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A Web-based Platform for Educating Researchers about Bioethics and Biobanking

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Abstract

Background—Participation in biobanking among individuals with familial risk for hereditary cancer (IFRs) and underserved/minority populations is vital for biobanking research. To address gaps in researcher knowledge regarding ethical concerns of these populations, we developed a web-based curriculum.

Methods—Based on formative research and expert panel assessments, a curriculum and website was developed in an integrative, systematic manner. Researchers were recruited to evaluate the curriculum. Public health graduate students were recruited to pilot test the curriculum.

Results—All 14 researchers agreed that the curriculum was easy to understand, adequately addressed the domains, and contained appropriate post-test questions. A majority felt the dialogue animations were interesting and valuable. 22 graduate students completed the curriculum and 77% improved their overall test score.

Conclusions—A web-based curriculum is an acceptable and effective way to provide information to researchers about vulnerable populations' biobanking concerns. Future goals are to incorporate the curriculum with larger organizations.

Keywords

bioethics; eLearning; biobanking; medically underserved; education; genetics

Introduction

Since 2000, the Collaborative IRB Training Initiative (CITI) Human Subjects Training Program has become the standard certification option for researchers, providing a “basic

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course” with an overview of the rules, ethics, and best practices required when conducting research with human subjects [1, 2]. The Human Subjects Research (HSR) course includes topics such as the basics of IRB regulations and the review process, assessing risk to participants, genetic research, informed consent, research with vulnerable subjects, and other relevant issues [2]. As technological innovations [3] and precision medicine evolve, new ethical concerns are surfacing that may influence patient/community members’ participation in biospecimen science. Of particular interest to biomedical and bio-behavioral researchers is the ability to sensitively recruit diverse subjects, such as individuals with familial risk for hereditary cancer (IFRs) and/or individuals from underrepresented racial-ethnic communities to participate in biobanking research. Further, our previous research suggests discordance between researchers’ perceptions and the expressed concerns and perceived ethical issues among vulnerable and underrepresented populations [4]. To address this educational gap, we describe the steps and processes used to create a web-based curriculum to provide biomedical and bio-behavioral researchers examples of common concerns and ethical issues that may arise in the process of conducting research involving biospecimen donation for storage in biobanks. When bio-behavioral researchers are aware of community members concerns and use sensitive methods for recruitment and communicating about biospecimen donations, the community is likely to develop trust and confidence needed to participate in biobanking research.

As background, biobanks are repositories of blood, tissue, and other biospecimens used for research with the purpose of identifying links between genetic and environmental influences of diseases, such as cancer [5, 6]. Genetic data for many hereditary cancers, however, such as breast cancer, are mostly limited to Western European and North American Caucasian populations [7] and racial/ethnic minority populations are not well-represented in large-scale cohort studies and biobanks [8]. In addition, high quality biospecimens from IFRs are instrumental in advancing cancer research, and can be used to assess gene-environment interactions, estimate cancer risk in mutation carriers, and develop prevention and early detection strategies [9]. The recruitment of IFRs and underrepresented multi-ethnic community members in biobanking studies offers new opportunities for advancing science. Yet, involvement in biospecimen research entails a number of unique ethical concerns, which researchers should be aware of when reaching out to specific at-risk or vulnerable populations. For example, IFRs may be reluctant to donate a biospecimen if they fear potential discrimination by insurers and employers [4]. Research suggests IFRs are often unaware of the Genetic Information Discrimination Act (GINA), or do not trust the law to protect their personal health information [4]. Individuals from underrepresented multi-ethnic communities may be distrustful of research due to historical abuse, have concerns about pain associated with biospecimen donations, such as needle pricks, or fear their DNA will be used for purposes they deem unacceptable, such as cloning [4, 3]. Therefore, Community Engaged Research (CEnR) plays a significant role for outreaching to IFR and racial/ethnic minority populations [10] by providing the researcher with an understanding of what a new innovation means to a specific community. The insights and perspectives gained from outreach to IFR and racial/ethnic minority populations can inform the development and evaluation of human subjects’ protections training materials [11].

Presently, the CITI HSR training program offers short modules on research with vulnerable populations, such as employees, medically vulnerable populations, prisoners, children, pregnant women, human fetuses, and neonates [12]. An additional module presents the challenges of conducting genetic research in human populations including ethical, legal, and regulatory concerns including a discussion of the issues surrounding the use of stored biological samples [12]. While these modules provide essential information for biomedical and bio-behavioral researchers recruiting vulnerable participants for biospecimen donation, such as IFRs and racial/ethnic minorities, they only offer a brief overview of each topic presented in the same format as other HSR modules. The present lack of racial/ethnic minority and IFR participation in biobanking studies may be alleviated with additional, more in-depth training opportunities for researchers. This training can aid in increasing awareness of factors facilitating and/or impeding biospecimen donation [13, 14]. To address this training gap, Project 4B: **Bioethics and Biobanking Training for Biomedical and Bio-behavioral Researchers**, aimed to test the feasibility, acceptability, and effectiveness of a novel web-based training curriculum for researchers to improve knowledge of IFR and underrepresented multi-ethnic populations' perceptions about biobanking.

Methods

Previous research conducted with IFRs, vulnerable community members, and biomedical and bio-behavioral researchers provided the framework for identifying key curriculum content areas. Detailed results from these focus groups are reported elsewhere [citation removed]. Our approach was rooted in the framework of Diffusion of Innovations [15] with additional questions exploring the novel concept of opportunity loss. The Institute of Medicine recommends that training for health disparities researchers and clinicians requires the integration of **ASK** (Attitudes, Skills and Knowledge) methodology in combination with the ethical principles of the Belmont Report [16]. For example, the ASK methodology directs researchers to think about the needs of vulnerable and high risk populations by focusing on: 1) Attitudes: examine and understand attitudes, such as mistrust, subconscious bias and stereotyping, that practitioners and/or patients may bring to the clinical encounter; 2) Skills: acquire the skills to effectively communicate and negotiate across cultures, including trust-building and the use of important tools to improve communication, such as culturally appropriate language services; and 3) Knowledge: gain knowledge of the existence and magnitude of health disparities, including the multi-factorial etiology of health disparities and the multiple solutions required to eliminate them [16].

Figure 1 depicts a flow diagram of our curriculum development process. A 4B Expert Advisory Panel (EAP) comprised of bioethicists, behavioral and clinical researchers and trainees, and a medical geneticist was engaged throughout the development of the curriculum, including analysis of results and review of case study content. Using the steps described in the diagram, five key domains were identified for inclusion in the curriculum: 1) privacy and confidentiality, 2) communication of personal results, 3) communication of overall results, 4) informed consent, and 5) community mistrust and fear of cloning and genetic research. The content for each of the five key domains was drafted in the form of a case study with scenarios depicting relevant interactions between physicians, researchers, and participants. Table 1 describes the case study content for each domain. Two members of

the 4B EAP (RP and SS) who have bioethics specialty were identified to provide more targeted comprehensive feedback and edits for the case studies, including suggestions for post-assessment questions. Based on consultant feedback, a final version of the curriculum was prepared for next steps.

A 4B website (Figure 2) was created to host the curriculum along with informative pages for project results and papers, other relevant publications, and links to additional online resources (such as the Human Genome Project and Genome.gov)[17]. A web-based curriculum was chosen based on researcher learning preferences identified during the formative research phase. To create an engaging course that may be more effective at generating interest than standard formats, four of the case studies were selected to include animated, audio portions. A large, searchable database of cartoonists (CartoonStock) was utilized to identify an animator with the desired art style for our case studies. The case study dialogue audio was recorded by members of the research team and volunteers and sent to the animator, as well as transcripts of the dialogue which included detailed information about preferred backgrounds, poses, character details, and context. A snapshot of the case study animation is presented in Figure 3. A snapshot of the pre/post-assessment questions can be found in Figure 4.

To test the feasibility and acceptability of the web-based training curriculum, we collected preliminary feedback from researchers and obtained their reactions to the curriculum. Researchers who previously agreed to be re-contacted during the formative research focus groups received an email invitation to review the Project 4B curriculum. Using modified Delphi procedures [18, 19], participants were requested to complete six evaluation forms: one form for each case study and one form for the overall website structure. Case study forms assessed case study effectiveness, content relevance, clarity of post-test questions, and accompanying dialogue animations. The website form assessed ease of navigation, appropriateness of aesthetics (font, layout, colors, and images), overall appeal, and reader engagement. All sections of the forms included free response boxes for detailed suggestions and comments. A waiver of informed written consent was obtained from the University of South Florida Institutional Review Board. Participants received a \$30 gift card after completing the evaluation forms.

To pilot the effectiveness of the curriculum, we recruited current public health graduate students to pilot test the curriculum. A study flyer was posted on the College of Public Health bulletin board. Interested students contacted the study coordinator by email or telephone and were scheduled to attend one of the pilot test sessions. Sessions were held in a reserved computer lab within the college and required no more than 60 minutes of participant time. At the start of each session, students were provided with a hard copy of the pre-test (identical to the online post-test). After completion of the pre-test, students received a link to the Project 4B website, a unique username and password, and headphones for the audio portions. Students were provided with detailed instructions on navigating the course website, which included all five case studies and corresponding post-assessment questions. Students received a \$30 gift card for their time.

Results

A total of 14 researchers evaluated the website and five case studies in terms of case study effectiveness, relevance, clarity of post-test questions, and accompanying dialogue animations. The majority either strongly agreed or agreed that the case studies were easy to understand (100%), adequately addressed the issues for that domain (84%), and contained appropriate post assessment questions (90%). Suggestions for improvement included creating additional, more challenging questions, expanding on key terms or issues, and rephrasing statements for clarity. The majority either strongly agreed or agreed that the animations were interesting (92%) and would appeal to biomedical and bio-behavioral researchers (85%). A few researchers (36%) perceived that the animations facilitated learning and retention of the content. In addition, one researcher noted the lack of animation for case study 3 and perceived a decrease in effectiveness of “delivering the message.” When assessing the website as a whole, the majority of researchers either strongly agreed or agreed that it was easy to navigate (73%), was laid out using appropriate colors (73%), fonts (91%), and images (90%), and would appeal to biomedical and bio-behavioral researchers (82%). Suggestions for improvement included increasing the overall font size and expanding resources to include news articles.

For the pilot test portion of the study, 22 public health graduate students were recruited to complete the curriculum and 19 pre and post-test questions. Seventeen students (77%) improved their overall test score after completing the case studies. Three students (14%) had no change in score and 2 students (9%) did slightly worse. Overall, there was an average 1.9 point score increase after completing the curriculum. The average pre-test score was 69.6% and the average post-test score was 79.4%.

Discussion

Focus group results [citation removed] from the initial project highlighted the need to address gaps in researcher knowledge specific to ethical concerns on biobanking and biospecimen donation among IFRs and ethnical/racial minority populations. This research led to the development of a novel, web-based training curriculum focusing on key ethical concerns of this population. The decision to host this curriculum on the web was based on previous focus groups [citation removed] where researchers were asked about their learning preferences, specifically regarding the best format for disseminating the curriculum, their interest in a web-based course, their experiences with web-based platforms, and if the 4B curriculum should be required in a mandatory module program, such as CITI. The majority of researchers felt that an in-person or web-based course would be significantly more effective at improving knowledge compared to a mandatory module within CITI. Although they acknowledged that standard CITI coursework was informative and necessary, they felt that many learners often complete the modules as quickly as possible and do not focus on specific, detailed information that may not be relevant to their field of study.

Consequently, the goal of this curriculum was to present content in a new and engaging way that would generate interest while assisting learners in processing difficult research concepts. It has been shown that visual aids, such as animation and acted analogical

scenarios of concepts, are successful at “demystifying” research concepts and engaging learners at a greater level compared to textbooks and other typical methods used in research training [20]. In addition, including a video supplement to a typical text-based case study resulted in higher frequencies of clauses relating to data exploration, theory building and theory evaluation, suggesting that video components stimulate cognitive processes [21]. A survey of medical students’ learning preferences revealed that half of the respondents perceived that visual aids of any sort increased their concentration ‘a lot’ and that animations combined with the Blackboard platform [22] were optimal teaching aids [23]. When choosing an animation art style, the goal was to identify a balance between the gravity of the topic and success at generating interest with the animated component. The selected animator created a simple, traditional style with vivid colors that did not introduce a comedic or caricature aspect to the message being conveyed. In addition, the animator received detailed guidelines on the appearances of the case study characters, including body position, facial expressions, race and/or ethnicity, and gender.

Previous research has shown that the use of CEnR with the intended population improves the quality of researcher training materials, resulting in higher scores on relevance of the material, overall satisfaction, module quiz scores, and a trend toward higher self-efficacy [11]. By conducting focus groups with IFRs and other vulnerable populations, the final curriculum included material directly contributed by the population under study. Incorporating the beliefs, attitudes, and knowledge of community members in the development of researcher training materials can help ensure that the curriculum highlights key concerns, provides culturally sensitive and responsive education, and is reflective of the target population [11, 24, 25].

Conclusion

Participation in biobanking among underserved racial/ethnic minorities and other vulnerable populations is crucial to reducing cancer health disparities. One way to improve participation is to educate biomedical and bio-behavioral researchers about common concerns, which include fears regarding loss of privacy and confidentiality, discrimination from employers or insurance companies, mistrust of researchers due to historical abuse, and fears of cloning and invasive procedures. A web-based bioethics and biobanking curriculum with animated case studies is a feasible and acceptable way to provide information to these researchers. Future plans focus on incorporating the Project 4B website and curriculum with national organizations for wider dissemination of material.

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Figure 1.
Project 4B Curriculum
Development Process

Figure 2.
Project 4B Website Home Page

Figure 3.
Case Study 2 Animation Screenshot: “Communication of Personal Results”

Figure 4.
Case Study Pre/Post-Assessment Questions Screenshot

Table 1**Project 4B Case Studies**

Case Study Title	Case Study Objectives
1. Privacy & Confidentiality	<ul style="list-style-type: none"> • Identify the unique privacy concerns of healthy controls with a family history of hereditary cancer • Explain the scope of the Genetic Information Discrimination Act of 2008 • List ways participants may perceive this law • Identify layman's terms that facilitate subject's understanding to use in the consent form • Be prepared to provide verbal explanations in conjunction with the consent form document • Identify signs indicating participants may have questions or concerns they cannot articulate
2. Communication of Personal Results	<ul style="list-style-type: none"> • Develop a plan for patient recontact in the case of a clinically actionable accidental discovery • Evaluate the consent form document to ensure that participants are informed about the terms of recontact • Identify the role of an honest broker in biobanking research • Explain how biospecimens and health information will be stored and accessed by the research team
3. Communication of Overall Results	<ul style="list-style-type: none"> • Develop a plan to provide study updates to research participants • Identify ways to present research results and progress that are appropriate and relevant to participants • Identify the need for effective communication during each stage of the research study • Describe the unique concerns of participants with a family history of cancer, such as viewing biospecimen donation as an "investment" and wanting researchers to acknowledge a "face behind the sample."
4. Informed Consent	<ul style="list-style-type: none"> • Identify different formats for consent form documents (blanket consent, menu consent, study specific consent) • Identify the ethical and research advantages/disadvantages of each format
5. Community Mistrust and Fear of Cloning and Genetic Research	<ul style="list-style-type: none"> • Identify concerns that may arise when conducting research with racial-ethnic minorities and underserved populations, such as fear of cloning and invasive procedures. • List ways in which this population may be mistrustful due to historical abuse in research • Identify ways to address these sensitive topics in a manner that acknowledges and addresses participant concerns