SUMMARY STATEMENT

PROGRAM CONTACT:
Elizabeth Thomson
301-402-4997
thomsone@mail.nih.gov

(Privileged Communication)

Release Date: 10/14/2011

Application Number: 1 R21 HG006293-01A1

Principal Investigators (Listed Alphabetically):
KLEIN, DAVID WASHINGTON PHD
SCHARTZ, HELEN A JD, PHD
SIMON, CHRISTIAN MICHAEL PHD (Contact)

Applicant Organization: UNIVERSITY OF IOWA

Review Group: SEIR
Societal and Ethical Issues in Research Study Section

Meeting Date: 10/06/2011
Council: JAN 2012
Requested Start: 04/01/2012

RFA/PA: PA11-182
PCC: X5ET

Project Title: Interactive Multimedia and Biorepository Informed Consent

SRG Action: Priority Score

Human Subjects: 30-Human subjects involved - Certified, no SRG concerns
Animal Subjects: 10-No live vertebrate animals involved for competing appl.
Gender: 1A-Both genders, scientifically acceptable
Minority: 1A-Minorities and non-minorities, scientifically acceptable
Children: 3A-No children included, scientifically acceptable
Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested
1	150,000
2	125,000
TOTAL	275,000

DC Recommended

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R21HG006293-01A1 SIMON, CHRISTIAN

RESUME AND SUMMARY OF DISCUSSION: This project will evaluate the effectiveness in a 2 x 2 design of multi-media technology and interactive strategies to improve the informed consent process for biorepositories. If successful, this project will provide important information that can easily be adopted by other informed consent protocols and has the potential to increase enrollment in biobanks while decreasing the burden to staff. The investigator is outstanding and has gathered a strong team for the project. The project is innovative with the use of a theoretical framework for the development of the multimedia consent format. The approach is appropriate and uses multiple outcome measures. The investigators were highly responsive to the previous critiques and have strengthened the application. The project now uses actual patients who have been approached for a biorepository protocol rather than a hypothetical consent process. The strengths outweigh any minor weakness in this significant project from an outstanding investigator.

DESCRIPTION (provided by applicant): the long-term goal of this research is to develop multimedia technology and interactive instructional strategies to improve the effectiveness and efficiency of obtaining informed consent for human DNA and tissue biorepositories. Studies suggest that individuals do not sufficiently understand the information presented during biorepository consent processes, and that traditional consent processes pose resource challenges for large-scale biorepositories. Based on experiments testing multimedia presentations for patient education purposes, multimedia has the potential to improve the effectiveness and efficiency of obtaining biorepository informed consent by increasing participant understanding and recollection of information presented. Yet, this potential has not been systematically investigated in the unique context of biorepository consent. In particular, there is a need to understand the separate effects of interactivity (i.e., question asking, feedback provided to subjects) and multimedia (i.e., multiple information delivery formats) on participant knowledge, understanding, and decision to participate. This study will compare a standard paper-based consent process (control) to multimedia and interactive consent processes, using an experimental design with random assignment, integrated into actual recruitment at the University of Iowa Hospitals and Clinics' (UIHC) comprehensive DNA and tissue biorepository. To assess the separate effects of interactivity and multimedia, low and high interactivity conditions will be tested for both the paper and the multimedia conditions. In the high interactivity conditions, participants will be asked questions about the information presented and provided feedback on their responses. Interactivity and multimedia are expected to significantly improve subject knowledge and understanding when compared to the paper-based control. High interactive multimedia is expected to decrease staff time devoted to obtaining informed consent. Two hundred (200) patients will participate in the study from the Dermatology and Immunology/Rheumatology Clinics at the UIHC. Participants will be enrolled into the UIHC biorepository via one of the four study conditions. Results of the study will be used to develop a multisite comparative study designed to demonstrate the effectiveness and efficiency of interactivity and multimedia consent under different environments, forms of media, and informed consent protocols. This research has the potential to improve on current paper-based informed consent processes and to establish the feasibility of alternative, and more effective, multimedia consent processes for human DNA and tissue biorepositories and other research-driven efforts in genetics and genomics.

PUBLIC HEALTH RELEVANCE: Biorepositories may ask thousands of people a year to donate biological samples, allow access to their health information, and participate in research. Yet, there is little research on the best ways to deliver informed consent information to individuals so that they can make an informed decision about participating in biorepositories. This study will test an interactive, multimedia tool for delivering informed consent information about biorepositories to individuals in an understandable and effective way.

CRITIQUE 1:

Significance: 2
Investigator(s): 2
Innovation: 2
Approach: 1
Environment: 2

Overall Impact: This application proposes to improve the effectiveness and efficiency of obtaining informed consent for DNA and tissue biorepositories through the use of multimedia technology and interactive instructional strategies. The significance of the project is explained well, and reinforced by appending the current informed consent form in use at the PI's institution. The design is innovative, particularly insofar as it adopts a 2x2 design that allows measurement of the effect of interactivity (which has improved consent in other studies) as well as the multimedia format. The outcome assessment instruments are appended and appear reasonable. The investigative team has excellent credentials, and has situated the proposed study well in terms of preliminary work and future research plans.

1. Significance:

Strengths

- The proposal argues convincingly that the current consent process for biobanking places significant cognitive demands on participants; the proposed approach would facilitate learning by participants
- The proposal also notes that, if successful, the interactive, multimedia approach might facilitate enrollment into biobank projects (or donations) while lightening burden on staff.

Weaknesses

- None noted.

2. Investigator(s):

Strengths

- The PI's background in medical anthropology and bioethics is impressive and he has a solid track record of past research
- The team assembled clearly has the knowledge, skills and experience to execute the project.

Weaknesses

- None noted.

3. Innovation:

Strengths

- This project is innovative insofar as it applies consent enhancement techniques to the area of bioresponsitory consent and incorporates a theoretical framework into the development of the multimedia consent format.

- The 2x2 design is very good; many "high tech" consent interventions only compare the intervention to standard consent without a comparison to increased interactivity, which is a fairly well-proven low tech method of improving understanding even if it is time intensive for staff.

Weaknesses

- None noted.

4. Approach:

Strengths

- The study articulates clear, theory-supported, testable hypotheses
- Multiple outcome measures are used (e.g., a multifaceted test of understanding, decisions to participate, and staff time); relevant instruments are provided in appendices and appear appropriate for the studies aims
- Inclusion of actual patients approached to donate to the biorespository as participants in the study enhances ability to gain knowledge of impact on decision making
- The 2x2 design allows measurement of the effect of interactivity (which has improved consent in other studies) as well as the multimedia format

Weaknesses

- None noted.

5. Environment:

Strengths

- The environment will provide appropriate access to space, computers, libraries, technological consultants, and other content experts.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- The protections plans are sufficiently detailed and they will operate according to an approved IRB protocol.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C3A - No Children Included, Acceptable

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- This application was highly responsive to initial reviewer feedback, which led to several significant improvements in the study design, including a change in the participant population.

Resource Sharing Plans:

Acceptable

- I think it's acceptable, though it does not address the sharing of data or the multi-media product.

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2:

Significance: 2
Investigator(s): 2
Innovation: 2
Approach: 1
Environment: 1

Overall Impact: This is a responsive revision to what was already a very strong application for a research development project (R21) to investigate the effectiveness of multimedia technology and interactive instructional strategies to improve the effectiveness and efficiency of obtaining informed consent for human DNA and tissue biorepositories. The investigative team is well qualified to conduct the work proposed. Although multimedia consent studies are not particularly new, this study is unique in the degree to which the proposed enhancements have been carefully grounded in a clear and relevant conceptual model. The revised protocol has been further strengthened by changing from plans to use hypothetical consent to linking the study to an actual host biorepository protocol. The research design itself is clean, straightforward, and appropriate to achieve the stated aims.

1. Significance:

Strengths

- All the strengths in terms of significance noted in the prior Summary Statement remain valid in regard to the revised proposed project. In addition, one weakness noted in the prior application was the need to more directly consider barriers to dissemination and adoption of efficacious enhanced consent methods. (The impact of the work being limited if it does not actually affect

real world consent practices.) In response, the investigators have added plans to hold a ½ day workshop (sponsored by the CTSA at their institution) to strategize data dissemination and a future research (R01) collaboration among a variety of biorepository sites devoted to the application of multimedia to biorepository informed consent. Whether this will be sufficient is uncertain, but in the context of a research development (R21) project, it appears an appropriate first step.

Weaknesses

- Other than the lingering uncertainty of whether common consent practice can really be altered (given the absence of such changes despite decades of research documenting the ineffectiveness of printed consent documents), no other lingering substantive limitations in significance is noted.

2. Investigator(s):

Strengths

- The investigative team remains well suited to the work proposed.

Weaknesses

- None noted.

3. Innovation:

Strengths

- As was true in the original application, a key and relatively unique strength of this project, relative to many of the published studies of multimedia consent enhancements, is that the content, structure, and implementation of the enhanced consent methods are explicitly grounded in a clear conceptual model. The overarching principle is to use and implement multimedia materials to the degree and where they help manage cognitive load of the potential participants – striving for a balance between sufficient stimulation to engage the participant, without overwhelming the participant's capacity to process the information.
- The 2*2 design is being employed to enable the investigators to examine the independent and interactive effects of multimedia and interactivity. This effort to dissemble the effective components of enhanced consent is itself somewhat unique but important in that the multimedia materials are obviously more costly and burdensome to develop. It is useful to know the value added specifically by this costlier alternative.
- Related to the above, the investigators also have clear plans to investigate efficiency (in terms of participant time) associated with the enhanced consent versus routine consent methods. While not completely unprecedented, this is an important aspect that has not been at the forefront of many studies.
- A particular concern in the context of biorepository protocols has been the issue of how to handle individual genetic/genomic research results (IGRR) that may only be discovered at some unspecified future time. This has not been systematically addressed in prior research on enhancing the consent process. However, in response to suggestions in the prior Summary Statement, the application has been revised to include examination of the effects of the consent enhancements on participant understanding of this element.

Weaknesses

- Although there has been limited research focused in a biorespository context, and very little well controlled research grounded in a cogent conceptual model of effective consent, investigation of multimedia consent in itself is not particularly novel.

4. Approach:

Strengths

- Straightforward 2*2 (paper/multimedia and low versus high interactivity) between subjects comparison, with randomized assignment to groups, appropriate to the study aims.
- In response to concerns noted in the prior Summary Statement, this study will no longer use hypothetical consent, but rather will be tied to the enrollment process for an actual biorepository protocol.
- Results of this initial research development project are appropriately envisioned as informing and supporting development of a subsequent multisite comparative study to more definitively determine the effectiveness and efficiency of these consent procedures.
- Specific plans to obtain and incorporate perspective/feedback from stakeholders in a formative evaluation of the multimedia presentation (graphics and animations) and the interactive components (questions and feedback) for the high interactivity conditions

Weaknesses

- This is a highly responsive revision and no substantive lingering weaknesses in the proposed approach are found.

5. Environment:

Strengths

- The environment remains well suited to the work proposed.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

- Risks are minimal, and adequate provisions are described to protect the rights and welfare of study participants.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

- Given the minimal risk nature of the work proposed, the described plan to rely on the investigators plus oversight of the IRB to ensure safety of participants and integrity of the data appear appropriate.

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C3A - No Children Included, Acceptable

- Women and ethnic minorities are included. The proportion of the latter is rather small, and one would hope that specific efforts might be made within the context of the host study to increase minority enrollment beyond the specific proportions within this particular community. However, given the value of linking this study to an actual host study, the investigators for this study are limited by the enrollment of the biobank host protocol.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Resubmission:

- The investigators have been highly and appropriately responsive to comments made in the prior Summary Statement

Resource Sharing Plans:

Acceptable

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3:

Significance: 1
Investigator(s): 1
Innovation: 1
Approach: 2
Environment: 1

Overall Impact: This is a well-written application with a well-thought out design to develop and test a multimedia informed consent tool for biorepository research. The study will compare paper-based consent to multimedia and interactive consent processes. The investigator has carefully and thoughtfully addressed the reviewers' critiques. Improving the effectiveness and the efficiency of informed consent is important and the proposed study's examination of the separate contributions of interactivity and multimedia on the consent process will make a unique contribution to the field. The methods are strong and straightforward. The investigators are well suited to perform the proposed work; the assembled team has expertise in law, ethics, instructional design and technology. The environment is excellent. The use of an actual rather than a simulated study is a key strength.

1. Significance:

Strengths

- This is timely as many institutions are creating biobanks and understanding of risks/benefits of biobanking has become increasingly more complex. Patients often do not sufficiently understanding or remember information presented during the consent process. An automated process for consent/re-consent that would increase understanding and recollection of information would be valuable.
- Having actual biorepository participants rather than a simulated study is a strength
- Assessing time staff members' time investment on the differing consent processes is interesting.

Weaknesses

- None noted

2. Investigator(s):

Strengths

- The investigators are well qualified. The assembled team has expertise in areas that will enhance the project
- Including Dr. Brilliant to identify adoption barriers is a strength

Weaknesses

- None noted

3. Innovation:

Strengths

- Because biorepository consent protocols differ from traditional protocols, examining them separately can lead to better understanding of the unique needs of biorepository consent.
- As noted above, using real biorepository participants rather than simulating a study is strength and adds to the innovation of this project.
- Examining staff time efficiency is a unique contribution.

Weaknesses

- Using multimedia to consent is not overly innovative although assessing the separate contributions of interactivity and multimedia on the consent process does make a unique contribution.

4. Approach:

Strengths

- The well-conceptualized and well-designed approach is a strength
- The randomized trial structure is a strength

Weaknesses

- The randomization process is not fully explained.

5. Environment:

Strengths

- The environment seems strong
- The collaboration with the Patient Education Institute is a strength

Weaknesses

- None noted

Protections for Human Subjects:

Acceptable Risks and/or Adequate Protections

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Acceptable

Inclusion of Women, Minorities and Children:

G1A - Both Genders, Acceptable

M1A - Minority and Non-minority, Acceptable

C3A - No Children Included, Acceptable

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Budget and Period of Support:

Recommend as Requested

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): ACCEPTABLE

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE
The reviewers agreed that the inclusion of minorities is acceptable, but that efforts to increase the number of minorities would be beneficial for this study.

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-10-080 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-080.html.
The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.