Design Considerations for Smartphone-based Informed Consent

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Background

The US Department of Health and Human Services Office of Human Research Protections promulgates regulations, §45 CFR 46 Protection of Human Subjects, guiding the interaction between research study subjects and researchers. A fundamental consideration of these studies is ensuring that subjects understand the implications for their participation in the research. Respondents must actively agree to participate. The process of informing subjects and obtaining their agreement is called informed consent. This should facilitate an understanding of the study goals and the impact on the study subject.

Required Elements and Structure of Informed Consent.

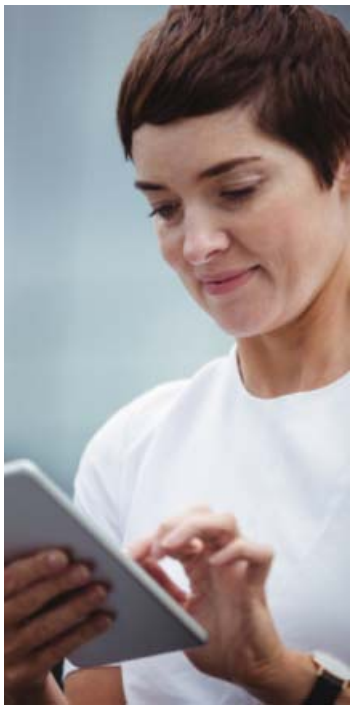
§45 CFR 46 regulations require the inclusion of certain elements in the informed consent process. In both the pre-2018 and 2018 regulations, the informed consent is required to have:

- A statement that the study involves research, the purpose of the research, duration of the subject participation, procedures to be used, and identification of experimental work;
- A description of the risks, benefits, and discomforts to the subject;
- Disclosure of alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A description of the extent, if any, to which subject confidentiality is maintained;
- Compensation (incentives), if provided, and available medical treatments if an injury occurs;
- Whom to contact to answer questions about the research or in the event of an injury;
- A statement that participation is voluntary and refusal to participate or discontinuing participation will not incur a penalty or loss of benefits.
- A statement about either removing identifiers for research that involves the collection of identifiable private information or identifiable bio-specimens, or that the subject's information or bio-specimens will not be used or distributed for future research even if identifiers are removed (2018 regulations only).

Prior to 2018, the regulations did not require a specific structure to the informed consent. The 2018 regulations require that the informed consent include key information to aid the subject in understanding why one would participate in the study. The consent must also present important information first, it should be concise and focused, and include what a reasonable person would need to make informed decision about participation. Statements should be short and straight forward. If there are no perceivable risks to the respondent or the risks are well known, such as discomfort for a venipuncture, a description of risk does not need to be included in the consent.

The Challenge

Informed consent regulations provide a clear description of the required elements needed for a study subject to understand the research study. However, the number of elements and



amount of text to convey this understanding can present challenges in studies that use a smartphone for data collection. For example, the size of a smartphone display may preclude simultaneous display of all the required consent elements. This necessitates alternative approaches to providing the consent information so that a subject may make an appropriate decision about study participation.

Pre-2018 Approach

We considered two design approaches for smartphone informed consent. They are:

1. Only show the required elements & provide a button to a table with more details. The Table includes links to more detailed information. This option is preferred because it is not as cumbersome for the respondent. That is, the respondent avoids scrolling for multiple pages and can be thoughtful about what information they need for the consent process. They can decide to read beyond the required elements.
2. Required elements + table on the same page. Requires more scrolling and is technically possible. However, this is not preferred do to the cumbersome / scrolling requirements.

An Implementation

For a 2018 study, we used the second approach for our first smartphone consent. We used this approach due to the programming ease, time constraints, and technical challenges. This approach required scrolling to view the required elements. However, we felt this was acceptable as scrolling is common to most smartphone users. Moreover, this requires the user to advance thru the required elements before proceeding to the start of the study.

As show in Figure 1, the left screen shot was the first screen presented to the user; the middle and right hand images was the second screen presented to the user. The second screen required scrolling in order for the respondent to review all of the required consent elements.

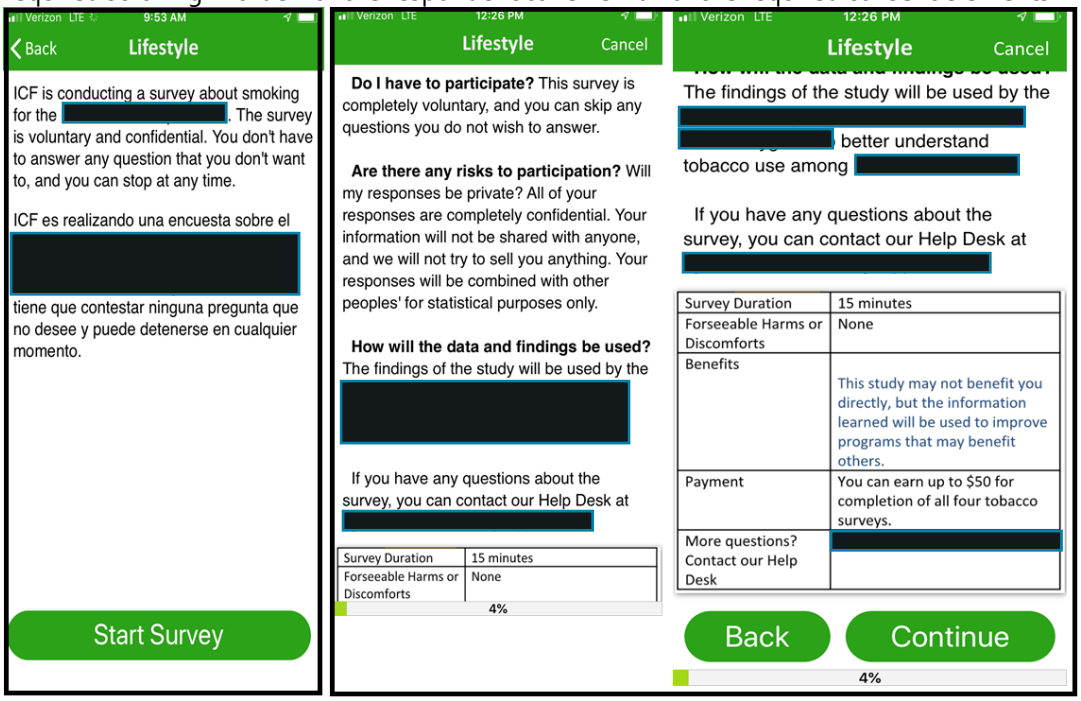


Figure 1.Example of smartphone consent for the introduction and required consent elements.

Next Steps

For future studies implemented on smartphones, we will revisit the implementation challenges for the first design approach to see if it offers any advantages in light of our experience from this first study. In addition, we will modify the order of the required consent elements to ensure alignment with the 2018 regulations.

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