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request for exemption form

RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY

INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION
OF HUMAN SUBJECTS IN RESEARCH (IRB)

REQUEST FOR EXEMPTION FROM FULL IRB REVIEW

Version 6.08

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Does this activity involve research?</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>Note: Program evaluation MAY NOT meet the definition of research.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note: Students investigators must review the special criteria for</td>
<td></td>
<td></td>
</tr>
<tr>
<td>students listed in section D of the instructions.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Do the individuals that will participate in this activity meet the</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>definition of human subjects?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note: For an individual to be considered a human subject, data ABOUT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>them must be collected.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: IRB review is ONLY required if an activity involves BOTH research AND human subjects. If you have answered “Yes” to questions 1 AND 2, proceed with completion of this form. Investigators may not self exempt.

Title of Project: Assessment of Barriers to Trusting Computer-Based Home Assistance

PRINCIPAL INVESTIGATOR (type name here): Paul B. Kantor

Please note that undergraduate student investigators may not be named as the principal investigator on protocols and must instead name their faculty advisor. Graduate students may serve as a Principal Investigator, with their advisor serving as CO-Principal Investigator.

CHECK ONE:

Faculty ____x__ Title: Prof. Dr. ____x____
Staff _______ Title: Mr.______
Graduate Student Ph.D. _______ Ms.______
Graduate Student Masters ______

Department/Unit: (DO NOT ABBREVIATE): Library and Information Science, School of Communication and Information

Mailing Address: 4 Huntington St. New Brunswick NJ. 0901
Home phone (optional):
Cell Phone (optional): 732 322 8412 Office Phone: 7332 932 7500x8216 Fax: 732 932 1504
E-Mail: paul.kantor@rutgers.edu

I certify that the statements made in this request are accurate and complete, and fall within the exemption categories described below to qualify for exemption from Full/IRB review. I will conduct this study in accordance with the recommendations of the Institutional Review Board for the Protection of Human Subjects in Research (IRB). I will not begin work on this project until I receive a Notice of Exemption from the IRB. I understand that I am responsible for reporting any serious adverse events or emergent problems to the IRB and for obtaining IRB approval before implementing modifications. I have read the Federal Wide Assurance (FWA), which is available at <http://orsp.rutgers.edu/Human.asp>, and understand my responsibilities as a Principal Investigator. If work will be done by an undergraduate student, I will properly mentor them.

Signature of Principal Investigator: [signed copy via pdf] Date __2009.07.24__

Name of Undergraduate Investigator: N/A
E-Mail: __________________________

Signature of Student: __________________________ Date: __________________________

Indicate the date that the undergraduate successfully completed the Human Subjects Certification Program:

If this project is being performed as part of an honors program, please check here and specify the program:

* See definition in the instructions.
Faculty Advisor as Co-Principal Investigator for Graduate Student Principal Investigator:

Faculty Advisor must serve as the Co-Principal Investigator if their graduate student serves as the Principal Investigator:

As faculty advisor for the graduate student named as Principal Investigator for this protocol, I certify that I am familiar with Rutgers University policies and federal regulations as they apply to research involving human subjects. I have advised and/or assisted the student in the preparation of this application and have reviewed it for completeness and accuracy. I endorse the study and certify that it fulfills all the guidelines and requirements for IRB review. I agree to serve as the Co-Principal Investigator for this project.

Name: (printed) N/A Signature: ______________________________ Date: _____________

Title: ______________________________

Department: ______________________________

Office Phone: ______________________________

Cell Phone (optional): ______________________________

Home Phone (optional): ______________________________

Fax: ______________________________

E-Mail: ______________________________

Human Subjects Certification Completion Date: ______________________________

Graduate Program Director:
The graduate program director will be contacted if problems arise from the protocol. Provide program director’s information below:

Name: (printed) ______________________________

Title: ______________________________

Department: ______________________________

Office Phone: ______________________________

Cell Phone (optional): ______________________________

Home Phone (optional): ______________________________

Fax: ______________________________

E-Mail: ______________________________

Complete this section if someone in addition to the PI is designated to receive and respond to correspondence.

CONTACT PERSON: ______________________________

Title: ______________________________

Department/Unit: ______________________________

Mailing Address: ______________________________

Phone: ______________________________

Fax: ______________________________

E-Mail: ______________________________

EDUCATION
Effective January 1, 2001, successful completion of the web-based Human Subjects Certification Program by the principal investigator and all other key personnel will be required prior to the Notice of Approval being issued for a protocol.

Indicate the date that the Principal Investigator successfully completed the Human Subjects Certification Program:

Date of Completion: Rutgers: 2001.02.16; UMDNJ: Human Subjects 2007.03.13; UMDNJ: HIPAA 2007.03.14

List below other key personnel including undergraduate investigators, who are responsible for the design OR conduct of the study. Attach additional sheets if necessary, marked 'Attachment 2'.

<table>
<thead>
<tr>
<th>Name</th>
<th>Email Address</th>
<th>Date of HSCP Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cecilia Gal, Ed. M.</td>
<td><a href="mailto:cgal@rci.rutgers.edu">cgal@rci.rutgers.edu</a></td>
<td>Rutgers: 2007.03.13 UMDNJ: Human Subjects 2007.03.13 UMDNJ: HIPAA 2007.03.14</td>
</tr>
<tr>
<td>Once funding is received, we will recruit other student personnel to conduct interviews. Their names are not yet known.</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### Funding Status

<table>
<thead>
<tr>
<th>Funded</th>
<th>Funding Request Submitted</th>
<th>Not Funded</th>
</tr>
</thead>
<tbody>
<tr>
<td>x</td>
<td>x</td>
<td></td>
</tr>
</tbody>
</table>

If the project is funded, or an application for funding has been submitted, indicate the name of the funding agency or organization: National Science Foundation

Does any member of the research team have a financial interest in the research or its products or in the study sponsor? __Yes _x__No

If yes, please describe. (University policies regarding Conflict of Interest should be reviewed at <http://orsp.rutgers.edu/policies/> ) Attach additional sheets if necessary.

### Instructions

**Instructions:** Answer each of the following questions, in order, (unless specifically directed otherwise) as they relate to the research project you would like to initiate. The comments immediately following each response will assist you in determining whether exemption is appropriate for this protocol. Continue until you reach “STOP”. Relevant definitions and clarifications are contained in Section B of the instructions. Failure to comply with directions will result in a return of the Request for Exemption and a delay in the review process.

1. **Does the activity present more than minimal risk* to subjects?**
   - Yes – STOP - the protocol is not eligible for exemption. Stop here on this checklist. You must complete an IRB application for full review.
   - No

2. **Does the research involve prisoners*, fetuses, pregnant women, human in vitro fertilization, deception or incomplete disclosure?**
   - Yes - STOP - the protocol is not eligible for exemption. Stop here on this checklist. You must complete an IRB application for full review.
   - No

---

### EDUCATIONAL ENVIRONMENTS

3. Will the research be conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods?
   - Yes- Exemption #1 may be applicable.
   - No – Exemption #1 does not apply.

---

### TESTS, SURVEYS, INTERVIEWS, OBSERVATION OF BEHAVIOR

4. Will the research involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior?
   - Yes – Exemption #2 may apply.
   - No – Exemption #2 does not apply. Go to question 10.
<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Yes Response</th>
<th>No Response</th>
</tr>
</thead>
</table>
| 7        | Is information that is obtained recorded in such a manner that:  
• subjects can be identified, directly or through identifiers linked to the subjects; AND  
• any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation? | Yes - the protocol is not eligible for exemption under Category #2. Proceed to question #9 to determine whether exemption category #3 may apply. | No - If subjects can be identified, Exemption #2 may apply only if their responses, if disclosed, would not be harmful to them. |
| 8        | For projects that involve the use of educational tests, survey procedures, interview procedures, or observation of public behavior, will minors be involved in this project, other than as subjects in public observation of activities in which the investigator does not participate? (If minors will ONLY be asked questions about standard educational practices in an accepted educational setting, "NO" is the appropriate response. In this situation, Category 1 is appropriate.) | Yes – STOP - the protocol is not eligible for exemption. Stop here on this checklist. You must complete an IRB application for full or expedited review. | No – Exemption #2 may be applicable. |
| 9        | Will the research:  
• involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under exemption #2 (see questions 6 through 8 above);  
• (i) the human subjects are elected or appointed public officials or candidates for public office; OR  
• (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter? | Yes – Exemption #3 may be applicable. | No – Exemption 3 does not apply. |

**USE OF EXISTING DATA**

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>Yes Response</th>
<th>No Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Will the research involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available OR if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects?</td>
<td>Yes – Exemption #4 may apply.</td>
<td>No Exemption #4 does not apply. Go to question 12.</td>
</tr>
<tr>
<td>11</td>
<td>Are the records involved those of Rutgers students?</td>
<td>Yes – STOP - the protocol is not eligible for exemption. Stop here on this checklist. You must complete an IRB application for full or expedited review.</td>
<td>No Exemption #4 may be applicable.</td>
</tr>
</tbody>
</table>
### RESEARCH OF FEDERAL GOVERNMENT BENEFIT/SERVICE PROGRAMS

<table>
<thead>
<tr>
<th>Q</th>
<th>Question</th>
<th>Yes – Exemption #5 may be applicable.</th>
<th>No – Exemption #5 does not apply.</th>
</tr>
</thead>
</table>
| 12 | Is the research or demonstration project conducted by or subject to the approval of Federal department or agency heads, and designed to study, evaluate, or otherwise examine:  
  - (i) public benefit or service programs;  
  - (ii) procedures for obtaining benefits or services under those programs;  
  - (iii) possible changes in or alternatives to those programs or procedures; or  
  - (iv) possible changes in methods or levels of payment for benefits or services under those programs? | | |
| 13 | Do the activities involve taste and food quality evaluation and consumer acceptance studies wherein, (i) wholesome foods without additives are consumed or (ii) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture? | | |

### FOOD TESTING

<table>
<thead>
<tr>
<th>Q</th>
<th>Question</th>
<th>Yes – Exemption #6 may be applicable.</th>
<th>No – Exemption #6 does not apply.</th>
</tr>
</thead>
<tbody>
<tr>
<td>14</td>
<td>Do ALL procedures of the proposed research activity fall into one or more of the exemption categories described in questions #5 through 13?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 15 | Will any of the research under this protocol be conducted outside of the U.S.A?  
See Guidance and procedures at:  
http://orsp.rutgers.edu/Humans/irb_guidance.php | | |

In order to perform a substantive review of the protocol, and to ensure that exemption is appropriate, a complete research protocol (narrative description of the project), consent documents and study instruments are required. **If study instruments, consent forms or assent forms have not yet been developed, please supply sample documents.** The final versions must be submitted to the IRB for review and approval prior to implementation.
Please attach one copy of each of the following (if applicable):

Appendix A  Use of Rutgers Students as Experimental Subjects in Research *(included in following page)*
Appendix B  Investigator Checklist
Appendix D  Exempt Studies Involving International Research
Attachment 1  Research Protocol (narrative description of the project) including, but not limited to:
*(required)*
Background, Objectives, Subject population & recruitment, Methodology, Provisions for protection of private, identifiable information
Attachment 2  Additional Key Personnel Information, if all information did not fit in the space provided on p.1
Attachment 3  Advertisement or Recruitment Notice, if applicable
Attachment 4  Consent Form(s), if applicable
Attachment 5  Assent or Script for Oral Consent, if applicable
Attachment 6  Authorization from Non-Rutgers Research Sites, if applicable (e.g., school, business)
Attachment 7  Questionnaire(s), Survey(s), Interview Questions, if applicable
Attachment 8  Focus Group Guide, if applicable
Attachment 9  Use of Rutgers Students as Experimental Subjects in Research form, if applicable (see instructions).
Attachment 10  Authorization to Use Data, if existing data will be used and the data are not publicly available
Attachment 11  IRB Approval Notices from Participating Institutions, if applicable.

****NOTE THAT YOU MUST SUBMIT ONE ORIGINAL OF THE APPLICATION AND ALL RELEVANT MATERIALS****
The procedures outlined in this statement are designed to reduce the element of coercion or influence in any use of Rutgers students as subjects the research projects conducted by faculty or instructional staff. These procedures DO NOT apply to students studying research techniques in courses that require them to perform experiments; rather, they apply to experimentation that uses students not as investigators, but as subjects.

The ethical principles of professional societies insist that all consent to participate in research must be voluntary, and that all potential subjects must be treated as autonomous agents, with the right to choose or not to choose to take part in experiments. Federal regulations (e.g., 45 CFR 46.116) are explicit: “An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.”

By action of the Rutgers Board of Governors, all research in this university that involves human subjects is required to conform with federal regulations.

Consequently, individual faculty members and instructional staff, students, and departments that use students as experimental subjects, or that maintain “subject pools” of students from which investigators may draw research participants, are asked to adopt procedures that meet the following conditions:

1. Before they enroll in a course, students must be informed of the possibility that they may be asked to serve as research subjects in experiments under direction of the faculty.

2. If there is a course requirement that students serve as research subjects in such experiments, then alternative ways must be provided for students to meet this requirement. During the first week of classes, students should receive a written description of the various ways of meeting the requirement.

3. Each department that regularly requires students to act as research subjects should establish a committee composed of faculty and students to review the research projects involved. This committee should be responsible for hearing and acting on any student complaints in connection with the research-participation requirement.

4. All members of the faculty who invite students to act as subjects in their research must be acquainted with the ethical standards that govern such activities, such as those promulgated by the American Psychological Association or other discipline-related professional organization, or those in the so-called Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. A copy of the latter report is obtainable from ORSP. (Website: <http://orsp.rutgers.edu>)

Please check one box below, sign your name, and include this form with your application:

___I have read the above statement and agree to follow the procedures recommended.

OR

_x__I will not be using Rutgers students as subjects in this protocol.

Name (Printed): Paul B. Kantor
Signature: ____________________________________________ Date: 2009.07.23

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Version 6.08
INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

INVESTIGATOR CHECKLIST

This checklist is to be completed by the PI and submitted with the IRB t
Principal Investigator: __Paul B. Kantor________ Date: __2009.07.23________

Type of IRB review requested:  _full panel  _expedited  _exempt

APPLICATION:  (use X if "yes"  and  NA if "not applicable")

_x__Justification provided for expedited review or exemption, if requested See beginning of this form
_x__Application typed or computer-generated, not hand written
_x__Summary in non-technical terms (2 sentence maximum)
_x__Risks specified see consent
_x__Benefits specified see consent
_x__Informed Consent Form appended
_x__All draft instruments appended (e.g. questionnaires, standardized tests, interview schedules) included in proposal, attachment 1,
_N/A__Form: "Use of Rutgers Students as Experimental Subjects..." signed, appended
_N/A__Advertisement for recruitment of participants appended, if relevant
_x__Performance site(s) specified
_x__Names of all investigators specified
_x__Study dates specified (beginning, ending)
_x__Funding source(s), if any, specified
_N/A__Approval letter(s) from ALL relevant off-campus site(s) (e.g. school principal, other IRB's) appended
_x__FINAL disposal of data (and time) specified
_N/A__If applicant is a STUDENT, advisor signature on page 2
_x__Inclusion/exclusion criteria specified
_N/A__Appendix C: FULL / EXPEDITED studies involving International Research, attached.
_N/A__Appendix D: EXEMPT studies involving International Research, attached.

Check ONLY ONE of the following:  Participants' identity will be:  _x_anonymous  ___confidential  __neither

INFORMED CONSENT FORM (must be written in non-technical terms for participants)

_x__Study description and goals
_x__Clear description of what will be done to the participant (e.g. withdraw __ amount of blood)
_x__Clear description of what will be required of participant (e.g. physical exertion)
_x__Risks (e.g. side effects, toxicities, radiation) to participant specified
_x__Benefits to participant specified
_x__Duration of participation (e.g. minutes, days, months, number of sessions, etc.)
_x__Provision and procedure for accessing counseling specified, if participants may be affected adversely
_x__Alternatives to participation, if applicable
_x__Payment to participant specified, including reimbursement for expenses, if applicable
_x__Freedom to withdraw from study at any time without penalty: STATED PROMINENTLY
_x__Pro-rating specified, if participant withdraws early from study
_x__Costs to participant specified (i.e. those not reimbursed, if any)
_x__Conditions under which INVESTIGATOR may terminate subject's participation, if relevant
_x__Number of participants in overall study
_x__Line for participant to initial EACH page of informed consent form
_x__Rutgers Disclaimer / Coverage for adverse effects specified
_x__Names, phone numbers, addresses of contact persons (investigators AND IRB)
_x__Signature lines for participant AND investigator; witness signature line if appropriate
_x__Video, audio, and/or photographic consent, if applicable

_x__Consent for the use of subjects’ genetic material, if applicable
_N/A__Translation into appropriate foreign language, if applicable
_N/A__Pregnancy waiver, if applicable
_N/A__Specification of any groups to be excluded from the study (e.g. women, minorities)
_x__Specification of whether research results (individual, group) will be provided to participant
_x__Explicit assurance of participant's confidentiality/anonymity in investigator's reports of findings
_x__Consistent use of "I / you" in the text

****Full/ Expedited Protocols: SUBMIT ONE ORIGINAL AND TWO COPIES OF THE APPLICATION AND ALL RELEVANT MATERIALS****

****Exemptions Protocols: SUBMIT ONE ORIGINAL OF THE APPLICATION AND ALL RELEVANT MATERIALS****

Investigator Comments (optional):
We provide here additional information indicated in the Protocol Instructions, but not provided for in the Exemptions application form.

Study dates specified (Sept 2009, August 2012) the proposal is written for two years but we anticipate the possibility of a no-cost extension to complete the data analysis.

Funding source(s), if any, specified: National Science Foundation (under review)

FINAL disposal of data (and time) specified. Data will be destroyed three years after completion of the study and associated publications or the latest retention date required by sponsors or publishers, whichever is later.

Inclusion/exclusion criteria specified.

Inclusion: Persons who have been advised to have a cardiac defibrillation device implanted and have either accepted or refused.

Exclusion: persons who are unable, because of language, mental state, hearing or speech limitations, to participate in a telephone interview.

Inclusion of women and/or minorities addressed in text. Women and minorities will be included in the group contacted, in proportion to their membership in the included population, as we are able to access it via health care providers. Sex and minority status will play no role in selection of persons invited to participate.

Recruitment information: Recruitment will be one of the research challenges, and this messages for contacting physicians and medical device suppliers and manufacturers will be developed and submitted for IRB if so requested. We anticipate that the contact material to subjects themselves will be precisely the consent information, made up into a letter.

List of attachments:
Attachment 1. Complete copy of the research proposal summary and narrative
Attachment 3. (no separate document)
Attachment 4. Consent forms: 4a: interview 4b: focus group 4c: web survey
Attachment 7a. (no separate document)Questions are listed in the protocol, Attachment 1.
Attachment 8. [Note: The instructions are ambiguous, indicating Attachment 8 both for focus group and for deception]. There is no deception in this study.
Project summary

EAGER: Assessment of Barriers to Trusting Computer-Based Home Assistance
Paul Kantor and Cecilia Gal

Computer instrumentation of living environments promises to extend the independent life span of our aging populations. This technological potential will not be realized unless people are willing to trust their lives to such support systems, as a replacement for human support. Very little is known about how and why people make these important decisions. The proposed research will study this issue using a widely adopted, computer-dependent life-saving device, the Implantable Cardiac Device (ICD).

This research does not fit well into the usual set of NSF programs. It is clear that gathering this kind of information is critical to the overall goal of developing computer support that will actually help people cope with medical problems and with daily life. But, there is no research in computer science, per se, which addresses this specific problem of how people come to entrust their support and safety to a computer system that they cannot understand in any sort of detail. Thus, while there are important programs that address the issue of making computers more usable, there are none addressing the specific interaction among the computer, the algorithmic design, and the decision to trust it. Since this proposal does not fit into any existing NSF program areas it is being submitted as an EAGER. This research will provide a foundation for understanding how and why people agree to place their life in the hands of computerized equipment that they cannot fully understand or control. The study will design and validate instruments for gathering data on this decision. The study will use in-depth interviews, and survey methods, and will gather data from persons who have accepted or refused implantable defibrillators. Phase I, will be an interview study, working through cardiologists, to reach their patients. Phase II will develop, an extensible Web-based survey that can be readily adapted to other patient populations and other technologies.

Impacts on Education. The project will support one graduate student for two years. This individual will learn many aspects of survey research, including the design of questionnaires, conduct of interviews, training other interviewers, taxonomic [“grounded analysis”] interpretation and organization of qualitative results, and use of SPSS to extract quantitative results. A number of advanced undergraduates will work as survey workers, gaining experience in surveys as a scientific tool.

Broader Impacts. First, this research will enhance our understanding of the key factors in the decision to entrust one’s life to a complex computer whose workings are not understood. It will also add to the meager collection of instruments for collecting this kind of data. Second, the information gained about the decision to accept implant will be new, and can serve as a guide in the design of patient information material. Third, the information will guide the design of patient information for “pervasive computing home environments” and will therefore be useful to scientists and engineers as they consider what will be the most useful features of any proposed design.

The project will support information scientists, social scientists, graduate students, and some undergraduate students. It is budgeted at $200,000 (Phase I) plus $100,000 (Phase II).
Narrative:

Assessment of Barriers to Trusting Computer-Based Home Assistance
Paul Kantor and Cecilia Gal

Statement of the Problem

With the growth of pervasive computing, many engineers, computer scientists and physicians can see a future world in which small inexpensive sensors, distributed about a person’s body or house, and connected to contemporary artificial intelligence, can learn the normal action patterns of the person in the house, and raise an alarm at the appropriate level when there is a deviation from these patterns. These have enormous social potential, as we have an increasing aging population in this country, more and more of whose members have been accustomed to directing the courses of their own lives, while their children are in small and dispersed families, much less able to care for them in their homes than they were in the past. We take it as a given that this population of aging Baby Boomers would like to remain self-sufficient and in their own residences for as long as possible. While we share the technical optimism, in this research we propose to address a human-oriented problem that arises in this setting: how and why do people make the decision to entrust their lives to a device which is basically a computer, whose workings are quite incomprehensible to them? Can we learn, from those who have decided to have a device, and those who decided not to, how to frame the discussion, elicit fears and concerns, and present truthful and reasoned answers, to increase the overall welfare of society? Many of us personally know elderly individuals who have gradually accepted severe restrictions on their lifestyles, in some cases while taking advantage of the best that medicine has to offer. But in other cases, fearful of those benefits and their attendant and unknown risks, people artificially circumscribe their lives in ways that are quite shocking to their children and grandchildren as those restrictions are discovered, often tragically.

The proposed research will attempt to determine the salient considerations when an American decides to accept or to reject an approach to health and lifestyle that will require dependence on a complex computer-based device or system, whose workings cannot be well understood by most patients. Specifically we propose to study the patient decision-making process with regard to implantable cardiac defibrillators (ICD). A literature scan reveals a number of papers about satisfaction but only one study (˚Agard et al., 2007) about the decision process. That study, indicating essentially reliance on physician advice, does not seem applicable to the American patient population in the 21st Century.

It is clear that gathering this kind of information is critical to the overall goal of developing computer support that will actually help people cope with medical problems and with daily life. But, there is no research in computer science, per se, which addresses this specific problem of how people come to entrust their support and safety to a computer system that they cannot understand in any sort of detail. Thus, while there are important programs that address the issue of making computers more usable, there is not one addressing the specific interaction between the computer and algorithmic design, and the decision to trust it. Therefore, this proposal does not fit into any existing NSF program areas and is being submitted as an EAGER.

Background and Significance

No amount of engineering and computer science ingenuity will have an impact on public health if the results
of this innovation are not widely accepted by the target population. While the question of primary interest is how to move into the future, we can best learn about the response of patients to an existing technology. We propose to study the patient decision-making process with regard to implantable cardiac defibrillators (ICD). This surgery, which has significant impacts on life and on lifestyle, has been done several hundred thousand times already (see Table 1).

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of ICD operations Performed in US</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>114,000</td>
<td>Lloyd-Jones et al., 2009</td>
</tr>
<tr>
<td>2005</td>
<td>91,000</td>
<td>Rosamond et al., 2008</td>
</tr>
<tr>
<td>2004</td>
<td>68,000</td>
<td>Rosamond et al., 2007</td>
</tr>
<tr>
<td>2003</td>
<td>64,000</td>
<td>Thom et al., 2006</td>
</tr>
</tbody>
</table>

**Table 1.** Available statistics on inpatient implantable defibrillator procedures in the United States (see text).

In 2006, the last year for which data is available from the National Hospital Discharge Study conducted by the Centers for Disease Control, there were 114,000 inpatient implantable defibrillator procedures conducted in the United States. In a short three-year span, from 2003 to 2006, the rate at which this procedure was performed almost doubled. However, the majority of those who are believed to be eligible do not have the procedure performed. Of those who are deemed to qualify, in a study conducted between 1996 and 2001, only 30.7% had the procedure (Voigt et al., 2004). Among patients eligible for ICD, in a study conducted between 2005 and 2007, about 33% of eligible patients had an ICD implanted, with notable differences among demographic groups: white men were most likely to receive implantation (43.6%) versus other groups (black men 33.3%, white women 29.8%, or black women 28.2%) (Hernandez et al., 2007).

These data make it clear that (1) there is a very large frame (several hundred thousand persons) from which to draw a sample and (2) there is an even larger number of people who either did not have the procedure recommended or chose not to have it done. These latter are a particularly important population, and one arm of the study will be focused on finding and learning from them.

Previous Research by the Investigators

P. Kantor has conducted a number of NSF-funded projects, including NSF#CBET-0735910 and DHS#2008-DN-077-ARI003-02. In particular, “Indexing and Retrieval of Dynamic Brain Images” NSF-ITR-0205178 is an investigation of the problem of matching or retrieving complex fMRI datasets, by content rather than metadata. This program has had considerable technical success, as indicated by some 3 dozen reports and conference papers, and is seeking to address the social and cultural barriers to information sharing that limit data exploitation in the cognitive science community. The essential technical finding is that approximate image matching techniques based on the “Earth-Mover’s Distance” algorithm can be extended to three-dimensional images composed of voxels. The ability of these algorithms to match dynamic brain images, based on the cognitive processes that they characterize, was assessed in a multi-class retrieval task. The average value of the area under the ROC curve is as high as 80% (for a collection of 430 images representing 5 different classes).
However, the research most closely related to the present is a study done by Kantor and Gal, on the adoption of computerized resources at a large Medical School. That study included 3 focus groups, 41 phone interviews, 1200 Web survey responses, with detailed quantitative and qualitative analysis of the results (Barrett et al., 2008; Barrett et al., 2007; Kantor & Gal, 2007a; Kantor & Gal, 2007b).

Impacts of the Proposed Research

Scientific Impacts
This research will increase our understanding of the key factors in the decision to entrust one’s life to a complex computer whose workings are not understood. It will also add to the available collection of instruments for collecting this kind of data.

Impacts on Education
The project will support one graduate student for two years. This individual will learn many aspects of survey research, including the design of questionnaires, conduct of interviews, training other interviewers, taxonomic [“grounded analysis”] interpretation and organization of qualitative results, and use of SPSS to extract quantitative results. A number of advanced undergraduates will work as survey workers, gaining experience in surveys as a scientific tool.

Broader Impacts
We anticipate that this work will have two kinds of broader impacts. First, the information gained about the decision to accept implant will be new, and can serve as a guide in the design of patient information material. Second, the information, abstracted to a more general level, will guide the design of patient information for “pervasive computing home environments” and will also be useful to scientists and engineers as they consider what will be the most important features of any proposed design, from the point of view of patient uptake and compliance.

Proposed Plan of Research

Overall Considerations
We will study this issue using a mixture of telephone interview techniques, and a Web-based survey. We realize that the Web probably does not have excellent penetration for the population of people who are currently dependent on computationally-based devices, but as a mechanism for gathering information it is so cost effective that it cannot be ignored.

Key Design Questions
The key design decisions for this study are: (1) which computationally-based device or devices should be studied? (2) How should the frame of potential interviewees be defined for the selected device? (3) How should the sample be drawn from this frame? (4) What procedures for initial contact, re-contact and second re-contact will be used, and (5) what principles of analysis will define the questions to be asked? These questions will be addressed and resolved during the first three months of the proposed research. However, we have a tentative working plan, which is sketched in what follows.

Proposed Population
With regard to item (1), we believe that persons who have considered implantable cardiac defibrillators (ICD; a small electronic device installed inside the chest to prevent sudden death from cardiac arrest) represent the most natural target population. These devices clearly can save the lives of those who use them, and there are a substantial number of them, made by a variety of device manufacturers, implanted in Americans living normal lives.

Building the Frame
In building the frame from which the sample will be drawn, a key concern is, how do we reach this population of patients, and what are the privacy and legal barriers. A project survey does not require OMB approval (NSF GPG 811.1), so government approval of the instrument itself is not required.

We see two paths towards developing the frame of persons who have received these devices: through the
device manufacturers who maintain a database, and through the physicians. We doubt that the device manufacturers would grant approval to interview the patients, but we may be able to negotiate access to the physicians, together with some information about the names of the patients who are on the register. This will proceed in a two-level snowball process (a) asking interested physicians to refer us to colleagues and (b) asking respondents to refer us to friends, neighbors or colleagues who have (or have refused) implantation. As one parallel recruitment path we will explore the possibility of asking device manufacturers to mail our recruitment letter to their patients, without revealing the names and addresses of those patients to us. We anticipate that a number of legal issues will have to be resolved before undertaking this approach, including IRB review, conflict of interest issues, since the manufacturers are materially aiding the study, and questions of whether this could be interpreted as government aid or support to the manufacturers.

As noted, it is at least as important to identify those patients who have declined to be implanted. Here there are several considerations. Presumably, each cardiologist who has a significant number of patients who accepted implantation, also has patients who have declined implant. We will seek permission through the cardiologist to contact the patients for interview. It is also possible that cardiologists differ in their preferences, and that patients who decline implantation also move to the care of another physician who has a larger practice of non-implanted patients. So a similar snowball approach will be used to access physicians of this type if they exist and, through them to contact their patients. A further complication is that patients in this group may, in fact, have obtained conflicting second opinions and while we can explore their reasons for declining implantation, we would have to expect, in some subset of the cases, that a major reason is “a second doctor told me I didn’t need it and I believe him or her”.

**Representative Questions, Design Issues, Qualifications**

Details of the interview schedule will be worked out, and pilot tested with a group of 10-12 patients, to improve the design. Rutgers IRB approval will be obtained for all procedures, and an initial contact by paper or electronic mail will include an informed consent.

We propose to pay respondents $50 for a single extended telephone interview. Interviewers will be trained by Kantor and Gal, and paid $20/hour for their work. They will be provided with Netbook computers from our laboratory, and digital recorders for use during the interviews. Interview records will not contain personally identifiable information about the respondents.

Table 2 shows some representative questions that will be considered. Drawing on a technique that has proven effective in some of our other work (Saracevic & Kantor, 1998), we may also use a relatively small set of closed-end scale questions some of which are used as probes to elicit open-ended responses, which will be tape recorded for later analysis. All questions will be assessed in a pilot study. In addition, we will explore the possibility of transforming some of the 15 questions in the Florida Patient Acceptance Survey (FPAS) instrument (Burns et al., 2005) to a form that might affect decision. As an example, their item “6. I am confident about my ability to return to work if I want to” can be transformed to “do you expect that an ICD will let you go back to work whenever you want to?” We note that this survey, done in the US within the past five years, showed that their item “16. I am knowledgeable about how the device works and what it does for me.” is included only as a filler item, for future scale development, and is not included in computing the score. Thus, at present, it was not seen as contributing enough to the patient satisfaction to be needed in the scale.

| Interviewer Name ________________ | Please have the digital recorder ready and connected before placing the call. Before asking any questions say: “This is (your name) calling from the Rutgers University study on Implantable Heart Devices. May I speak to |
[SUBJECT NAME]. When SUBJECT is on the line say [if appropriate/otherwise, read introduction and assent] “We sent you by mail the Informed Consent, which you have signed and sent back to us. So now I am going to turn on a recorder, so I can concentrate on talking with you. Is that OK? Thank you. [TURN ON RECORDER]. As you pose each question, please note the recording time in the first column. Make notes directly on this form

<table>
<thead>
<tr>
<th>Time Mark</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>When were you first told that you might need an ICD (an implantable cardiac defibrillator)? _______</td>
</tr>
<tr>
<td></td>
<td>What was the reason you needed an ICD?</td>
</tr>
<tr>
<td></td>
<td>How did the doctor explain that you needed the device? _______</td>
</tr>
<tr>
<td></td>
<td>What was your main concern about the device?</td>
</tr>
<tr>
<td></td>
<td>What was reassuring about getting the device?</td>
</tr>
<tr>
<td></td>
<td>When did you decide to have it/not have it?</td>
</tr>
<tr>
<td></td>
<td>What was most helpful in making the decision?</td>
</tr>
<tr>
<td></td>
<td>What was a hindrance in making the decision?</td>
</tr>
<tr>
<td></td>
<td>What was your main concern about getting/not getting the device?</td>
</tr>
<tr>
<td></td>
<td>Can you remember how long it took you to make the decision?</td>
</tr>
<tr>
<td></td>
<td>In making the decision what was the most important factor to you?</td>
</tr>
<tr>
<td></td>
<td>Did you discuss the decision with anyone else? Y N If so, what was important about this/these discussions?</td>
</tr>
<tr>
<td></td>
<td>How long have you had the device?/How long has it been since you decided not to get the device?</td>
</tr>
<tr>
<td></td>
<td>What has been a positive outcome of having/not having the device?</td>
</tr>
<tr>
<td></td>
<td>What has been a negative outcome of having/not having the device?</td>
</tr>
<tr>
<td></td>
<td>If you had to make this decision now would you make a different one? Y N How so?</td>
</tr>
<tr>
<td></td>
<td>Is there something with regard to getting/not getting the device that I should have asked about that would be important for me to know?</td>
</tr>
<tr>
<td></td>
<td>How old are you? _____(record if offered) I have some ranges here 30s; 40s 50s 60s 70s 80s even more. (circle)</td>
</tr>
</tbody>
</table>

Table 2. Sample of questions under consideration. This form will be provided in machine readable form, together with an editor, so that interviewers may either make notes on a paper version, and transcribe them, or make notes directly in the form itself.

Size of Study

We have drawn up a budget for interviewing about 350 persons, to be divided between patients who accepted and those who refused implantation.

Analysis of Data: The Hierarchy of Salient Concepts

Data will be analyzed in a two-step process that has been used in several previous studies. Together they form a rigorous approach to content analysis. The first step is to process all of the interview texts, to select meaningful phrases. These will be organized, in an iterative process, into a hierarchy. This is a variant of “grounded theory” and results in a hierarchy with low fan-out, so that utterances can be grouped in meaningful ways. This is challenging work, which requires good language skills, and the ability to infer meaning that may not be explicit in the text, but is inferred from the context in which the utterance occurs. Thus the end-result of the analysis is a tree of concepts, together with texts that are considered to be representative of the concept. This technique has been used effectively in major studies of the value of
libraries (Saracevic & Kantor, 1997a,b) and of information quality (Bai et al., 2004; Rittman et al., 2004; Ng et al., 2003)

The second phase of the work involves tagging the interview texts with the concepts, and counting occurrences, to complete a frequency analysis. However, the results are indicative, but, due to the nature of the sample, cannot be regarded as representative of the entire population of ICD implant patients and candidates. This is because the snowball sampling technique produces a sample with unknown bias. This limitation is addressed to some degree by the Web-based design discussed below.

Option Phase II: Web-based Follow Up

In addition, after the first phase of data collection, we will extract and categorize the major considerations, and mount a parallel Web-based survey that will be less detailed, but will have the potential to capture a much larger number of responses, and is readily extensible to other technologies and other patient populations. We maintain an account with Survey Monkey, which has been accepted by many IRBs as meeting standards for the protection of confidential information. We have experience in using this instrument in previous work, and will be able to adapt it easily to the needs of the proposed study.

The essential research challenge is to convert the key concepts found in the analysis done in Phase I, and express those concepts in brief phrases that will be meaningful to the respondents. This will make it possible to formulate closed questions whose alternatives cover the great majority of the concepts that are salient for the respondents.

The Team

Paul Kantor is a Fellow of the American Association for the Advancement of Science, and a Member of the Rutgers Center for Dynamic Data Analysis (DyDAn), the Rutgers Center for Operations Research (RUTCOR) and the Center for Discrete Mathematics and Computer Sciences (DIMACS). He is Professor of Information Science at Rutgers, The State University of New Jersey, and a member of the Graduate Faculty of Computer Science. He is the founding editor of the journal Information Retrieval and serves on several other editorial boards. He has authored over 200 refereed papers and technical reports, and his research has been supported by the National Science Foundation, the Intelligence Community (via ARDA and the KDD program of ITIC), DARPA, DHS and ONR.

Cecilia S. Gal has experience in academic and market research. She has prior work experience as an evaluation researcher for a ten-town substance abuse prevention project in Eastern Massachusetts for the U.S. Department of Health and Human Services, and in market research with Fortune 500 companies as clients. Currently she is the Program Coordinator for Rutgers SCILS LAIR laboratories. Both researchers are experienced in the design of interview instruments. P. Kantor has been designing surveys for more than 30 years and C. Gal has worked as a survey interviewer for 6 years before joining Rutgers. Both members of the team have been certified for research with human subjects, by both Rutgers University and by the University of Medicine and Dentistry of New Jersey.

Dissemination

Results of this research will be disseminated via the Web, scholarly publications, and presentations at conferences. This project has the potential to also attract considerable attention from science media, and from the general media.
Approximate Budget Summary

Phase I: Salary (Gal $20,000; Kantor $17,700; GA for Calendar Year $26,400; Other Interviewer 400 hours at $15/hour=$6000); Tuition $12,200; Fringe $12,600; Purchase of Contact List and Supplies (such as recorders, transcribers) $4000; Postage to mail 5000 pieces ($1.11 per piece) $6000; Participant Payments $50 per interview (350 interviews) plus payments to cardiologists for creating/mailing to patients $19,000; Travel to 1 Conference for each of 3 people $4000; F&A $66,200; approximate total of $200,000 for one year of project/design instruments and sample; conduct 350 interviews/develop the concept hierarchy of salient factors.

Phase II: Salary (Gal $9,000; Kantor $9,700; GA for Calendar Year $28,456; Tuition $12,959; Fringe $9,964; F&A $30,794; approximate total of $100,000 for one year of project/Flexible extensible website for ongoing data collection.
Attachment 4a Consent: interview (next page)
Invitation and Consent to Participate in a research study. (Telephone)

We invite you to participate in a research study about how and why people decide whether to have a cardiac stimulator device implanted. This research will help us understand how and why people agree to place their life in the hands of computerized equipment that they cannot control. The study will design and validate instruments for gathering data on this decision. The study will include people who have accepted or who have refused implantable defibrillators.

This research will not benefit you directly, but it will help to better provide computer supported health care to others in the future.

The records of anything that you tell us will be completely anonymous. This means that there will be no record linking what you tell us to your own name or other identification.

We would like to audio tape our interview with you so that we can review it, and make notes. As soon as that is done, we will destroy the audio record itself, keeping only the anonymous notes.

If you decide to participate, please sign here, if you do approve the use of audio recording.

*    ________________________________________

We expect that it will take between 20 and 30 minutes to complete the telephone interview. We may do this in one long call, or in two shorter ones in the same week if you prefer.

There are no foreseeable risks to participating in this research, although recalling and talking about the experience of deciding whether to be implanted with a device may be uncomfortable.

Your participation in our study is completely voluntary, and refusing to participate will involve no penalty. You may stop the interview at any time without penalty. If you decide to stop partway through an interview you will be paid for the fraction of the interview that has been completed, plus $5.

For a completed interview, we will pay you fifty (50) dollars.

If you have any questions about your rights as a research subject, you may contact the IRB Administrator at Rutgers University at:
Rutgers University Institutional Review Board for the Protection of Human Subjects
Office of Research and Sponsored Programs
3 Rutgers Plaza
New Brunswick, NJ 08901-8559
Tel: 732-932-0150 x 2104
Email: humansubjects@orsp.rutgers.edu

We are available to answer your questions about this research. You may contact us at
Cecilia Gal
732 832 7500 x8220
cgal@rci.rutgers.edu
4 Huntington St.
New Brunswick NJ 08901 Room 302

Please indicate your consent to participate in this study by giving us the best phone numbers at which we may contact you, and signing this form. Then please return one copy to us in the envelope we have provided.

We and our interviewers look forward to talking with you.

Cecilia Gal ____________________ (signature) Investigators
Paul B. Kantor ____________________ (signature) and

Best telephone number: _______________________
Best times: morning noon afternoon evening (please circle)
Best days: Monday Tuesday Wednesday Thursday Friday Saturday Sunday (please circle)

Participant: _______________________ Date: __________ Signature: ___________________
(Please print your name) (write the date) (Please sign)

* Did you remember to approve audio recording too?
Invitation and Consent to Participate in a research study. (Focus Group)

We invite you to participate in a research study about how and why people decide whether to have a cardiac stimulator device implanted. This research will help us understand how and why people agree to place their life in the hands of computerized equipment that they cannot control. The study will design and validate instruments for gathering data on this decision. The study will include people who have accepted or who have refused implantable defibrillators.

This research will not benefit you directly, but it will help to better provide computer supported health care to others in the future.

The records of anything that you tell us will be completely anonymous. This means that there will be no record linking what you tell us to your own name or other identification.

We will audio tape this focus group so that we can review it, and make notes. As soon as that is done, we will destroy the audio record itself, keeping only the anonymous notes.

If you decide to participate, please sign here, to approve the use of audio recording.

*    ________________________________________

We expect that it will take between 60 and 90 minutes to complete the focus group meeting.

There are no foreseeable risks to participating in this research, although recalling and talking about the experience of deciding whether to be implanted with a device may be uncomfortable.

Your participation in our study is completely voluntary, and refusing to participate will involve no penalty. You may leave the focus group discussion at any time without penalty. If you decide to stop partway through, you will be paid for the fraction of the discussion that has been completed, plus $5.

For a completed participation, we will pay you one hundred (100) dollars.

We are available to answer your questions about this research. You may contact us at

Cecilia Gal
732 832 7500 x8220
cgal@rci.rutgers.edu
4 Huntington St.
New Brunswick NJ 08901  Room 302

If you have any questions about your rights as a research subject, you may contact the IRB Administrator at Rutgers University at:

Rutgers University Institutional Review Board
Office of Research and Sponsored Programs
3 Rutgers Plaza
New Brunswick, NJ 08901-8559
Tel: 732-932-0150 x 2104
Email: humansubjects@orsp.rutgers.edu

Please indicate your consent to participate in this study by giving us the best phone numbers at which we may contact you, to schedule the focus group meeting, and by signing this form. Then please return one copy to us in the envelope we have provided.

We, and our interviewers, look forward to talking with you.

Cecilia Gal ____________________ (signature)  Investigators
Paul B. Kantor _________________ (signature) and

Best telephone number: ________________________________
Best times: morning noon afternoon evening (please circle)
Best days: Monday Tuesday Wednesday Thursday Friday Saturday Sunday (please circle)

Participant: ______________________________ Date: __________ Signature: ______________________
(Please print your name)  (write the date)  (Please sign)

* Did you remember to approve audio recording too?
Invitation and Consent to Participate in a research study. (Web based)
We invite you to participate in a research study about how and why people decide whether to have a cardiac stimulator device implanted. This research will help us understand how and why people agree to place their life in the hands of computerized equipment that they cannot control. The study will design and validate instruments for gathering data on this decision. The study will include people who have accepted or who have refused implantable defibrillators. This research will not benefit you directly, but it will help to better provide computer supported health care to others in the future.

The records of anything that you tell us will be completely anonymous. This means that there will be no record linking what you tell us to your own name or other identification. We expect that it will take between 10 and 15 minutes to complete the survey online. Because we will not collect any personal identification information about you, we ask that you set aside time to complete the whole survey in one sitting. There are no foreseeable risks to participating in this research, although recalling and talking about the experience of deciding whether to be implanted with a device may be uncomfortable.

Your participation in our study is completely voluntary, and refusing to participate will involve no penalty. You may stop at any time without penalty.

We are available to answer your questions about this research. You may contact us at
Cecilia Gal
732 832 7500 x8220
cgal@rci.rutgers.edu
4 Huntington St.
New Brunswick NJ 08901 Room 302

If you have any questions about your rights as a research subject, you may contact the IRB Administrator at Rutgers University at:
Rutgers University Institutional Review Board for the Protection of Human Subjects
Office of Research and Sponsored Programs
3 Rutgers Plaza
New Brunswick, NJ 08901-8559
Tel: 732-932-0150 x 2104
Email: humansubjects@orsp.rutgers.edu

Please indicate your consent to participate in this study by clicking this link, which will give you access to the survey. If you would prefer to do it later, please come back to this page when it is convenient, and click the link at that time.
[I have understood these conditions and agree to participate]

Thank you.
Cecilia Gal ____________________ (signature) Investigators
Paul B. Kantor ____________________ (signature) and
Hello, Good Morning …
Thank you for coming today.
I’m [NAME] and I’m with the School of Communication and Information at Rutgers.
And this is [NAME OF STUDENT] who is helping me today.
We’re studying how people decide whether or not to get a defibrillator implanted.
You might have noticed that I’m reading from a script; that’s to make sure that I say exactly the same thing to each group.

I’ll start by telling you a little about our long term goal -- and also about how a discussion group like this works. We hope these discussions will help us understand what’s working well with the information technology services, and what be might improved. You’ve probably noticed the snacks over there. Please help yourself whenever you like.

About our long term goal: It is to understand better how people decide whether or not they will trust their lives and their health to some device that relies on a computer. Because that is how an “ICD” (implantable cardiac defibrillator) works. It has a computer that decides whether your heart is behaving the way it should, and automatically steps in if there is a problem. Scientists now are working to build much more complicated systems, that can watch an elderly or a disable person in his home, and decide whether they should call for help from his family, or from a doctor. A kind of “robot home care aide”.

Before we start talking about the ICD decision, I’d like to go over a few ground rules for focus groups. Here’s a consent form. The discussion will be anonymous, meaning that our records will include information about whether or not you decided to have an ICD, but it won't be possible to identify you from the records. I would like to audio tape this discussion. When we transcribe the discussion and prepare our report, we will edit the information to remove any specifics that would identify you. In other words, we’ll be using your comments, but not your names. Do I have your permission to tape our conversation? [if someone declines, pay $5 token, and give them time to leave. Then turn on recorder]

There are a few things I should mention to you:
* Participation is voluntary.
* There are no obvious physical risks.

There is no immediate direct benefit to you from participating; however, your participation will help us to learn more about this important decision that people make.

Thanks.

Our institutional review board, which makes sure that your rights are protected, requires that I collected a signed consent form from each of you. Would you please pass me your forms? Please be sure to sign at the bottom, and also on the line in the middle that approves the use of a recorder.

[distribute and collect forms]
Well, we are about ready to begin. I just want to remind everyone that when I ask a question, I am hoping to hear all your points of view about it. We know that there are no right answers to these questions. That’s why we are talking with you.

Let’s take a minute for introductions and go around the table. Would you please introduce yourself briefly…tell us your name and something about yourself.. Let’s start with you

Thank you. It’s nice to meet all of you.

Now let’s talk about the real questions. I’m going to turn the tape recorder on.

1) I’d like to begin by asking you how the need for an ICD was first presented to you? Where were you? Who first talked about it. Anybody, please start the ball rolling.

2) Thinking back to the decision, did you make it all by yourself, or did you talk with other people? Were they family, or friends, or medical people that you didn’t already know? Write down a note so you remember your answer for our conversation.

[This question depends on which group: implanted or refused, is meeting]

3) When you made the decision, what fact was most important to you in deciding [not] to have the device implanted. [NAME OF STUDENT] will make some notes on those big pieces of paper, and we’ll hang them on the wall, just so we can keep track.

4) Well, we are really moving along here. Now that we have got a pretty complete list of the important facts, I would like to know whether some of those facts were much more important to you than others. We’ll start off just with a show of hands. [NAME OF STUDENT] will point to each one of them, and read it, and I’d like you to raise your hand if you feel that this is a really important, the most important fact in making the decision. Thank you. [Student records number]

Now raise you hand if you think it is pretty important, but not the most important. [Student records number]

Now, I don’t want us to start any fight here, but please raise your hand if, for you, that fact really wasn’t important at all. [Student records number]

[Repeat this process for each major point listed. This will take a while. If people are getting restless, suggest a 5 minute bathroom break or ‘seventh inning stretch’]

5. Time flies. And we are just about done. But before we all leave, I always like to ask whether there is some question that you think that we, the researchers, should have asked you, but we didn’t.

Thank you very much. Before you go, I just want to check whether anyone is uncomfortable with anything that we have recorded you saying. If so, please just stay an extra few minutes and tell me privately, so that we won’t include it in our written summary.

I see we have a few extra snacks. Feel free to take something for the trip home.
And thank you again.

[Turn off tape. Stand up and move to the snack table].

[Gather up all the equipment, the notes. Clean away any left over snacks, and leave the room neat to the next group to use it.]