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"Forward-Thinking" in U.S. Biobanking

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Aims: Do biobanks enact policies and plans that allow them to anticipate and respond to potential challenges? If a biobank has one such policy or plan, is it likely to have more? Using survey data from 456 U.S. biobanks, we assess four possible indicators of such ''forward-thinking.''
Methods: We present response frequencies and cross-tabulations regarding policies for return of results and ownership of specimens, and for having a formal business plan and a plan for what happens to specimens if the biobank closes. We analyze the relationships among these indicators, using chi-square for tests of statistical significance.
Results: *Policies*—Sixty-two percent of biobanks have a policy about returning individual research results; 70% have a policy designating ownership of specimens and/or technology. Having these two policies is significantly related ($p < 0.001$). *Plans*—34% of biobanks have a formal business plan; 26% have a written plan for what will happen to the specimens if the biobank closes. Having these two plans is significantly related ($p < 0.001$). *Relationships among indicators*—only 7% of biobanks are forward-thinking across all four indicators; 12% are forward-thinking across none.
Discussion: The two policies we examined tend to occur together, as do the two plans. These policies and plans seem to tap different aspects of accountability and responsiveness. Specifically, the policies reflect issues most commonly raised in the ethical and legal literature on biobanking, while the plans are indicators of sustainability, a separate area of concern in biobanking.

Keywords: biobanks, policy, return of results, ownership, termination plan, business plan

Introduction

Biobanks are extremely heterogeneous institutions (Gibbons, 2009; Henderson *et al.*, 2013a). They vary in multiple ways, including size, purpose, types of specimens collected, affiliations with larger organizations, and sources of funding (Henderson *et al.*, 2013a). While biobanks have been in existence for decades, only recently has there been a ''boom'' in the industry (Tupasela and Stephens, 2013), generating increased interest in the ethical, legal, and social issues (ELSI) associated with biobanks, as well as their long-term sustainability. The ELSI literature on biobanking has focused on issues such as informed consent, data sharing, privacy, identifiability, public trust, and approaches to governance (e.g., Haga and Beskow, 2008; Hansson, 2009).

The biobanking industry has been described as ''highly dynamic'' (O'Doherty *et al.*, 2011) and ''precarious'' (Stephens and Dimond, 2015a). This, coupled with the tremendous growth of the industry, has necessitated that responsible biobanks reflect upon and address the implications of relevant challenges, including potential identifiability of specimen donors, government requirements for data sharing, and other developments in technology, regulation, and funding. The literature on biobanking has suggested that biobanks continuously evaluate how they are meeting their goals, anticipating and planning for challenges rather than simply responding to problems when they arise (Laurie *et al.*, 2011; O'Doherty *et al.*, 2011).

The need for biobank policies and plans to facilitate such analysis and foresight is frequently addressed in the ELSI literature (e.g., O'Doherty *et al.*, 2011; Laurie *et al.*, 2012; Stephens and Dimond, 2015b) and the literature on sustainability (e.g., Albert *et al.*, 2014; Simeon-Dubach and Henderson, 2014). In this article, we use data from our U.S. Biobank Survey to examine whether biobanks have policies

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and plans that allow them to anticipate and be responsive to potential challenges. Specifically, we look at ways biobanks deliberately address potential challenges, and we call these indicators of ''forward-thinking'' biobanks.

We use the following as indicators of forward-thinking biobanks: having a policy on ownership of specimens or rights to technologies developed from research uses of the specimens, having a policy on return of individual results derived from use of specimens, having a formal business plan, and having a plan for termination. Each feature is discussed in the Background section.

Background

Elsewhere, we have reported on biobank practices, detailing how biobanks steward specimens from collection through storage and use by researchers (Henderson *et al.*, 2013b). In this article, we turn to biobank policies and formal plans, arguing that they represent ways that biobanks anticipate and address potential future challenges, or exhibit forward-thinking. Furthermore, we explore whether forward-thinking in one such policy or plan is associated with forward-thinking in others.

Policies on return of individual research results and on designation of ownership rights have long been foci of debate among ELSI scholars (e.g., Dressler, 2007; Rao, 2007; de Faria, 2009; Wolf *et al.*, 2012; Jarvik *et al.*, 2014). Biobank best practice guidelines acknowledge the need for biobanks to address them, yet no specific strategies are described (NCI, 2011; ISBER, 2012). In contrast, creating a business plan and a plan for termination are both strongly recommended within practice guidelines (OECD, 2009; NCI, 2011; ISBER, 2012) and are familiar generally in the world of business, but are largely ignored by ELSI scholars (Cadigan *et al.*, 2013).

Return of individual results policy.

With few exceptions (Johnson *et al.*, 2012), little is known about biobanks' policies regarding returning individual research results [elsewhere we describe biobanks' reported *practices* regarding the return of research results (Henderson *et al.*, 2013b)]. The question of whether or not biobanks have a responsibility to return individual research results to participants is deliberated by those interested in the ethical and legal concerns regarding biobanking (Wolf *et al.*, 2012). The International Society for Biological and Environmental Repositories (ISBER) acknowledges that return of results is a complex and important ethical issue that should be discussed with an ethics review board before repositories are established (ISBER, 2012). Similarly, National Cancer Institute (NCI) guidelines state that biobank governance plans should outline protocols for handling research results (NCI, 2011).

Dressler (2009:94) notes that while international guidelines related to biobanking often support an ethical duty to disclose research results, ''There are no consistent criteria to aid a biobanker or researcher in determining when and if a research result may be of benefit to an individual participant. Therefore, the practical interpretation and application of these guidelines, on a daily basis, is still a challenge.'' Other researchers have argued that if a biobank fails to address the issue of return of individual results, it could undermine its relationship with existing and future specimen contributors, and the resulting ''lack of trust could lead to operational unsustainability'' (Simeon-Dubach and Henderson, 2014:288). Consequently, we regard having a policy on return of individual results as an indicator of a biobank's consideration of this contentious issue; so for our analyses, a biobank is forward-thinking if it has such a policy.

Policy on designation of ownership rights.

Collecting and storing specimens for long periods of time for future research raises questions about ownership. To date, there is little federal law addressing ownership of specimens in biobanks or rights to technologies developed from research use of the specimens. Given that uncertainty, best practice guidelines largely sidestep ownership of specimens or technology altogether, orienting their guidance toward authority to control the use and storage of specimens, such as references to biobanks as ''custodians'' of specimens (NCI, 2011; ISBER, 2012). Thus, neither policy nor practice regarding ownership of specimens and/or related technologies is well-developed. Common law has offered some guidance, although incomplete.

Rights to the physical property of human specimens have been litigated in the United States (Moore v. Regents of the University of California, Washington University v. Catalona, Greenberg v. Miami Children's Hospital) and more recently before an Ontario, Canada, superior court (Piljak Estate v. Abraham, 2014). Some cases, like Moore and Greenberg, address relevant related technologies as well (Lepsch, 2012; Ormond and Cho, 2014). However, the numerous ownership disputes that are not litigated remind us that courts of law do not remedy all ownership issues (e.g., De Souza and Greenspan, 2013; Ormond and Cho, 2014). Furthermore, high profile cases brought to public attention through the publication of a book detailing the story of Henrietta Lacks and the HeLA cell line (Skloot, 2010) or by the media's portrayal of the plight of the Havasupai Native Americans in a legal battle over the extent of research uses of their specimens (Havasupai Tribe v. Arizona Board of Regents; Mello and Wolf, 2010), highlight how contentious perceptions of ownership can become.

Consequently, we view having a policy about ownership of specimens and/or rights to technologies developed from the use of specimens to be evidence of a forward-thinking biobank because it displays consideration of the complexities of the rights associated with ownership and anticipates challenges that could ensue from it.

Formal business plan.

Best practice guidelines for biobanks recommend that biobanks create a business plan to formalize their operations and account for their operational costs (NCI, 2011; Vaught *et al.*, 2011b; ISBER, 2012). Other guidelines recommend that a biobank should be ''explicit and transparent about the nature and source of its financing/funding'' (OECD, 2009:4). These recommendations hinge on the need for long-term funding to build and sustain a biobank. Others have argued that a biobank must communicate its commitment to fundamental business practices and its understanding of the costs of conducting business to persuade potential funders (Vaught *et al.*, 2011a).

Funding for biobanking is notoriously insecure (Vaught *et al.*, 2011a). Elsewhere, we have reported results from our U.S. Biobank Survey, which indicate that most biobanks are funded from multiple sources and dependent on government funding, and that support is often in the form of short-term grants (Cadigan *et al.*, 2013; Henderson *et al.*, 2013a). Over

70% of our survey respondents said that they had major or moderate concerns about their biobank running out of funding (Henderson *et al.*, 2013a).

While having a business plan does not necessarily indicate increased financial security for a biobank, accounting for business costs, customer needs, and areas of growth required when creating a business plan can lead to future stability (Simeon-Dubach and Henderson, 2014). In addition, a business plan is an expression of accountability to others interested in the legitimacy of the biobank. These parties include not only potential funders but also the researchers who serve as their customers and the individuals who contribute specimens. Consequently, we view having a business plan as an indication of forward-thinking.

Plan for termination. Biobanks may be terminated, often due to lack of funding (Zawati *et al.*, 2011; Cadigan *et al.*, 2013; Tupasela and Stephens, 2013; Stephens and Dimond, 2015a, 2015b). Best practice guidelines for biobanks recommend creating plans for termination and that any transfer of specimens or data to third parties upon termination should be consistent with the informed consent under which specimens or data were obtained (OECD, 2009; NCI, 2011; ISBER, 2012). Plans for termination, also called legacy plans, can address the uncertainty arising from the potential mismatch between the original purpose of collection and subsequent use of specimens (Matzke *et al.*, 2016).

Some have argued that termination plans that promote the use of the biobank's resources in accordance with its original purposes can promote public trust (Laurie, 2011). Recent data reveal that potential specimen contributors think it is very important to be informed, before joining the biobank, of the contingency plan for specimens and data in the event of closure (Long *et al.*, 2015). Ensuring that future use of specimens is in line with what contributors expect is an important issue to consider if biobanks' collections are to be transferred to new owners and/or combined with other collections.

In other businesses, plans for termination (or other contingency plans), may be set forth in statutory requirements, such as provisions for corporate dissolution. Such plans for corporations contemplate disposition of assets and property, accounting for liabilities and proper notice provisions to parties who may have outstanding claims (see e.g., NCGS 55-14-01 et seq). These existing models, and an appreciation that biobanks have failed in the past (by disappearing, bankruptcy, or acquisition), are convincing reasons for forward-thinking biobanks to create plans for termination.

Methods

Detailed information about our 2012 national survey of biobanks, including our recruitment methods, is provided elsewhere (Henderson *et al.*, 2013a). We employed a multifaceted search strategy to create a list of U.S. biobanks, which we defined as ''organizations that acquire and store human specimens and associated data for future research use'' (Boyer *et al.*, 2012). For each biobank on our list, we recruited the director (or other knowledgeable representative) to complete the survey. We asked that the representative be thoroughly knowledgeable about the policies and practices of the biobank and encouraged the representative to confer with others in the biobank, if necessary, to answer the survey questions accurately. We also instructed representatives that if they could not find the answer to a survey question, to please skip it (see Cadigan *et al.*, 2013 for more information).

Representatives were sent an invitation letter, followed by an email with a link to the 30-min online survey, which was preceded by an informed consent statement. Of 636 eligible biobanks, representatives of 456 (72%) completed the survey. For the analyses presented in this study, we exclude 27 biobanks that store specimens for researchers who collected and deposited them, but do not share with other researchers. The University of North Carolina IRB approved this study. Survey data were collected using Illume software version 4.7 (Datstat, Inc., Seattle, WA).

Data were analyzed in SAS version 9.2 (SAS Institute, Inc., Cary, NC). We present response frequencies and cross-tabulations, with percentages where appropriate. Where percentages do not add to 100, it is due to rounding. In examining bivariate relationships, we use chi-square to test the null hypothesis that the variables are independent.

Results

Below, we report results for each of our forward-thinking indicators and then discuss relationships among them.

Return of individual results

To be eligible to answer our questions about return of results, we first asked respondents whether their biobank has access to identifying information for any of their specimen contributors because we reasoned that without access to identifying information, a biobank could not return results. Three hundred twenty-seven (77% of the total sample) indicated they had access to identifying information. We asked these survey respondents whether their biobank has a policy about returning individual results to specimen contributors (or to their surrogates, in the case of pediatric or postmortem specimens). Sixty-two percent of these 327 survey respondents said that the biobank does have a policy, 28% reported that it does not, and 10% said they were not sure. For the 62% with a policy, we asked what the policy specifies—whether results will be returned always, under certain conditions, or never. For the majority, 57%, the policy states that results will never be returned, for 38% results will be returned under certain conditions, and results will always be returned for only 5%.

For those biobanks that do have a policy on return of individual results, we also asked whether the policy addresses the issue of incidental findings, which we defined as ''findings beyond the initial aims of the research.'' Fifty-two percent of respondents indicated that the policy also addresses this issue. These respondents were then asked whether the incidental findings policy states that they will be returned always, under certain conditions, or never. Just over half (51%) responded that incidental findings are returned under certain conditions, while 42% responded that they are never returned, and 7% indicated that they are always returned. For this article, a biobank is forward-thinking if they have a return of results policy, regardless of whether the policy includes incidental findings.

Policy on designation of ownership rights

We asked survey respondents, ''Does [biobank] have a policy that designates who owns its specimens?'' Sixty-one

percent responded "yes," 16% said "no," and 22% said they were "not sure." We also asked respondents whether the biobank has a policy that designates who owns the rights to technologies developed from research done with the specimens. Forty-four percent of respondents said their biobank has a policy designating ownership of these rights, 19% said the biobank does not, and 15% said they were not sure. An additional 21% indicated that the question was "not applicable" because no technologies are developed. Fewer respondents indicated their biobank has a policy about ownership rights to technologies developed from research with the specimens than ownership of the specimens themselves. One hundred seventy-three respondents said the biobank has a specimen ownership policy and also answered the question regarding ownership rights to technologies with a "yes" or "no" (i.e., they did not respond "not sure or "not applicable"). Of these 173 respondents, 132 (76%) indicated that the biobank does have a policy regarding ownership of rights to technologies. Only 14 respondents indicated that their biobank has a policy regarding ownership of rights to technologies, but not a policy on ownership of specimens. For this article, we label a biobank as forward-thinking if it has *either* a policy on ownership of specimens or on ownership of technologies developed from research use of the specimens.

Formal business plan

In our survey, we asked all respondents, "Does [biobank] have a formal business plan?" Thirty-four percent reported that they do, while 66% said they do not.

Plan for termination

We asked survey respondents, "Does [biobank] have a written plan for what will happen to the specimens should the biobank be terminated for any reason?" Twenty-six percent reported that the biobank does have a plan for termination, 51% reported that it does not, and 24% said they were not sure whether the biobank has a termination plan.

Table 1. Ownership and Return of Results

Policy about ownership of specimens and/or technologies	*Policy about return of individual results*[a]		
	Yes	*No*	*Total*
Yes—*n*	157	56	213
Row %	73	27	100
Column %	89	70	84
No—*n*	19	23	42
Row %	45	55	100
Column %	11	30	16
Total—*n*	176	79	255
Row %	69	31	100
Column %	100	100	100

$\chi^2 = 13.30$, $p < 0.001$.

Seventy-eight additional respondents answered one or both of the questions with "Not Sure" or left it blank and are therefore omitted from this table.

[a]Ninety-six respondents were not asked this question because their biobank does not have identifying information for any of its specimens and therefore could never return results.

Table 2. Ownership and Plan for Termination

Policy about ownership of specimens and/or technologies	*Plan for termination*		
	Yes	*No*	*Total*
Yes—*n*	97	143	240
Row %	40	60	100
Column %	94	77	83
No—*n*	6	43	49
Row %	12	88	100
Column %	6	23	17
Total—*n*	103	186	289
Row %	36	64	100
Column %	100	100	100

$\chi^2 = 14.08$, $p < 0.001$.

One hundred forty respondents answered one or both questions with "Not Sure" or left one/both blank and are therefore omitted from this table.

Bivariate relationships among the forward-thinking variables

We investigated whether and how these four variables are related because we hypothesized that if a biobank was forward-thinking in one area, it was more likely to be forward-thinking in others. Thus, we examined cross-tabulations between each pair of variables. Three relationships are statistically significant (depicted in Tables 1–3): having a policy about ownership of specimens and/or technology is associated with having a policy about return of individual results (χ^2 13.30, $p < 0.001$; Table 1). Having a policy about ownership of specimens and/or technology is associated with having a plan for termination (χ^2 14.08, $p < 0.001$; Table 2). Having a plan for termination is associated with having a formal business plan (χ^2 17.11, $p < 0.001$; Table 3). Because we have no causal hypotheses about the relationships, we include row and column percentages in Tables 1–3.

Patterns of forward-thinking variables

To further explore relationships between the indicators of forward-thinking biobanks, we examined our four variables in combination. In this way, we could examine the proportion of biobanks that may be forward-thinking in only one or two ways and those that are forward-thinking along all four variables.[1] Biobanks were excluded from these analyses if they were not asked or chose not to answer any of the related survey questions. A total of 312 biobanks are included in this analysis. We analyzed all possible combinations of the four forward-thinking indicators. The results are shown in Table 4.

We observed patterns among the 312 biobanks that answered questions about all four forward-thinking variables. One-fifth of these biobanks ($n = 62$) have policies on return of results and ownership, but no business plan or plan for

[1]In this analysis, we first used only the "yes" and "no" responses, omitting the "not sure" answers for the three variables that included this response option (policies on ownership and return of individual research results and a plan for termination). When we found that combining "not sure" with "no" responses did not change the results, we included those "not sure" responses with the "no" responses.

Table 3. Formal Business Plan and Plan for Termination

Formal business plan	*Plan for termination*		
	Yes	*No*	*Total*
Yes—n	52	56	108
Row %	48	52	100
Column %	50	27	35
No—n	51	153	204
Row %	25	75	100
Column %	50	73	65
Total—n	103	209	312
Row %	33	67	100
Column %	100	100	100

$\chi^2 = 17.11$, $p < 0.001$.
One hundred seventeen respondents answered one or both questions with ''Not Sure'' or left one/both blank and are therefore omitted from this table.

termination (row 4). Fourteen percent ($n = 45$) have a return of results policy, but are not forward-thinking in any other variables (row 2). Twelve percent ($n = 38$) are not forward-thinking for any variable (row 1). Eleven percent ($n = 34$) have only ownership policies (row 3). Finally, only 7% of these biobanks ($N = 23$) are forward-thinking across all four variables (row 16).

Discussion

Biobanking is an evolving field. What began as small collections, often based at academic medical centers and focused on fulfilling the needs of specific studies, have grown into an emerging industry (De Souza and Greenspan, 2013; Henderson *et al.*, 2013a). This is evident in publications of guidelines for best practices in biobanking (OECD, 2009; NCI, 2011; ISBER, 2012) as well as the development of an extensive accreditation program for biobanks (College of American Pathologists). These efforts may help to improve the quality and consistency of biobank collections. They may also help to increase public trust and confidence from research users and funders by, among other things, providing evidence of professionalism, adaptability, and foresight (O'Doherty *et al.*, 2011; Laurie *et al.*, 2012; Simeon-Dubach and Henderson, 2014). Commentators suggest that biobanks have been guided mainly by the ''quest for research'' rather than by the standard conventions of business practice, where examination of supply and demand, and the application of basic business principles would guide the creation and maintenance of a successful business (Vaught *et al.*, 2011a).

We argue that forward-thinking policies and plans are other indicators of anticipatory planning. In this article, we use four variables from our survey of U.S. biobanks. The variables we highlight as indicators of forward-thinking biobanks are just some that could be examined. For example, elsewhere, we report on biobanks' ''reach through'' practices after distributing specimens or data to researchers (Henderson *et al.*, 2013b). We defined ''reach through'' as the extent to which biobanks retain or relinquish control of the specimens or data after sharing them. We could have argued here, for instance, that forward-thinking biobanks are those that require researchers to return aggregate results to the biobank from the studies using its specimens (Henderson *et al.*, 2013a). Alternatively, we could have examined the presence or absence of oversight committees (Henderson *et al.*, 2013a).

However, for this article, we chose our variables of interest because they reflect two different kinds of anticipatory planning that are frequently discussed in the literature on biobanking, but usually not together: ethical and legal issues and sustainability of the biobank. Policies on return of individual research results and incidental findings, as well as policies on ownership of specimens and technologies, reflect planning related to contentious ethical and legal issues. Debate over the ethical issues raised by return of research results is commonly found in the bioethics literature, while ownership issues have

Table 4. Patterns of Forward-Thinking Variables

Row no.	*Formal business plan*	*Plan for termination*	*Ownership policy*[a]	*Return of results policy*	*Frequency*	*Percentage*
1	N	N	N	N	38	12
2	N	N	N	Y	45	14
3	N	N	Y	N	34	11
4	N	N	Y	Y	62	20
5	N	Y	N	N	3	1
6	N	Y	N	Y	3	1
7	N	Y	Y	N	5	2
8	N	Y	Y	Y	28	9
9	Y	N	N	N	13	4
10	Y	N	N	Y	10	3
11	Y	N	Y	N	18	6
12	Y	N	Y	Y	22	7
13	Y	Y	N	N	2	1
14	Y	Y	N	Y	2	1
15	Y	Y	Y	N	4	1
16	Y	Y	Y	Y	23	7
Total					312	100

[a]Y if policy on ownership of specimens and/or technology.
Y, Has policy/plan; N, Does not have policy/plan.

been debated in courts and in the media. Having a business plan and a plan for termination of the biobank reflect formal planning related to sustainability, which we have argued elsewhere is also an ethical issue (Cadigan *et al.*, 2013).

In our survey, 62% of biobanks that have access to identifying information report they have a return of individual results policy. Interestingly, although international guidance on biobanking leans toward returning individual results to contributors, for the majority of biobanks in our study with a policy (57%), the policy states that results will never be returned. Seventy percent of the biobanks in our survey report having a policy on ownership of specimens and/or technology. Biobanks were far less likely to have plans related to sustainability (34% have a business plan and 26% have a termination plan). When we examined patterns among biobanks that provided answers to all four variables, we discovered that only 7% were forward-thinking across all four variables, and 12% were not forward-thinking for any of the variables.

Having a return of results policy and an ownership policy were significantly related, as were having a business plan and termination plan. Interestingly, we also found a significant relationship between biobanks having an ownership policy and a plan for termination. This may indicate that biobanks that find it important to formally designate ownership are also more mindful of the need to develop legacy plans for the specimens and data should the biobank close. In fact, one best practice guideline recommends, regarding "business risks," that biobanks "provide [specimen contributors] information that ownership could change and explain the uncertainties associated with the establishment and operation of the [biobank]" (OECD, 2009:24).

Our study of biobanks has limitations. It is not a longitudinal study, so we cannot examine whether biobanks' policies have changed over time, which might further indicate their ability to be adaptive (O'Doherty *et al.*, 2011). In addition, our survey did not ask respondents about the return of individual results if they reported that their biobank does not have access to identifying information for any of its specimen contributors. We could have labeled these biobanks as not forward-thinking for our analyses in this study, arguing that biobanks with specimens and data that are linked to individuals are forward-thinking by anticipating that the value of the collection is increased with such linkages. However, we chose not to do so because we lack data on *why* these biobanks do not have access to identifying information. It is possible, for instance, that an honest broker has access, but the biobank itself does not (Boyd *et al.*, 2007). Therefore, we did not feel comfortable labeling them as not forward-thinking. Further research should be done to understand the different circumstances under which biobanks do not retain identifying information.

We argue that given the uncertainties of biobanking, it is critical to develop policies and plans such as those we examine in this report. Furthermore, in the new era of "precision medicine," which hopes to capitalize on specimens and data already collected and stored for large-scale research projects (Collins and Varmus, 2015), it is increasingly important that biobanks evidence professionalism and accountability. For any organization to be sustainable, certain levels of planning must be met. Forward-thinking in biobanking means anticipating future challenges and creating both policies and procedures to address them.

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