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## Cancer Donor Preferences for Disposition of their Biospecimens after Biobank Closure

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### Abstract

**Background**—Biobank funding is unstable and biobank administrators are concerned about loss of funding and subsequent biobank closure; yet a minority of biobanks have policies about distribution or destruction of tissue if the biobank were to close. This is the first study to report oncology biospecimen donors' preferences about the handling of their biospecimens in the event of biobank closure.

**Methods**—98 biospecimen donors diagnosed with cancer at the Georgia Cancer Center at Grady Memorial Hospital or the Winship Cancer Institute were interviewed about their preferences for handling of their biospecimens in the event of biobank closure.

**Results**—Most biospecimen donors (62/83, 75%) wanted their biological materials transferred to another biobank, specifically an academic bank or a national bank. The most unacceptable options for the handling of tissue were transfer to a for-profit/pharmaceutical biobank (39/98, 40%) or a biobank based outside of the United States (31/98, 32%). Non-white participants were more likely to view the transfer of their tissue to a for-profit/pharmaceutical tissue bank, international tissue bank, or a national tissue bank as unacceptable compared to white participants.

**Conclusion**—According to these biospecimen donors, the most acceptable options for the handling of biospecimens following biobank closure were transfer to an academic or national bank. The most objectionable options were transfer to a for-profit/pharmaceutical biobank or a biobank based outside of the United States. These findings can be used as the basis of educational interventions directed at the public and can inform the policies of biobanks that serve oncology research.

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**Contributors:** SCA conceptualized the study, conducted patient interviews, performed qualitative analysis, wrote the original draft of the manuscript, and reviewed and edited subsequent versions. JS conducted statistical analysis and reviewed and edited draft versions. MD supervised data collection, and reviewed and edited draft versions. RP approved the conceptualization, supervised data collection and analysis, and reviewed and edited draft versions. All authors approved the final version.

## Keywords

Tissue bank; Tissue donor perspectives; Tissue donation; Tissue bank closure; Research

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## INTRODUCTION

The future of biobanks is often uncertain due to infrequent or sporadic funding through public or private grants<sup>1,2</sup>. Funding for biobanks can simply expire or be withdrawn if the productivity or output of the biobank does not reach its anticipated potential<sup>3</sup>. A case study of biobank administrators (representing 456 biobanks) found that two of the most pressing issues for biobanks are the lack of funding to exist indefinitely and the absence of planning for what will happen when the banks close<sup>2</sup>. Moreover, the survey found that 40.3% of biobank administrators consider the loss of funding to be a “massive concern” and 30.6% reported it being a “moderate concern”<sup>2</sup>. Despite the funding insecurity, only 26% of biobanks reported having a written plan for the handling of biospecimens and data in the event of biobank closure<sup>2</sup>.

The Organization for Economic Co-operation and Development’s (OECD) international *Guidelines on Human Biobanks and Genetic Research Databases* recommend that each biobank make a plan to either destroy biospecimens or transfer them to another facility if the current bank closes<sup>4</sup>. The *Guidelines* further specify that a biobank should only transfer their biospecimens or data to equivalent institutions with the resources to appropriately handle the materials<sup>4</sup>. The OECD thus holds the closing biobank responsible for ensuring that the future facility can adequately manage the biospecimens and data. The European Genetic Alliances Network Guidelines add that the transfer of donor biospecimens must be restricted to institutions that comply with the terms of the original informed consent document<sup>5</sup>.

When the Armed Forces of Pathology biobank, which housed 90 million samples dating back to 1862, faced closure in 2005, The National Defense Authorization Act of 2008 created a separate body, The Joint Pathology Center, to house the biospecimens and data<sup>6,7</sup>. The Joint Pathology Center did not retain the original consent forms and it is highly unlikely that the consent forms authorized the transfer of biospecimens to another institution or the use of biospecimens for educational or research purposes<sup>6</sup>. This case study shows the ethical dilemmas that arise from the transfer of biobank samples, especially when informed consent for this transfer is not obtained.

Although guidelines exist and biobank administrators are concerned about the possibility of bank closure, it is not known what biospecimen donors prefer in the event of bank closure. Previous survey and focus group studies that asked potential and actual donors about the preferred *research use* of their biospecimens found that biospecimen donors prefer local and non-profit researchers to pharmaceutical/for-profit and international researchers<sup>8–11</sup>. Whether these preferences apply to bank closure is unknown. We therefore queried oncology biospecimen donors regarding destruction or transfer of their biological materials following biobank closure as well as the type of biobank they would prefer to receive their biospecimens.

## Methods

Oncology biospecimen donors at the Winship Cancer Institute, the Preoperative Anesthesia Clinic of the Emory University Hospital, and the Georgia Cancer Center of Grady Memorial Hospital were approached to participate in the study. Any patient who had previously donated their biospecimens for research purposes was eligible to participate in the interview. The interview was created by the research team based on a thorough literature review. It was cognitively tested with 7 biospecimen donors in September 2016 for clarity and completeness of topics. The first section of the final interview consisted of four open-ended questions: what donors would want to happen to their biospecimens and information in the event of bank closure; would they want to be notified; how they would feel; and would closure affect their trust in medical research. This section was qualitatively coded by SA with the original code book checked by RP. The second section presented five options for the handling of biospecimens in the event of bank closure: transfer to a local academic biobank, a national biobank, a biobank based outside of the United States, a for-profit/pharmaceutical biobank, or destruction of their donated biospecimens. A script was utilized to briefly explain the different types of biobanks with 'banks outside the United States' described last. After the investigator read the script, donors were asked to indicate which options they found absolutely unacceptable and then to rank the options they found acceptable from most preferred to least preferred. Given that participants were asked to only rank acceptable options, the participant-reported ranks (1 for most preferred to 5 least preferred) were scaled to sum to 1 and more preferred ranks were given a larger weight. The weighted scores were the reverse order of their recorded rank divided by the sum of the ranks. For example, if a participant's responses were 1-2-3-4-5, the associated weighted scores were 5/15-4/15-3/15-2/15-1/15; if a participant's responses were 1-2-3 (with 2 unranked options), the associated weighted scores were 3/6-2/6-1/6. Five donors refused to rank or listed two or more of the options as equal so their responses were counted as missing (N=93).

Binary endpoints, such as trust in medical research and the acceptability of transfer to biobanks/destruction of biospecimen, were compared across categorical variables using chi-squared tests or Fisher's Exact tests, where appropriate, and across numeric variables such as age using ANOVA. Continuous endpoints, such as the scaled preference scores, were compared across categorical variables using ANOVA, and across continuous variables using Pearson's correlation coefficient. Multivariable linear regression models for scaled scores were fit as a function of patient demographics. Significance was established at  $\alpha=0.05$ , and the analysis was performed using SAS 9.4 (SAS Institute Inc., Cary, NC). The study was approved by the Emory University Institutional Review Board and verbal consent was obtained from all participants.

## Results

Of the 105 biospecimen donors approached, 7 donors refused (7/105, 7%) and 98 donors (98/105, 93%) agreed to participate and were included in the study. Demographics are described in Table 1.

In response to the open-ended questions, most biospecimen donors (62/83, 75%) preferred to have their biological materials transferred to another biobank if their bank closed. A minority of donors (34/98, 35%) wanted to be notified of the closure of their biobank with phone or email being the preferred notification method (22/32, 69%). Most donors (54/93, 58%) would not care if their biobank closed, while other participants indicated they would be sad/disappointed (29/93, 31%) or frustrated/angry (3/93, 3%). The overwhelming majority of donors (83/98, 88%) responded that biobank closure would not reduce their trust in medical research.

As detailed in Table 2, the most unacceptable option for the handling of donors' biological materials following biobank closure was the transfer of their biospecimens to a for-profit/pharmaceutical biobank (39/98, 39.8%). Moreover, a moderate number of donors (31/98, 31.6%) viewed the transfer of their biospecimen to a biobank based outside of the United States as unacceptable, while a few donors (8/98, 8%) found the transfer of their biospecimen to a national biobank unacceptable. Only one donor each viewed the transfer of his/her biospecimen to a local academic biobank (1/98, 1%) or its destruction (1/98, 1%) as unacceptable. When asked to rank the options they deemed acceptable, donors indicated that the most preferred option was transfer to a local academic biobank (mean scaled score = 0.36) followed by transfer to a national biobank (mean scaled score = 0.27), transfer to an international biobank (mean scaled score = 0.14), destruction of the biospecimen (mean scaled score = 0.13) and transfer to a for-profit/pharmaceutical biobank (mean scaled score = 0.093) (Table 2).

Non-white participants were more likely to view the transfer of their biospecimen to a for-profit/pharmaceutical biobank (60.9% vs. 33.3%,  $p$  value=0.018), an international biobank (52.2% vs. 25.3%,  $P$ -value=0.015), or a national biobank (21.7% vs. 4.0%,  $P$ -value=0.016) as unacceptable compared to white participants. Participants who were not employed at the time of the interview (25/64, 39%) were more likely to believe the transfer of their biospecimen to an international biobank was unacceptable compared to participants who were working full- or part-time. (6/34, 18%) ( $p$  value=0.030). Donors employed full- or part-time preferred international biobanks more than unemployed donors (mean scaled score 0.18 vs. 0.13,  $p$  value=0.046). However, when employment was controlled for income and education level, employment status was no longer a significant determinant (Table 3).

## Discussion

Our study of the views of biospecimen donors provides some guidance for cancer biobank administrators on the preferred handling of biospecimens if a biobank closes. These donors preferred transfer to another bank, preferably another academic or national bank, with for-profit and international banks not preferred. This result was magnified by the novel finding that for-profit and international bank transfers were viewed as absolutely unacceptable by about a third of the donors.

These results agree with previous findings that donors are concerned with the use of their biospecimen in international and pharmaceutical/for-profit research<sup>8-11</sup>. A previous survey found that a significant minority (117/279, 42%) of donors believed broad consent is

unacceptable for pharmaceutical industry sponsored research<sup>8</sup>. Another survey found that biospecimen donors were most willing to allow local university researchers (263/273, 96.3%) to use their biospecimen for research followed by other U.S. institutional researchers (245/273, 89.7%), international researchers (215/273, 78.8%), pharmaceutical industry researchers (176/273, 64.5%), and “for-profit” researchers (124/273, 45.4%)<sup>9</sup>.

These combined findings suggest that an educational program is needed to alert the public to the importance of collaboration with for-profit pharmaceutical companies and international partners to excellent research.

Our sample found further evidence of some ethnic differences in preferences about biospecimen use. In our sample, whites were more likely to find the transfer of their biospecimen to both pharmaceutical/for-profit and international institutions acceptable compared to non-whites. In a similar study of biospecimen donors, Pentz et al. found that whites were more likely to allow their biospecimen to be used outside of the United States compared to non-whites<sup>11</sup> Moreover, Helft et al. found that whites were more likely to permit the use of their biospecimen in unlimited future research compared to non-whites<sup>9</sup>. These ethnic differences provide another rationale for a transfer policy to biobanks comparable to the original, since consent had been obtained for the original bank.

We found that about a third of donors (34/98, 35%) wished to be notified if their biobank closed or would be sad/disappointed (29/93, 31%) with a very few frustrated/angry (3/93, 3%). It is somewhat surprising that when simply asked, “Would you want to be notified if your biobank closed,” only just over a third answered ‘yes.’ Nor would biobank closure reduce trust in medical research. However, donors were asked these questions before we presented them with the option of a transfer to international or for-profit banks, so the fact that a third of oncology biospecimen donors found such transfers absolutely unacceptable must be taken into consideration. Again, educational efforts might be helpful. In any case, these findings support the imperative for biobanks to have well thought out guidelines in case of closure.

Further research should investigate the differences in biobanking preferences based on racial and employment variables, particularly since employment was not a significant determinant of preference when income and education were controlled for. Since 23 patients did not provide information on income, the lack of significance may be due to the smaller sample size, though this should be investigated. A better understanding into if and why different demographic groups differ could better equip tissue bank investigators and administrators in incorporating tissue donor preferences into their research protocols and policies. Moreover, since our study only included donors to academic biobanks, a multi-institutional follow-up study that includes donors to different types of banks (community, for profit, national or international banks, etc.) is needed to determine if the type of bank to which one has donated influences one’s perception of the best option for handling tissue upon bank closure.

## Limitations

One possible limitation to our study is that we do not know whether participants perceived the international biobanks to be academic or for-profit/pharmaceutical. If asked, the researchers explained that international biobanks could be either academic or for-profit; however, the novelty of the concept for the majority of participants may have prevented a full understanding of the term. This possible source of ambiguity may have influenced the participants' perceptions of international banks and their relationship to the other alternative biobanking options. Moreover, this study was based at an academic medical center and its affiliated sites, which may have influenced the donors' preferences for academic banks. This factor combined with the relatively small number of interviewees reduces generalizability. However, this is the first report to our knowledge of donors' views.

## Conclusion

According to these biospecimen donors, the most acceptable options for the handling of biospecimens following biobank closure were transfer to an academic biobank or a national bank. The most objectionable options were transfer to a for-profit/pharmaceutical biobank or a biobank based outside of the United States. These findings can be used as the basis of educational interventions directed at the public and can inform the policies of biobanks that serve oncology research.

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**Table 1**

## Demographics Information (N = 98)

Demographics	N = 98	%
Gender		
Female	62	63.3
Male	36	36.7
Education		
Some high school	5	5.1
High school graduate or GED	19	19.4
Some college	22	22.4
College graduate	32	32.7
Some post-graduate	6	6.1
Post-graduate or professional degree	14	14.3
Race		
Asian or Asian American	1	1.0
Black or African American	20	20.4
Hispanic, Latino, or Spanish origin	2	2.0
White	75	76.5
Employment status		
Employed full-time	33	33.7
Employed part-time	1	1.0
Student	4	4.1
Retired	35	35.7
Disabled	11	11.2
Unemployed	14	14.3
Income		
\$20,000 or less	18	22.8
\$20,001 to \$40,000	5	6.3
\$40,001 to \$60,000	11	13.9
\$60,001 to \$80,000	16	20.3
over \$80,000	29	36.7
Missing	19	-
Age		
Mean	59.25	-
Median	61	-



**Table 2**

Preferences of biospecimen donors (N=98) for the handling of their biological materials following the closure of their tissue bank.

Variable	N = 98	%
Which of the following are <b>absolutely unacceptable</b> following tissue bank closure?		
Transfer to for-profit/pharmaceutical tissue bank	39	39.8
Transfer to tissue bank outside the US	31	31.6
Transfer to national tissue bank	8	8.2
Transfer to local academic tissue bank	1	1.0
Destruction	1	1.0
Please rank the following options for the handling of your biological materials following tissue bank closure.*		
Academic tissue bank scaled score	Mean	0.36 -
National tissue bank scaled score	Mean	0.27 -
Foreign tissue bank scaled score	Mean	0.14 -
Destruction of tissue scaled score	Mean	0.13 -
For-profit or pharma tissue bank scaled score	Mean	0.093 -

\* Since unacceptable options were not included, the sum of each patient's preference ranks was scaled to 1, with the higher the mean for an individual preference, the higher the ranking.

**Table 3**

Multivariable analysis of demographics

Covariate	Level	Foreign tissue bank scaled score					
		B	95%CI Low	95%CI Up	B P-value	Type 3 P-value	
Employment status	Employed full- or part-time	0.05	-0.01	0.11	0.1111	0.1111	
	Other	-	-	-	-	-	
Education level	Some college or less	-0.00	-0.06	0.05	0.954	0.954	
	College degree or higher	-	-	-	-	-	
Income	\$60K or less	0.02	-0.04	0.07	0.587	0.587	
	\$60K or greater	-	-	-	-	-	

\* Number of observations in the original data set = 98.

Number of observations used = 75.

Backward selection with an alpha level of removal of .05 was used. No variables were removed from the model.