Official Title: The NEAT Study: An Examination of a Novel Consent Form Design in a Realworld Setting
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Study Title: The NEAT Study: An examination of a novel consent form design in a real-world setting

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Background, Rationale and Context

There is evidence that the current design and content provided by most biomedical research informed consent documents do not consistently meet the expectations researchers place on them to effectively inform research participants of information thought to be most important in facilitating their ability to make informed decisions about participation (Denzen et al., 2012). The need for revisions to the informed consent document design is supported by empirical research. Joffe et al. found in their 2001 study of 200 people in the United States participating in cancer trials that 70% of those interviewed did not realize that the treatments they were undergoing had not yet been proven effective, and 63% did not understand that additional risks were posed by participating in the research. In a manuscript published in 2008, Bergenmar, Molin, Wilking, and Brandberg reported that over half of the 325 patients consenting to phase I and II cancer trials incorrectly responded to questions about the unapproved nature of the study treatment and risks of participation.

The importance of informed consent in ensuring that participants in clinical research are provided the opportunity to make autonomous choices is a paramount ethical premise in human research. The effectiveness of consent document design and consent process to accurately and fully convey the elements of informed consent is critical and deserves further study. Development of an improved informed consent document design for clinical studies would be a valuable contribution to human research. With this study we seek to collect pilot data on a novel consent form design that incorporates a modified version of the "chunking" theory of learning. Clifton A. Casteel (1990) found that chunking sentences or phrases in text into related groupings resulted in a positive significant improvement in reading comprehension among students with poor reading skills. Because the information contained in consent documents in large epidemiologic studies is complex, detailed, and novel for potential research participants, the use of a modified form of chunking (grouping the related sections of consent into smaller documents), may be an effective and low cost way of improving comprehension of the elements of consent.

Objectives

This pilot study will examine the effectiveness of the New Executive and Appendix Template (NEAT) form when used in the consent process for individuals participating in the Atherosclerosis Risk in Communities (ARIC) Neurocognitive Study. Specifically, the primary objective of the study is to:

1. Determine if participants who receive the NEAT form report greater comprehension (as measured by the total score on the Comprehension tool instrument) at the end of the consent process, than participants who receive a standard form.

The secondary objectives are to:

1. Determine what types of characteristics participants value in a consent form, via a qualitative analysis of responses to the question "What do you like best, if anything about this consent form? and What do you like least, if anything about this consent form?"
2. Determine what types of characteristics study team members find helpful or burdensome when utilizing a consent form during the consent process.

Participation in the NEAT study will involve randomization of study participants to either the traditional consent form (detailing the ARIC study) or the NEAT form and the materials that accompany it (also detailing the ARIC study). The consent process will be conducted in the usual manner using the document to which the participant was randomized (NEAT or Traditional). Following the consent process, the interviewer will administer the Comprehension tool, a questionnaire which will measure participants' comprehension (Part 1) and opinions about the layout of the tool (Part 2). A qualitative analysis of the open-ended questions (Part 2) will provide subjective data on participant's opinions of the form design and arrangement, or other factors that they consider important. The Comprehension tool score and the qualitative data about the consent form qualities make up the outcomes to be measured. Ultimately, these data will provide pilot data showing whether differences in comprehension or subject preference may exist between the two consent form designs.

Methods and Measures

Design

This study will be conducted in conjunction with the consent process for the ARIC study in the Division of Public Health Sciences. The IRB approved consent forms will be presented to ARIC participants by the same study staff that would usually conduct the research consent process. The consent form will be either

the regular IRB approved version, or the same form presented in components placed within a bi-fold folder. The consent form wording will be unchanged between the two versions.

The NEAT form consists of a clear and concise overview document containing information satisfying all elements of consent. This is made up of IRB-approved wording from the regular consent form. More detailed information, such as specific clinic measures are provided as additional material and are discussed during the consent process after the general overview has been provided with the NEAT form. The HIPAA Authorization is provided as a separate document.

Approximately 200 participants will be randomized (via birth month) to receive either the regular form or the NEAT form. Following the consent process, each participant will be interviewed using the Comprehension tool measure. This design provides an opportunity to test a new consent form design in a real-world environment with all of the accompanying uncertainty that affects comprehension during the clinical research consent process.

If a participant scores poorly on the comprehension tool, elements of consent will be revisited in order to ensure appropriate understanding of the study information. A copy of the Comprehension tool is included as an appendix to this protocol.

Setting

This study will take place at a place consistent with the plan approved by the IRB for the ARIC study . Potential subjects will be identified by ARIC study staff in accordance with the ARIC protocol.

Subjects selection criteria

- **Inclusion Criteria**

  Individuals who are eligible for the ARIC study, with which this pilot study is cooperating.

- **Exclusion Criteria**

  Any individuals not eligible for the ARIC study.

- **Sample Size**

The proposed study is intended to be a pilot study to examine the impact of a novel consent form methodology on participant comprehension. The proposed enrollment is 100 participants in each arm of the study for a total of 200.

All study team members will be trained to administer the NEAT form and the comprehension tool.

Outcome Measure(s)

Following the consent process, participants will be administered the Comprehension tool to measure their comprehension. The summary scores will be used to address the primary aim of whether or not the NEAT consent form improves participant comprehension. In addition, subjects will be asked the qualitative questions about what they liked and disliked regarding the consent form. The study team member qualitative data about their opinion of using the form will also be collected at the end of the study. The comprehension score and the qualitative data about the consent form qualities as perceived by participants and study team members make up the outcomes to be measured.

Analytical Plan

Study participants will be randomized 1:1 to either the traditional versus NEAT consent documents. Differences in comprehension will be assessed by the Comprehension tool, which is an instrument to assess research consent comprehension.

Summary scores from the Comprehension tool will be analyzed initially using descriptive statistics which will be helpful in planning of a larger trial in the future. To test the differences in comprehension between the two consent forms, we will use a t-test (assuming the assumptions of the test are met) and compare the summary scores. The qualitative feedback will be reviewed to see if any consistent themes are present, both overall and by group.

Human Subjects Protection

Subject Recruitment Methods

Describe how and where subjects will be identified and recruited. Indicate who will do the recruiting, and tell how subjects will be contacted. Describe efforts to ensure equal access to participation among women and minorities. Describe how you will protect the privacy of potential subjects during recruitment.

- Under this limited waiver, you are allowed to access and use only the minimum amount of PHI necessary to review eligibility criteria and contact potential subjects. What information are you planning to collect for this purpose?
    - Participants in this study are members of the ongoing ARIC study.

- How will confidentiality/privacy be protected prior to ascertaining desire to participate?
    - Participants in this study are members of the ongoing ARIC study.

- When and how will you destroy the contact information if an individual declines participation?
    - The IRB approved processes for the destruction of contact information will be utilized as usual with no necessary changes required by the NEAT study. The NEAT study will not involve the recording of any subject identifiers at any time.

Informed Consent

A waiver of the requirements for **signed** informed consent is requested for the study team members who will provide anonymized feedback on the pros/cons of using the two consent forms. The justification for a waiver of signed consent is presented below.

> The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Study team members are simply providing information on the effectiveness of a form to communicate information (ARIC participants) and the usability of the form.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, no identifying information will be collected with the Comprehension tool form or likes/dislikes feedback. Subject identifiers will not be linked to any personally identifiable information. The comprehension tool will be conducted on paper directly after the consent process. After the tools are collected, they will be scored by the PI and then entered into REDCap for analysis. Data access to the data collection forms and the transcribed information in the electronic system will be limited to study team members. Data and records will be kept on the WF School of Medicine

campus in a locked office, and computer data will be password protected and secured on the WFBH network. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

References

1. Denzen, E. M., Santibáñez, M. E. B., Moore, H., et al. (2012) Easy-to-Read Informed Consent Forms for Hematopoietic Cell Transplantation Clinical Trials. *Biology of Blood and Marrow Transplantation 18*(2):183-189.
2. Joffe, S., Cook, E. F., Cleary, P. D. , Clark, J. W., Weeks, J. C. (2001) Quality of informed consent: a new measure of understanding among research subjects. *Journal of the National Cancer Institute 93*(2):139-47.
3. Bergenmar, M., Molin, C. Wilking N., Brandberg, Y. (2008) Knowledge and understanding among cancer patients consenting to participate in clinical trials. *European Journal of Cancer 44*(17):2627-33.
3. Casteel, C. A. (1990) Reading Improvement, v27 n4 p269-275

Appendix

A. Comprehension tool Form and Qualitative Assessment of Participant Perception