Research Consent Form

Survey Introduction

Instructions

- This consent template is intended to serve as a resource for investigators who are developing an email invitation, information sheet, or introductory text for research surveys. As a reminder, when subjects will not actually sign a consent form, request a "Waiver of Documentation of Consent" from the IRB.
- Enter all information below as it relates to your study. Sample text is provided; text should be adjusted as needed so that it is appropriate for your study. If any of the required elements of consent (see appendix) will not be included, request an "Alteration of Consent" from the IRB.
- Throughout this template, red text is instructions. Change the font color to black, and delete these and other instructions before submitting this form to the IRB.
- A 1-inch margin must be maintained at the top of the page for the IRB stamp

Key Information about this Study

This section is required for any studies approved by the Allina IRB on or after 01/21/2019 and should be specific to the research. When writing the "Key Information" section, include information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. Information should be organized in a way that facilitates comprehension. The IRB Office has provided a draft below that should be modified for the research.

[Insert the investigator's name and his/her hospital/clinic/organization. If applicable, indicate that the study is being conducted as part of an undergraduate project, graduate student project, thesis, or dissertation and include the student's name and affiliation in addition to the PI's.] invites you to be in a research study about [insert condition or modify this statement according to research topic]. The purpose of the study is to [insert text]. We are asking you to participate because you [insert text].

If you decide to be in the research study, you will be asked to fill out a computer questionnaire about your [describe questionnaire items, e.g., your health, what you eat, what medicines you take]. This questionnaire will take about [insert time] to finish. There are no right or wrong answers to these questions. You may skip any question you do not want to answer. Disclose any reasonably foreseeable risks and what any steps you are taking to address these risks, for example: Some of the survey questions ask about your [insert text] and it may be stressful for you as you think about your experiences. If you need to talk to someone about these feelings, please call [insert community agency] at [insert phone number]. Include this sentence if applicable: You will be contacted by email to do another survey later that will take about [insert time].

While this study may not help you, we hope that what we learn will help others with [insert condition].

Describe the extent, if any, to which confidentiality of records identifying the subject will be maintained, for example: Researchers will not be able to connect your answers in the questionnaire to you, but they will know that you were in the study because you will be asked to log in to a computer. The computer keeps your personal information separate from your answers in the questionnaire. The only people allowed to see your information will be the people who work on the study and people who make sure we run our study the right way. We plan to publish the results of this study but will not

include your personal information.

Participating in this study is voluntary. Even if you decide to be in the study now, you may change your mind and stop at any time. If you say no now, or decide to stop later, no one will treat you differently. You will not be penalized. You will not lose any benefits you have the right to have. Include this sentence when patients are being recruited; if patients are not being recruited, delete or replace with an appropriate sentence: The care you get from your doctor [or Allina Health] will not change.

For studies that offer a potential benefit, include a disclosure of appropriate alternatives, if any, that might be advantageous (for example, disclose if benefit is available without participating).

If you have any questions about the study or feel that you have been injured in any way by being in this study, please contact: [insert name, phone number, and/or email address of the pi and study contact (when applicable)].

The Allina Health Institutional Review Board (IRB) has reviewed this research study. If you have any concerns about your rights in this study, please contact the Allina Health IRB at 612-262-4920 or IRB@allina.com.

If you are interested in completing this survey, continue to read below for additional information.

Additional Information about this Study

If funded, identify the sponsor or funding agency. Include a conflict of interest statement from the Conflict Management plan, if applicable. If there is no funding or conflict, then delete this section.

[If it is possible that information from this study will be used for future research, insert the following, or similar, language]:

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

If there are plans to store or share data for future research, such as submitting the data to a repository, describe those plans here including whether identifying information will be shared and the purposes for which the data will be used.

By completing the questionnaire, you are consenting to participate in this research. The questionnaire can be accessed at: [insert link].

[Insert closing salutation and signature]