Perceptions toward establishing a biobank and clinical data warehouse: Voices from the community

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Abstract

As Biobanking projects become more prevalent as an enabling resource for large-scale genetic research, it is important to assess public opinions from the community whose samples populate Biobanks. Although major studies were conducted to engage community members in advance of establishing Biobanks, few have included the attitudes/perceptions and educational needs of residents in the planning process. This qualitative pilot project was designed to engage the community in the planning process of establishing a Biobank and Clinical Data Warehouse. A thematic analysis of transcripts from seven focus groups and ten individual interviews revealed four major themes: Altruism, Acceptance, Anxiety & Fear, and Education. The voices from our community indicated a willingness to accept and participate using medical waste (biomaterials), given appropriate education is provided to patients and communities and they can exercise autonomy by signing a consent. This is a pivotal time in health care, especially in lieu of the evolving genomic era. Nurses have a tremendous responsibility and opportunity to become leaders in the era of Biobanking, and bridging the gap between discoveries from Biobanking and improving the quality of clinical care from bench to bedside.

Key words
Community engagement, Medical waste, Opt out, Biobanks, Genetic research

1 Introduction

With recent advances in molecular biology, human bio specimens such as blood, surgical tissue, saliva, and urine that contain genetic material that researchers can analyze to identify gene variations associated with human diseases [1]. With identification of the role that genes play in disease formation, researchers are able to develop new diagnostic tests (BRCA1 and BRCA2) and targeted treatments for specific diseases. Furthermore, advances in genomic technology and computational approaches have significantly changed our understanding of the non-random distribution of human genetic variants, its impact on disease susceptibility and variable drug response across human populations [2]. Central to this success is the availability of large cohorts of unrelated individuals and families willing to donate biomaterials clinical and health data to Biobanks and Clinical Data Warehouse (CDW). Typically, Biobanks are repositories designed for storage of leftover human biomaterials (blood, fluid, DNA, urine, tissue sample) and health information from thousands of participants who voluntarily contribute their samples for future research. A clinical data warehouse is a facility or repository that houses all electronic health and clinical data. Both Biobanks and CDWs play a critical role in improving our
understanding of the genetics of common complex diseases [3]. Although some focus on specific diseases [4] and whole populations [5], others focus exclusively on pediatric and parent-child enrollment [6].

The process for collection of biomaterials from different sources is not new and has been carried out for many years in laboratories and hospitals. The first large DNA biobank was established in Iceland in 1998. Since then, large DNA Biobanks have been established in the UK, Estonia, Japan, Sweden, and Canada [7], France, Spain, Netherlands, Germany, and Japan. Similarly, several large-scale Biobanks have been established in the USA, including those at the Marshfield Clinic in Wisconsin, Vanderbilt University in Tennessee, Northwestern University in Chicago, and The Mount Sinai Medical Center in New York City [5, 8, 9]. The number of tissue samples in the US banks alone was estimated at more than 300 million at the turn of the century and is increasing by 20 million a year [10]. In order for DNA Biobanks to be a valuable reservoir of genetic information, large numbers of participants from all racial and ethnic backgrounds need to be included to ensure equal representation from all populations [2]. Although studies conducted to engage and consult community members in advance of establishing Biobanks have documented strong support from the public [11-17], there still exists distrust among some ethnic minorities [18, 19]. Further, few have included recommendations from the public to tailor an educational program for prospective donors to make an informed decision prior to contributing to a Biobank and CDW.

This study was designed to engage community residents in the planning process to develop approaches to educating the public about their participation in a Biobank and CDW at an academic institution. The study also sought to explore answers to the following questions. (1) What are the attitudes of community residents toward collection of biomaterials to be used in future research? (2) What are some strategies to address the educational needs of patients relative to their participation in the Biobank and CDW?

**Ethical and legal issues with biobanking**

Biobanks are usually comprised of biological samples associated personal health information, which are used together for biomedical research. Research results are generally very important for society and Biobanks have been heavily supported and funded by many governments. However, in recent few years, Biobanks have undergone rapid proliferation and have become increasingly complex. For example, various distinctions have been made between different types of Biobanks such as population-based vs. disease-based. Although they have become an important component of biomedical research, they have raised many questions regarding their ethical, legal and social implications (ELSI). Some of the key ethical concerns are: it is not clear how best to obtain informed consent for future research, who is actually competent to give informed consent and donate a sample, term storage of tissue, data sharing, guarantee of privacy, ownership, issues surrounding returning results and incidental findings. Although much progress has been made, there is still uncertainty and many Biobank developers lack common governance. Moreover, concerns about privacy may deter people from participating in biobank and genetic research. Furthermore, recruitment and retention of biobank participants require understanding the nature and magnitude of these ethical, legal and social implications. With the recent rapid developments in Biobanking, and no current standardized governances, all of these issues are magnified with plenty of new questions continuously arising. An important question is: how do we include public voice from community engagement in establishing a biobank or providing governance policies?

**Medical University of South Carolina (MUSC) Biobank Initiative**

MUSC was established in 1824 and is located in Charleston, South Carolina (SC). As a largely rural state with a population of approximately 4.3 million, SC is characterized by critical unmet health care needs. MUSC, a state supported university with a large medical center, joined other previously funded academic research centers initiatives to establish a Biobank and CDW through its 2009 Clinical Translational Science Award (CTSA). The Biobank initiative proposed that patients from local practices contribute biomaterials during clinical care from diagnostic treatment procedure and or hospitalization. The proposed disclosure was planned at the time of admission along with a patient teaching brochure. Under the proposed system, the hospital pre-admission packet Consent for Medical Treatment included a paragraph on retention, disposal and use of blood, body fluid or tissue.
Specific language regarding “opt out” for use and storage of medical waste for future research was similar to Vanderbilt’s initiative in that patients not wishing to have their samples used for future research had to check the “opt out” box, otherwise their samples would be stored for future research [20, 21]. However, before launching this planned Biobank initiative, CTSA/MUSC provided a pilot grant to a nurse scientist to engage the community in the planning process. The targeted community included a six county area where most of MUSC inpatients and ambulatory patients reside. The research project led by the author received approval from MUSC Institutional Review Board (IRB) to conduct a twelve months pilot study.

**Purpose**

The specific aims of this pilot project were to assess community attitudes and acceptance of the proposed Biobank practices and policies for storing biomaterials for future research, and to determine the best practice for educating the public regarding the biobank and CDW. This twelve-month study was divided into three phases. Phase 1 included focus groups and cognitive interviews, Phase 2 and 3 included a self-administered survey to patients, employees, students and staff and will be reported elsewhere.

**Community-engagement approach**

Different methods for engaging the public are increasingly being used in many areas of social policy. Reasons (public funding) for seeking input from the public will vary and at the minimum involve observation of democratic imperatives to involve those affected by a particular policy in the development of that policy [22]. This is critical in cases where social policy decisions are made in a bureaucratic sphere with no direct involvement of the wider public. Yet these policies will rely on the public for successful implementation.

It is well documented that collaboration with communities in research occurs along a continuum, and is known as Community-Engaged Research (CEnR). This terminology now used by the National Center for Research Resources (NCRR) at the National Institutes of Health (NIH) requires that people who are affected by governmental and institutional policies be a part of the planning process of actions that directly affect and or benefit them [23]. Biobanks affect the populations served because of the potential for genetic research and personalized medicine, and as such, need buy-in from the public. As Biobanking projects become more prevalent as an enabling resource for large-scale genetic research, it is important to assess public opinion from the community whose samples populate the banks [24]. To this end, we chose to use CEnR as the guiding principle for this study because it presents an avenue for the public to influence the direction of project development. This is supported by studies [25, 26] and is in line with project transparency and open-mindedness at all levels.

**2 Method/Study design**

In this qualitative design, eligibility was based on the following criteria: Participants must 1) be 18 years or older, 2) speak English, and 3) reside in one of the six target counties (Charleston, Beaufort, Berkeley, Dorchester, Georgetown and Horry).

**2.1 Cognitive Interview (CI) procedures**

CI is an established, valid, reliable, and practical tool for health purposes with validated techniques to retrieve accurate information [27]. The author, who has many years of qualitative research, conducted the majority of the CIs. Other members of the research teams had similar experiences and a standardized questionnaire was used. The ten (n=10) informant interviews were conducted to ensure community input into the design of the study and focus group questions. The research team consisted of three PhD prepared nurses and one non-nurse with a doctorate in education. The team created a list that included participants from the faith/scientific community, medical personnel, formal /informal and community leadership. Two interviews were conducted at local churches, one at a synagogue and the remaining interviews were conducted in the
informant’s office or at a neutral location. The ethnicity of the informants was matched to that of the researcher. For example, the director of the Biobank, a European American male (EA) and an EA Jewish nurse (ML) conducted the interview with the Jewish Rabbi. The CI interviews included 1 Hispanic female, 2 White ministers (Circular Reformed Presbyterian Church), 1 Jewish Rabbi, 1 African American (AA) state representative, 2 AA ministers (Baptist, African Methodist Episcopal (AME), 1 AA Department of Health and Environmental Control (DHEC) state health official, 1 white university professor, and 1 AA consumer.

2.2 Recruitment procedures/Focus Groups (FG)

Purposive sampling and public recruitment strategies for FGs included engaging the medical director of the ambulatory outpatient clinics, and leadership from community organizations and the faith community. Interested participants received potential dates, time and location of the focus groups with follow-up reminders from the RA (YG). Ninety percent of the patients who expressed an interest in the study attended and participated in the focus groups. Each consenting CI and FG participant was compensated with a $35.00 gift card.

2.3 Focus Group (FG) procedures

The PI /author (trained social worker) moderated all focus groups. All participants were consented by the RA or PI. Morgan [28] Methodology was used to facilitate group discussions. The PI provided an introduction and general purpose of the study. This was followed by details of the proposed procedure and the process for collecting the samples. Confidentiality was established and the PI used first names only during the discussion sessions. Table 1 describes the focus group questions. Similar to CI interviews, the sessions were recorded and held in a community setting accessible to participants. The only demographics collected on the participants were race, gender and zip codes.

2.4 Data collection

We conducted 10 key informant interviews (n=10) and seven digitally recorded focus groups (n=57) for a total of 67 participants (n=67). The FG guide consisted of ten open-ended questions suggested by CIs and directly related to the aims of the study (see Table 1).

Table 1. Questions for focus group discussion guide

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>Have you ever-participated in research? Genetic Research?</td>
</tr>
<tr>
<td>2</td>
<td>What comes to mind when you think of genetic research?</td>
</tr>
<tr>
<td>3</td>
<td>What might be some reasons that people will not participate in genetic research?</td>
</tr>
<tr>
<td>4</td>
<td>What are reasons that would keep you from participating in genetic research?</td>
</tr>
<tr>
<td>5</td>
<td>How do you feel about donating tissue and blood (medical waste) to MUSC Biobank?</td>
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<tr>
<td>6</td>
<td>What kind of information would you need to know before you participate in Biobank?</td>
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<tr>
<td>7</td>
<td>What are your thoughts about having your information in Bio Bank shared with other investigators?</td>
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<tr>
<td>8</td>
<td>How do you think we should educate people about the Biobank?</td>
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<tr>
<td>9</td>
<td>MUSC is considering a consent process known as “opt in”, or “opt out”. Discuss your feelings about “opt in” or “opt out”. Discuss your feelings about “opt in” or “opt out”.</td>
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<tr>
<td>10</td>
<td>Would you want to sign a separate consent to participate in the Bio Bank?</td>
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</table>

2.5 Data analysis

FGs and CIs discussions were transcribed and checked by the PI and YG to confirm accuracy and verbatim transcription. Qualitative Data Analysis (QDA), a software tool using Microsoft Word [29] was used to format a table for managing data. The research team conducted a thematic analysis of interview transcripts [30, 31]. The transcripts were manually coded and organized according to content categories.
A codebook was developed to identify key opinions and themes. An inter-coder reliability check was conducted on two transcript by IS and YG and agreement of 90% reached on the selected transcripts.

3 Results

The majority of the FG participants were AA females with zip codes from Georgetown and Beaufort counties. Eight interviews were conducted in Charleston County, one each in Columbia and Dorchester County.

3.1 What are the attitudes of community residents toward collection of biomaterials to be used in future research?

Four major thematic themes emerged from the data: Altruism, Acceptance, Anxiety & Fear, and Education (see Table 2).

Altruism: “As long as I can help somebody”

The theme of altruism was very evident in both frequency and content with CI and focus group participants. The frequency of “you can help somebody” speaks to the humanity of mankind and did not differ by gender or ethnicity. The negative aspect of altruism cited by CI included the risk of discrimination in matters related to insurance and employment. For example, one participant indicated that although they were supportive, they believe that the test could be used to discriminate against you with a job or getting insurance, however if they could be assured that this would not occur, they would still participate. Nonetheless, the spirit of altruism was not dampened by lack of education about biobank and CDW. For example, one participant stated that once education was provided, he or she would participate in a Biobank for the good of mankind. A prominent minister who was interviewed stated, “it’s medical waste and they are going to throw it away, so why not try to help somebody. I would help somebody, and I cannot think of a reason why I would not participate, it is free and one time only”. “My grandson has sickle call disease and they might find a cure”.

Acceptance: “I think it is a good thing”

The theme of acceptance was related to participants’ willingness to trust institutions and government despite past research exploitation among ethnic minorities from academic institutions. FG and CIs, participants were still accepting of the idea of storing biomaterials for future research as long as “it could help somebody”. Although when asked about past participation in research or genetic research, most participants reported that they had not participated in any research, especially genetic research and when asked what comes to their mind when they think of genetic research, their answers ranged from CSI, a CBS television program to DNA paternity tests.

Anxiety & Fear: “Can this information be used against me” (FG)

The theme of anxiety and fear was threaded throughout the CI and FG discussions. Both related to the possibility of genetic discrimination, employment, insurance and fear of the unknown. Common reasons cited for not participating in biobank included not having the understanding or enough information about Biobank and CDW. This lack of knowledge about the purpose of the biobank and CDW caused anxiety and mixed feelings regarding the return of results and data-sharing with other investigators. This was evident in the following remarks: “who owned the data”, “will it be shared” and “how will we be protected?” Another stated, “most people may be afraid to learn results about having a disease because they would be unable to treat it”. One participant asked the following questions, “can they link the information back to me?” “Can it be used to send people to jail?” “Will they send me results if they find something”. Additionally, anxiety and fear were related to poor understanding of the term “opt out”. Participants felt it raised suspicions and was tricky and non-transparent. More importantly, they felt that it places additional burden on the patient. However, once the “opt out” consent process was explained during the session, there seemed to be general consensus for acceptance of medical waste and or biomaterials for establishing the Biobank. Overall, participants indicated a willingness to participate and a desire to sign a consent form as opposed to making an X in a box to “opt out”. As one participant stated, “I want to sign my name and not make an X in a box”.

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Table 2. Inductive thematic analysis results

<table>
<thead>
<tr>
<th>Subtheme by domain</th>
<th>Meaning abstraction</th>
<th>Demonstrative quotes CI &amp; FG</th>
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<tbody>
<tr>
<td>“I want to help somebody”</td>
<td>Altruism Motivation to provide something of value Principle/practice of unselfish concerns/devotion for others</td>
<td>“It’s beneficial, and I think that considering some of what medical science has to deal with these days it’s necessary. I think as long as it's used properly.” (CI) “If you can help somebody, and you ain’t got nothing to lose, cause they throwing it way any way.” (FG) “It is the right thing to do.” (FG) “It's a one time opportunity for those that want to voluntarily participate and it's not ongoing.” (CI)</td>
</tr>
<tr>
<td>“I think it is a good thing”</td>
<td>Acceptance The act of taking or receiving something offered</td>
<td>“Well, number one, I would support it because it opens a door of opportunity ways to cure some type of diseases or something like that.” (CI) “Yeah, I have no problem with it; I think it's a good idea. I think anytime that you can do research without, you know, hurting somebody, or, like, cause this is the, it's pretty much a win, win.” (FG) “I think it would be a good idea. Because of the fact that, I mean, so many people come up with you know different illnesses and you know really trying to understand, to better treatment, you know, and things like that. So, I mean, really think that it would be, you know, a wonderful idea.” (FG)</td>
</tr>
<tr>
<td>“I am afraid and do not trust the government”</td>
<td>Anxiety &amp; Fear Confidentiality, most guarded Scared of finding out what they don’t want to know safe guarded</td>
<td>“But, they're afraid. And, you know, when you are younger, you are afraid of these things you don't want to know. But, when you get older, you want to know what's going on in your life.” (FG)</td>
</tr>
<tr>
<td>“We need to be educated about these things”</td>
<td>Lack of Education To impart knowledge, Provide instructions</td>
<td>“Education is a slow process.” “I think I would. With the proper education. I wouldn't see why I wouldn't participate. If not for me maybe something will come from it, and it could help my next generation of persons that come through. So I can see how it could be useful.” “I don't know that you could really educate the public, but you could educate the people who are actually going to be contributing to it. And probably the best way to do that is when their- when the act is occurring.” (FG)</td>
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**Implementation Strategies Recommendations**

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<tr>
<th>Implementation</th>
<th>Strategies</th>
<th>Recommendations</th>
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<tbody>
<tr>
<td>Do not burden the patient</td>
<td></td>
<td>“I do like the fact with admission testing. Like, when they coming to have a procedure, most of the time when you come in, you're with a nurse. So, that way, that nurse can present that information or whatever to you.” (FG)</td>
</tr>
<tr>
<td>Easy to read pamphlet for the patients at lab procedures</td>
<td></td>
<td>“I would say have a separate team do it, because you have the receptionist come in, or a nurse come in, or you have one of other people who do the paperwork to bring it up to the patient in the hospital, and all the patient is doing is just signing. They're not really explaining anything. So I think it should be a separate team that comes up a little bit later after the person is admitted into the hospital, and then let that group explain to that patient what it's all about.”</td>
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<tr>
<td>Send informational letter to patient population</td>
<td></td>
<td>“You can make an event like a health screening for churches. This church here, at my church, we do a health event every year. And so, we’ll have a bunch of people that you can talk to them that way. And then you could reach out further to other people, and then they bring back somebody the next following year, and then you could talk more about it.”</td>
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<tr>
<td>For inpatient, utilize the Health Monitor and discharge nursing staff</td>
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<td>“I think having a consent would be easier to me, I do not like “opt out”, I want to sign my name to participate something (FG). Send a letter to patients explaining the Biobank.”</td>
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Education/Implementation: “We need education about this and do not rush us to make a decision” (CI)
A majority of the participants expressed a need for more education about the Biobank and CDW. Especially, how it will help discover cures for common complex diseases such as diabetes, sickle cell and heart disease. When asked about the type of education needed, there was consensus regarding an explanation of Biobank, the purpose, the process to participate, social governance and confidentiality. Format and source of education included patient teaching brochure, newspaper, churches and community forums. When asked about reasons for non-participation, one participant stated that, “I think the main reason a person would not participate is because of lack of knowledge”. “I think once they understand that it can help our future generation, why would they not participate.” Both FGs and CIs agreed that lack of participation was related to lack of knowledge about Biobank. For example, when asked for a definition of Biobanking, answers ranged from some type of bank to something dealing with biology.

3.2 What are some strategies to address the educational needs of patients relative to their participation in the Biobank and CDW?
There was some consensus as to the best strategy for informing patients and the community about using biomaterials for future research. General suggestions ranged from using social media, informational letters to patients, easy to read pamphlets at admission, and utilizing nurses during discharge planning to obtain informed consent. Specifically, as it related to local implementation, participants proposed a two-tier patient education approach that involved: a) sending letters to patients explaining the process as well as b) presenting easy to read pamphlets at hospital pre-admission and outpatient lab clinical sites. More importantly, participants did not like the idea of having to make a decision to participate in the biobank at the time of admission. Instead, they suggested that information be presented on the Health Monitor Channel in the patients’ room followed by explicit explanations and consenting from the nurses during discharge planning. A summary of our results revealed consistent acceptance of the Biobank, altruism, and appropriate education provided so residents are well informed to make decisions in a non-rushed environment (See Table 2, Strategies for Implementation).

4 Discussion
The purpose of this project was to assess community attitudes and acceptance of proposed Biobank practices and policies for storing biomaterials for future research, and to determine the best practice for educating the public regarding their participation in the biobank and CDW. Although our results are similar to others such as Lemke and Wolf, in acceptance toward establishing a biobank and CDW, our participants (mostly female and AA) were more accepting of using medical waste to enhance their participation. As Biobanks strive to diversify participants, increasing public awareness regarding the utility of biomaterials / medical waste for future research maybe a future strategy to enhance the diversity of participants, especially minorities. As Biobank research continues to become ever more popular, the inclusion of ethnic minorities in the database is paramount. For example, in a 2007 study assessing the reasons why acute care patients with cardiovascular disease chose non-participation in Biobanks, results indicated that both age and certain minority demographic characteristics were associated with less likelihood of participation; with the main reason being wanting to avoid a blood draw [3]. Developers must also acknowledge the lack of trust by ethnic minority groups toward medical institutions [19, 32]. Over the years, as more Biobanks have been created, the idea of community consultation has become a necessity as community consultation incorporates the ideas, concerns and needs of the patients into the development of Biobanks. Moreover, consultation allows community members to better understand policies on how their biomaterials are being used and most importantly, reinforces public trust in research projects. Our participants embraced the consultation process and also stated that this type of venue could be important to educate the public. Furthermore, the consultation process helps researchers understand the needs of the community regarding having their samples stored in a Biobank [33].

Ultimately, it is important that careful planning and development of new Biobanks engage diverse community members [11], as their opinions may help with acceptance and the best practice for consenting and utilization of residual
samples. Giesbertz defines residual samples as leftover tissue obtained in the course of clinical care that can be included or collected through an opt-in method (a person explicitly expresses consent to include residual tissue) or an opt-out method and the tissue is stored unless a person explicitly refuses [34]. He further notes that the “opt in” is an appropriate approach to collect residual samples. However, the expansion of Biobanks and rapid developments in biomedical research underscore the need to evaluate the proper procedure, as each community will be different. Nonetheless, the development of Biobank has caused many legal and ethical issues to arise ranging from the need for community consultation, informed consent, legal measures enacted to protect patients and researchers, and reporting of return results [34-36]. Additionally, researchers need to have a better understanding of the reason for low opt-out rates. For example, do the low rates truly reflect well-placed trust or simply poorly informed apathy?

Although, our participants were accepting of the proposed Biobank and CDW, many demonstrated a sense of autonomy by voicing a need for a consent process that will allow them to sign their name in order to participate in the biobank and CDW.

Since the consent process can cause both financial and logistical issues, many researchers view the idea of informed consent in its purest form as unattainable because the idea of Biobanking involves future research ideas that may not come to fruition at the time of consent [37]. Nonetheless, several proposals have been made to address this problem, including the idea that patients can be given different options for consent, such as general formal long consent, short consent process or the informal placing an X in a box for “opt in or opt out”[21]. Ultimately, community consultation and engagement allow clearer communication between the involved parties about what is more acceptable for storage, recruiting and research purposes. As we explored the attitudes and lack of education of our target population toward collection of leftover biomaterials for establishing a Biobank and CDW, we came across three unanticipated findings related to patient education and acceptance that may be generalizable. 1) The utilization of health monitors in a patient’s room to inform the patient and family about biomaterials’ usage, process and purpose and 2) the use of nurses versus technical administrative staff to further educate and, 3) the use of nursing staff to consent patients during discharge planning. In reference to how the participants wanted educational materials regarding the Biobank disseminated at our institution, they recommended that more be information presented in venues sponsored by the faith community, group educational interaction, direct patient education and social media. Our work supports the idea of community consultation and engagement because understanding the purpose of biobank and the concept of informed consent process is vital to ensuring its success [13, 19, 38].

**Limitations**

This was a twelve-month pilot study with 67 participants conducted among residents in southeastern part of the country and results may not be applicable to other regions within or outside the United States.

**5 Conclusion**

Given the previous studies conducted on patient perceptions of and willingness to participate in Biobanking, the need for a diverse Biobank pool warrants further research to elucidate the attitudes and barriers from diverse US regions as well as the best strategies, This pilot study provided an opportunity to use principles from CEnR to give voice to communities affected by proposed policies for establishing Biobank and CDW. This is a pivotal time in health care, especially in lieu of the evolving genomic era and personalized medicine. The voices from our community indicated a willingness to accept and participate in a Biobank when using biomaterials and with appropriate education. Our next challenge is to ensure that their voices are heard.

**Acknowledgment**

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Conflict of interest
Ida J. Spruill received funding from South Carolina Clinical and Translational Research (SCTR)/ Medical University of South Carolina Clinical Transitional Science Award (CTSA), National Institute of Health National Center for Research Resources (NIH NCRR). Grant number ULIRR029882.
Youlanda C. Gibbs, Marilyn Laken, and Tiffany H. Williams declare that they have no conflict of interest.

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 (5). Informed consent was obtained from all participants for being included in this study.

References


