Public attitudes regarding the use of electronic health information and residual clinical tissues for research

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Abstract Use of electronic medical records (EMR) and residual clinical biospecimens have become important for the conduct of biomedical research. Currently, human subjects' protection regulations permit much of this research to be conducted without individual informed consent, posing a risk to biomedical research from public objection. We sought to understand public attitudes regarding access to EMRs and residual clinical biospecimens. This article reports the results of 12 focus groups with 131 participants conducted in Utah, Washington, Arizona, and Minnesota. Results indicate strong support for biomedical and genetic research in general and clear support for improved patient education regarding research access to individual data and biospecimens. Our participants were supportive of an opt-out approach to patient decision-making regarding research access to clinical data and biospecimens for research in general.

Keywords Biobanking · Electronic health records · Human subject protections · Public attitudes

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Background

Biomedical research using electronic medical records (EMRs) linked with banked biospecimens is becoming an increasingly powerful mode of research in many healthcare institutions. The management of the ethical, legal, and social issues inherent in biobanks has created considerable discussion with a general recognition that public trust must be maintained through public education and transparency.

Banked biospecimens are acquired for new research projects or may be residual specimens from clinical procedures or past research efforts. When prospectively acquired in research, informed consent for acquisition, banking, and research use is required by federal human subjects' regulations. However, under these same regulations, residual biospecimens obtained for other purposes, such as clinical care or from prior research, can be used for secondary research without the consent of the tissue source as long as the specimens are de-identified, or the research is deemed exempt from federal regulations, or the research has been granted a waiver of consent by an IRB (Office for Human Research Protections, 2013). Therefore, individuals who are the sources of tissue may not be aware that research is being conducted with their residual specimens. Similarly, many patients are not aware that their clinical records can be accessed for research purposes without their informed consent. A lack of public awareness can threaten the viability of these research resources if the public becomes concerned about these practices and loses trust in institutions to conduct research in a responsible fashion.

In 2009, the University of Utah, Intermountain Healthcare, and the Utah Department of Health initiated a collaboration to discuss avenues to provide access by qualified investigators to a federated system of clinical and public health databases and databases of clinical and research biospecimens that may be available for secondary use. More than 70 % of the 2 million

citizens of Utah obtain their healthcare at either Intermountain Healthcare or the University of Utah. These institutions have well-established electronic medical records. In addition, the University of Utah has been the steward of the Utah Population Database since 1982, a resource that contains records on over 7 million individuals, including family history (genealogical), birth, death, marriage, and driver's license records. This initiative will enable investigators to ascertain the number of individuals affected with selected health conditions within a large segment of the Utah population from the EMRs and determine whether there are associated biospecimens available in the University of Utah or Intermountain systems. The initiative does not involve the creation of a separate research repository but rather a system of query tools, biospecimen annotation tools, and access procedures for clinically acquired data and specimens.

The collaborators recognized from the outset that public transparency and trust would be critical to the success of the initiative. Therefore, an initial set of activities was to engage with Utah citizens to assess their attitudes regarding population-based research that would access EMRs and residual tissues. Of particular interest were public attitudes regarding the consent or permission process for research participation. This research did not focus on gathering attitudes toward biobanking, rather the research focused on developing a single system that would grant access to EMRs and residual biospecimens that may be stored in several institutions across the state. Given the project's interest in providing access by investigators to millions of medical records and biospecimens, our preferred approach is to develop an "opt-out" option for all patients served by the institutions. That is, EMRs and biospecimens would be available for research, with IRB approval, unless the individual opted out of research access. In contrast, an opt-in approach would entail prospective informed consent by each individual.

Methods

The study received institutional review approval at the University of Utah. To provide background information to the group participants, we created a 12-min video about the EMR initiative and access to residual biospecimens collected through clinical and research contexts. This video was developed by the Genetic Science Learning Center. The video is available at <http://learn.genetics.utah.edu/UBI/>. The purpose of this video was to inform focus group participants about the UBI and issues related to population-based research, use of EMRs and stored biological materials for research, protections for privacy and confidentiality in population-based research, and information about the proposed option to opt-out of research access to their data or biospecimens. The video was shown at the beginning of each group.

Focus groups were conducted across the state of Utah from August to November 2011 in urban, rural, and frontier areas of the state. After completion of these groups, an additional three focus groups were conducted in Washington, Minnesota, and Arizona ($n=35$) to ascertain whether the Utah results were qualitatively different from those of participants in other states. We hired an experienced company with over 20 years in public opinion research to recruit in each of the locations for the focus groups. The requirement for recruitment in Utah was for participants to be English-speaking members of the general population in which the UBI is targeting, 18 years or older, and not have attended a focus group previously in their lifetime. The focus groups were recruited by geographic location to represent urban and rural communities and were not stratified by race or ethnic background. Table 1 provides demographic information about the participants. We used the

Table 1 Participant demographics ($n=131$)

Gender	55.7 % female
Income	13.7 % under \$25,000
	16.8 % \$26,000–35,000
	9.9 % \$36,000–45,000
	23.7 % \$46,000–65,000
	18.3 % \$66,000–100,000
	16.0 % >\$100,000
Ethnicity	1.6 % no answer
	81.7 % White-Non Hispanic
	10.7 % White-Hispanic
	3.1 % African-American
	1.5 % American Indian
	1.6 % Multiracial/other
Education	5.3 % Technical degree/certification
	1.5 % Less than high school
	6.1 % High school degree
	26.0 % Some college
	12.2 % Associate degree
	33.6 % Bachelors degree
Religion	15.3 % Graduate degree
	45.8 % LDS
	17.6 % No religion
	0.8 % Atheist
	21.4 % Christian
	5.3 % Prefer not to answer
Age	6.1 % Catholic
	1.5 % Jewish
	1.6 % Other/missing
	10.7 % 18–29 years
	32.1 % 30–39 years
	20.7 % 40–49 years
	21.4 % 50–59 years
	19.8 % 60+ years

same educational video in all states but asked non-Utah participants to respond to the issues as if a resource like the one under development in Utah was being developed in their community. Participants were told that research with EMRs and residual clinical tissues has been conducted for many years and typically without the informed consent of patients. The video stated that the developers preferred an opt-out approach to patient decision-making due to the challenges of an opt-in approach given the large number of patients and records/specimens involved.

The focus groups lasted 1.5 to 2 h. One of the researchers (ER) who is experienced with focus group research moderated the groups. The other moderator (JB) is an expert on the topic and answered questions from the participants. A semi-structured moderator guide was created by the research team to help guide the discussion with the participants (see Table 2). Open-ended questions were asked and participants were encouraged to share their opinions as well as interact with other participants. All of the focus groups were recorded and transcribed.

Data analysis

The data were analyzed using a qualitative content analysis. Consistent with the approach used in our previous work (Rothwell et al. 2010; Rothwell et al. 2011), the codes were generated from readings of the transcripts and questions in the semi-structured moderator guide. One member of the research team read and re-read the transcripts for the initial development of the codes. The codes were then reviewed and refined with another member of the research team who observed all of the focus groups. Next, the codes were systematically applied to the transcripts by one member of the research team, with the ability to add additional codes that may have been missed in the development of the codebook (Miles and Huberman 1994). Then all coded data was queried and reviewed by the research team for accuracy of coding. Meetings with the research team were conducted to review interpretation and emerging themes and categories through written summaries and direct quotes. The team reviewed codes and linked them together until all of the data fell into distinct categories (Miles and Huberman 1994). The researchers followed the qualitative research approach of reflexivity to minimize the influence of their own beliefs by requiring the researchers to consider their influence on interpretation of the data (Mason 2002).

Trustworthiness of the data collection and analysis were maintained through two procedures. First, an “audit trail” was maintained using a software program (Atlas.ti) to keep a detailed record of the entire analysis process from development of the coding template to final interpretation of the results. Second, integrity of the data analysis was achieved by reviewing all of the coded data as well as the entire

Table 2 Questions in the semi-structure interview guide

1. What are your thoughts and opinions about medical research in general? Genetic research in general?
2. How much did you know about medical records and biobanks before this group?
3. What are some of your opinions about the risks and benefits of research that uses electronic medical records and banked tissues?
4. Imagine that researchers were interested in understanding more about an important, common disease like heart disease. Imagine that the researchers wanted to review hundreds of electronic medical records of people with and without heart disease to better understand why some people get sick. It would be expensive and difficult to contact every person to ask their permission. The regulations protecting subjects in research allow researchers to review records without consent if the risk is judged to be very low. In this situation, would it be OK for researchers to use your medical information without your consent?
5. What are your thoughts about conducting this type of study without written consent from people whose records are reviewed?
6. Some people recommend that everyone be told about this type of research when they visit the hospital or clinic. People would be informed that, if they do not want their records used in this type of research, they could check a box on a form or call a phone number to refuse access to their records. What are your thoughts about the option to refuse approach for conducting this type of study?
7. Imagine that the researchers who are studying, say, heart disease also want to do tests on tissues that are left over from patients in the clinic and hospital after blood tests or surgery are done. The research would involve both access to medical records and the testing of tissues to learn about why some people get sick from heart disease (or other diseases). It would be expensive and difficult to contact every person to ask their permission. The regulations protecting subjects in research allow researchers to do research without consent if the risk is judged to be very low. In this situation, would it be OK for researchers to use your leftover tissues without your consent?
8. What are your thoughts about conducting this type of study without written consent from people whose tissues are used?
9. Would it be acceptable to do this kind of research on leftover tissues if people had the option to refuse?
10. Would it be acceptable to do this kind of research on leftover tissues without consent if the tissues had all identifiers removed first? This means that no one, including the investigators, could find out who the tissues were from.
11. What role do you think the local community should play in overseeing this type of research?
12. What are some ways that you find acceptable to notify researchers about opt-outing of access to their records or tissues (i.e., call in, email)?

transcripts to ensure accuracy of the results (Morrison-Beedy et al. 2001; Sandelowski 1986).

The codes also provide a measure of the frequency of statements made and were used to help identify prominent themes among the groups in this study as opposed to only the researchers' own interpretation of the data. Less frequently occurring codes were collapsed into the more prominent codes within each of the main categories. Also, the additional three focus groups' transcripts were analyzed separately. Frequency

of codes is only an “indication” of the type of themes that emerged and returning to the transcripts is required to verify the coded data. This approach was used to provide a comparison between all of the focus groups and between the Utah and non-Utah groups. The results presented below are the themes that emerged within and across all of the 12 groups in this study.

Results

The findings were consistent across all focus groups with the majority of participants reporting little or no knowledge about biobanking and use of electronic medical records in research. Overall, there was strong support for medical and genetic research in general. An opt-out approach for population-based research was supported by a majority of the participants in this study. We identified no differences in responses between Utah and non-Utah groups in terms of frequency and content of the codes, therefore the data is presented together. Listed below are the general themes with the relevant categories from the data.

General knowledge and attitudes

Prior knowledge Participants were asked about any knowledge or experience with research from EMRs and/or stored biospecimens or blood samples. Almost all of the participants were unaware that EMRs were accessible and used for research purposes and most of the participants thought leftover blood or tissue samples were destroyed after clinical acquisition. *“People are going to be paranoid about ‘how did you get my information?’ Will we receive it by looking through medical records as part of a study” and “We all have procedures done, and they’re taking their samples, and we don’t know nothing about it.”*

Medical records and leftover clinical samples Participants were asked about any perceived differences between the use of EMRs and leftover clinical biospecimens for research. Most participants did not see a difference between the two in terms of benefits and risks. However, a few participants stated that use of EMRs is more personal than use of leftover clinical specimens because EMRs contain additional information about them such as psychological information and their entire medical history. *“I would say medical records would be more sensitive than tissue samples because they can get more about you from your medical record than they can from a piece of my skin.”* Conversely, a few participants stated that the leftover biological specimen was a part of their body and contained their genetic information, and, as such, these participants thought it posed more risks than a review of their EMR. *“It becomes personal. It’s part of me. It’s a completely different level, than just records.”*

Questions by participants The most frequently occurring code within the data was participant-driven questions. Despite watching an educational video prior to the group discussion, many of the participants had unanswered or additional questions. There were over 30 questions asked in each of the focus groups. An additional content analysis was conducted on the questions; Table 3 summarizes these data. In general, the questions asked by the participants mirror many of the results presented in this paper and reinforce key issues among the public. For example, the structure and development of a biobank generated a significant amount of questions as well as the safeguards and communication issues. They also serve as indication of what additional information participants may be interested in after receiving some education about this topic.

Perceived risks and benefits

The group discussions also focused on how participants saw the perceived benefits and risks of this type of research. The most commonly mentioned risks were individual privacy issues and insurance/employment discrimination if an individual was found to have a genetic predisposition for a disease followed by security breaches to the stored data. Other perceived risks included cloning, companies profiting from an individual’s samples, and a government DNA database for tracking. There were several references to the books *The Immortal Life of Henrietta Lacks* (Skloot 2010) and *1984* (Orwell, 1949). Overall, there were fewer comments about potential benefits and these comments differed from risks in that they were not focused on the individual benefits but more on the potential benefits to society. Benefits mentioned by participants included improving health, improving understanding of a disease, and improving the health of future generations. Representative quotes include the following:

Risks:

I really worry about insurance companies, government, and those kinds of entities getting a hold of it and having access.

Leftover clinical data, to me, sounds like stem cell research, sounds like stuff that might have come from an abortion, sounds like something that might have been in that ethical gray area.

Benefits:

I see a large benefit from the use of this in that it could help identify possible defects. It could help come up with cures.

The reason we have Polio vaccine, cancer—whatever we have, has been because they’ve had samples of people’s DNA.

Table 3 Questions raised by participants

Structure/development:	<ul style="list-style-type: none"> • How does information get into the database? • What types of databases are included? • Where are you in the process of developing the UBI? • What are the sources of samples/data? • What is the role of the physician/hospital? • How does this work? History of this initiative? • Is there a difference between past vs future sample/data acquisition? • How long has research like this been going on?
Access/safeguards:	<ul style="list-style-type: none"> • Who gives and gets access to data? • What type of personal information is included? • How do you move from anonymous research to identifiable research? • How do you link data?
Type of research:	<ul style="list-style-type: none"> • What type of research will be conducted with the UBI? • What type of health conditions will be targeted? • Will specific communities be targeted? • What is the primary purpose of the UBI?
Funding:	<ul style="list-style-type: none"> • Who is funding this database? • Who will fund it in the future? • Who are the key stakeholders?
Return of results/ communication of research:	<ul style="list-style-type: none"> • If something is found, will I be notified? • Where can I find information about the type of research being conducted? • How will everyone be educated about this research? • Where will education take place?
Opt-out:	<ul style="list-style-type: none"> • How can I opt-out? • Can I change my mind? • Can I opt-out of medical record use and not tissue use and vice versa?
Risks:	<ul style="list-style-type: none"> • What are the risks associated with the UBI? • Have there been any lawsuits?
Protections:	<ul style="list-style-type: none"> • What is their legal authority to collect and use our data? • What health laws/legislation are in place to support this project and protect our rights/privacy? • Will insurance companies have access?
Storage:	<ul style="list-style-type: none"> • How long are the samples stored? • How are the data and samples stored?
Population-based research:	<ul style="list-style-type: none"> • How is population-based research different from other research studies? • Why can this not be conducted like HIPPA?

Responses to different decision making approaches

The next series of open-ended questions focused on acceptable or unacceptable uses of an opt-out approach for population-based research that utilizes EMRs and/or stored

blood and tissues samples left over from clinical procedures (Table 4).

De-identified specimens In the context of research in which the individual contributing the biospecimen or data was not identifiable to the investigator, there were numerous participants who stated that individuals should not be allowed to opt-out of this type of research if the purpose was to improve the public's health and/or understanding of a disease. Reasons for this perspective were the small risk to an individual compared to potential gains for healthcare and creating additional barriers to research. *"It seems like that would really clog up the system for every little thing, get consent when it is anonymous and it's not really going to be traced back to."* *"If that makes our population healthier or (healthier) aging, I don't think consent is necessary."* It is important to emphasize that there were a few participants who were against this approach because it did not give individuals a choice, potentially resulting in a negative public reaction. Furthermore, lack of choice might conflict with some personal values (*"Well, I love choice,"* and *"I'd want an option."*).

Opt-out for electronic records Almost all of the participants in the focus groups were supportive of an opt-out approach for conducting population-based research that involved access to EMRs. Many participants stated that when they visit a healthcare provider, this is not the optimal time to be discussing research-related concerns (*"I think people might get confused if they're receiving medical care and not realize that there might be separate consent involved with something like this;"* and *"If you go into a hospital, you're sick... and not really thinking."*). In addition, access to their information is already available (*"I mean, it's going on right now. Who isn't willing to participate?"*). Many participants stated the opt-out option allows people who are really concerned to opt out but those who do not care are included, thus increasing the potential for population-based research (*"You have the choice to opt out of it, as long as you are aware of that, I don't see any problem."*).

Opt-out for tissue use Similar to research access to EMRs, most participants were supportive of the opt-out approach with leftover clinical biospecimens. However, this topic generated more discussion among the participants and, although the opt-out approach was supported, some participants stated there was a need to provide education because of the perception that leftover specimens were more *"personal"* and contained DNA. Furthermore, support for the opt-out approach was based on several other factors as follows: a concern that the timing for the acquisition of the clinical samples is not the optimal time to address the use of these specimens for research; this research practice is

Table 4 Responses by moderators

Structure/development:	What the project would do is help pull together databases that would have a variety of different origins. One would be medical records from folks who receive care at the different institutions. One would be the population database that was illustrated in the movie that has information about pedigrees within the state. There is information that would come from the state such as birth records and death records and things of that sort that would help track individuals. Then the tissues that would be part of this could come from a couple of resources. One would be leftover tissues that people have stored in institutions after they have had say an operation or tissues that were acquired for people who were involved in one sort of research project. Those tissues are used and there is leftover tissues and those would be banked for availability for other kinds of projects that investigators might want to do so the idea is that there is a variety of different databases that, depending on the particular research question, you could pull information from each of those or several of those.
Access/safeguards:	There are safeguards within the software itself but they would have to go through the kind of committee structure that was talked about in the movie. It would be an Institutional Review Board, an IRB, that they did have to justify that and if you got justified for certain data elements that you could get then the people who control the different databases would approve access to those.
Type of research/ population-based research:	Well let me explain basically how that would likely occur. So an investigator is interested in a particular disease; how many people have had a heart attack in their forties within this certain population. Well you could get that number without knowing who any of the people were. You would get back this many men, this many women in these general locations but without identifiers. Then if you were an investigator and you want to say well I am interested in a couple of families that look like they have early heart attacks at a young age and we want to recruit those people into a study. At that point, the investigator would be given names and addresses and contact information so that they could go out and invite people to participate and folks at that point could say no I do not want to participate or yes I am willing to join. So a lot of the research that would be done with the databases and with the tissue would be done on anonymous information and only if the investigator needed identifiers and could justify

Table 4 (continued)

Funding:	getting identifiers would they potentially be given access to identifiable information. If this Bio Health Initiative is successful, we would hope to get more grant money into the university and do more research. Now that does not generally make the investigators rich. I mean they do not get a cut of it but it is money to the institution and it is important so that might influence people's decisions but then drug companies would come forward too and say we want to do research at the University of (Name) because of this extraordinary research because we have an important new drug for diabetes. Well is that a good thing or a bad thing? I mean there is profit that is going to be involved but that is how the system works sometimes to get better medications available to the public. I mean there is always that sort of tradeoff.
Return of results/ communication of research:	And what we do know is a lot of people want to know this kind of information, but a lot of people do not, and so it becomes a real ethical challenge about how to get back to people. For the most part, this is research that seeks to learn general truths about how bodies work and how diseases work, it is not supposed to be designed to get results back to individual people, but it is a dilemma when that arises.
Opt-out:	Let me see where the group is with sort of clarifying some of the terminology here because I think the terms opt in and opt out have been used, I think, in different ways. So, generally, when we talk about opting in, we are usually talking about a system where you sign a piece of paper that says it is okay, and unless you have that signed piece of paper, the assumption is it is not okay. As opposed to the opt out, where you educate folks about what their opportunities are, they have an opportunity to call you or use some mechanism to tell you that they are out, at which point, you are out. So, whether the person going to the surgeon for a procedure and presented a piece of paper, whether that piece of paper says, "Here is what is going to happen. If you do not like it, call this number," or, "Sign this piece of paper, and unless we get that signature, nothing is going to happen..." Well, and I think that is why folks have been thinking about the opt in approach as being so complicated, because if you rely on seeing that signature to use something, then you have got to track all those signatures and if you go to the doctor six times a year and you get presented the same form six times a year and you did

Table 4 (continued)

	not sign it once, what is that mean? Whereas if you have the opt-out, somebody goes to the website and said, “I am out,” then they are out until they might opt back in. But it is—the point being, it is a much simpler system do to the opt-out, but it is not necessarily the right system. So, that is why we are here to talk with you.
Risks:	In other words, the systems that are set up have very high levels of security and you have to have the right qualifications in order to get access to any of the information. Is there a risk that hackers could get in there? Yeah. There is always that. There is that kind of risk but folks understand the sensitivity of this kind of information and so the systems are designed to be as secure as people know how to make them these days. Now increasingly folks will decide themselves to put their health information on, make it available. Some folks have a lot of personal stuff on Facebook and that type of thing and obviously University and Healthcare organizations do not have control over that but stuff that the institutions have control over will have a high level of security; meaning that only certain people would be able to have access.
Protections:	And so, nothing the investigators or researchers would acquire would get to insurance companies. Insurance companies may learn information because you send in your bills to get paid for whatever your healthcare issue is, and so, there is always a concern that, in this particular domain, insurance companies and employers might use genetic information to discriminate against you. But from a research standpoint, there have not been any instances at the University of information having been lost in a research context and then getting to insurance companies that then use it for underwriting.
Storage:	One is the electronic medical record itself and, of course, that is stored forever. If an investigator accesses that for a particular research and pulls out some information and puts it in his or her database that needs to be saved for a certain number of years but then it is destroyed later so that does not become sort of immortal in the hands of the investigator. The regulations require that the hospital keep that sample for 10 years or more, and that is to protect you as a patient because if there was a mistake made, somebody could go back and recheck that later and see whether the diagnosis was correct. So, a lot of tissues are, say,

Table 4 (continued)

	for clinical reasons and then they can become available for researchers who want to study those tumors. So, if you had a bunch of tumors stored away from people with, say, cancer of the pancreas, a researcher who is interested in cancer of the pancreas could look at those clinical samples and do some research. So, those would be samples that were required for clinical reasons, but may be made available for research. Then there are samples that you go and you sign up for a research project and they takes samples, and they say, “Now, we have stored these samples away because we are doing research on multiple sclerosis, for example,” then those would be stored away. But then they might be used for other purposes as well. It is possible that those stored samples that were obtained for one reason would be used by investigators for a separate reason.
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already occurring with virtually no adverse consequences; and obtaining consent for population-based research would be too cumbersome, potentially inhibiting the conduct of research. “*The tissue samples are already there, we’re not using them. If you have the right to opt out, you can opt out.*”

The importance of education Most of the participants stated that it was the quality of education efforts that were most important and not the type of consent approach (opt-out or opt-in) for conducting population-based research. What was important was to focus time and resources toward education and for the institutions conducting the research to be open and transparent about these practices. Suggestions for how to inform individuals about this research included interactions in the clinic, public service announcements, Facebook, Twitter, health fairs, postcards, DVDs, movies in offices, etc. Participants also noted that it would be important to communicate about the safeguards that are part of the system (IRBs, for example), information about who would have access to the data, and to highlight that research would not include controversial research projects such as cloning (“*and it’s not about cloning so that’s not an issue.*”). Several participants also suggested the importance of educating the public about the positive aspects of population-based research. For example, “*And you’re going to get a lot of people that opt out that don’t realize what they’re doing. You need to make sure you educate them first.*” and “*If it was explained in a positive way, that it’s for medical research and helping people with different diseases, I think most people would not have an issue with it.*”

Discussion

Prior to participating in one of our focus groups, participants were almost entirely unaware of current research activities at academic medical centers involving access to medical records and the use of residual clinical specimens. The participants found the topic interesting and had many questions seeking clarification after viewing an educational video. It was clear that our educational movie was not, in and of itself, sufficient to address the range of issues of interest to our participants. We suspect, however, that the movie gave the participants sufficient knowledge to enable them to form questions about a previously unfamiliar topic. We found strong support for biomedical research in order to improve the quality of health care. The primary concerns about this type of research involve breaches of confidentiality and the potential loss of insurability.

A central topic presented to the focus groups was the decision-making model for access to EMRs and residual clinical biospecimens. There is an active national discussion about how patients should be engaged in decision-making regarding access to records and tissues including a number of public attitude surveys. The BioVU project at Vanderbilt involves a repository of residual clinical tissues that are linked with EMRs (Pulley et al. 2010). The biospecimens are de-identified and patients are offered the ability to opt-out. In a population-based survey of Nashville residents, Brothers et al. found that the approval for the BioVU concept was high (Brothers et al. 2011). Of their participants, 93.9 % somewhat or strongly agreed, on a four-point scale of strongly agreed to strongly disagree, with the statement “DNA biobank research is fine as long as people can choose not to have their DNA included.” However, only 45.5 % somewhat or strongly agreed to the statement, “Researchers should be allowed to use de-identified genetic information without getting written permission from patients.” The reason for the discrepancy between these findings is unclear. In a recent study of general population attitudes in the catchment area for the University of Iowa using focus groups and a survey, Simon et al. found that 63 % of the focus group participants and 67 % of the survey participants preferred an opt-in approach over an opt-out approach for biobank participation (Simon et al. 2011).

Veteran’s Affairs patients were surveyed by Kaufman et al. specifically on the question of an opt-in versus opt-out approach to biobank participation. They found that 80 % of respondents were willing to participate under an opt-in model while 69 % were willing to participate under an opt-out approach (Kaufman et al. 2012). Vermeulen et al. (2009) surveyed cancer patients in the Netherlands regarding preferred consent models. They described three approaches to consent as follows: a “one-time consent” group in which patients are approached for a single decision regarding biobanking, an “opt-out” approach in which no specific

information was given about biobanking but patients could opt-out of participation, and an “opt-out plus” approach in which patients were informed verbally with a written document regarding biobanking and their option to decline. They found that 43 % of participants preferred the “opt-out plus,” while 34 % preferred the “one-time consent,” and 16 % preferred the simple “opt-out” approach. Similar to our findings, a small number of their participants (8 %) indicated that neither information nor choice were necessary for their participation in the biobank.

This literature suggests that individuals are generally willing to contribute tissues to biobanks and related research under a variety of consent models, although the opt-in approach tends to be preferred. Answers to surveys on the subject are likely influenced by a variety of factors including knowledge of the issues, respondent health status, and trust in the institution responsible for the biobank. Our assessment of public opinion differed in important respects. First, we prepared an educational movie that provided a broad overview of the Utah initiative and the conduct of this type of population-based research. The movie was augmented by the ability of participants to ask questions about the topic during the focus groups. Therefore, our respondents may have had a higher level of background information on the topic. Second, we specifically presented the opt-out approach as our preferred approach. Because of the substantial complexities of an opt-in approach when research involves records and tissues from large numbers of individuals, our leadership group made a preliminary determination that the opt-out approach was preferable with respect to scientific utility and feasibility. Of note, the opt-out approach described to our participants was similar to the “opt-out plus” approach described by Vermeulen et al. (2009) in which patients would be informed of research access to residual tissues in EMRs and of their ability to refuse access. Furthermore, local experience and the literature illustrate that biobank-dependent research has been safe with no published reports, to our knowledge, of harm to individuals from breaches of privacy or confidentiality. Therefore, we considered it appropriate to present our preferred approach to participants and then determine whether the participants considered this approach to be acceptable. We suspect that most of our participants found the opt-out approach to be acceptable because they had a better appreciation for current standards, the complexity of an opt-in approach for this type of research, and for the safeguards routinely employed.

The support for an opt-out approach was contingent on providing adequate information to patients and assuring that there is a relatively easy process for individuals to opt-out. Conversely, like Vermeulen et al. (2009), we found that a number of our participants did not think either notification of these research practices or patient choice were necessary, although these individuals were in a minority.

There are several potential limitations to this study. The majority of our focus groups were conducted in Utah, so there may be regional factors that influenced responses. More specifically, the University of Utah and Intermountain Healthcare are the predominant health systems in the state and trust in these institutions may have influenced responses. However, as noted, we did not identify substantive differences in focus groups with participants from Washington, Minnesota, or Arizona. In addition, the focus groups were not stratified by race or ethnic group, so any difference in attitudes in subgroups in the population may be less evident in focus groups with mixed racial/ethnic backgrounds. A significant potential limitation is that the investigators expressed a clear preference for the opt-out approach. While this almost certainly influenced our results, our primary research question was whether our preferred approach was acceptable to the public, not what approach the participants would prefer if given an open choice. This parallels how clinical research is generally conducted in which potential subjects are asked whether they are willing to participate in a given protocol.

Our overall conclusion is that members of the general public who are informed about current practices and the complexity of the issues are supportive of research approaches that involve information and an element of choice with an opt-out mechanism being generally acceptable.

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Compliance with ethical guidelines All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

Conflicts of interest Jeffrey R. Botkin, Erin Rothwell, Rebecca Anderson, Louisa Stark, and Joyce Mitchell have no conflicts of interest.

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