Ensuring Effective Utilization of Biospecimens: Design, Marketing, and Other Important Approaches

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A number of studies have shown that underutilization of biospecimens from bioresources (biobanks and biorepositories) is a significant concern. In addition, biospecimen underutilization has been identified as an ethical as well as practical concern. The utilization of biospecimens is affected by many factors, including the establishment of a scientific need for the biospecimens, the design of the bioresource, strategic planning, biospecimen quality and fitness for purpose, informed consent considerations, access policies and procedures, and marketing. This article discusses the impact of these factors on biospecimen utilization and provides suggestions for how bioresources can optimize biospecimen utilization from their collections.

Keywords: biospecimen, utilization, biobank, biorepository, marketing, ELSI issues

Introduction

BIORESOURCES (BIOBANKS AND BIOREPOSITORIES) are critical resources that can lead to major advances in basic, translational, and clinical science and in the development of personalized therapies.¹ However, their usefulness will be limited if efforts have not been made to ensure effective utilization of the biospecimens and associated data collected and stored by the bioresource. Two published surveys of the biorepository community, one in the United States^{2,3} and another worldwide survey,⁴ suggest that bioresource personnel consider biospecimen underutilization to be a major concern. It is our view, based on our personal experience and observations, that biospecimens stored in bioresources may remain underutilized for a number of reasons. These include the fact that the biospecimens may have been collected without an identified scientific need, may not be fit for purpose or of sufficient quality, and/or may have been collected with inadequate informed consent to allow secondary usage. In addition, bioresource access policies may be too complex or restrictive or researchers may be unaware the biospecimens exist. Although a few surveys have been published regarding the extent of underutilization of biospecimens from bioresources,^{2–5} additional research is needed to clarify and harmonize the metrics used to define utilization and to further quantify biospecimen underutilization from bioresources and the impact of contributing factors.

Ensuring effective biospecimen utilization is important for a number of reasons. Underutilization of biospecimens

from bioresources has been identified as an ethical as well as a practical concern.^{6,7} There is an ethical imperative to ensure that biospecimens from consented participants are used for research and that they are used appropriately, as participants who donate their biospecimens expect. In addition, bioresources are expensive to establish and maintain, and wasting scarce resources by not adequately utilizing biospecimens to support biomedical research is ethically questionable. Furthermore, effective utilization of biospecimens is a key factor in bioresource sustainability, especially as bioresources need to demonstrate use to justify continued support to sponsors and funding agencies and to obtain adequate cost recovery.^{8,9} Finally, bioresources cannot foster biomedical and scientific advances if their biospecimens are not well utilized.

A number of factors are important for ensuring effective utilization of the biospecimens collected and stored by bioresources. These include (1) market research to evaluate biospecimen demand to make sure that the biospecimens that will be collected are needed and that other sources of these biospecimens are not otherwise available, (2) proper design of the bioresource based on an identified scientific need, (3) choice of the appropriate bioresource model, (4) biospecimen quality and fitness for purpose, (5) strategic planning, (6) informed consent approaches that will maximize downstream uses, and (7) effective marketing to make sure researchers are aware of the availability of the biospecimens. Also important are access policies that provide appropriate stewardship and oversight of uses of biospecimens, but are not so onerous that researchers are discouraged

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from applying or cannot get access because the requirements are too restrictive. In addition, it is important for the bioresource to consider expanding its base of operations and to perform an ongoing evaluation of changes in science and technology and the needs of investigators to make any appropriate adjustments in the bioresource to continue to meet the needs of potential users. This article discusses each of these factors, how they relate to biospecimen utilization, and how biospecimen utilization can be optimized using various approaches.

Assessing the Need for a New Bioresource and Designing a Bioresource to Meet Biomedical and Scientific Needs

Perhaps the most important factor in ensuring effective bioresource utilization is assessing the need for a new bioresource by identifying scientific needs, determining whether a new bioresource is needed, and designing the bioresource to meet those needs. It is critical to design bioresources to meet identified scientific needs.³ Market research should be performed to determine the needs in the field and, in particular, the needs of the researchers whom the bioresource will serve. The requirements of the researchers that the bioresource is intended to serve should define what types of biospecimens are needed and the extent of their accrual, processing, and data annotation.¹⁰ Once the needs are defined, the goals of the bioresource can be identified to best meet those needs. Sometimes bioresources are established without significant evaluation of the needs of the scientific community, which has led to underutilization of biospecimens. For example, one company established arrangements with a number of academic medical institutions to collect residual biospecimens during the course of routine care. They quickly found that the types of biospecimens they were collecting were not needed by the scientific community because many were commonly available (e.g., colorectal cancer; personal communication), resulting in a change in their business model, and ultimately, the sale of their collection.¹¹

There are a number of ways to identify the scientific need for biospecimens. One approach is to consult scientific experts in the field of study to advise on current and future biomedical and scientific directions. This was one of several approaches used for the establishment of the National ALS Biorepository.¹² Another approach is to perform market research by asking researchers what types of biospecimens and associated data they need for their work and how the biospecimens need to be collected, prepared, and stored. An additional strategy that has been used for determining the scientific need for biospecimens is to examine trends of the types of biospecimens utilized in publications or the applications for biospecimens.¹³ Research portfolio online reporting tools, such as the National Institutes of Health RePORTER database,¹⁴ can also be used to analyze the types of biospecimens that are being evaluated in funded grants in certain areas, for example, in certain diseases.

As part of market research, it is important to determine what sources of biospecimens already exist, for example, from other widely available bioresources, to avoid duplication of effort. Funding agencies and other organizations maintain information on existing collections and bioresources (e.g., The NCI Specimen Resource Locator¹⁵ and

the International Society for Biological and Environmental Repositories International Repository Locator¹⁶). These types of listings should be reviewed and other bioresources examined to determine whether they can provide the needed biospecimens before new bioresources are established.

It is important to note that bioresources need to operate within the constraints and limitations of the funding provided and the requirements of bioresource funders. The long-term research need for biospecimens is not always synonymous to the immediate need that may be imposed by sponsors of the bioresource.

Choice of Bioresource Model

Another important factor in ensuring that biospecimens are effectively utilized is choosing the most appropriate model for acquiring and distributing biospecimens for the intended research need. For example, the classic biobanking model in which biospecimens and associated data are collected under standard operating procedures and protocols and then banked for future use is a frequently employed model that may be most useful for studies requiring significant clinical or follow-up data, or for large numbers of biospecimens and/or biospecimens from patients with rare diseases or conditions. In contrast, the prospective model in which biospecimens are collected and then provided in real time may be more useful for basic and developmental studies and may result in greater utilization depending upon the types of research for which the biospecimens may be needed.¹⁷ A number of other models of biobanking (e.g., the population biobanking model or models based on the use of residual clinical archives) may also be considered depending on the research needs and the goals of the bioresource. The advantages and disadvantages of these models and the types of research for which they are most useful are discussed in another article in this special issue.¹⁸

Biospecimen Quality and Fitness for Purpose

Other factors affecting biospecimen utilization are biospecimen quality and fitness for purpose. Once a scientific need has been identified and an appropriate model has been chosen for the bioresource, the biospecimens and associated data must be collected in such a way that they are suitable for the intended use; that is, they must be of sufficient quality and fit for purpose. It is important to anticipate which biospecimens might be most useful to support future research based on biomedical advances and to collect biospecimens under an extensive quality management system with vigorous quality control.¹⁹ In addition, bioresources can use various assays to assess the quality of their collections and participate in external quality assurance schemes that may help assure potential end users regarding the levels of quality of the biospecimens needed for their analyses.²⁰

In order for the biospecimens to be of optimum utility, their quality should be sufficient for the intended purpose(s), techniques, and methodologies for which they are intended. As an example, a bioresource intended to provide human biological material from which DNA can be extracted for molecular analysis would need to collect the biological material according to the best practices for collection, storage, and use of the material for molecular technologies.

It is important to note that sufficient quality for one intended methodology may not be sufficient for another. This is discussed in a companion article in this issue²¹ and in a separate article.²² Careful review of the literature is needed to determine appropriate procedures for the collection of the biospecimens based on the intended methodologies and technologies for which the biospecimens will be used to ensure fitness for purpose and optimal utilization of the bioresource biospecimens. Fitness for purpose may also apply to the data that may be associated with the biospecimens. For example, a bioresource intended to support studies of diagnostic and prognostic factors would need to collect or have access to clinical follow-up data; without these data, the biospecimens would not be fit for purpose for these types of studies.

It is important to note that the fitness for purpose of biospecimens held in a bioresource may vary over time. For example, in a classic biobank that collects biospecimens and associated clinical data over many years to obtain needed outcome data, the biospecimens may degrade over time such that they are no longer of sufficient quality and suitable for the originally intended purpose. In addition, scientific technologies and methodologies evolve over time and may have new requirements for how the biospecimens should be handled for optimal quality. Bioresources should follow scientific developments closely to ensure that the biospecimens and associated data that are being collected and stored continue to be fit for the intended purpose(s) to optimize the utilization of the biospecimens in their collections.

Strategic Planning

As noted by others, careful strategic planning is necessary to ensure optimal biospecimen utilization.^{8,9,23} A well-documented strategic plan should include a plan for identifying potential end users, and the infrastructures and services that may be required to serve them. In addition, it should include the establishment of internal stock targets for the biospecimens as well as plans for culling over time to ensure there is an appropriate balance between stocks of biospecimens and researcher demand.²⁰ As noted by others, the business plan for a bioresource should also include a robust marketing plan.²⁴ Such a plan is needed to ensure that information about the bioresource and services the bioresource can provide is widely communicated.⁹ Continual review of a bioresource strategic plan and ongoing activities is essential to make sure that the biospecimens and associated data that are being collected meet the needs of current investigators. Active review of utilization targets and continued engagement with researchers accessing the bioresource will help determine adjustments that may be needed in the services provided. This may require reallocation of resources to ensure that the collection and distribution of biospecimens are on target as well as identify adjustments that may be needed to bioresource marketing strategies.^{9,23} Bioresource marketing strategies are discussed further in a subsequent section.

Informed Consent Approaches

An appropriate informed consent process is critical for ensuring the optimal utilization of biospecimens for future research. Multiple approaches have been used for obtaining

informed consent for future use of biospecimens for research, such as study-specific consent, tiered consent, general consent for future research use of biospecimens, and more recently “dynamic consent models,” which involve an ongoing discourse and negotiation between researchers and participants.²⁵ The advantages and disadvantages of these models and their impact on downstream utilization are summarized in Table 1.

Future uses of biospecimens should be carefully considered at the time the informed consent is designed so that the scope of the consent encompasses those uses. Although different countries and institutions may have their own requirements regarding the nature and content of the consent form, a general consent for future use of biospecimens, when permissible by regulations and policies, allows significant flexibility in downstream uses. Study-specific informed consent forms can restrict downstream uses and sharing and can limit the utility of biospecimen collections. Additional consent may be required for the use of biospecimens for new uses. In addition, language that is unnecessarily specific can sometimes limit downstream uses, such as language that identifies the specific investigators who will use the biospecimens and associated data or the precise location of storage. Bioresources should discuss the informed consent content with their IRB/ethics review boards and consider the impact of the language on downstream uses to ensure optimal use of their biospecimen collections.

Marketing

Researchers are often unaware of existing bioresource services and collections; thus, it is critical to market bioresources to assure that investigators are aware of the types of biospecimens and services that can be provided.^{9,26} A variety of approaches have been mentioned in the literature regarding how to market a bioresource, such as maintaining a website, dissemination of brochures or other literature describing the bioresource, and organizing meetings or publishing articles about the bioresource’s activities and services.^{9,26} The development of individualized marketing materials that describe the products and services a bioresource can provide and the types of scientific questions they can help answer has also been suggested.²⁶ Mission-driven approaches for marketing have been utilized by the nonprofit sector and these approaches are increasingly being used in other sectors.²⁷

Mission-driven marketing focuses on the importance and value of achieving the organization’s purpose and goals and communicating them to the relevant stakeholders. Market factors are considered in this approach but the organization’s mission is the major determinant.²⁸ This type of approach may be particularly valuable for communicating the contributions of the research resulting from use of the bioresource and its broader societal benefits.

We discuss some of these marketing approaches as well as others that may be considered in more detail herein.

Appropriate marketing efforts may depend upon whether or not a bioresource will offer services only within a specific institution (closed), or will also elect to provide biospecimens to researchers outside the institution (open). Approaches will also depend upon the resources available to the bioresource. Some marketing efforts could include the following:

TABLE 1. INFORMED CONSENT MODELS AND THEIR IMPACT ON BIOSPECIMEN UTILIZATION

<i>Type of consent</i>	<i>Description</i>	<i>Advantages</i>	<i>Disadvantages</i>
Study-specific consent	A consent approach that is limited to a specific research project/study	Provides the most specific information to biospecimen donors May be the most acceptable form of consent in some study populations	Limits downstream secondary use of biospecimens for other research projects
Tiered consent	A consent approach that allows participant/donors to choose among various types of research or types of biospecimens they wish to donate	Provides greater choices to participants than general consent for future use of biospecimens Biospecimens can be used for a wider array of types of research than a study-specific consent	Choices require rigorous tracking systems to ensure that participant choices are honored Decisions must be made about whether a future use fits within the type of research category to which the participant has agreed
General consent for future use of biospecimens	A consent approach that describes the general types of research for which the biospecimens will be used	Allows maximum flexibility for a wide array of downstream future research uses and facilitates optimal biospecimen utilization	May not be acceptable in some jurisdictions or study populations
Dynamic consent	A consent approach that uses information technology to permit an ongoing discourse and negotiation between researchers and participants/donors to decide whether they wish to consent broadly to future uses or to each subsequent future research project	Provides the greatest choice to participants/donors Enables ongoing engagement of participant/donors	Requires considerable infrastructure and resources to implement (e.g., time, money, expertise) May work better for certain types of projects and study populations than others

- Consistent bioresource identification—A logo, tag line (catchphrase or slogan), and certain colors/hues should be selected and used consistently throughout all marketing efforts so that bioresources can easily be identified and remembered by potential users. For example, the Cooperative Human Tissue Network (CHTN)²⁹ utilizes a dark blue/gray scheme on its website and marketing materials.
- The design of a website—Websites are an important tool for making researchers aware of a bioresource and the services they can provide. A website should clearly describe the biospecimens, data and services offered by the bioresource, provide instructions as to how to apply, and provide contact information. The website may also discuss bioresource procedures and policies. In addition, it may be useful to include successful examples of uses of the bioresource as well as any other information (e.g., a list of publications that resulted from use of provided biospecimens) that could assist potential investigators to determine whether or not the bioresource can provide the biospecimens and data needed for their research. An analysis of existing bioresource websites has been suggested for determining best practices in bioresource marketing.³⁰
- Biospecimen/data catalogue—Creation of a data/biospecimen catalogue to make investigators aware of biospecimens that are immediately available could also be highlighted on the bioresource website. This “catalogue” may be a simple description of the types of

biospecimens and data available, or can be an online inventory of individual biospecimens in the collection, depending upon the type of bioresource, the resources available to it, privacy, confidentiality, and other issues.

- Exhibiting at functions and scientific meetings—This could include local or extramural venues (i.e., for an open bioresource), and can provide a unique opportunity for staff of the bioresource to meet in person with current and prospective researchers. If adequate funding is available, the bioresource may elect to have an exhibit produced by a commercial company. Alternatively, the bioresource could set up an inexpensive tabletop exhibit, or design and purchase a retractable banner that looks professional, but is relatively inexpensive and easy to set up and transport. Of note, although it is possible to obtain relatively inexpensive exhibits, the total cost of participating in extramural venues (e.g., rental of space and furniture, shipping of exhibit, and travel for personnel) can be quite expensive.
- Give-away items—Items that include the bioresource name, website, and phone number offer an easy way to disseminate information to potential researchers. Such items can be expensive, but they do not have to be, as many inexpensive items (e.g., pens, small rulers) are often quite popular. Since researchers who receive biospecimens from a bioresource may later forget the source from which they were received, these items (especially those that are not expendable) can serve as an effective reminder of the bioresource and are useful to give out when exhibiting.

- E-mail blasts—Periodic e-mails providing information about the bioresource can be sent to potential investigators. Of note, it may take several attempts before results are noticed, as a researcher may not respond until ready to utilize the bioresource.
 - Commercial contact management software—Various contact management software (CMS) can be used to track leads and inquiries from users and potential users. In addition, notes about conversations with potential leads can be maintained on such software, and data as to which leads resulted in clients can be tracked. Many CMS systems can allow biobank personnel who use them to create and classify leads, provide follow-up reminders, and track interactions with potential customers. Many of these functions can be automated, saving personnel resources. Some of the CMS systems can be customized, allowing bioresource personnel who use them to create their own fields, reminders, and reports, thus facilitating productivity and efficiency and a better understanding of customer stratification. User friendliness of such software should be taken into consideration when selecting a product.
 - Communication vehicles—Newsletters, seminars, departmental communications, and working with local administration to highlight the bioresource are all ways to promote the bioresource and the services it provides (both locally and extramurally).
 - Presenting data—Bioresource personnel can present information at scientific meetings, and can publish articles about bioresource issues or experiences, or biorepository science. Highlighting specific research successes using biospecimens can be helpful in emphasizing the usefulness of a bioresource.
 - Requiring acknowledgement—In addition to having a marketing impact, requiring investigators to credit the bioresource for utilizing its biospecimens in publications that result from use of biospecimens or services provided can also help the bioresource with future funding by demonstrating scientific impact. The bioresource should provide researchers with suggested wording for such acknowledgments. Tracking publications in this way is one of the most important ways that researchers can learn about a bioresource and the types of research it can support. However, in our experience, and as noted previously by others,³⁰ it is often difficult to establish the contributions of a bioresource to research published in the literature because the contribution may be referenced in a confusing manner or not referenced at all. A number of initiatives have been launched to address these problems by developing approaches to standardize the reporting and tracking of publications arising from studies of biospecimens and data obtained from bioresources (e.g., Bioresource Impact Factor and CoBRA).^{31,32}
 - Social media—The utilization of social media can serve a variety of marketing functions such as to remind followers of the bioresource, alert followers as to when bioresource personnel may be attending scientific meetings, or make followers aware of significant publications. A recent survey of the biobanking community suggests that some bioresources are already marketing their biospecimen collections using social media; this approach is likely to be used even more frequently in the future.³⁰
 - Advertising—The bioresource may elect to purchase advertising in professional journals/trade magazines; however, such advertising is typically quite expensive. The potential return on investment of such advertising should be carefully considered.
 - Personal referral—As noted previously by others,²⁶ “word of mouth” from one investigator utilizing a bioresource to another can often be one of the most effective forms of marketing. Thus, it is critical for a bioresource to try to make sure its investigators are pleased with its services so they will be willing to recommend the bioresource to their colleagues.
 - Bioresource referral—Collaborations could be developed with other bioresources for referrals. This could be helpful if the bioresources have different areas of specialization.
 - “Cold calls”—Identifying researchers who utilize biospecimens in their research, then contacting those researchers to make them aware of the bioresource can be effective, but can also be labor intensive. Examples of how to identify such researchers include review of posters at scientific meetings and having a funding agency identify grantees who utilize biospecimens.
 - Data mining—Data mining is one approach that some businesses have used to obtain information about their customers’ behaviors and buying habits, helping businesses to more effectively market their products and services.³³ However, these approaches require access to large data sets, may require specialized expertise, and may be expensive for bioresources to employ. In addition, their use may be limited by ethical considerations³⁴ and relevant privacy regulations, such as the European General Data Protection Regulation.³⁵
 - Soliciting proposals—If adequate funding is available from a funding body or sponsor, proposals may be solicited to support projects that use biospecimens from the bioresource. This might be particularly appropriate for specialized or rare collections. A recent example of this approach was the publication of a funding announcement to solicit applications for support of projects using biospecimens and associated data from the NCI-sponsored Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial.³⁶
- It may be useful to repurpose or reuse marketing content that may be developed from many of the aforementioned approaches. To save money and time, existing content can be reused to create multiple different marketing pieces from each marketing effort. Content that was previously used for one purpose and found to be particularly effective can be tailored for specific needs or end users. For example, content developed for a presentation on a bioresource could be further developed for publication, used for blog posts, etc. Older marketing content can be improved upon and/or updated.
- The advantages and disadvantages of various marketing approaches for bioresources are summarized in Table 2. All of these approaches may not be applicable or affordable for every bioresource. A bioresource should monitor the cost-effectiveness of the marketing approaches it attempts, and refine its future marketing approaches accordingly.

Access Policies and Procedures

To achieve effective biospecimen utilization, access policies and procedures must be carefully considered and

TABLE 2. MARKETING EFFORTS

<i>Type of marketing effort</i>	<i>Description</i>	<i>Advantages</i>	<i>Disadvantages</i>
Consistent bioresource identification	Logo, tag line, and colors used consistently throughout marketing efforts	Easily identifies bioresource throughout all marketing materials Establishes brand recognition	Requires personnel with time and effort to devote to design, and requires resources to implement
Website design	Website clearly describing bioresource, biospecimens and services provided, instructions on how to apply	Easy way for potential users to find out about bioresource; good way to market and include information to disseminate to a broad audience Can be easily updated to add new information	Requires resources and access to personnel experienced in website design to implement and keep updated Also must continually monitor to make sure website is appearing in searches
Biospecimen/data catalogue	List of biospecimens and data available	Makes potential or existing users aware of what is available	Requires resources to create and keep updated Constantly changing inventory could be a challenge to keep current Privacy issues must be considered
Exhibiting	A booth/exhibit created to highlight the bioresource	Allows bioresource staff to meet in person with current and prospective users and engage in a dialogue about current and future needs for biospecimens and associated data	Cost of design and creation of the exhibit, as well as costs of exhibiting (e.g., rental of space, shipping, travel), can be substantial
Give-away items	Items that include the bioresource name and contact information	Easy way to disseminate information about bioresource, may attract traffic to exhibit, serves as reminder of bioresource	Can be expensive. May attract large number of people interested only in give-away item and not in bioresource
E-mail blast	Sending e-mails that provide information about bioresource	Relatively easy to do, cost-effective, can reach large number of potential users	May require several attempts before results are seen, e-mail blasts may be ignored Must be carefully done so as not to burden and annoy recipients
Contact management software	Commercial software used to track leads and inquiries.	Allows creation, classification, and tracking of leads, and can provide many other uses to assist with productivity	Can be expensive. Requires time and effort to investigate options and select the best one for needs of bioresource Requires time and effort to effectively implement and utilize
Communication vehicles	Newsletters, seminars, departmental communication	Easily accessible communication routes that are typically low cost to utilize	Requires personnel time, effort, and resources to produce, target to the appropriate audience, and disseminate May impact only limited audience
Presenting data	Presenting information through participation in scientific meetings and/or publications	Opportunity to highlight bioresource, services provided, and specific successes	Costs associated with travel and presentation to meetings and/or for publication

(continued)

TABLE 2. (CONTINUED)

<i>Type of marketing effort</i>	<i>Description</i>	<i>Advantages</i>	<i>Disadvantages</i>
Requiring acknowledgment	Requiring users to credit, in publications, bioresource for utilization of specimens	Helps bioresource with future funding by demonstrating scientific impact; markets bioresource to those reading the publication and illustrates the ways in which the biospecimens and data from the bioresource may be used	Difficult requirement to enforce and to track; may require hiring a medical editor May not completely and/or adequately capture the contributions of a bioresource to research published in the literature because of incomplete compliance and lack of standards for citing sources of biospecimens from bioresources
Social media	Use of social media to market the bioresource	Fairly broad dissemination tool; can remind or alert followers of information regarding bioresource	Requires personnel and resources to maintain active social media presence
Advertising	Advertisement in professional journals, trade magazines	May reach large number of potential users	Can be very expensive Requires professional design of advertisement
Personal referral	One user telling another about bioresource through “word of mouth”	First-hand knowledge and recommendation can be extremely effective	Unhappy users can be detrimental to a bioresource
Bioresource referral	Having other bioresources refers users to you the bioresource	Could be a mutually beneficial arrangement among bioresources	May require some collaboration with other bioresources
Cold calls	Identifying and contacting potential researchers individually	The personalized contact can be very effective	Method is usually very labor intensive Requires careful handling not to burden and annoy researchers
Data mining	The use of data mining tools to better understand end user’s “buying habits”	Has the potential to help bioresources more effectively market their products and services.	Requires access to large sets of data to which a beginning or small bioresource might not have access Requires resources to access software to mine the data May be expensive and require experienced personnel to understand and apply the results
Soliciting proposals	Soliciting and funding proposals for the use of biospecimens	Could result in effective utilization for specialized or rare collections	Requires commitment, funding, and resources from the entity funding the proposals/sponsor

developed to ensure the biospecimens are used in ways that are scientifically and ethically sound. However, the access policies should not be so stringent and the process for receiving biospecimens should not be so difficult that investigators are discouraged from using the resource. Importantly, biospecimen utilization should be considered an important function of the bioresource. Ensuring that biospecimens are used and that their use is appropriate requires a delicate balance. Finding that balance can be difficult, especially with a scarce bioresource.

Access policies and procedures should be defined early in the process, before the bioresource is marketed and biospecimens are distributed. The application process and access requirements should be clear and transparent. It is important for the bioresource to work closely with researchers before biospecimen requests are submitted to assist them in refining their requests, to educate them on appropriate uses and limitations as to what is reasonable to request, to help them to anticipate future specimen use for their project(s), and to facilitate any regulatory or institutional approvals. Access policies and procedures should be evaluated periodically to streamline them and ensure they are user friendly. Investigator feedback may be particularly useful in helping to further refine policies and procedures. For example, one bioresource used such an approach to ask researchers who received biospecimens from the bioresource to rate aspects such as the application process, communication, turnaround time, cost and quality of samples, and type of service, as well as overall service. The results indicated overall satisfaction with the bioresource but suggested some areas of improvement, such as the need to streamline and simplify the application process.³⁷ Regular reviews of bioresource processes and policies can help ensure that they are efficient and effective and that they promote optimal biospecimen utilization.

Expanding the Base

To increase utilization, a bioresource may consider expanding its base of operations. If operated as a closed bioresource, making biospecimens available to researchers beyond the traditional base should be considered, provided that such sharing is consistent with the protocol approved by the institutional review/ethics board, the informed consent under which the biospecimens were collected, other regulatory or policy requirements, and the goals of the sponsors and funding agencies of the bioresource. An example includes allowing investigators located at for-profit companies to have access to biospecimens, since many significant research developments are made by commercial companies. Specifically, most drug developments require the primary involvement of a for-profit company. Other examples include making biospecimens accessible to investigators located at other institutions, and even providing services to investigators in other countries. It is important to protect the core mission and goals of the bioresource, but if excess biospecimens are available, broadening of the base and allowing biospecimens to be utilized by researchers outside the traditional base is an option that may be explored. As an example, the CHTN made a conscious decision early on to provide biospecimens to for-profit institutions in addition to academic institutions. Later, to increase biospecimen utilization, the CHTN made the decision to expand distribution

to researchers outside of North America as long as it did not adversely impact the availability of samples to its "core" users in North America.

Continuing Evaluation of Scientific Need

Once the need for a new bioresource has been identified and the bioresource established, it is important for the bioresource to continue to monitor changes in science and technology and potential users' needs. As mentioned previously, sometimes changes in the science may necessitate changes in the types and/or ways biospecimens for the bioresource are collected. For example, in the 1990s, NCI established a serum collection to support monoclonal antibody development. However, as new molecular approaches were developed, the field moved away from monoclonal antibody development and investigators' needs changed from serum biospecimens to frozen material more appropriate for molecular approaches (author's personal experience). Thus, bioresources will need to continue to evaluate changes in the science and technological approaches and specimen demand to determine whether adjustments may be needed in the types of biospecimens and the ways in which they are collected, processed, and stored.

Ways of assessing specimen demand may include querying current and potential users, for example, by performing surveys or querying current users when they receive their biospecimens or periodically during the year as to what future needs might be. For example, the CHTN uses the following methods for determining whether trends or problems can be identified and allocates resources to ensure that collection and distribution of biospecimens continue to meet investigator needs: (1) investigators are asked to provide immediate electronic feedback on each shipment to identify problems with the shipment that can be immediately addressed, (2) investigators are queried annually regarding their research focus (e.g., basic, discovery, translational, and pharmacogenomics), research modalities (e.g., RNA, DNA, or protein isolation; immunohistochemistry; RT/PCR), and research outcomes (e.g., were CHTN provided biospecimens used in externally funded research, publications, or commercial products?) The annual survey asks whether adequate demographic and clinical data are being provided by the CHTN, and if not, what additional data are needed. It also asks about satisfaction with the CHTN, specifically regarding timeliness of receipt and specimen quality. The survey also asks investigators whether they are aware of other specific services offered by the CHTN, which they may not be utilizing. (3) When exhibiting at annual meetings, CHTN personnel document biospecimen requests and preparations that are mentioned by investigators in an attempt to identify trends. The results of these surveys, as well as CHTN annual distribution metrics, are carefully reviewed to identify trends and/or issues that can be identified, allowing the CHTN to allocate necessary resources to address these trends/issues.

Approaches to evaluate changes in biospecimen demand can aid in optimizing biospecimen utilization by helping to ensure that the biospecimens are fit for purpose based on current science and technological approaches. As an example, one commercial bioresource was able to modify its collection strategies to meet an increased demand for tissue

samples with matching blood for use in the development of liquid biopsy diagnostics for oncology.²⁶

In summary, effective utilization of biospecimens is critical to the success of bioresources and to their impact on science. Biospecimen utilization can be optimized for bioresources by identification of the scientific needs the bioresource is intended to fill, choice of the most appropriate biobanking model and biospecimen and data collection procedures to best meet those needs, aggressive marketing, implementation of access policies and procedures that facilitate biospecimen use, and regular evaluation of the state of the science and the needs of potential users so that the bioresource continues to meet the needs of the scientific community.

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