| | | |
|---|---|---|
| PI: **SIMON, CHRISTIAN MICHAEL** | Title: Interactive Multimedia and Biorepository Informed Consent | |
| Received: 07/15/2011 | FOA: PA11-182 | Council: 01/2012 |
| Competition ID: ADOBE-FORMS-B1 | FOA Title: RESEARCH ON ETHICAL ISSUES IN BIOMEDICAL, SOCIAL, AND BEHAVIORAL RESEARCH (R21) | |
| 1 **R21 HG006293-01A1** | Dual: | Accession Number: 3410651 |
| IPF: 3972901 | Organization: UNIVERSITY OF IOWA | |
| Former Number: | Department: Internal Medicine | |
| IRG/SRG: SEIR | AIDS: N | Expedited: N |
| Subtotal Direct Costs<br>(excludes consortium F&A)<br>Year 1: 150,000<br>Year 2: 125,000 | Animals: N<br>Humans: Y<br>Clinical Trial: N<br>Current HS Code: 30<br>HESC: N | New Investigator: N<br>Early Stage Investigator: N |
| | | |
| *Senior/Key Personnel:* | *Organization:* | *Role Category:* |
| Christian Simon PhD | University of Iowa | PD/PI |
| David Klein PhD | University of Iowa | MPI |
| Helen Schartz PhD, | University of Iowa | MPI |
| Murray Brilliant PhD | Marshfield Clinic Research Foundation | Consultant |
| Jennifer McCormick PhD, | Mayo Clinic Rochester | Consultant |
| Jamie L'Heureux MS | University of Iowa | Co-Investigator |

*Appendices*

ui_biorepository_description1006976206,irb_approved_consent1006976208,recruitment_diagram1006976210,heuristics_eval1006976212,participat_decision_form1006976214,participant_questionnaire1006976216,summary_sheet100697620

# 424 R&R and PHS-398 Specific Table Of Contents



**Appendix**

*Number of Attachments in Appendix: 7*

**Interactive Multimedia and Biorepository Informed Consent**

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.

**Interactive Multimedia and Biorepository Informed Consent**

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.

## Resources

The University of Iowa is a research extensive university with all the necessary infrastructure and resources that would be expected at such an institution. All study personnel have direct access to the full range of library and computer facilities at the University of Iowa. Therefore, only those specific university entities most directly relevant to this application are noted here.

### Office

All University of Iowa study personnel have secured, private offices at the University of Iowa within a 5-15 minute walk from each other. All study personnel at the University of Iowa have adequate space for secure data storage, office support (photocopy machines, fax, etc.), and conference rooms.

Program in Bioethics and Humanities Offices
The Program in Bioethics and Humanities is located within the University of Iowa Carver College of Medicine. The Program's mission is to advance a rigorous understanding of human health and healthcare through knowledge gained from bioethics, the medical humanities, and related disciplines. The Program occupies roughly 1400 square feet of office and conference space. The space consists of two individual faculty offices (this includes the contact PI's office), one shared faculty office, one research associate office (Shinkunas), one student/research staff office, one administrative secretary office, a copy/work room adjoining the central office area, and a program conference room that houses the program library and work stations for research staff or students. Research meetings will occur in the conference room of the Program in Bioethics and Humanities at the University of Iowa.

Law, Health Policy & Disability Center (LHPDC) Offices
A division of the University of Iowa College of Law, the Law, Health Policy & Disability Center (LHPDC) is an interdisciplinary unit dedicated to social science, health and disability policy, and legal research. LHPDC's mission is to improve the quality of life for Iowans and others living with health issues and disabilities. In support of this mission, LHPDC maintains two offices in Iowa City. One facility houses office space with private offices for all staff, and additional space for interns, meetings and small conferences. A separate office houses University Survey Services, LHPDC's survey research unit. Offices have accessible meeting and conference space. LHPDC offices are located in accessible buildings. Administrative and other support is available as-needed from College of Law staff and the University of Iowa according to its policies, including grant accounting, travel, accounts payable, and other standard support. The College of Law provides research assistants according to the needs of individual projects.

### Computers

All study personnel have personal computers in their offices with word processing and high-speed internet connections.

Program in Bioethics and Humanities Computers
The Program in Bioethics and Humanities has 2 Windows workstations available to students and staff. Both are located within accessible office space and available to the project. An additional 2 Windows workstations are used for specific staff, who will be working on this project. Any of these may be configured to individual user needs. SPSS, Microsoft Office, and other software are available through the University site licensing. Nvivo 8 qualtitative software is installed on Ms. Shinkunas' personal computer as well as the computer in the student/research staff office.

Law, Health Policy & Disability Center (LHPDC) Computers
LHPDC's central office has 3 Windows systems available to students, clients and staff, all are located within accessible office space and available to the project. An additional 4 Windows and 2 Macintosh workstations are used for specific staff. Any of these may be configured to individual user needs. SPSS, Microsoft Office, and other software are available through the University site licensing. Several workstations have assistive

technology in place for testing, evaluation needs, and as accommodations for Center staff, students, or partners.

Research Services (RS) is an information technology resource set up to assist and collaborate with University of Iowa faculty and research support groups in a variety of fields and activities. RS staff is available to consult with UI researchers on a number of application areas. Services are offered in high performance computing, scientific consulting, training and consultations, and explorations into new technologies.

**College of Law Library**

As part of the College of Law, LHPDC staff have access to the University of Iowa Law Library. The University of Iowa Law Library has the second largest collection of volumes and microform volume equivalents and the second largest number of unique individually cataloged titles in all formats including electronic among all law school libraries. As of June 2010, the collection of the Law Library contained more than 1.26 million volumes and microform volume equivalents and over 948,000 unique individually cataloged titles in all formats including electronic. According to the ABA/AALS Annual Survey for 1999-00, the Law Library contains the seventh largest collection of bound volumes and microform volume equivalents among all law school libraries in the United States. In March 2010, The National Jurist ranked the University of Iowa's Law Library first in the nation among law school libraries (Carter, 2010).

References

Carter, K. (2010). What makes a great library. The National Jurist, 19 (6), pgs. 22-24.
Kyrillidou, M., & Bland, L. (2009). ARL Statistics 2007-2008. Association of Research Libraries: Washington, D.C. Available at: http://www.arl.org/bm~doc/arlstat08.pdf

**The University of Iowa Health Center**

The Health Center comprises the facilities and activities of the University's four health science colleges: Medicine, Dentistry, Nursing, and Pharmacy; and University Hospitals and Clinics, Psychiatric Hospital, Hospital School, University Hygienic Laboratory, Speech and Hearing Clinic, and Oakdale Campus. The University Hospitals and Clinics and the buildings of the College of Medicine are located on the health science campus which is part of the 1300 acre main campus of the University.

Health Science Library

In the center of the Health Colleges and Hospitals, the Hardin Health Sciences Library provides books, journals, study facilities and computer facilities (Health Sciences Arcade) to health professionals and other scientists on campus, and physicians and other professionals throughout the state. This building occupies 60,000 square feet, has 211,038 volumes and subscribes to 3,434 journals. A facility for searches by MEDLINE, SIDLINE and CANCERLINE is provided and a staff operator is available for assisting patrons in designing and executing searches. The newest library service is Health Net, an expanded search capacity available from the Campus Computer Network or from a modem.

National Networking for Information Sharing

As do most major research and educational institutions in the United States, the University of Iowa provides free access to the Internet to all faculty, staff, and students. Such access allows on-line communication (e-mail) throughout the world and the transmission of large data sets economically. The only cost to users is for log-in (CPU) time on the WEEG computer, for which rates are set at a very low and extremely reasonable level.

**The University of Iowa Hospitals and Clinics (UIHC)**

The University of Iowa Hospitals and Clinics, the largest university-owned teaching hospital in the United States, provides the clinical base for study in the health disciplines, which include medicine, nursing, as well as dentistry, pharmacy, hospital administration, physical therapy, public health, social work, and vocational training.

UIHC Mission
The UIHC, in compliance with the Code of Iowa, serves as the teaching hospital and comprehensive health care center for the State of Iowa, thereby promoting the health of the citizens of Iowa. The UIHC, in concert with the University of Iowa health science colleges, functions in support of health care professionals and organizations in Iowa and other states by: 1) offering a broad spectrum of clinical services to all patients cared for within the Center and through its outreach programs; 2) serving as the primary teaching hospital for the University; and, 3) providing a base for innovative research to improve health care.

Department of Dermatology (recruitment clinic for study and UIHC biorepository)
The Department of Dermatology is located in the UIHC and is recognized nationally and internationally for excellence in patient care, teaching and research. The Department provides full medical and surgical dermatologic services at the UIHC. The Department provides general dermatology care and specialty services to patients with skin diseases that include acne vulgaris, autoimmune blistering diseases, cancer of the skin, cancer of the skin, Dermatitis or eczema, cutaneous infections, hematologic/oncologic skin disease, psoriasis, rheumatic skin disease (lupus erythematosus, dermatomyositis, scleroderma), rosacea, and vasculitis/vasculopathies.

Division of Immunology (recruitment clinic for study and UIHC biorepository)
The Division of Immunology is located in Department of Internal Medicine at the UIHC and is recognized nationally and internationally for excellence in patient care, teaching and research. In its 135-year history, the Department of Internal Medicine has sustained a tradition of robust achievement and growth in research, patient care, teaching, and service. The Department includes 230 active faculty (and nearly 400 professional and clerical support staff). The Division of Immunology encompasses Rheumatology and provides care for patients with a range of primary immunodeficiency and autoimmunity conditions. The Division cares for approximately 800 new allergy/immunology and 1200 new rheumatology patients a year.

**Institute for Clinical and Translational Science**

University of Iowa Institute for Clinical and Translational Science is an overarching structure for all clinical and translational research at the UI. Approved by the Board of Regents, State of Iowa in December 2006, the Institute includes researchers from the colleges of dentistry, nursing, pharmacy, public health, engineering and liberal arts and sciences, as well as medicine. The Institute for Clinical and Translational Science will advance research at the UI in several ways: through organizing research efforts across the UI campus, bringing together researchers from multiple disciplines to share knowledge and ideas that may lead to new or better treatments; creating a cohesive infrastructure for new training programs specifically designed to prepare students and junior faculty for careers in clinical and translational science; and it engaging the State of Iowa as a partner in clinical and translational research. The Institute builds on a strong tradition of community outreach by creating a statewide network of community practitioners to help facilitate clinical research being performed by the UI and bringing cutting-edge treatments to patients in outlying communities. These partnerships bring cutting-edge treatments to a wider population and at the same time enhance community trust in clinical and translational research. Greater community involvement gives community practitioners the opportunity be involved in research. Finally, findings from investigators involved in the Institute provide important health information to improve the lives of Iowans as well as people across the country and world.

Institute for Clinical and Translation Research Core
The Institute for Clinical and Translation Research Core was established to assist University of Iowa Principal Investigators with pilot grants, industry and NIH clinical trials. To date, the Clinical Research Core staff has assisted in the clinical trial process with over 45 Principal Investigators and over 65 clinical research studies.

The Core currently consists of a regulatory office, 6 Coordinators and 7 research assistants. Assistance is given to the PI as requested. This may include protocol development, Institutional Review Board submissions, completion of regulatory documents, budget development/negotiation, consenting and coordination of clinical trial enrolling, data collection, data entry, and ensuring billing compliance.

**Patient Education Institute (PEI)**

The Patient Education Institute, located in Coralville, Iowa, is a private, for-profit business that develops interactive patient education software, implements it in healthcare settings, and evaluates it to provide clients with metrics.

PEI main quarters are located at 2000 James Street, Coralville, Iowa. The offices were built according to PEI's design specifications to accommodate the organization's needs. This includes an insulated recording room. PEI has 6,200 square feet of office/development area. PEI's facilities can accommodate 40 employees with 13 private offices and a large conference room.

PEI has 40 computer stations and a server room. On-site servers are used for development and testing. Client servers are offsite. PEI hosts its servers at various geographical locations in the U.S. in order to achieve maximum availability and maximum redundant routes. The PEI infrastructure is designed to be able to switch data operation from one location to another and restore full normal service in a matter of less than five minutes. PEI currently hosts its client servers (a total of 11 servers) at Raleigh, North Carolina; Louisville, Kentucky; and Secaucus, New Jersey. They selected data centers that meet regulatory compliance and that are fully redundant. Up-time has consistently been more than 99.93% over the past three years (the majority of the balance being for scheduled maintenance; the unplanned downtime was 0.012%).

PEI's development includes 3 proprietary systems: a content management system (Flash, ASP, XML, SQL), an online learning management system (Flash, asp, XML, SQL), and an online update management system (Flash, asp, XML, SQL). The content management system is an online system that allows PEI to (a) manage master medical content and documents; (b) receive simultaneous edits from medical contributors; and (c) search 60,000 pages of medical information for medical content. The online learning management system is a proprietary PEI system developed to deliver and manage online patient education. It is a full online learning management system to the degree that it was licensed and adapted by Honeywell and the Police Legal Services to train thousands of hospital staff and police officers, respectively, every month. The online clients can receive automatic updates of their software. The online update system is integrated with the online learning management system.

# PHS 398 Modular Budget, Periods 1 and 2

OMB Number: 0925-0001

## Budget Period: 1

Start Date: 04/01/2012 End Date: 03/31/2013

### A. Direct Costs

| | * Funds Requested ($) |
|---|---|
| * Direct Cost less Consortium F&A | 150,000.00 |
| Consortium F&A | 0.00 |
| * Total Direct Costs | 150,000.00 |

### B. Indirect Costs

| | Indirect Cost Type | Indirect Cost Rate (%) | Indirect Cost Base ($) | * Funds Requested ($) |
|---|---|---|---|---|
| 1. | On_Campus Research | 51 | 150,000.00 | 76,500.00 |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |

Cognizant Agency (Agency Name, POC Name and Phone Number) DHHS, Theodore Foster, (214) 767-3441

Indirect Cost Rate Agreement Date 04/21/2010

Total Indirect Costs 76,500.00

### C. Total Direct and Indirect Costs (A + B)

Funds Requested ($) 226,500.00

## Budget Period: 2

Start Date: 04/01/2013 End Date: 03/31/2014

### A. Direct Costs

| | * Funds Requested ($) |
|---|---|
| * Direct Cost less Consortium F&A | 125,000.00 |
| Consortium F&A | 0.00 |
| * Total Direct Costs | 125,000.00 |

### B. Indirect Costs

| | Indirect Cost Type | Indirect Cost Rate (%) | Indirect Cost Base ($) | * Funds Requested ($) |
|---|---|---|---|---|
| 1. | On_Campus Research | 51 | 125,000.00 | 63,750.00 |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |

Cognizant Agency (Agency Name, POC Name and Phone Number) DHHS, Theodore Foster, (214) 767-3441

Indirect Cost Rate Agreement Date 04/21/2010

Total Indirect Costs 63,750.00

### C. Total Direct and Indirect Costs (A + B)

Funds Requested ($) 188,750.00

# PHS 398 Modular Budget, Periods 3 and 4

**Budget Period: 3**

Start Date: | End Date:

**A. Direct Costs**

| | * Funds Requested ($) |
|---|---|
| * Direct Cost less Consortium F&A | |
| Consortium F&A | |
| * Total Direct Costs | |

**B. Indirect Costs**

| | Indirect Cost Type | Indirect Cost Rate (%) | Indirect Cost Base ($) | * Funds Requested ($) |
|---|---|---|---|---|
| 1. | | | | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |

Cognizant Agency (Agency Name, POC Name and Phone Number)

Indirect Cost Rate Agreement Date | Total Indirect Costs

**C. Total Direct and Indirect Costs (A + B)** Funds Requested ($)

**Budget Period: 4**

Start Date: | End Date:

**A. Direct Costs**

| | * Funds Requested ($) |
|---|---|
| * Direct Cost less Consortium F&A | |
| Consortium F&A | |
| * Total Direct Costs | |

**B. Indirect Costs**

| | Indirect Cost Type | Indirect Cost Rate (%) | Indirect Cost Base ($) | * Funds Requested ($) |
|---|---|---|---|---|
| 1. | | | | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |

Cognizant Agency (Agency Name, POC Name and Phone Number)

Indirect Cost Rate Agreement Date | Total Indirect Costs

**C. Total Direct and Indirect Costs (A + B)** Funds Requested ($)



Tracking Number:GRANT10924713 Funding Opportunity Number:PA-11-182 Received Date:2011-07-15T13:09:24-04:00

# PHS 398 Modular Budget, Periods 5 and Cumulative

**Budget Period: 5**

Start Date: | End Date:

## A. Direct Costs

| | * Funds Requested ($) |
|---|---|
| * Direct Cost less Consortium F&A | |
| Consortium F&A | |
| * Total Direct Costs | |

## B. Indirect Costs

| | Indirect Cost Type | Indirect Cost Rate (%) | Indirect Cost Base ($) | * Funds Requested ($) |
|---|---|---|---|---|
| 1. | | | | |
| 2. | | | | |
| 3. | | | | |
| 4. | | | | |

Cognizant Agency (Agency Name, POC Name and Phone Number)

Indirect Cost Rate Agreement Date | Total Indirect Costs

## C. Total Direct and Indirect Costs (A + B)

Funds Requested ($)

## Cumulative Budget Information

### 1. Total Costs, Entire Project Period

| | | |
|---|---|---|
| *Section A, Total Direct Cost less Consortium F&A for Entire Project Period | $ | 275,000.00 |
| Section A, Total Consortium F&A for Entire Project Period | $ | 0.00 |
| *Section A, Total Direct Costs for Entire Project Period | $ | 275,000.00 |
| *Section B, Total Indirect Costs for Entire Project Period | $ | 140,250.00 |
| *Section C, Total Direct and Indirect Costs (A+B) for Entire Project Period | $ | 415,250.00 |

### 2. Budget Justifications

| | | | | |
|---|---|---|---|---|
| Personnel Justification | Personnel_Justification1006976 | | Delete Attachment | View Attachment |
| Consortium Justification | | Add Attachment | | |
| Additional Narrative Justification | Addl_Narrative_Justification1 | | Delete Attachment | View Attachment |

## Personnel Justification

### Senior/Key Personnel

**Christian Simon**, PhD, Associate Professor of Bioethics and Humanities in the Department of Internal Medicine at the University of Iowa, will be a Principal Investigator on this project. He will devote 15% effort per year for a total of two years (1.8 calendar months/yr, for a total of 3.6 calendar months for the duration of the project). Dr. Simon is the contact PI for this study. He provides expertise in bioethics for the project. Dr. Simon will be responsible for the development and implementation of the data collection tools and measures. He will also coordinate the summative workshop in Year 2 of the grant. Dr. Simon will coordinate communication among PIs and the NIH and initiate progress reports. He will oversee research activities of team personnel and timely completion of group activities according to the project timeline. He will oversee management of the budget and maintain weekly communication with the project RAs and Investigators, maintenance of project records, storage of study data, and development of reports.

**Helen Schartz**, PhD, JD, Associate Research Scientist and Director of Research in the Law, Health Policy & Disability Center at the University of Iowa be a Principal Investigator on this project. She will devote 15% effort per year for a total of two years (1.8 calendar months/yr, for a total of 3.6 calendar months for the duration of the project). Dr. Helen Schartz provides expertise in social science research and law for the project. She will oversee the experiment design, sampling, and implementation of the design. Dr. Schartz will work with Dr. Simon to complete the application for and process of obtaining approval for the study from the University of Iowa's IRB. She will collaborate with Drs. Simon and Klein in the data analysis and write-up phases of the project. Dr. Schartz will be the contact person for any concerns that participants may raise during the experiment.

**David Klein**, PhD, Director of Technology in the Law, Health Policy & Disability Center at the University of Iowa will be a Principal Investigator on this project. He will devote 50% effort per year for a total of two years (6 calendar months/yr, for a total of 12 calendar months for the duration of the project). Dr. Klein will provide expertise in instructional design, educational psychology, and technology. Dr. David Klein provides expertise in instructional design, educational psychology, and technology. He will be responsible for the instructional design and development of the modules for the research, including the organization of information and the selection of graphics or other media components. Dr. Klein will also oversee the heuristic evaluation of the multimedia delivery system. He will work directly with and oversee the Patient Education Institute (PEI) for their implementation of the multimedia modules. He will be responsible for addressing any technology issues that arise during the implementation of the research and with data collection during the experiment. He will oversee the training and supervision of the research assistants. Dr. Klein will collaborate with Drs. Simon and Schartz in the data collection, analysis, and write-up phases of the project.

**Jamie L'Heureux**, MS, Biorepository Development Leader in the Department of Pediatrics at the University of Iowa Hospitals and Clinics will be a Co-Investigator on this project. She will devote 10% effort per year (1.2 calendar months/yr for a total of 2.4 calendar months for the duration of the project). Ms. L'Heureux will help refine the project instruments; assist in organizing the heuristic evaluation of the multimedia modules; and help train the clinic staff and research assistants in the conduct of the experiment. Ms. L'Heureux will also assist in the data analysis and interpretation phases from the perspective of her leadership role in the University of Iowa biorepository and background in genetic counseling.

### Consultants

**Jennifer B McCormick, PhD, MPP,** Assistant Professor of Biomedical Ethics in the Divisions of Internal Medicine & Health Care Policy Research at the Mayo Clinic in Rochester, Minnesota, will be a consultant on this project. Dr. McCormick will provide initial suggestions and advise on the design of the multimedia tool that will be used in the proposed research. She will review and make suggestions for refining the project's data collection instruments, including those that will be used to measure knowledge and understanding. This work will be conducted via conference calls and email correspondence. Dr. McCormick will also participate in a summative workshop in Year 2 of the grant, designed to strategize data dissemination and logical future research opportunities, including a regional Iowa/Marshfield/Mayo (R01) collaboration on multimedia biorepository consent.

**Murray Brilliant, Ph.D.,** Senior Research Scientist, Director, Center for Human Genetics and Marshfield Clinic Research Foundation, Institute for Clinical and Translational Research's Translational Technologies and Resources Core at the Marshfield Clinic will be a consultant on this project. Together with Ms. Wendy Foth, Dr. Brilliant will draw on Marshfield Clinic's study of computer-based biorepository consent to provide initial suggestions and advise on the design of the multimedia tool that will be used in the proposed research. He will help identify barriers that may need to be negotiated in our longer term effort to incorporate and routinize multimedia into multiple biorepository environments regionally and nationally. He will participate in a summative workshop in Year 2 of the grant, designed to strategize data dissemination and logical future research opportunities, including a regional Iowa/Marshfield/Mayo (R01) collaboration on multimedia biorepository consent.

**Other Personnel**

**Laura Shinkunas**, BA, Research Associate in the Program for Bioethics and Humanities at the University of Iowa, will be a Research Assistant on the project. She will devote 15% effort per year (1.8 calendar months/yr for a total of 3.6 calendar months for the duration of the project). Ms. Shinkunas will be one of two individuals supporting Ms. L'Heureux in the training of clinic staff; supporting the clinic staff in the conduct of the experiment; retrieving paperwork from clinic personnel and processing parking vouchers on a case-by-case basis. Ms. Shinkunas will assist with IRB paperwork, qualitative data analysis, preparation of project progress reports, conducting literature searches for manuscripts, and other manuscript preparation activities (e.g., formatting). Ms. Shinkunas is a member of the Institutional Review Board at the University of Iowa.

**Jill Smith**, PhD, Project Supervisor in the Law, Health Policy & Disability Center at the University of Iowa will be a Research Assistant on the project. She will devote 25% effort during year 1 only (3 calendar months total). Dr. Smith assisted with the development of modules, instruments and data collection on Schartz and Klein's pilot study (Interactive, Multimedia Informed Consent Pilot Study); thus, she is very familiar with the development of modules, instruments and the data collection process. In collaboration with Dr. Klein, Dr. Smith will assist in the development of the multimedia modules and the interactivity component of the high interactivity, paper-based process. She will conduct the pilot testing of the modules with volunteers and assist with the formative review. She will develop the training materials for the research assistants. During the beginning of the data collection process, she will support Ms. L'Heureux in the training of clinic staff; supporting the clinic staff in the conduct of the experiment; setting up the computers for running subjects; retrieving paperwork from clinic personnel on a case-by-case basis; and checking the data for completeness.

**Research Assistants** (TBD) Currently, the UIHC biorepository utilizes research assistants to recruit participants. Two research assistants in the first year and four additional assistants in the second year will be trained on integration of the study into the current, IRB-approved biorepository informed consent process. By integrating the study into the biorepository recruitment process, experiment duties will be added to the research assistants' current obligations (e.g., informed consent for the experiment, random assignment of participants to a biorepository informed consent condition, high interactivity component for high interactivity, paper-based process, administration of experiment questionnaire on knowledge and demographics, tracking time spent with each participant, etc.) Therefore, the budget proposal includes 7 hours of experiment training per research assistant and up to 45 minutes of research assistants' time per research participant (for a total study sample of 200 participants, with flexibility to oversample by an additional 20 participants) for the duration of data collection.

| | |
|---|---|
| Year 1 | 7 hours of training for two research assistants; data collection for approximately 50 participants at 45 minutes/participant |
| Year 2 | 7 hours of training for four additional research assistants; data collection for approximately 150 participants at 45 minutes/participant |

## Additional Narrative Justification

Additional $25,000 module in Year 1 for purchasing of touchscreen tablets for data collection, additional staff time and payment to PEI for development of multimedia modules.

OMB Number: 0925-0001

# PHS 398 Research Plan

## 1. Application Type:

From SF 424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated for your reference, as you attach the appropriate sections of the Research Plan.

*Type of Application:

☐ New ☒ Resubmission ☐ Renewal ☐ Continuation ☐ Revision

## 2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

| | | | | |
|---|---|---|---|---|
| 1. Introduction to Application (for RESUBMISSION or REVISION only) | Introduction1006976173.pdf | | Delete Attachment | View Attachment |
| 2. Specific Aims | Specific_Aims1006976174.pdf | | Delete Attachment | View Attachment |
| 3. *Research Strategy | Research_Strategy1006976218 | | Delete Attachment | View Attachment |
| 4. Inclusion Enrollment Report | | Add Attachment | | |
| 5. Progress Report Publication List | | Add Attachment | | |

Human Subjects Sections

| | | | | |
|---|---|---|---|---|
| 6. Protection of Human Subjects | Human_Subjects1006976136.pd | | Delete Attachment | View Attachment |
| 7. Inclusion of Women and Minorities | Inclus_Women_Minorities1006 | | Delete Attachment | View Attachment |
| 8. Targeted/Planned Enrollment Table | TPETForm1006976219.pdf | | Delete Attachment | View Attachment |
| 9. Inclusion of Children | Inclus Children1006976106.p | | Delete Attachment | View Attachment |

Other Research Plan Sections

| | | | | |
|---|---|---|---|---|
| 10. Vertebrate Animals | | Add Attachment | | |
| 11. Select Agent Research | | Add Attachment | | |
| 12. Multiple PD/PI Leadership Plan | MultiplePI_Plan1006976107.pd | | Delete Attachment | View Attachment |
| 13. Consortium/Contractual Arrangements | | Add Attachment | | |
| 14. Letters of Support | Letters of Support1006976192 | | Delete Attachment | View Attachment |
| 15. Resource Sharing Plan(s) | Resource_Sharing_Plan100697 | | Delete Attachment | View Attachment |

16. Appendix Add Attachments | Remove Attachments | View Attachments

List of Research Plan Attachments

**INTRODUCTION TO RESUBMISSION**

| Previous Score (31) | Critique | | |
|---|---|---|---|
| | C1 | C2 | C3 |
| Significance | 5 | 2 | 2 |
| Investigators | 1 | 1 | 1 |
| Innovation | 4 | 2 | 1 |
| Approach | 3 | 1 | 2 |
| Environment | 2 | 1 | 1 |

Responses to the Resume and individual Critiques (C) are summarized below. Major changes include a substantively reworked *Significance (S), Innovation (I)* and *Approach (A)* section. Bolded brackets preceded by the number of the response (e.g. **R1**) demarcate these changes in the research strategy. **RESUME:** The original was considered significant because it assessed patient understanding of biobanking, innovative for being theoretically driven, and appropriate in approach because of its broad assessment of outcomes. Summary weaknesses were 1. *lack of thorough review of other multimedia (m-media) tools*. An expert (D. Klein) in m-media and computer-based instruction wrote the original, extensive review of the literature in this field. We have added to the review of m-media tools, including details on tools being used at Marshfield and Mayo biorepositories (*see **R1** in I&A*)**.** Total m-media related citations now number 42. 2. *greater detail needed on specifics of proposed m-media tool.* We clarified the structure and content of the m-media tool and integrated a visual exemplar (see **R2** *in A*). 3. *A minor weakness was need to evaluate barriers to tool adoption.* We included a senior consultant (*M. Brilliant, MD, Marshfield Clinic*) to help identify potential adoption barriers. We also secured financial support from our CTSA (see *Rosenthal letter*) for a summative workshop to plan for adoption barriers, strategize data dissemination, and outline a collaborative (Iowa/Mayo/Marshfield) R01 for evaluating and testing a composite m-media tool in a randomized way (*see* **R3** *in A, "Future Directions"*).

**IMPACT:** Critique 1 (C1): *lack of aggressive exploration of other m-media tools leaves unique contribution of study unclear.* We reworked the literature review (see above) and reorganized *Innovation* to highlight the separation of interactivity and m-media as a leading innovative element of our study (*see* **R1** *in I & A*). We added pilot data to support our study hypotheses and claims to innovation (see **R8,** "Preliminary Data" in A). C1: *little detail about parameters of m-media tool provided* (see response in Resume, above). C1: *omission of return of results issues disappointing.* We integrated a focus on return of results (*see* **R4** *in S & I*) and modified study instruments accordingly (*see Appendix, "Questionnaire"*).

**SIGNIFICANCE**: C1 and C3: *actual biorepository candidates/focus on decision to consent would add value*. We secured Institutional Review Board (IRB) support (see *Bertolatus letter*) for integrating the study into the biorepository recruitment process. The study will measure actual, rather than simulated, behavior, exploring possible relationships between participant comprehension and decision to participate (*see* **R5** *in Aims, I & A*).

**INVESTIGATORS**: The investigators were considered well qualified and no weaknesses were noted.

**INNOVATION**: *C1: overall idea of creating and evaluating m-media presentations for consent is not so innovative.* We clarified that m-media has been used to improve consent, including among some biorepositories, but that no efforts have controlled for separate and combined effects of interactivity and m-media (*see **R1** in I & A*). Pilot data we collected (*see A, "Preliminary Data"*) suggest that interactivity and m-media enhance each other's effectiveness, but do not reveal their separate contributions, thus supporting need for this research (see ***R1** in I*). Where the original application included an extensive review of theory-based research of m-media in *Innovation*, we moved the bulk of the theory to Approach *(see* **R6** *in A)*. We also clarified that efficiency and return of results, both of which this study addresses, are understudied variables in m-media/consent research.

**APPROACH**: *C1 and C3: study lacks outcome measure for decision to participate in biorepository.* This measure is now included (*see* **R7** *in S, I & Appendix, Decision to Participate in Biobank Form*). *C1: Have many resources available through m-media arm.* Where adding content may improve the experience of participants, for this feasibility study we chose to control for content, using only IRB-approved content in all arms. Our pilot data indicated that m-media content was well received (See **R8** *in A*). *C1: do not adequately address downside of becoming "more efficient" by reducing human element*. We clarified that consent efficiency/human element of consent is a key but complex issue, allowing for only limited consideration of a core efficiency metric, staff time, and added citations to support this point. We included pilot data to demonstrate that use of m-media consent tools are not onerous to participants. We broadened measurement of staff time to all 4 conditions (previously restricted to high-interactivity conditions) (**R9** *in Aims, I & A*). *C1: Collection/scoring of outcome data should be conducted by blinded staff.* Blinding recruiters is not possible because they are administering the conditions. However, nearly all questionnaire data are numeric, except for a few open-ended questions, and therefore not subject to bias (*see Appendix, "Participant Questionnaire"*). Data will also be collected with recruiters out of the room. *C3: study lacks consideration of literacy issues/effect on intervention.* We cited this as a limitation of the study, and have included plans to address literacy issues in future (R01) research (*see* **R10** *in A, "Limitations"*).

**ENVIRONMENT**: The environment was adequate and no weaknesses were noted.

**HUMAN SUBJECTS:** The plan for protecting human subjects was acceptable, steps have been taken to account for the integrated nature of the revised study design *(see revised Protection of Human Subjects*).

## Specific Aims

The long-term goal of this research is to use multimedia technology and interactive instructional strategies to improve the effectiveness and efficiency of obtaining informed consent for human DNA and tissue biorepositories. Using an experimental design with random assignment **[R5** integrated into actual recruitment for a biorepository /**R5]**, we expect interactivity and multimedia to significantly improve subject knowledge and understanding and multimedia to decrease staff time devoted to obtaining consent, when compared to a standard, paper-based informed consent process (e.g., control group). Studies suggest that many individuals do not sufficiently understand the information presented during informed consent processes, and that traditional informed consent processes pose resource-related challenges for large-scale biorepositories.

This study will demonstrate the feasibility of integrating interactivity and multimedia to efficiently enhance and standardize biorepository consent processes. Biorepository consent must address a spectrum of issues, including the nature, purpose, future use, and potential risks and benefits of participating in tissue and DNA biorepositories, as well as the prospect of returning research results and confidentiality issues. Using a theory-driven approach based on principles of human learning and cognition, the study will compare a standard, IRB (Institutional Review Board) approved paper-based consent process (control) to interactive and multimedia consent processes. The multimedia consent process will present information using multiple media (text, audio, relevant graphics, and content specific, simple animations). To demonstrate the effects of interactivity, separate from 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 to enhance understanding and correct misunderstanding. A formative evaluation of the interactive and multimedia consent processes will precede the experiment and include input from a bioethics expert, a genomics researcher and biorepository director, an IRB Chair, a genetic counselor, researchers at other biorepositories, and a panel of community representatives.

The informed consent processes will be tested in a four group experimental design with (1) the current, IRB-approved standard, paper-based informed consent (low interactivity) as the control (PBLI), compared to (2) paper-based with high interactivity (PBHI), (3) multimedia with low interactivity (MMLI), and (4) multimedia with high interactivity (MMHI). **[R5** The study will be integrated into the current, IRB-approved informed consent process for the comprehensive DNA and tissue biorepository at the University of Iowa Hospitals and Clinics (UIHC). Two hundred (200) patients being seen at the UIHC Dermatology (n=100) and Immunology/ Rheumatology (n=100) Clinics, which are currently enrolling patients into the UIHC Biorepository, will participate in the study. /**R5]** 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 interactive 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.

**Specific Aim:** Systematically develop and test the use of multimedia and interactivity to (1) improve participant knowledge and understanding and (2) reduce staff time devoted to obtaining informed consent, using an experiment with random assignment of participants integrated into live recruitment processes for a biorepository.

**Hypothesis 1:** Multimedia Will Result in Improved Participant Knowledge and Understanding – Participants learning about informed consent from multimedia (MMHI and MMLI) will demonstrate better knowledge and understanding of biorepository consent information, compared to participants in the paper-based (PBLI and PBHI) conditions.

**Hypothesis 2:** Interactivity Will Result in Improved Participant Knowledge and Understanding – Participants in the high interactivity conditions (MMHI & PBHI) will demonstrate better knowledge and understanding, compared to participants in the low interactivity conditions (MMLI & PBLI).

**Hypothesis 3:** Multimedia Will Result in Reduced Staff Time for Informed Consent – **[R9** Staff time will be lower in the multimedia (MMHI & MHLI) conditions, when compared to the paper-based (PBHI & PBLI) conditions. /**R9]**

**Research Strategy - Significance of the Proposed Work**

This proposal addresses an NHGRI recognized and critical need to improve the obtaining of informed consent for genomics research, including biorepository-based genomics research, involving human participants, biospecimens, and health information (Green & Guyer, 2011; Fabsitz et al., 2010; McGuire & Beskow, 2010; Miller et al., 2008). Researchers and institutional review boards have been urged to pay careful attention to the need to obtain informed consent from genomics research participants (Mehlman, 2001; Rotimi & Marshall, 2010). Genomics research challenges standard approaches to informed consent because of the broad utility and sharing of research data beyond any immediate studies; **[R4** the potential for returning incidental findings and other types of research results /**R4]**; concerns that participants may have about confidentiality and discrimination; issues with respect to data sharing and re-consent; and the substantial resources that are needed to approach and consent large numbers of participants (Green & Guyer, 2011; McCarty et al., 2011a; Ormond et al., 2010; Parker, 2008; Pulley et al., 2010; Simon et al., 2011). Members of the public are concerned about the time-consuming and potentially confusing nature of traditional consent processes for biorepositories (Murphy et al., 2009; Simon et al. 2011). Research indicates that participants have emerged from traditional consent processes with misperceptions about the potential risks and benefits of biorepository participation, biospecimen ownership, and the voluntary nature of participation (Allen & McNamara, 2011; Barr, 2006; Maradiaga & Maultsby, 2011; Neidich et al., 2008; Ormond et al., 2009; Toccaceli et al., 2009). Recent court cases demonstrate the potential consequences of these misperceptions for researchers and institutions, including disruption of research, financial settlements, and destruction of samples (*Beleno v. Tex. Dept. of State Health Servs.,* 2009; Harmon, 2010; *Havasupai Tribe v. Arizona Board of Regents,* 2008; Trinidad et al., 2011). These consequences impede scientific advances which could contribute to improving the health of individuals (Trinidad et al., 2011).

Although no single solution will address all the needs, we propose to use multimedia technology and interactive instructional strategies to improve the effectiveness and efficiency of informed consent processes for biorepositories. **[R1** Preliminary research suggests that multimedia presentations are feasible for obtaining informed consent from potential biorepository donors (McCarty et al., 2011b; K. Yost, personal communication, May 16, 2011). /**R1]** By comparing interactivity and multimedia as separate constructs to traditional, paper-based processes for consenting individuals into a comprehensive DNA and tissue biorepository, the research will demonstrate the individual and combined effects of these strategies on participant knowledge of and staff time for **R5. [**obtaining informed consent in an actual (not a simulated) recruitment process**]**. Where multimedia has potential advantages for standardizing the process, interactivity could be implemented with its own advantages into paper-based approaches without the added cost of multimedia production. **[R7** Individuals will be randomly assigned and formally consented to the biorepository through one of four conditions, allowing comparison of actual decisions to participate in the biorepository by informed consent condition. /**R7]** *This project is significant, therefore, because it tests a technology-based solution with potential to diminish the challenges of conducting informed consent for tissue and DNA biorepositories. By identifying the individual and combined effects of interactivity and multimedia, the project will provide empirical evidence for theory-based best practices that DNA and tissue biorepositories can implement to improve the effectiveness and efficiency of obtaining informed consent from potential biospecimen donors.*

**Research Strategy - Innovation of the Proposed Work**

**[R1.** Although multimedia has been applied to informed consent for research (Cohn & Larson, 2007; Flory & Emanuel, 2004; Henry et al., 2009; Jeste et al., 2008), and a few biorepositories are experimenting with multimedia approaches for informed consent (e.g., McCarty et al., 2011b; K. Yost, personal communication (p.c.), May 16, 2011), the proposed research integrates a number of original and important design elements:

*1. An experimental approach that controls for interactivity and multimedia in an actual biorepository recruitment context.* Most studies of informed consent described as multimedia have failed to control for the effects of interactivity. In Flory and Emanuel's (2004) review of multimedia consent research, most multimedia were videos or PowerPoint presentations where participants watched and listened to information, but were not required to interact with or use that information. These design limitations may account for the finding that multimedia was superior to standard (paper-based) informed consent in only 1 of 12 studies (Flory & Emanuel, 2004). In contrast, multimedia informed consent has been successful in studies of patient education for routine care (e.g., Jeste et al., 2008; Lewis, 1999; Schenker et al., 2011). In review articles of studies using interactive "test/feedback" techniques of which a proportion were also multimedia, all studies showed improvement in patient knowledge of informed consent (Flory & Emanuel, 2004; Schenker et al., 2011). Interventions in these studies tested patient knowledge during the learning process and provided corrective feedback.

Several biorepositories are also experimenting with multimedia approaches to informed consent. Users of the Marshfield Clinic's video consent process accessed via touchscreen reported feeling "well informed" in a focus group study (McCarty et al., 2011b) The Mayo Clinic is in the early phases of testing a multimedia consent process for a disease-specific biobank, in which video is used and participants are prompted to ask for more information. No evaluation data are available yet on this system (K. Yost, p.c., May 16, 2011). **[R5** Neither the Marshfield nor the Mayo studies control for the separate effects of multimedia and interactivity. *Therefore, our experimental design will investigate the effects of multiple media (text, audio, graphics and content specific, simple animations) and interactivity (predefined questions to patients with feedback) as separate constructs integrated into actual biorepository recruitment.***/R5]** Our pilot data indicate a strong effect for interactive multimedia as a delivery strategy over paper-based delivery ($p = .008$), where interactivity and multimedia appear to enhance each other's effectiveness (see *Preliminary Data* in *Approach*). Knowing what effects interactivity and multimedia respectively have on consent knowledge/understanding will not only permit multimedia consent tools to be more rationally designed, but demonstrate how interactivity can improve paper-based consent processes. **/R1]**

**[R9** *2. A focus on informed consent effectiveness and efficiency:* The effectiveness of informed consent in conveying knowledge and understanding of the research is a key component of protecting human subjects' rights (Beauchamp & Childress, 1979; Lavori et al., 1999; National Commission, 1979). As a result, we plan to measure informed consent knowledge and understanding as separate but interconnected constructs, using several measures adapted specifically for the biorepository and UIHC Biorepository contexts (*see Appendix, Participant Questionnaire*). However, resources allocation is also an important consideration for large-scale biorepositories (Pulley et al., 2010). Most emerging studies of informed consent among biorepositories have focused predominantly on measuring effectiveness or perceived effectiveness (e.g., Allen & McNamara, 2011; Maradiaga & Maultsby, 2011). Marshfield Clinic's pilot study demonstrating that their multimedia consent took participants slightly less time than the paper-based process (17.5 vs. 18.25 min.; McCarty et al., 2011b) speaks to the feasibility of multimedia consent tools from a user perspective. However, research on informed consent has not considered efficiency from the standpoint of staff time invested in the consent process. While efficiency in informed consent is a complex construct and raises questions such as whether actual and/or perceived *effectiveness* may be compromised as consent efficiency improves and the human element is decreased (Ellickson & Hawes, 1989), staff time is an important metric of efficiency and budgetary impact of technology-based consent (Lavori et al., 1999). The study begins the process of examining efficiency constructs and metrics with those of consent effectiveness in the biorepository informed consent context. **/R9]**

**[R4** 3. *A timely focus on return of research results:* Individual genetic/genomic research results (IGRRs) and the challenges they pose are a major interest and concern (Bredenoord et al., 2011; Christensen et al., 2011; Fabsitz et al., 2010; Hens et al., 2011; Kolleck & Petersen, 2011). To our knowledge, no studies have examined whether multimedia can potentially improve understanding of the prospect of IGRRs. Therefore, our study and study instruments now accommodate an exploration of the potential effects of interactive multimedia on knowledge/understanding of the possible return of IGRRs. The UIHC Biorepository's consent document is ideal for this purpose because it includes a description of the qualified disclosure policy that the Biorepository is taking on return of IGRRs (see p. 4, biorepository consent document). This type of policy is likely to be increasingly adopted as guidelines, consensus statements, and experts advocate for some limited return of IGRRs (Beskow & Burke 2010; Bredenoord et al., 2011; Fabsitz et al., 2010). We expect that individuals enrolled in the interactive multimedia condition of our study will understand the UIHC Bio-repository's statement on the return of results better than those enrolled in the paper-based conditions. If this expectation is borne out, our study will help advance in an important and novel direction, interactive multimedia consent, evolving efforts to convey IGRR disclosure policies to prospective biorepository participants. **/R4]**

## Approach

**Introduction.** The objective of this project is to systematically develop and test the use of multimedia and interactivity to improve participant knowledge and understanding and reduce staff time devoted to obtaining informed consent for biobanking. We will test our working hypotheses using a 2 x 2 randomized, experimental design incorporated into the current UIHC, IRB-approved biorepository recruitment process, with delivery type (paper-based versus multimedia) and interactivity (low versus high) as the independent variables; and knowledge, understanding, decision to enroll in the Biorepository, and staff time as the dependent measures. Ultimately, the proposed research will provide strategies that biorepositories can use to improve the effectiveness and efficiency of their informed consent processes.

**Justification and Feasibility.** The informed consent process requires participants to learn about the research study and use that information to make a decision about participating (Krathwohl, 2002). Traditionally, a researcher summarizes and/or a participant reads a paper informed consent document. While previous research has focused on improving participants' decision making (Kass et al., Mintz et al., and Merz & Sankar in Agre et al., 2003; Benson et al., 1988), this study aims to improve effectiveness by increasing participant knowledge acquisition during informed consent so that participants can make an informed decision. Research on informed consent has often focused on content issues such as decreasing the length of informed consent documents or simplifying the language (e.g., Beskow et al., 2010; Dresden & Levitt, 2001; Epstein & Lasagna, 1969; Wittenberg & Dickler, 2007) with mixed results (see Wittenberg & Dickler, 2007, for a review). Our study will focus on improving the delivery and acquisition of consent information using interactive multimedia.

**[R1, R6.** *Using Multimedia to Improve Informed Consent.* Well-designed multimedia delivery platforms are theorized to enhance learning because words and pictures are presented simultaneously. *Multimedia* is a combination of visual and auditory information such as pictures, animations, recorded words, live words, sounds, and video (Mayer, 2009; Sims, 1997). According to dual coding theory (Paivio, 1990), people process information through two simultaneous pathways, verbal (words and symbols) and spatial (pictures and movement). By strategically presenting information through both modalities, information is learned more efficiently and learning is enhanced (Clark & Mayer, 2008; Mayer, 2002, 2009; Mayer & Moreno, 1998; Mousavi et al., 1995; Sadoski & Paivio, 2001). Multimedia also enhances learning by maintaining *cognitive load* at an optimum level, when designed on principles of Cognitive Load Theory (CLT) (Schnotz & Kirschner, 2007; Sweller et al., 1998; van Merriënboer & Sweller, 2005). Optimal learning engages but does not overwhelm the learner. Thus, by designing both content and presentation of instruction to optimize load, multimedia instruction facilitates the control of content and presentation of information (Chandler & Sweller, 1991; Mayer & Moreno, 2003; Paas & van Merriënboer, 1994; Sweller et al., 1998). To manage cognitive load, investigators must focus on instructional design. By improving the way in which information is presented, participant learning is expected to improve. Thus, by strategically adding graphics and designing multimedia to manage cognitive load, we hypothesize (Hypothesis 1) that multimedia will result in improved participant knowledge and understanding. Participants learning about informed consent from multimedia (MMHI and MMLI) will demonstrate better knowledge and understanding of biorepository consent information, compared to participants in the paper-based (PBLI and PBHI) conditions.

*Using Interactivity to Improve Participant Understanding.* Although many prior studies of informed consent for medical research refer to interactive multimedia or provide some form of interactivity in their treatments, interactivity is not explained by a theoretical model and not defined or measured as a separate construct. Although few studies separate interactivity from other characteristics of multimedia, in studies of informed consent for medical research, interactive features of multimedia have included conditions where users control the pace or sequence of the instruction (Campbell et al., 2004; Jeste et al., 2008, 2009; Llewellyn-Thomas et al., 1995), periodic quizzes (Dunn et al., 2002; Karunaratne et al., 2010; Palmer et al., 2008), simulations, such as scenarios or vignettes requiring patient input (Mintz et al. and Merz & Sankar in Agre et al., 2003), repetition of content after assessment (Dunn et al., 2002), and hyperlinks to support deep processing of information (Karunaratne et al., 2010; Llewellyn-Thomas et al., 1995).

Although many theories of interactivity have been proposed (Downes & McMillan, 2000; Jensen, 2008; Kiousis, 2002; McMillan, 2005), for this project, *interactivity* is the degree to which an individual is 1) asked to respond or use information and 2) provided with feedback on his responses (Kiousis, 2002; Koolstra & Bos, 2009; Yacci, 2000), in contrast to passive reception of information such as watching a video. This type of interactivity can be manipulated in any instructional situation (e.g., computer-based or paper-based; Sims, 2003). Prior studies have used two kinds of interactivity, 1) user control and 2) engagement with the information. This research focuses on engagement with the information as it is more likely to improve participant learning (Palmer et al., 2008) and, therefore, understanding of consent information.

According to information processing and interactivity theories (Yacci, 2000), interactivity can enhance learning by making learners actively process information, selecting relevant information, organizing it, and integrating it into their memory structure (Mayer, 2002). In addition, interactivity can benefit learner engagement by providing a sense of social presence (Yacci, 2000), perception of reduced effort (Downes & McMillan, 2000), or by attracting and maintaining learner attention (Lustria, 2007). Even the expectation of receiving feedback can improve learning behavior (Vollmeyer & Rheinberg, 2005). /**R1, /R6]** Because well-designed interactions can enhance learning, we hypothesize (Hypothesis 2) that interactivity will result in improved participant knowledge and understanding. Participants in the high interactivity conditions (MMHI &

PBHI) will demonstrate better understanding of the content, compared to those in the low interactivity conditions (MMLI & PBLI).

*Improving Efficiency by Reducing Staff Time to Obtain Informed Consent.* Even if a multimedia consent process takes as much participant time to complete as paper-based, it can reduce staff time invested in delivering basic knowledge. Staff need not be present for the entire time that participants view or work with the multimedia presentation. While efficiency is a complex construct and will ultimately require closer investigation than this study can allow, we predict (**Hypothesis 3**) that the multimedia conditions will demonstrate better efficiency, defined as less staff time devoted to obtaining informed consent, than the paper-based conditions.

**[R8 Preliminary Data.** A recent pilot study ($n$ = 95) by Schartz and Klein found that participants who completed interactive, multimedia informed consent in a mock study of a clinical trial reported significantly better understanding ($M$ = 15.9 correct out of 18 possible multiple-choice questions) and found the process easier to use ($M$ = 2.32 rating on a scale from 1 to 5, with 1 as "excessively easy" and 5 as "excessively difficult") than those who received paper-based informed consent ($M$ = 14.9 and $M$ = 3.16, respectively; understanding $F(2,92) = 5.10$, $p = .008$, ease of use $F(2, 93) = 7.29$, $p = .001$). The mean for multimedia without interactivity fell between the two ($M$ = 15.2, $M$ = 2.77, respectively). Although the interactive, multimedia condition ($M$ = 20.7 min.) took approximately 2 more minutes than the paper-based ($M$ = 18.7 min.) to complete, participants in the interactive, multimedia condition perceived that it took less time than those in the control condition ($M$ = 3.58 rating, $M$ = 4.03 rating, respectively, on a scale from 1 to 5, with 1 as "excessively short" and 5 as "excessively long"; $F(2,92) = 3.53$, $p = .03$). However, the pilot study did not test the effects of interactivity and multimedia separately, did not assess staff time, nor gather data on participants' likelihood of enrolling in the clinical trial. The proposed study is needed to address these issues, determining the effects of interactivity and multimedia separately assessing staff time needed to complete informed consent, and measuring participants' decisions about enrollment in an actual biorepository /**R8].**

**Research Design.**

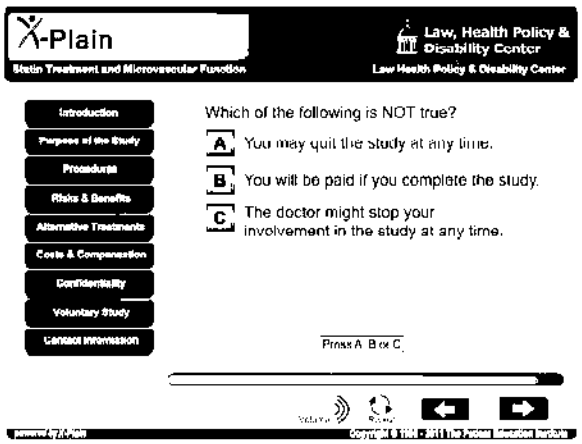
*Study Recruitment and Sample.* **[R5** The study will be integrated into the UIHC Biorepository's recruitment plan as currently being implemented in the Department of Dermatology and Division of Immunology/Rheumatology at the UIHC (see letters from Murray, Fairley, Ballas, & Zabner). We anticipate enrolling 220 participants (110 from Dermatology and 110 Immunology/Rheumatology respectively) over a 6-month period, with 200 complete data and 10% (i.e., 20) additional participants to accommodate unforeseen issues such as technology glitches, interruptions of participants, etc.

Procedures. Eligible participants will be approached regarding participation in the UIHC Biorepository. Those who are interested in learning about the Biorepository will also be informed about this study. Under a waiver of written consent, participants will receive a one-page description of the study, consent verbally to the experiment, and be randomly assigned to one of the four consent conditions. After completing the consent condition, participants will complete the Participant Questionnaire (*see Appendix*), and then be asked to decide about participation in the Biorepository. Staff will have on-site access to the knowledge assessment results. Participants who correctly answer all knowledge questions will be asked to confirm their decision to participate in the Biorepository and be enrolled in it, if they agree. For participants who answer any questions incorrectly, staff will review relevant information with them and determine that the participant understands her rights and responsibilities before enrollment (*see Recruitment Method diagram in Appendix*). Participants will receive 2 one-hour parking vouchers for participating. /**R5]**

*Paper-based conditions.* The paper-based low interactivity (PBLI) is the current IRB-approved informed consent process (control). Staff review the informed consent document with the participant, allow him/her to read the document, and respond to any participant questions. In the paper-based high interactivity (PBHI) condition, the informed consent document will be divided into sections (i.e., nature of research, procedures, risks, benefits, etc.). Staff will verbally review and allow the participant to read one section at a time; then staff will ask at least one scripted question about a critical element of the section to assess participant knowledge. Staff will provide feedback on the participant's response to the question, reinforcing correct answers and clarifying misperceptions. Staff will be trained for consistency in their communication style and feedback.

**[R2** *Multimedia conditions.* Limited data and research are available on interactive, multimedia delivery system for the obtaining of biorepository consent. Therefore, we will develop and test the interactive module templates (see Figure 1), widely used principles of instructional design and the expertise of PEI (see PEI letter), and on the experience of our Mayo and Marshfield consultants. CLT principles for effective multimedia learning will be used to guide the design, including the chunking of text, selection of supporting graphics, and

simple animations. To control sequencing, hyperlinks will not be used. The multimedia modules will use the IRB-approved informed consent document as the text and narration. However, the multimedia will be presented via a computer in the clinic where participants are recruited for the Biorepository. In the multimedia high interactivity (MMHI) condition, participants will respond on the computer to the same questions at the same points in the presentation as the paper-based high interactivity (PBHI) condition. In both interactive conditions, participants will receive feedback on their responses and will be allowed to review the presented information for incorrect responses./**R2]**




***[R2.** Figure 1. Example of an interactive question using the X-Plain interface. The interface includes user controls (forward, back, replay, and sound buttons) as well as buttons for responding to the question./**R2**]*

*Formative evaluation.* Although the words for the multimedia informed consent will not be modified because they will be from the Biorepository's IRB-approved consent document, stakeholders and consultants will participate in a formative evaluation of the multimedia presentation (graphics and animations) and the interactive components (questions and feedback) for the high interactivity conditions. Project consultants (Brilliant & McCormick), along with a University of Iowa genomics researcher and biorepository director (J. Murray), an IRB Chair (A. Bertolatus), and a genetic counselor and coordinator (J. L'Heureux) will participate in the evaluation (*see corresponding letters of support*). Additionally, the UI Institute for Clinical and Translational Science community outreach program will identify five community members to participate in the formative evaluation. Stakeholders will complete the multimedia high interactivity module, respond to a heuristic evaluation form (Alessi & Trollip, 2001; *see Appendix*) for the multimedia presentation, and participate in a verbal debriefing with study investigators. The research team will use stakeholder feedback, where feasible and appropriate, to improve the presentation. This formative evaluation process will be reported in ensuing publications to contribute to the process literature on multimedia consent development.

***Outcome Measures.*** To test for knowledge and understanding, a four-part questionnaire (see Appendix) has been developed. Participants in all conditions (PBLI, PBHI, MMLI & MMHI) will complete this questionnaire post-experiment, on a computer in the clinic using an online survey format with recruiters out of the room. Staff will be available to guide participants through the questionnaire and answer any questions. The questionnaire is expected to take 20-30 minutes to complete. Questionnaire Sections A and B will measure participants' objective knowledge and subjective (self-assessed) understanding of the Biorepository consent information. These measures are based on instruments developed and validated by Joffe et al. (2000) for cancer research, and recently adapted by Ormond et al. (2009) for biorepository research. Section A measures the participant's recall and recognition, while Section B assesses self-perceived level of understanding of this knowledge. We have maintained the design, format, and testing domains of the original validated instruments. Following Ormond et al., we have modified some content to reflect the unique characteristics of the UIHC Biorepository (*see Appendix, UIHC Biorepository Description and Consent Document*). Section C measures how well participants grasp the implications of biorepository participation based on what they have learned. Whereas Sections A and B measure participants' ability to recall basic information about the biorepository and their perceived understanding, Section C measures how well participants are able to use that information, for a more objective assessment of their level of understanding. Following the revised Bloom's Taxonomy of Educational Objectives (Krathwohl, 2002), which provides a framework for assessing levels of understanding, we developed a multiple choice instrument that measures the participants' ability to interpret, classify, infer, and compare learned information. This measure enriches the data from Sections A and B by objectively assessing deeper understanding of the presented consent information. Section D collects demographic and health data on participants and asks them to reflect on their experience in the experiment. These data will be used to explore any possible variability in knowledge and understanding scores within and across conditions and to gain participant perspectives on the experiment.

**[R5, R7** Participants' decision to participate/not participate in the UIHC Biorepository will be captured after they have had an opportunity to ask questions/allay concerns about Biorepository participation, but before they fill out the study questionnaire. Their decision will be confirmed after their knowledge/understanding of the consent information has been assessed and remediated, if necessary (see *Appendix, Decision to Participate in Biobank Form, and Recruitment Method diagram*). /**R5, /R7]**

[**R9** Staff time devoted to informed consent has been previously used in empirical research as a key efficiency variable (Beebe & Smith, 2010; Lavori et al., 1999). The dependent variable, staff time, will be measured as the total number of minutes that staff actively spend with the participant from the start of the consent process (e.g., handing them the paper form or setting up the multimedia process) to the end point of the consent process, and includes interactions and answering questions. Staff will be trained to record these time segments reliably using standard digital timers (Migden et al., 2008). /**R9]**

***Data Management and Analysis***

*Data Management*. The study's working hypotheses will be tested using quantitative data from the dependent measures. We will replicate Ormond et al.'s (2009) scoring procedures for the data from the Knowledge and Understanding Measures. The 31 items in Part A will be individually scored (correct = 100, unsure = 50, incorrect = 0), with scores summed and averaged. Part B consists of 21 5-point Likert scale questions, which will be averaged and normalized to create an overall score from 0 to 100, with higher scores reflecting higher perceived understanding. Part C will consist of 9 questions which will be scored as correct or incorrect and summed to create an overall objective understanding score. Responses to Part D, the demographic, health, and qualitative items, will be descriptively summarized. Data will be organized and managed in *SPSS*, organized in linked databases to allow for comparison between the measures.

*Data Analyses and Power*. Data will be analyzed using a 2 x 2 factorial MANOVA using SPSS, with format (paper-based and multimedia) and interactivity (low and high) as the independent variables and total scores on the knowledge, self-assessed understanding, objective understanding instruments, and staff time as the dependent variables. *G*Power* (Faul et al., 2007) Version 3.1.2 was used to calculate sensitivity of the research design. Based on 200 total participants, 50 per group, at the 0.05 significance level, our design will be able to detect an effect size of 0.7 SD (difference expressed in standard deviation units) with 0.80 power. Qualitative feedback from participants will be managed using *Nvivo* software, and analyzed for recurring themes within and across the experiment's conditions.

***Study Limitations, Timeline, and Expected Outcomes and Future Research***

*Limitations.* Although participants will be recruited from different clinics, this feasibility study will not have sufficient power to control for demographic and environmental (i.e., clinic) differences. Those analyses are planned for the subsequent multi-site R01. **[R10** Additionally, low literacy, including scientific, health, and genetic literacy, is a barrier for obtaining informed consent (Raich et al., 2001). While this study is unable to explore literacy because of feasibility, our future work will aim to enhance the sensitivity of multimedia informed consent for biorepositories to individual literacy, as well as educational and cultural background. Colleagues at the Mayo Clinic, participating in our summative workshop, are ideally positioned to contribute in this respect given their ongoing work in this area (e.g., Yost et al., 2010)./**R10]**

*Timeline.* The study will be completed within 24 months. The first 6 months of Year 1 will be devoted to development and formative evaluation of informed consent processes. Data collection will begin in the second 6 months of Year 1 and be completed in the first 6 months of Year 2. Analysis, interpretation, and manuscript preparation will be conducted during the remaining 6 months.

*Expected Outcomes and Future Directions.* This study determines the feasibility of using interactive multimedia to improve knowledge/understanding of biorepository consent information, and the potential effects of these improvements on the decision to enroll in DNA and tissue biorepositories. Results will allow the team to pursue a multisite comparative study to demonstrate the effectiveness and efficiency of interactive multimedia consent across distinctive biorepository environments. **[R3** *Summative workshop* - Our CTSA has offered (see Rosenthal letter) to sponsor a ½ day workshop to strategize data dissemination and a future research (R01) collaboration among the University of Iowa, Marshfield Clinic, Mayo Clinic, and other biorepository sites (e.g., NuGENE – see Smith letter) devoted to the application of multimedia to biorepository informed consent. Planning for possible barriers to the transportability and adoption of multimedia innovations will be a central focus of the workshop. Consultants McCormick, Brilliant, and one of their personnel (Catherine Yost, Mayo; Wendy Foth, Marshfield), who have helped design multimedia consent systems and oversee their day-to-day operations will participate in the workshop. The workshop will aim to produce an R01 study outline aiming to test in a multisite randomized trial a multimedia application that capitalizes on the R21 results, other experimental systems, and the lessons learnt with multimedia in the Iowa/Mayo/Marshfield consortium. /**R3]**

**Potential Problems and Alternative Strategies** Paper-based informed consent processes can vary significantly from one recruiter to another (Schenker et al., 2011). Since data will be collected in two clinics using several recruiters, we will train recruiters and conduct follow-up monitoring and case-by-case data quality control in an effort to reduce the potential for individual bias to affect the study.

## 6. PROTECTION OF HUMAN SUBJECTS

### 6.1 Risks to Human Subjects

a. Human Subjects Involvement, Characteristics, and Design

As part of recruitment for the University of Iowa biorepository, participants will be asked to participate in a one-session experiment comparing informed consent processes. All participants will need to meet the following study criteria: 1) able to communicate in English, 2) age 18 or older, 3) non-prisoner status, 4) currently a University of Iowa Hospitals and Clinics patient, and 5) capable of providing informed consent for the study.

b. Sources of Materials:

Sources of material will include electronic copies of a participant questionnaire as well as electronic usage data from the multimedia informed consent modules, which will be collected by computer servers. For this study, all research materials will be de-identified. No names or other participant identifiers will be recorded on electronic data. An idiosyncratic coding number will be used to ensure linkage of the participant questionnaire and usage data, which will be separate and distinct from the participant's UIHC patient medical record number. Data for the post-session assessment and questionnaire are collected using web-based forms over an encrypted (https) connection. The computer server that holds subject assessment data is located in a restricted-access room, with access only by the research team. Login access to the server is restricted to only one member of the research team, the systems administrator and members of the College of Law IT department. Once data collection is complete these data will be transferred to Excel or SPSS files, which will be stored on a computer in the PI's locked office. Computer security is consistent with the university's electronic security policies as described here http://cio.uiowa.edu/policy/policy-information-security-framework.shtml.

Names of participants will be collected only to ensure that someone is not accidentally reenrolled in the study. The biorepository already has an IRB-approved process to ensure that potential participants are not approached more than once.

c. Potential Risks

This study involves the collection of data from an experiment on informed consent involving the administration of an electronic questionnaire and collection of usage data. It is believed that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, meeting the criteria for minimal risk. Furthermore, the integration of this study as the informed consent process for the biorepository does not increase the risks from the current biorepository informed consent process. This study will be reviewed and all procedures as specified by The University of Iowa IRB will be followed.

### 6.2 Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

All procedures as specified by The University of Iowa IRB will be followed. Patients will be recruited and enrolled into the study along with recruitment for the biorepository over a 12-month period from the Dermatology and Immunology/Rheumatology clinics. Approximately 200 patients are expected to express interest in this study.

Eligible participants will be approached regarding participation in the UIHC biorepository. Those who express an interest in learning about the biorepository will also be informed about this study. Under a waiver of written consent, participants will receive a one-page description of the study, consent verbally to the experiment, and be randomly assigned to one of the four consent conditions. After completing the consent condition, participants will 1) be asked whether/not they intend to participate in the biorepository; 2) complete the Participant Questionnaire; 3) be given an opportunity to remediate any gaps in knowledge/understanding of biorepository participation; and 4) be asked to confirm their decision as to participation in the UI Biorepository (*see Appendix, Recruitment Method Diagram*). Step 3 (i.e., opportunity to remediate gaps) will be undertaken to help ensure that participants in all four study conditions complete the study and confirm their decision to participate/not participate in the biorepository based on a uniformly robust knowledge/understanding of the content of the officially approved UI Biorepository informed consent document (*see Appendix*). Step 3 will be

undertaken only with participants who do not score correctly on all knowledge/understanding questions in the Participant Questionnaire. Recruiting staff will have immediate, on-site access to the knowledge/understanding assessment results, in order to be able to assess if some informational element or elements of the consent document need to be reviewed again. If the participant answers any questions incorrectly, staff will review relevant information with the participant and determine that the participant understands her rights and responsibilities before enrollment (see Recruitment Method diagram in Appendix). All participants will be asked to confirm their decision to participate in the UI Biorepository and will be enrolled in the biorepository dependent on their decision. All participants will be provided with two, one-hour parking vouchers for their time.

b. Protections Against Risk

There is a risk of loss of confidentiality of materials obtained for this study. In order to minimize this risk, all study materials will be coded. No names or identifying information will be retained on any collected data sources (questionnaire and usage information). All research materials will be de-identified. No names or identifiers will be recorded on electronic data. An idiosyncratic coding number will be used to ensure linkage of the participant questionnaire and usage data, which will be separate and distinct from the participant's UIHC patient medical record number. Data in electronic form will be stored on secure computers in the research offices and will be accessible only to authorized research staff. Names of participants will be collected only to ensure that someone is not accidentally reenrolled in the study. The biorepository already has an IRB-approved process to ensure that potential participants are not approached more than once.

**6.3 Potential Benefits of the Proposed Research to the Subjects and Others**

Individual participants may not benefit from participating in the research.

**6.4 Importance of the Knowledge to be Gained**

Insights gained from this study may be useful to health policy makers, IRBs, and researchers who have a stake in biorepository-driven research. Study data will advance understanding of the potential utility of multimedia informed consent in biorepository recruitment procedures.

**6.5 Data and Safety Monitoring Plan**

A true Data Safety Monitoring Board is not required, as the proposed study is not a clinical trial, but an examination of informed consent in biorepository recruitment procedures. A plan is in place to insure the safe handling of all data and the maintenance of confidentiality. This plan should be sufficient; however, the ultimate responsibility for data safety rests with the Principal Investigators.

An important aspect of this research is instituting procedures to assure the safe management of all data obtained from participants. In order to protect participants, the Institutional Review Board will review the study. All appropriate guidelines will be followed, including the use of Informed Consent procedures. Data safety procedures will be part of the annual review by the appropriate IRBs and any changes suggested by these groups will be incorporated into the delineated data safety plan.

## 7. Inclusion of Women and Minorities

We will enroll male and female participants in the project, and we anticipate that the sample will be approximately 50% female.

Approximately 5.6% of residents of Iowa are members of minority groups and 4.0% are of Hispanic origin. Based on our prior focus group and survey research on biobanking, we expect that at least 5% of our sample will be English-speaking members of minority groups.

# Targeted/Planned Enrollment Table

**Study Title:** Interactive Multimedia and Biorepository Informed Consent

**Total Planned Enrollment:** 220

| TARGETED/PLANNED ENROLLMENT: Number of Subjects | | | |
|---|---|---|---|
| **Ethnic Category** | **Sex/Gender** | | |
| | **Females** | **Males** | **Total** |
| Hispanic or Latino | 6 | 6 | 12 |
| Not Hispanic or Latino | 104 | 104 | 208 |
| **Ethnic Category: Total of All Subjects *** | 110 | 110 | 220 |
| **Racial Categories** | | | |
| American Indian/Alaska Native | 1 | 1 | 2 |
| Asian | 2 | 2 | 4 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | |
| Black or African American | 4 | 4 | 8 |
| White | 103 | 103 | 206 |
| **Racial Categories: Total of All Subjects *** | 110 | 110 | 220 |

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

## 9. Inclusion of Children

Children will not be enrolled in the study, as they are not currently eligible for participation in the DNA and tissue biorepository at the University of Iowa Hospitals and Clinics.

## 12. MULTIPLE PI LEADERSHIP PLAN

This is a collaborative research project for which multiple PIs provide specific expertise to meet the project purpose and accomplish project aims. Drs. Simon, Schartz and Klein will be the PIs responsible for oversight of the entire program, and development and implementation of all policies, procedures and processes. Drs. Simon, Schartz and Klein will be responsible for the implementation of the Scientific Agenda, the Leadership Plan, and the specific aims and ensure that systems are in place to guarantee institutional compliance with US laws, DHHS and NIH policies including human research, data and facilities. The leadership plan specifies division of responsibilities for achievement of study aims.

### A. Responsibilities, Management and Communication

The multiple PI format on this grant is designed to maximize the expertise in bioethics, law, and education technology that Drs. Simon, Schartz, and Klein respectively bring to this project.

Dr. Christian Simon is the contact PI. He provides expertise in bioethics for the project. Dr. Simon will be responsible for the development and implementation of the data collection tools and measures. He will also coordinate the summative workshop in Year 2 of the grant. Dr. Simon will coordinate communication among PIs and the NIH and initiate progress reports. He will oversee research activities of team personnel and timely completion of group activities according to the project timeline. He will oversee management of the budget and maintain weekly communication with the project RAs and Investigators, maintenance of project records, storage of study data, and development of reports.

Dr. Helen Schartz provides expertise in social science research and law for the project. She will oversee the experiment design, sampling, and implementation of the design. Dr. Schartz will work with Dr. Simon to complete the application for and process of obtaining approval for the study from the University of Iowa's IRB. She will collaborate with Drs. Simon and Klein in the data analysis and write-up phases of the project. Dr. Schartz will be the contact person for any concerns that participants may raise during the experiment.

Dr. David Klein provides expertise in instructional design, educational psychology, and technology. He will be responsible for the instructional design and development of the modules for the research, including the organization of information and the selection of graphics or other media components. Dr. Klein will also oversee the heuristic evaluation of the multimedia delivery system. He will work directly with and oversee the Patient Education Institute (PEI) for their implementation of the multimedia modules. He will be responsible for addressing any technology issues that arise during the implementation of the research and with data collection during the experiment. He will oversee the training and supervision of the research assistants. Dr. Klein will collaborate with Drs. Simon and Schartz in the data collection, analysis, and write-up phases of the project.

The PIs will meet weekly throughout the life of the project regarding the activities of the project.

### B. Intellectual Property

Publication authorship will be based on the relative scientific contributions of PIs and key personnel, in accordance with professional standards, and in accordance with recommendations of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication.

### C. Conflict Resolution

PIs shall meet to discuss the resolution of any conflicts. If they are unable to resolve the conflict, standard University of Iowa procedures for resolving any dispute, claim or controversy arising out of or relating to a subcontract will be followed. If a potential conflict develops, the PIs shall meet and attempt to resolve the dispute. If they fail to resolve the dispute, the disagreement shall be referred to an arbitration committee consisting of one impartial senior executive from each PI's College and a third impartial senior executive mutually agreed upon by both PIs. No members of the arbitration committee will be directly involved in the research grant or disagreement.

### D. Change in PI Location

If a PI moves to a new institution, attempts will be made to transfer the relevant portion of the grant to the new institution. In the event that a PI cannot carry out his/her duties, a new PI will be recruited as a replacement at one of the participating institutions.

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The following letters of support were included as part of the original application and are provided with the permission of Dr. Murray. An additional 9 letters were included in the original application but have been redacted to protect the privacy of individuals providing letters of support.

UNIVERSITY of IOWA
CARVER COLLEGE
OF MEDICINE

*Craniofacial Anomalies Research Center*

University of Iowa Health Care

*Roy J. and Lucille A.
Carver College of Medicine
500 Newton Road 2182 Med Labs
Iowa City, IA 52242
319-384-4464 Tel
319-335-6970 Fax
www.uihealthcare.com*

June 30, 2011

Christian Simon, MA, PhD
Associate Professor, Department of Internal Medicine
Program in Bioethics and Medical Humanities
Director, Clinical Research Ethics Consultation Service
Roy J. and Lucille A. Carver School of Medicine
500 Newton Drive, 1-103 MEB
Iowa City, IA 52242-1190

Dear Chris, Helen, David, and Jamie:

I am writing to give you my enthusiastic support for your proposed project on multi-media and informed consent for biobanking. This project is a logical outgrowth of the current interest in biobanking activities and concerns associated with the ethical procurement of biobanked tissue, DNA and access to electronic medical records.

Currently, I am the Director of the Genetics/Genomics Key Function for the NIH-CTSA grant that is part of the University of Iowa ICTS (Institute for Clinical Translational Science). At the present time, we have begun sample collection for the University of Iowa's hospital-wide biorepository linking discarded biologic specimens to electronic medical records. Participating clinics include the Department of Dermatology and Division of Immunology.

I have worked closely with you and Jamie L'Heureux in developing the initial activities around the biobank, including the informed consent protocol. We consulted many biobank experts in developing this protocol, including at Vanderbilt University, Mayo Clinic, Marshfield Clinic, and Northwestern University. Especially important, however, were the focus groups and state-wide survey you and Jamie conducted, which showed decisively that there were strong preferences in the state of Iowa for a prospective opt-in consent process using a broad consent approach for future research.

The use of multi-media has terrific potential to make the informed consent process for biobanks more accessible and facilitative for affected patients, families, and consenting staff. One of the early challenges that we have had in our neonatal bank, which has enrolled more than 4,000 individuals to date, is the promotion of an understandable and efficient consenting process. Your proposal will make major steps toward addressing the best ways to carry this out. An important strength of your proposal is the inclusion of a rigorously developed informed consent document in your randomized experiment to compare use of the multi-media and standard consent processes.

You and Jamie have played an excellent leadership role in developing an evidence-based consent protocol for the hospital-wide biobank, and in partnering with Helen Schartz and David Klein and their deep background in the use of multi-media. I look forward to the important

results that are likely to come from this wonderful collaboration. I am always available to consult and work with you, including for purposes of reviewing your multimedia prototype.

Sincerely yours,

Jeffrey C. Murray, MD
Professor, Departments of Pediatrics, Epidemiology and Biological Sciences
University of Iowa Carver College of Medicine
500 Newton Road, 2182 ML, Iowa City, IA 52242-1181
319-335-6897 phone; 319-335-6970 fax
E-mail: jeff-murray@uiowa.edu

## 15. Resource Sharing Plan

This project will yield quantitative and some qualitative data generated by a post-experiment questionnaire. Aggregated data from the questionnaire and findings resulting from the analysis of these data will be shared through publications and conference proceedings resulting from this project. A summative workshop will be held at the end of Year 2 of the grant to identify potential barriers to adoption of the multimedia consent tool, strategize data dissemination, and plan for a future research (R01) collaboration among researchers from the University of Iowa, Marshfield Clinic, Mayo Clinic and potentially other institutions experimenting with or interested in the application of multimedia to biorepository consent processes. The workshop will produce an R01 study outline for a collaborative multi-site, multi-environment randomized experiment of a composite multimedia consent tool.

# PHS 398 Checklist

OMB Number: 0925-0001

## 1. Application Type:

From SF 424 (R&R) Cover Page. The responses provided on the R&R cover page are repeated here for your reference, as you answer the questions that are specific to the PHS398.

* Type of Application:

☐ New ☒ Resubmission ☐ Renewal ☐ Continuation ☐ Revision

Federal Identifier: HG006293

## 2. Change of Investigator / Change of Institution Questions

☐ Change of principal investigator / program director

Name of former principal investigator / program director:

Prefix:
* First Name:
Middle Name:
* Last Name:
Suffix:

☐ Change of Grantee Institution

* Name of former institution:

## 3. Inventions and Patents (For renewal applications only)

* Inventions and Patents: Yes ☐ No ☐

If the answer is "Yes" then please answer the following:

* Previously Reported: Yes ☐ No ☐

**4. * Program Income**

Is program income anticipated during the periods for which the grant support is requested?

☐ Yes ☒ No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

| *Budget Period | *Anticipated Amount ($) | *Source(s) |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

**5. * Disclosure Permission Statement**

If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)?

☐ Yes ☒ No