Consent Cover Letter

Comparing Game Facilitated Interactivity to Genetic Counseling for Prenatal Screening Education

BACKGROUND

You are being asked to take part in a research study. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you want to volunteer to take part in this study. Participation in this study is completely voluntary. You can choose not to take part in any component or stop the study at any time.

The purpose of this research study is to examine different ways to educate pregnant couples about prenatal screening. We are doing this study in order to identify the best way to improve knowledge and shared decision making across different settings for prenatal screening.

STUDY PROCEDURE

If you agree to participate, you will be randomized to one of the three education groups and asked to complete surveys. All the education content is the same for each group but delivered in a different format. The three different groups include online brochure, game interaction with the content or genetic counseling to discuss prenatal screening, and can take from 5 minutes up to 45 minutes to complete. The surveys should take about 10 minutes to complete, and you will be asked to take them before and after your clinical appointment and again around 20 weeks gestation. Your participation is completely voluntary. You may choose not to answer a question or are free to withdraw consent and discontinue participation in the surveys at any time for any reason without penalty or loss of benefits.

The education will take place at your own home or in a private area in the clinic. The surveys will be stored on a password-protected computer and will be de-identified.

RISKS & BENEFITS

There are no known risks associated with participating in this study. You may experience a benefit in the form of increased insight and awareness into your research practices and support needs.

PERSON TO CONTACT

If you have any questions complaints or if you feel you have been harmed by this research please contact Erin Johnson, PhD, University of Utah, at erin.p.johnson@hsc.utah.edu .

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu .

COSTS AND COMPENSATION:

There will be no cost to you to take part in this research study. For study participation, you will receive a $15 gift card for the first survey and $20 for each of the two follow-up surveys, for a total potential of $55.

CONFIDENTIALITY

We will keep all research records that identify you private to the extent allowed by law.
Records about you will be kept on computers that are password protected and encrypted. Only those who work with this study or are performing their job duties for the University of Utah will be allowed access to your information. Research records may be reviewed by the following people who are working with us on this research project:

- Members of the research team and University of Utah Health
- The University of Utah Institutional Review Board (IRB), which reviews research involving people to make sure the study protects your rights
- The United States Office for Human Research Protections (OHRP).
- The National Institutes for Health which sponsors this study, including persons or organizations working with the sponsor.

In publications, your name will be protected. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

CONSENT

By participating in this research, you are giving your consent to participate in this research. Thank you for your willingness to participate!