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Stewardship Practices of U.S. Biobanks

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Abstract

Biobanks require new governance models that address their ethical and regulatory challenges. One model relies on stewardship of specimens throughout their life course. Here, we discuss findings from our survey of 456 U.S. biobank managers that addressed whether and how biobanks steward their specimens. The findings reveal that most bio-banks do not create ongoing relationships with contributors but do practice stewardship over storing and sharing of specimens. Biobanks now need guidance to fully articulate stewardship practices that ensure respect for contributors while facilitating research.

The use of biobanks to collect and store human specimens for biomedical research has raised questions about protections for specimen contributors. The regulatory framework for informed consent for research requires an explicit description of the reasons for specimen and data collection, the potential risks and benef ts associated with their use, the specif cation of future users and uses, and a stated duration of research activity (*1*). These expectations are bending under the weight of a paradigm shif brought about by researchers who turn to biobanks, rather than to individuals, to obtain specimens (*2*, *3*). Biobanks often collect specimens for unspecified, unpredictable uses, and their relationships with specimen contributors are increasingly hard to define because biobanks acquire specimens both directly and from other collectors. Many consent forms now incorporate agreement to broad, unrestricted use with no specified end date, a trend encouraged by funding agencies, researchers, and regulators to facilitate the most effficient and effective use of available

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specimens and data (*4*, *5*). At the same time, the rise of large-scale genomic technology and new f ndings about the inherent identif ability of specimens have introduced challenging questions about responsibilities researchers or institutions have to those who contribute human specimens (*6*). Professional societies have begun to address these responsibilities, but guidance is far from settled (*7*–*9*).

Emerging models of biobank governance, such as stewardship, attempt to address these complexities (*10*, *11*). In proposing that biobanks are stewards of the resources they maintain, the stewardship model identifies biobanks' obligations to contributors throughout the "life" of the specimen, even as the strength and duration of their relationships with the original contributors change (*10*). The stewardship role may extend to identified communities when the sources of specimens are linked by geography, disease condition, or another feature. Biobanks might offer forms of community engagement—such as those designed to enhance understanding of the research or improve experimental design; invite joint governance (*12*, *13*); or return individual-level or aggregate research results to contributors (*3*, *14*, *15*). The stewardship model also requires biobanks, in their relationships with researchers, to ensure that specimens and data are used for agreed-upon purposes set forth in the terms of consent or the biobank mission (*11*). These governance practices thus define broader responsibilities and more complex research relationships for biobanks than have been typical in the past.

Another key attribute of the stewardship model is proper internal care and oversight of the stored specimens. Oversight agencies and professional societies promote their own best practice standards (*16*, *17*) that also include adherence to federal regulatory protections for contributors and data-sharing policies when applicable. These standards do not invoke stewardship terminology, but they are consonant with features of the model.

Although the stewardship model is viewed favorably as a frame for addressing ethical issues raised by the complexities of research that relies on banked specimens, there is a dearth of empirical information on how stewardship is implemented in practice. Data from our 2012 survey provide the opportunity to examine three sets of biobank practices relevant to this model: practices related to contributors, practices within the biobank, and practices related to researchers.

PRACTICES CONCERNING CONTRIBUTORS

We examined biobank practices that address whether and how contributors are informed that their specimens will be stored, and whether contributors are financially compensated for their specimens, given individual or aggregate results, or sent a newsletter.

Informing donors about storage and use

To determine whether and how contributors are informed that their specimens will be stored for future research, biobank managers were first asked whether specimen contributors are typically informed that their specimens will be stored (Fig. 1A); 96% responded "yes"; 3% responded that contributors are not typically informed; 2% were "not sure." The 412 respondents who said "yes" or "not sure" were then asked whether the biobank ever accepts

specimens from contributors who are not informed that their specimens will be stored, and 10% (41 respondents) said "yes." We did not ask whether the biobank itself informed contributors about storage, because contributors may be informed by an individual or organization not related to the biobank, such as a researcher or a hospital that collected the biological specimens.

Of the 404 biobank respondents who said that contributors are typically informed about storage of their specimens, 79% reported that the approach typically used is an opt-in method [defined as "contributors (or their surrogates) are asked for permission to store their specimens"]; 12% reported that it is typically an opt-out method ["contributors (or their surrogates) are notified that their specimens will be stored unless they refuse"]; and 9% reported that it is typically some "other" method. Among the 314 biobanks typically using an opt-in method, 76% report use of global or broad consent for future research uses, 16% report a limited consent for certain kinds of research uses, 5% report uses of both types, and 2% wrote in a response that was later coded as a "tiered" approach, meaning that contributors are given an option in the consent form to allow their specimens to be used for broad or limited purposes. Of the 35 biobank respondents who reported that they used "other" methods, 13 wrote that they use both opt-in and opt-out consents, while the remaining 22 declined to answer or described other situations that could not be classified as either opt-in or opt-out.

Return of results and f nancial com-pensation

We also asked whether a bio-bank had access to identifying information for any of its specimen contributors—information that would be needed in order to return results directly to contributors; 72% responded "yes," 23% "no." (Fig. 1B). For the 327 biobanks in our survey with access to identifying information, we asked whether the biobank ever offers specimen contributors individual results from research that uses their specimens; 19% said "yes," 81% said "no." When asked if the biobank *ever* offers aggregate research results to contributors 38% said "yes," 62% said "no." Cross-tabulation shows that biobanks that offer individual results are also more likely to offer aggregate results to contributors. Of those that offer individual results, 56% also offer aggregate results; of those that do not offer individual results, only 33% offer aggregate results (56 versus 33%; chi-square, $P < 0.01$). When asked whether the biobank ever provides f nancial compensation to specimen contributors, 18% indicated that they do, while 82% do not.

We hypothesized that returning results (either individual or aggregate) directly to contributors might be viewed by a biobank as a form of compensation, and thus less common if a biobank provides f nancial compensation to contributors. However, we found no relationship between "ever offering f nancial compensation" and "ever returning individual results." In contrast, we found a positive association between "ever providing financial compensation" and "ever providing aggregate results" (64 versus 37%; chi-square, $P < 0.01$). Among the bio-banks that ever pay contributors, 64% offer aggregate results, while among those that do not pay, only 37% offer aggregate results.

Sending a newsletter

When asked whether the biobank had sent a newsletter to specimen contributors in the past two years, 20% reported that they had done so. Among biobanks that have sent a newsletter within the past two years, 28% offer individual research results; of those that have not sent newsletters, only 14% do so (28 versus 14%; chi-square, $P < 0.05$). Biobanks that have sent newsletters are also more likely to offer aggregate research results than those that have not (78 versus 28%; chi-square $P < 0.001$).

Sets of contributor practices

Important elements of a biobank's relationship with its contributors can be drawn from both bioethics literature and human subjects regulations. In order to explore relationships that might be obscured by looking at each contributor practice independently, we explored four of the practices described above in combination: providing financial compensation, sending a newsletter, and returning individual and aggregate results. In this way, we could distinguish biobanks that take a minimalist approach, engaging in few or none of these practices, from others that take a maximalist approach by using most or all of these practices. Likewise, biobanks might regard these practices as substitutes for one another—for example, giving aggregate results or individual results, but not both.

Our analysis was, by necessity, limited to those biobanks that could maintain direct relationships with contributors. Thus, we excluded biobanks that do not keep identifying information, that only collect specimens from secondary sources (not from individuals directly), and that store only postmortem specimens. After excluding these, 224 biobanks remained. Thus, the first result of our analysis is that only about half (51%) of our surveyed biobanks are in a position to create and sustain a relationship with contributors over time. We analyzed all possible combinations of the four contributor practices among the 224 biobanks (table S1). The largest number of these biobanks, 100 (45%), reported using none of the four contributor practices (row 16). Fifty-five biobanks (25%) reported using only one of the four practices (rows 8, 12, 14, and 15); of these, the most common approach was to give aggregate results only ($n = 32$, row 14). Forty-five biobanks (20%) reported using two practices (rows 4, 6, 7, 10, 11, and 13); and 19 (8%) reported using 3 practices (rows 2, 5, and 9). Only five bio-banks (2%) report using all four contributor practices (row 1).

Of biobanks that ever pay contributors, 77% also engage in at least one other relationship-building practice. Among bio-banks that do not ever pay, 47% also provide at least one other service (77 versus 47%; chi-square, $P < 0.01$). Thus, as we found in our bivariate analyses, if a biobank ever pays contributors, it is more, not less, likely to ever provide individual or aggregate results or have sent a newsletter in the past two years.

PRACTICES WITHIN THE BIOBANK

Practices that entail stewardship of the specimens within the biobank are described in the technical literature as best practices (*18*), but such stewardship is rarely discussed in the bioethics literature. Although steward-ship within the biobank was not a main focus of our survey, we have some measures that address it. Ninety-four percent of bio-bank respondents reported that their bio-bank has standard operating procedures for processing specimens.

Eighty-five percent reported having a computerized laboratory information management system (LIMS), which we defined as a computer-based inventory system that tracks the location and status of every specimen in the biobank. To provide oversight for proper research uses of the stored specimens, 90% of biobanks require IRB approval from researchers requesting specimen use; 26% have a community advisory board (not defined for our respondents); and 81% reported having other oversight boards, such as a scientific review committee or internal advisory board. Finally, we examined two practices that have been recommended in the best practice literature (*16*, *17*): a business plan and a plan for specimens if the bank closes. Just 34% of biobanks have a formal business plan; 26% have a written plan for specimens upon termination of the biobank (*19*).

PRACTICES CONCERNING RESEARCHERS

Next, we examined how the biobank's role as steward may be reflected in the practices that guide interactions with researchers using its specimens. To begin, we asked respondents the number of requests the biobank typically receives per year for specimens or associated data. Most biobanks (70%) receive between 1 and 50 requests per year, distributed fairly evenly across the categories of 1 to 5, 6 to 15, and 16 to 50 requests; the most common response was 1 to 5 (27%). The remaining biobanks receive between 51 to 100 (12%), 101 to 500 (9%), 501 to 1000 (2%), and over 1000 requests (3%). The majority of respondents (77%) indicated that researchers typically receive both specimens and data; 20% reported that they typically receive specimens only, and 3% said researchers typically receive only data.

Procedures for acquiring specimens

We examined procedures for acquiring specimens in three ways: asking whether the biobank (i) has application forms for specimen and/or data use; (ii) charges researchers for specimens; and/or (iii) has standardized material transfer agreements (MTAs). Eighty-two percent of biobanks have application forms; 41% typically charge researchers for specimens (beyond just shipping or handling charges); and 78% have standardized MTAs. Table S2 shows the relationship between each of these three measures and the average reported number of requests for specimens each year. For each measure, we found a monotonic trend: The larger the number of requests, the more likely it was that biobanks have application forms, (chi-square, $P < 0.05$), typically charge for specimens (chi-square, $P < 0$ 0.01), and have standardized MTAs (chi-square, $P < 0.05$). For application forms, values ranged from a low of 61% to a high of 89%. The percent of biobanks that charge for specimens ranged from 0 to 52%. Among the biobanks with the lowest number of requests per year, 67% had MTAs, rising to 86% for biobanks receiving 16 to 50 requests per year, and then a slight decrease to 82% among the banks with more than 50 requests per year. Finally, we explored whether there is any relationship between financial practices for contributors and for researchers, but found no relationship between ever offering financial compensation to contributors and typically charging researchers for specimens.

Limiting researcher access

In response to themes raised in the bioethics literature about limited versus broad access, we measured, in two ways, whether biobanks restrict researcher access to their specimens and

data. First, we asked biobank respondents whether they approve all, some, or none of the requests they receive. Forty-one percent approve all, 58% approve some, and 2 biobanks (<1%) said they approve none. We followed up with an open-ended question that asked under what circumstances requests for specimens or associated data are not approved (Table 1). Respondents offered one or several reasons, the most common of which were scientific merit of the proposed research (57%) and lack of specimen availability (43%). The latter includes statements that explicitly reference balancing availability against the merit of the proposed use. Second, we asked whether biobanks give certain researchers priority access to their specimens. Forty-six percent of biobank respondents reported that they do. We did not define or ask respondents to define "priority access." Instead, on the basis of responses to an open-ended question in our pilot study, we provided a list of possible factors and asked biobank respondents to indicate which ones were considered in determining a researcher's priority level. The factors most frequently cited for determining priority access were scientific merit of the proposed study (66%) and feasibility of the study (56%) (Table 2).

In addition to limiting who can use specimens or data from its collection, a biobank might limit the nature of the specimens or data provided to researchers. Thus, we asked whether biobanks ever provide identifying information about contributors to researchers who obtain specimens or data. Among the 77% of biobanks with access to identifying information about their contributors, only 18% ($n = 56$) report ever providing identifying information to researchers who obtain their specimens or data. When asked in an open-ended question to describe the circumstances under which identifiers are provided, 59% said when approved by an IRB, 20% said when contributors consented to release, and 21% listed other reasons specific to their situation.

Biobank reach-through

To explore biobanks' role as stewards for the life of specimens, we asked about the degree to which they maintain or relinquish control of what happens to the specimens or data after they leave the biobank (so-called reach-through). A third (33%) of biobanks require researchers to return remaining specimens to the biobank at the conclusion of the research project; 21% require that remaining specimens be destroyed. The remaining bio-banks (43%) place no requirements on disposition of the specimens (Fig. 2). Biobanks that require researchers to pay for specimens (beyond shipping and handling costs) are less likely to require that researchers return the specimens (26 versus 38%; chi-square, $P < 0.05$) or destroy them (24 versus 40%; chi-square, $P < 0.01$). Another method of reach-through is not linked to the physical specimens, but to the results generated. We found that 54% of biobanks require the researcher using its specimens to share aggregate results of the research with the bio-bank. Biobanks that require researchers to pay for specimens are less likely to require researchers to share aggregate results with the biobank (45 versus 60%; chi-square, $P < 0.01$). Thus, these bivariate analyses seem to show that when biobanks require researchers to pay for specimens, they exert less reach-through control over specimens or results generated.

Sets of researcher practices

As with contributor practices, we examined researcher practices in combination in order to identify patterns that might be obscured by viewing each practice independently. We included measures that might be related to stewardship of the specimens as they are released to and used by researchers: requiring payment for specimens; limiting researcher access by denying certain requests or only letting researchers who contribute specimens to the biobank use its specimens; requiring return or destruction of remaining specimens; and requiring sharing of aggregate research results with the biobank. We did not include application forms or standardized MTAs in the matrix because they are so commonly used among biobanks (82 and 78%, respectively). Our analysis excludes the few biobanks that, on average, receive zero requests per year for specimens and those that typically get requests for data only. Table S3 presents a matrix of the remaining 370 biobanks as they fall into sets of researcher practices. Only 6% (n = 24) of biobanks report no restrictions for researchers (row 16). Thus, the majority of biobanks restrict researchers' use of specimens, from as few as one restriction to as many as all four of the practices we examined. The most common set of practices, representing 17% (n = 64) of biobanks (row 9), is exhibited by biobanks that do not require payment but do limit access, require return or destruction of specimens, and require researchers to share aggregate results with the biobank. In fact, biobanks that do not require payment are more likely to require all three restrictions than are those that do require payment (30 versus 20%; chi-square, $P < 0.05$). The remaining 83% of biobanks are distributed fairly equally across the other possible sets of practices. In contrast to the matrix for contributor-oriented practices, table S3 demonstrates a much more even distribution of biobanks across the various types of practices concerning researchers.

ADDRESSING CHALLENGES

Within the context of rapidly expanding genomic and bioinformatic capacities and the rise of "next-generation biorepository research" (*10*), challenges remain in obtaining consent, protecting participant privacy, and maintaining public trust (*20*). One response to these challenges is greater emphasis on the stewardship model of governance. Stew-ardship itself, rooted in religious ethics, offers a commitment to care for and preserve that which we value (*21*). In biobanking, the model provides a powerful ethical framework on which to augment our current reliance on and specificity of informed-consent protocols to guide decision-making and preserve public trust (*13*, *22*). The model can also address the ethical quandary that emerges from the need to balance the rights of specimen contributors with scientists' quest for broad open access to data derived from human tissue (*11*).

Several scholars emphasize the importance of establishing governance models when addressing the various challenges of biobanking, and present models consonant with stewardship (*23*). For example, O'Doherty and colleagues offer a conceptual model of adaptive governance, which holds management accountable for participant interests through specific governance bodies, existing mechanisms (such as Institutional Review Boards and scientific oversight committees), and communication channels (*13*). The "honest broker" model, currently in use at a number of U.S. institutions, ensures access to clinical specimens for research while protecting contributor identities (*24*, *25*). Others focus on the protection

inherent in responsible researcher actions. For example, in an international study of ethical norms and rules governing biobanking, Capron and colleagues found that investigators and policy-makers generally regard MTAs as an “effective and appropriate vehicle for ensuring responsible management of the samples and data entrusted to genetic repositories” (*26*). Reflecting the values of nonmaleficence and f delity, respondents interviewed for the Capron study said that such restrictions “would prevent abuses (material ‘falling into wrong hands’), would protect participants’ autonomy (against secondary uses not authorized in the original informed consent document), and would honor participants’ trust in the repository” (*26*).

Although recent biobank best practices guidance documents do not specifically discuss stewardship as a model of governance, they do address standards for trustworthy acquisition, storage, management, and transfer of specimens and related data (*16*, *17*). In addition, the College of American Pathologists (CAP) created a Biorepository Accreditation Program (BAP) in 2012. The BAP and best practices documents provide guidance for technical procedures, effective organizational features, and practices regarding responsible relationships with specimen contributors and researchers (*18*). However, implementing these various forms of guidance recommendations is voluntary, and there is no required registration of biobanks that might facilitate adoption of certain standards. Thus, there are almost no data on the extent to which biobanks are following these recommendations. Our study provides such empirical data and also articulates various dimensions of steward-ship to demonstrate how the model might be applied to address ethical tensions that arise in storage and use across the life span of human specimens for biomedical research. We found that, among biobanks that are able to engage with contributors because they retain identifying information, most take a minimalist approach, with very few biobanks creating such relationships.

If we include practices that span the life of the specimen—that is, how biobanks care for specimens even when no relationships with contributors persist—our conclusions are quite different. Biobanks protect the interests of their contributors with the use of internal practices and in their dealings with researchers, and demonstrate considerable stewardship of the specimens, albeit with variability on some measures. Our assessment of internal practices reveals a high level of standardization of processing, tracking procedures, and oversight of proper research use. Less common are the practices more recently highlighted in the literature regarding biobank sustainability, such as business or termination plans, where we find a minority of biobanks reporting that they have taken such steps (*19*). With regard to stewardship during and after specimen transfer, our results show that most bio-banks impose restrictions on researchers. Our matrix analysis of 370 biobanks demonstrates that 72% impose at least two of the four restrictions measured, and that most biobanks fall between a minimalist and maximalist approach, with no dominant pattern of researcher practices.

This exploration of stewardship practices in a national survey of biobanks is not without limitations. Future surveys should include additional measures of how specimens are cared for within the biobank. In addition, while we report the type of consent approach used, we do not know which consent approach offers more protections to contributors and their

interests, an important topic to be pursued (*27*–*29*). Likewise, we report whether biobanks require researchers to pay for specimens beyond shipping and handling fees, but we do not know whether these are intended for cost recovery or profit. Lastly, given the great heterogeneity in biobanks' organizational features (*30*), there are a number of contextual factors related to their mission, governance structure, and funding sources that may limit the appropriateness or their ability to adopt particular stewardship practices.

In viewing biobank practices, did we glimpse stewardship in action? We think so. However, what is now needed is a full articulation of the range of best practices for bio-banks that address the ethics of stewardship and research that examines whether and how a fully articulated stewardship model can meet the fundamental challenge inherent in biobanking: ensuring respect for the individuals who contribute specimens while facilitating research conducted for the public's benefit.

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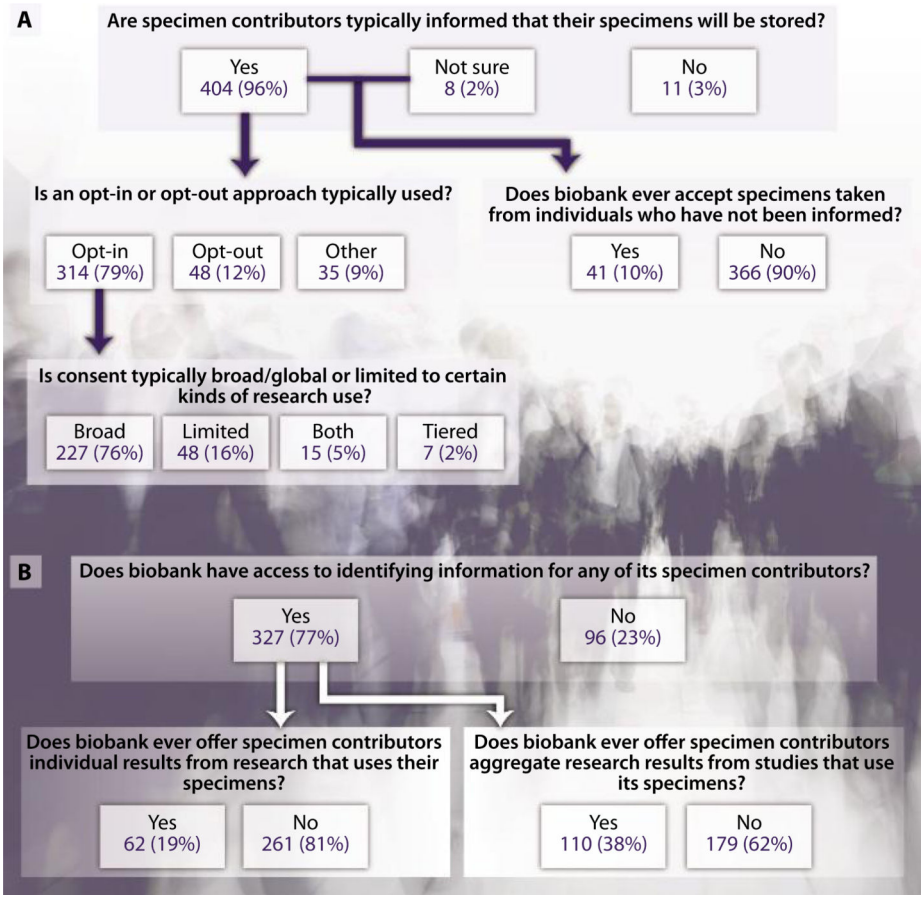

Fig. 1. Practices for contributors

(**A**) Questions and skip patterns used to determine whether and how contributors are informed that their specimens will be stored for future research. (**B**) Questions and skip patterns regarding return of results to contributors.

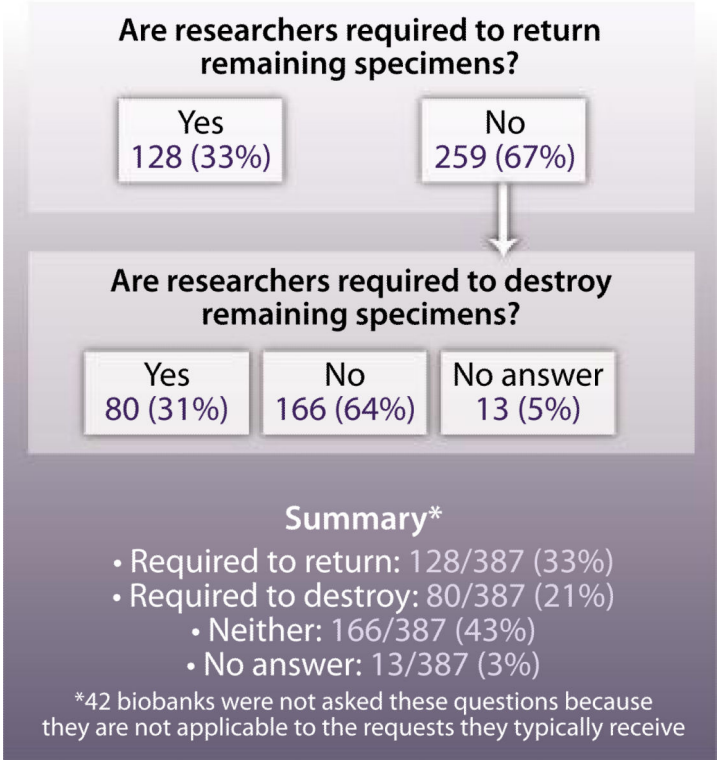

Fig. 2. Biobank reach-through

Questions and skip patterns regarding disposition of remaining specimens.

Table 1

Reasons biobank does not approve some requests.

Reason	*n*	%
Scientific merit of proposed study	123	57
Lack of specimen availability	92	43
Lack of IRB approval	45	21
Lack of other needed approvals	26	12
Research aims do not address biobank mission	19	9
Funding	17	8
Researcher credentials	15	7
Researcher not affiliated with biobank	13	6
Ethical concerns about proposed research	8	4
Other reason	10	5
Total	**216**	

Table 2

Basis for giving priority access to some researchers.

Reason	*n*	%
Scientific merit of proposed study	124	66
Feasibility of proposed study	105	56
Researcher affiliated with biobank	85	45
Research aims address mission of biobank	83	44
Researcher contributed specimens to biobank	79	42
Track record of principal investigator/team	68	36
Other reason	48	26
Total	**187**	