology, pediatrics, dentistry, and pathology came together and developed a small biobank for the processing, storage, and dissemination of specimens. Three decades later, it is a major resource for investigators at UCSF and throughout the world (see below).

The National Cancer Institute (NCI) announced in late 2009 the establishment of the US National Cancer Human Biobank, caHUB [9]. The creation of this biospecimen resource was in response to a survey sent out in 2002 to investigators funded by NCI, to members of other federal agencies, cancer centers, industry, and advocacy groups concerning needs for human biospecimens. The responses revealed that a lack of standardized, high-quality biospecimens with well annotated data has slowed the progress of cancer research. The goal of caHUB is to improve and modernize the field of biobanking by creating evidence-based Standard Operating Procedures (SOPs) and biospecimen quality standards. Describing caHUB, Vaught *et al.* [10] state that collection strategies and standardized protocols for the collection, processing, and annotation of specimens would be developed. There would be centralized quality control and analysis of every specimen. On July 2012, caHUB released their first set of SOPs [11] on genome tissue expression protocols (see also below).

A virtual biobank is an electronic database of biological specimens and other related information, regardless of where the actual specimens are stored. The University College London (UCL) biobanks [6], one based at the Royal Free Hospital (RFH) and the other based at Bloomsbury supporting Pathology and the Cancer Institute, act as physical repositories for collections of biological samples and data from patients consented at UCL Partners Hospitals and external sources. The UCL Virtual Biobank incorporates collections of existing and new biospecimens. Their virtual biobank will eventually be a data repository for biospecimen collections across the health sciences center. The founders are in the process of developing a software system to house sample and phenotype data for UCL studies, with a powerful search engine to view information across all collections.

Best practices

The goal of a biobank/biorepository is to collect, store, and disseminate specimens and related data. In order to provide high-quality biospecimens with well characterized data, the management team must insure that they follow 'best practices'. Factors to be considered in the design and development of a biobank are discussed in a number of best practice publications, notably those of International Society of Biological and Environmental Repositories (ISBER) and NCI. Publications that review these and other aspects of bank design and operation are listed in Table 2.

International Society of Biological and Environmental Repositories

In 2000 the International Society of Biological and Environmental Repositories (ISBER) was formed (http://www.isber.org/). Investigators, biobank managers and directors, NIH institute representatives, bioinformatic managers, patient advocates, lawyers, and others with interest in biobanking meet yearly to share knowledge in the field. This group of biobankers includes those working with human, animal, plant, and environmental repositories. Each year the attendance at ISBER annual meetings grows and new working groups are formed to address areas such as biospecimen science, informed consent, informatics, rare diseases, and

Table 2. Selected publications on bank design and operations.

Topic	Reference
Community-based hospital biorepository	[12]
Epidemiological issues in design and use of biological specimens	[13]
Epidemiological research and public health	[14]
Human tissue monitoring and specimen banking	[15]
ISBER 2012 best practices for repositories	[16]
Interdisciplinary clinical research	[17]
NCI best practices for biospecimen science	[18]
Prospective thyroid biobank	[19]
Sample storage management	[20]
Sample management	[21]
Single-investigator biobanks	[22]
Stakeholder analysis	[23]
Standard preanalytical coding for biospecimens	[24,25]
Technological and administrative factors implementing a virtual biobank	[26]
UCSF AIDS specimen bank (ASB)	[8]
UK Biobank – sample handling	[27]

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automated repositories, to name a few. One of the most important publications of ISBER is *Best Practices for Repositories,* first published in 2005 [28] and revised in 2008 [29] and 2012 [16]. This is the first 'handbook' for biobankers. Topics such as cost recovery, facilities, equipment, safety, quality assurance and quality control, shipping, ethical issues, specimen collection, processing, and retrieval, training, specimen culling, and many more are discussed. ISBER's journal, *Biopreservation and Biobanking* (formerly *Cell Preservation Technology*) is the first journal to provide a forum for peer-reviewed communication on recent advances in the emerging and evolving field of biospecimen procurement, processing, preservation, and banking.

National Cancer Institute office of biorepositories and biospecimen

High-quality biospecimens for molecular applications are essential in order to produce reliable and consistent results. Moore *et al.* [30] reported evidence indicating that multiple factors in the handling of biospecimens can affect the detection of molecular analytes in downstream applications. They also reported that among NCI-supported biorepositories, most programs collected frozen biospecimens for genomic and proteomic research. However, there were no common SOPs or quality assurance and quality control measures, and the programs lacked a common database. NCI established the Office of Biorepositories and Biospecimen Research (OBBR) in 2005 and the Biorepository Coordinating Committee (BCC), which has an advisory role to OBBR. The mission of the BCC is to coordinate efforts to improve the availability and quality of human specimens needed for research supported by the NCI. OBBR's mission is to facilitate cancer and biomedical research by improving the quality and consistency of human biospecimens. In 2005 [31] the NCI developed the *First-Generation Guidelines for NCI Funded Biorepositories*. These guidelines were posted for public comment prior to final release. Subsequently revised versions were released in 2007 [32] and 2011 [18] and renamed the *NCI Best Practices for Biospecimen Resources*.

Rand Corporation

The Rand Corporation was the first to publish information on stored tissue samples in the US [4]. At the time of the publication, they estimated that there were more than 307 million specimens from more than 178 million individuals stored in the US. In 2003, the Rand Corporation published [33] '*Best Practices' for a Biopsecimen Resource for the Genomic and Proteomic Era*. This monograph addressed biospecimen collection, processing, annotation, storage, and distribution; bioinformatics; consumer, and user needs; business plans and operations; privacy, ethical concerns, and consent issues; intellectual property rights and legal issues; and public relations, marketing, and education.

University of California, San Francisco Institutional Review Board

In 2005, members of UCSF IRB, the Medical Center Associate Privacy Officer, the ASB co-director, the Cancer Center Tissue Core manager, and faculty members prepared a guidebook for investigators and staff on research with human biological specimens [34].

Biospecimen science

Biospecimen research in recent years has focused on preanalytical variables, defined as any variation taking place between the moment of specimen collection and the moment of specimen analysis [35]. Preanalytical variables can be grouped broadly under three categories: physiological, specimen collection, and influence or interference factors [36]. Examples of preanalytical variables are collection, blood tube selection, order of blood draw, centrifugation speeds, storage and processing; all affect the consistency and molecular composition of biospecimens [37–39]. The ISBER Biospecimen Working Group has compiled a more extensive list of publications on biospecimen research that can be found at http://www.isber.org/wg/bs.html.

Moore *et al.* [30] emphasize that to improve the quality of research utilizing human biospecimens, it is critical that information regarding how the biospecimens were handled be reported in an accurate and standardized system. This reporting system is identified as the Biospecimen Reporting for Improved Study Quality or BRISQ. The authors suggest that this reporting tool will help to strengthen biospecimen-related studies.

Legal and ethical issues

The evolving regulatory landscape affects biobanks. HIPAA, also known as 'The Privacy Rule', set new standards and regulations to protect patients from inappropriate disclosures of their 'protected health information' (PHI) that may affect a patient's access to insurance, employability, and privacy. Specimen bankers and investigators who manage specimen data and others who have access to it are legally and ethically obligated to protect data that are considered private information. At UCSF, institutional oversight of banking of human specimens for research requires approval by several regulatory committees, including biosafety, radiation safety, animal safety, human research, and sponsored research.

The increased demand for human specimens in genome-wide association studies (GWAS) and data sharing raises

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concerns of privacy, confidentiality, and human protection.

One important issue that will affect biobanks in the future is the concept of providing research results to participants in studies. Most biobanks are not certified by the Clinical Laboratory Improvement Amendments (CLIA). Thus is it not legal in the US for biobanks to provide study participants/patients with results generated by those projects [40]. Recently, the Office for Human Research Protections (OHRP) announced an ambitious effort to update the regulations concerning research on humans [40]. One of the changes proposed would require consent for all research use of biological specimens, even those that have been rendered anonymous. The general view of those in the field is that this is impractical, for the vast majority of biobanks, have neither the infrastructure nor financial support to fulfill such a mandate.

Another ongoing debate is the question of whether investigators or biobanks have responsibility to report a participant's incidental findings or individual research results (IRRs) generated by genetic research [41]. Both incidental findings and IRRs are defined as a research finding concerning an individual participant that has potential health or reproductive significance. The difference is that incidental findings are discovered beyond the specific aims of a study, whereas IRRs are findings discovered as defined by the specific aims of the study [42]. However, in the context of GWAS, incidental findings and IRRs are not distinct. Thus, there is considerable debate surrounding the issue of whether biobanks should be responsible for reporting genetic findings. Over time there may be policies developed regarding returning a participant's research results due to pressure from the participants themselves and the public pressure [43].

In the state of California, Bill SB 1267 [44], passed, raises a primary concern over the requirement that each specimen recipient, through various steps of the research chain, must obtain authorization to use the specimens for genetic research, even if the specimen is de-identified. Civil and criminal penalties would apply in the case of violation. This action sparked an immediate reaction from the University of California, Stanford University and other California academic institutions. The bill has been amended to eliminate the need for consent for each step of the research chain and is still in committee as of August 2012.

Certification of biobanks

Standard operating procedures and quality assurance and quality control programs are implemented in the majority of biobanks. However, to insure that a biobank is consistent in its practices it has been proposed that biobanks obtain accreditation. The College of American Pathologist (CAP) [21,45] has announced a plan for biorepository accreditation beginning in 2012. This will be a 3-year peer-based accreditation program.

In order to achieve consistency in specimen management, some European biobanks are implementing a Quality Management System (QMS) and have identified the International Organization of Standardization Standard 9001 [46] as their system. The UK DNA Banking Network [47] implemented ISO9001 standards to support their biobanking research infrastructure.

The Department of Pathology and Laboratory Medicine at the University of California Los Angeles (UCLA) has a 2-year accredited neuropathology program. A component of this program is a course on biorespository science. Trainees are encouraged to participate in this course because the process of collection, processing, and storage of specimens is an essential part of a neuropathologist's practice [48].

International Society of Biological and Environmental Repositories is in the process of developing a global certification program for biorespository technical professions [49]. ISBER will collaborate with the American Society for Clinical Pathology in the administration and development of this program.

The process of accreditation requires dedication of staff and resources. In order to increase the value and quality of a biobank collection, the management team must develop SOPS, along with a quality assurance and quality control program. ISBER's, NCI's Best Practices, and Rand Corporation's documents are excellent resources for those undertaking these tasks [16,18,28,29,31–33] The American Association of Tissue Banks provides a course on tissue banking. ISBER has developed (http://www.isber.org/sat/) a self-assessment tool [50] for biorepositories to help identify areas that need improvement. ISBER has launched a Proficiency Testing Program for biorespositories to assess the accuracy of their quality control programs and to identify any problems. The four inter-laboratory testing areas are DNA quantification and purity, RNA integrity, cell viability, and tissue histology [51,52].

University of California, San Francisco AIDS Specimen Bank: 30 years of experience

In its infancy, ASB was a small laboratory with single ultra-low and liquid nitrogen freezers. Data collected on

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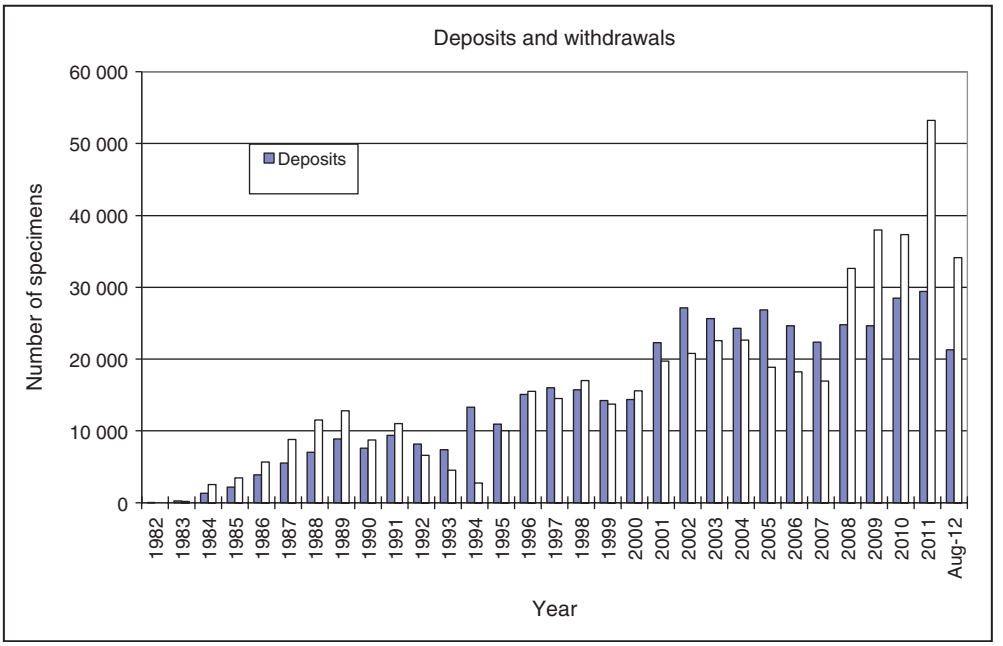

Fig. 1. UCSF AIDS Specimen Bank – deposits and withdrawals during December 1982 to August 2012.

specimens was recorded in a notebook, then a word processor, and ultimately a computerized database. In December 1982, ASB received 25 specimen deposits, now ASB has received over 463 000 specimens and has shipped over 500 000 vials or other forms of biospecimens worldwide (see Fig. 1). ASB supports the UCSF HIV research community by providing a wide variety of high quality biospecimens to investigators; offers consultation and training in specimen acquisition and handling for early-career investigators and research staff, and fosters collaboration among HIV investigators involved in multidisciplinary translational research. ASB processes and stores specimens from both HIV and non-HIV studies (see Fig. 2). The workflow processes are summarized in Figs 3 and 4.

The essentials of specimen banking at ASB: processing, storage, and providing high-quality specimens linked to clinical information remain constant. However, new and improved services and technologies that support an evolving user base, investigating new domains of science, demand the evolution of the biorepository. High impact and reproducible basic science or translational research demands the availability of stringently collected specimens that have been properly labeled, processed, and stored. ASB supports new investigators' insights into specimen-related issues through a training program. Workshops are developed for researchers interested in designing a biorepository or those that seek to understand the process of specimen collection, processing, and storage. The workshops provide instruction in the proper collection and processing crucial for downstream applications for which the specimen will be used. The goal is to reduce the number of preanalytical variables that maybe introduced during the collection, shipping, processing, and storage phases of a biospecimen.

To maintain biospecimen integrity, ASB has developed stringent quality assurance and quality control (QC) programs. The quality assurance and quality control programs are an on-going process that requires the daily attention of ASB staff. These programs are reviewed annually at staff meeting to insure all members take 'ownership' of the process. ASB participates in the Adult AIDS Clinical Trials Group (ACTG) Immunology Quality Assessment Program (IQA). Cryopreserved peripheral blood mononuclear cells (PBMCs) are shipped quarterly to the IQA to test for viability and viable cell recovery. This a rigorous national monitoring effort in which ASB has successfully participated for 8 years.

The IQA reports that ASB's viable recovery ranges from 70 to 120% and their PBMC viability is usually above 90%. ASB provides the UCSF Immunology Core laboratory with frozen PBMCs for quality control purposes. This collaboration provides another source of quality control testing of the viability of ASB PMBC preparations. To date, the Immunology Core Director reports that PBMCs are of the highest quality with a viability of more than 90% and are essential to their quality control program. The efficient operations of ASB allow other UCSF Cores and major research programs to avoid the costs and risks of maintaining separate, redundant, and perhaps lower-quality specimen repositories.

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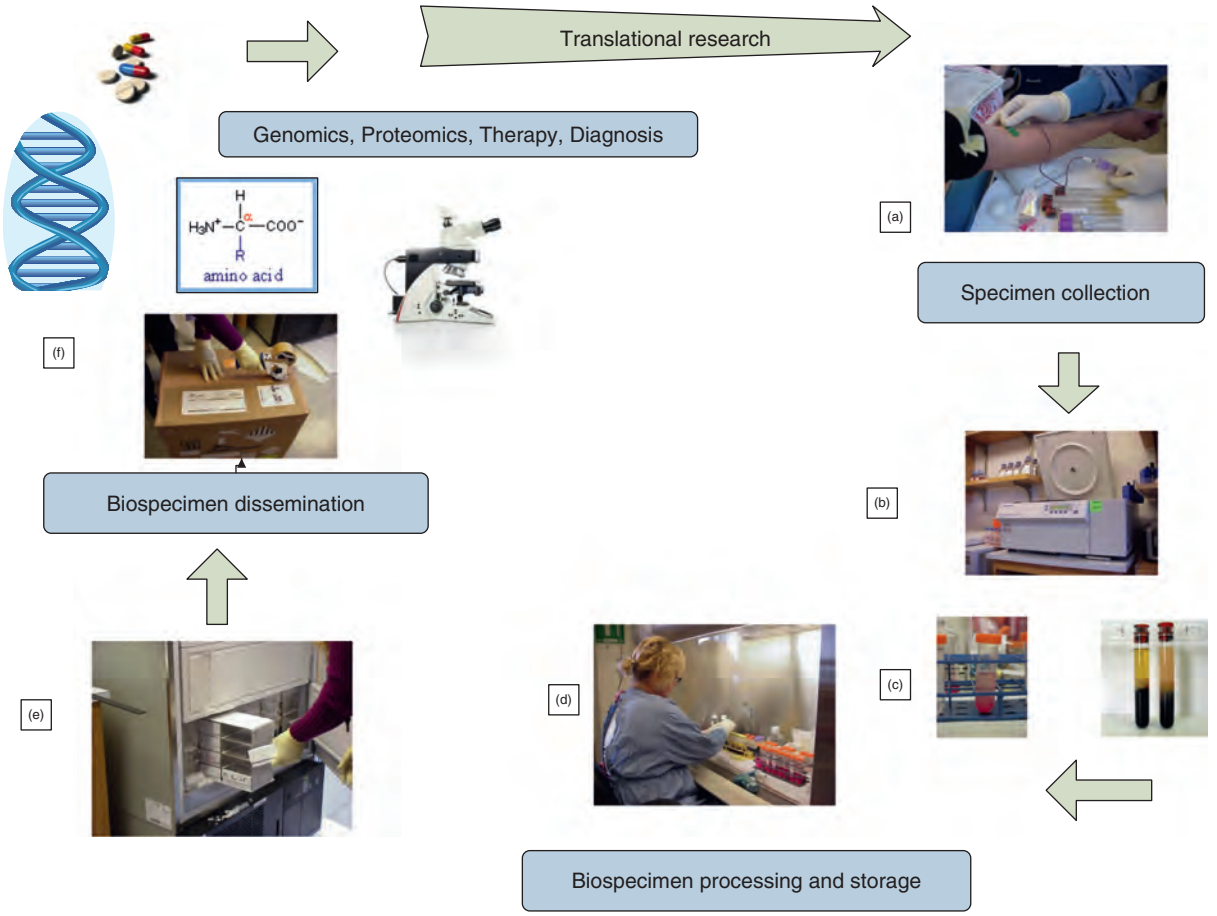

Fig. 2. Biobanking work processes. These are the steps involved in a typical biobank. (a) Specimen collection (consent has been obtained prior to collection). (b) Centrifugation of specimens for processing. (c) Serum (red top blood tubes) and 50 ml conical containing peripheral blood mononuclear cell layer sitting on ficoll after centrifugation. (d) Sub-aliquoting specimens under a biosafety laminar flow cabinet. (e) Putting specimens into long-term storage. (f) Specimens will be shipped to investigators for translational research.

AIDS Specimen Bank's policies and procedures require that all specimens processed and/or stored must have IRB approval. Personal identifiers are not entered in ASB's database, any PHI remains with the depositing investigator. ASB's specimens are assigned a unique accession number that is linked to the study identification of the participant. Recipients of ASB's processed specimens only have the bar coded accession number as the identifier. Within the UCSF research community, ASB facilitates new collaborations among investigators from academic institutions and private sector. Innovative research collaborations arise, given the availability of specimens at ASB and the caliber of UCSF investigators who contribute these specimens.

AIDS Specimen Bank's 25 ultra-low and 14 liquid nitrogen freezers are monitored by a wireless, web-enabled alarm monitoring system (Opto-Solutions Inc.), which monitors all units both on and off campus. This alarm system has improved the quality assurance program within ASB by providing accurate recordkeeping of each freezer's temperature.

Problems and successes

AIDS Specimen Bank has had its share of the problems and successes that occur in biobanking. ASB had a policy of not accepting specimens that were previously thawed and aliquoted. An investigator was not pleased with this policy and was requesting that a collaborator from an external laboratory must return previously thawed and sub-aliquoted specimens to ASB. After much discussion with the ASB Advisory Committee, it was agreed that if specimens were to be returned the external laboratory must supply sufficient documentation and SOPs before specimens were returned to ASB. This is to assure

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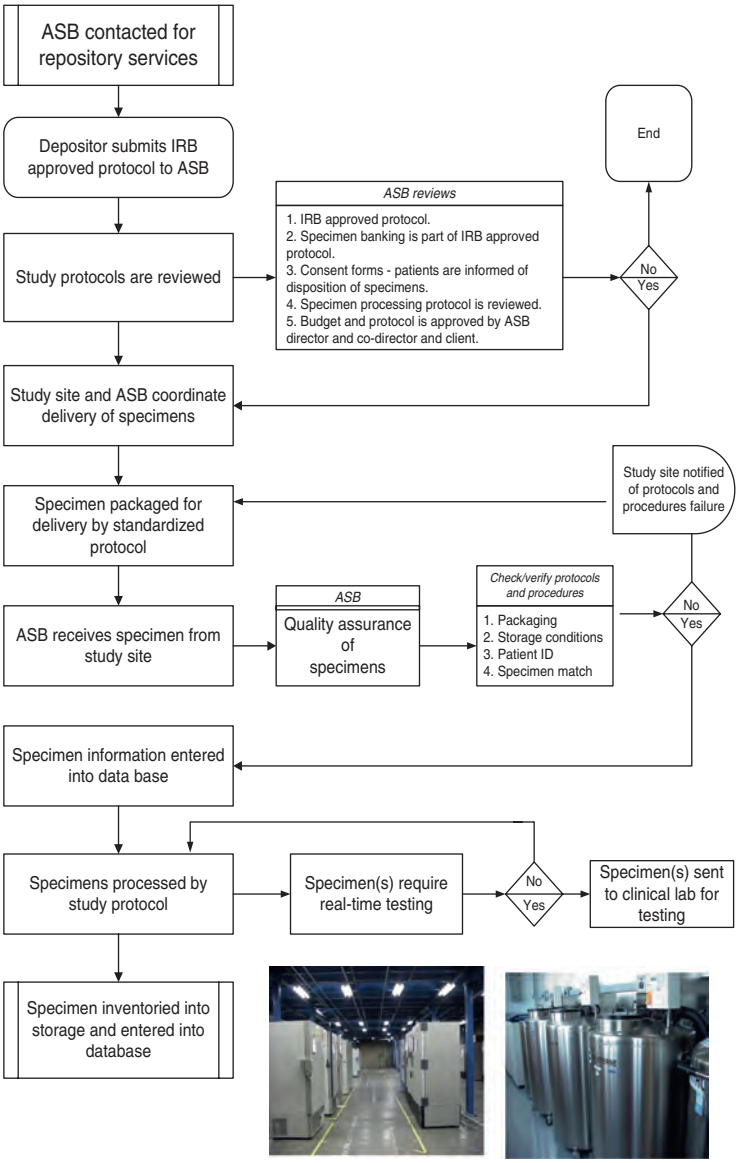

Fig. 3. UCSF AIDS Specimen Bank – specimen accessioning, processing and storage workflow.

compliance with minimum acceptable standards in specimen handling and operations. The requesting principal investigator was financially responsible for each specimen being returned to ASB. To date, ASB has received no additional request for previously thawed specimens to be returned.

Another issue that arose for ASB was when two faculty members were co-investigators on a study. They left the University and both claimed ownership of the data and specimens. The Director of ASB contacted the University's legal department for consultation. An agreement was drawn up stating that the specimens would remain with ASB and the data remained with the department in which the investigators had appointments. It was agreed that the co-investigators may contact ASB or their department for specimens or data as long as they had IRB approval and funds to support the transfer of specimens or data.

AIDS Specimen Bank's success as a biobank lies partly in the fact that since 1982, ASB has provided specimens that have been stringently collected, labeled, processed, and stored for investigators involved in high impact and reproducible basic, translational, clinical, and populations sciences. During the early days of the AIDS epidemic, ASB provided specimens that contributed to the identification of the agents that cause AIDS and Kaposi's sarcoma. ASB also collaborated with biotech firms developing rapid diagnostic kits for HIV. ASB serves as a resource for investigators new to HIV research and for the active UCSF HIV research community. ASB's success relies on its ability to process, store, and provide well characterized specimens to researchers worldwide.

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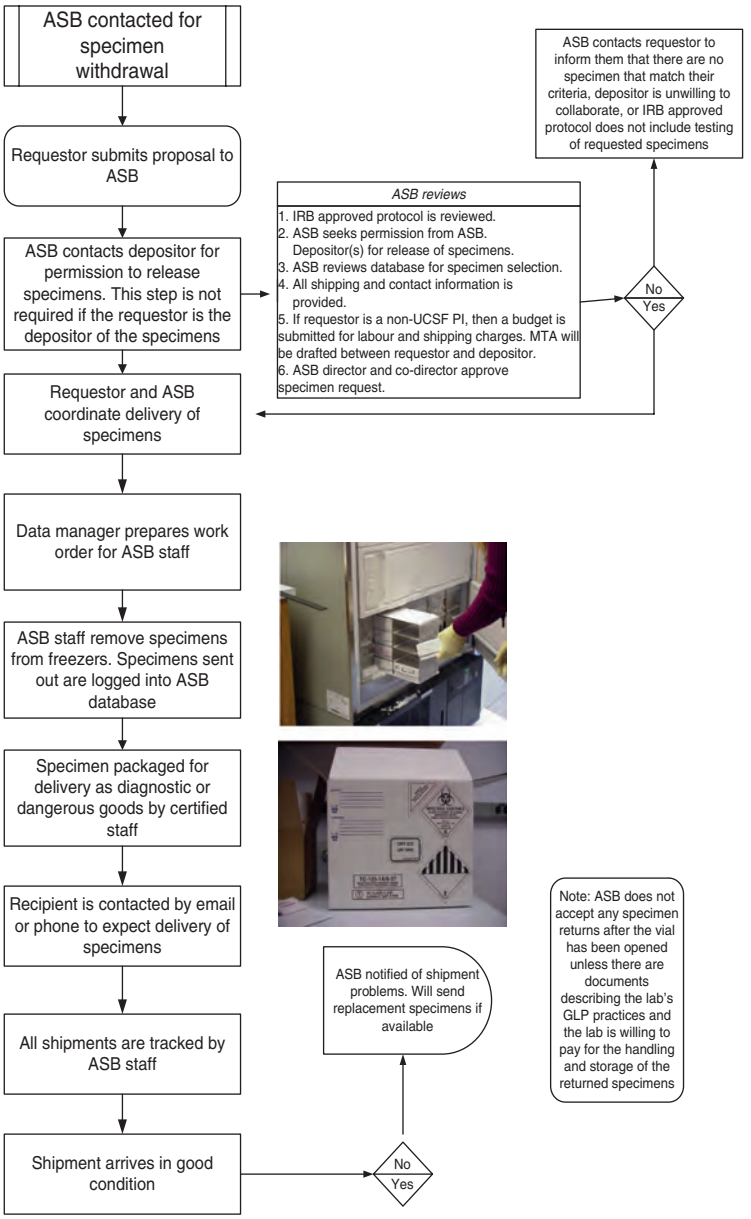

Fig. 4. UCSF AIDS Specimen Bank – specimen withdrawal/request workflow.

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Conflicts of interest

There are no conflicts of interest.

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