KEAN

INFORMED CONSENT FORM

Title of Project: Assessing the Experiences and Psychosocial Effects of At-Risk Individuals Who Pursue Predictive Testing for Huntington Disease and Receive Negative Results

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i) Invitation to Participate:

You are invited to participate in a research study that aims to investigate the psychosocial effects of receiving a negative predictive testing result for Huntington disease.

ii) Purpose of Study:

A variety of adverse psychosocial effects have been associated with predictive testing for HD, regardless of test result. Therefore, follow-up counseling and support is recommended for all individuals who undergo predictive testing. However, the guidelines that outline this specific type of follow-up support are limited, especially for individuals who receive a negative predictive testing result. The purpose of this study is to explore the experiences and psychosocial effects of individuals who pursued predictive testing for HD, but received a negative result. Investigating this topic will be beneficial to address this knowledge gap, and help identify how genetic counselors can better support these individuals during the post-test counseling process.

Research goals:

1. Investigate the predictive testing process for individuals who test negative for HD.
2. Qualitatively analyze and identify common psychosocial themes seen in patients who have participated in predictive testing and have received a negative result, including “survivor guilt”.
3. Explore strategies for genetic counselors to offer better support to these individuals

iii) Participant Selection:

All participants must have pursued predictive testing for Huntington disease and received a negative result in the past 10 years. Eligible individuals must be 18 years or older and have at least one family member who has tested positive for HD. Participants with a positive psychiatric history less than 5 years prior to the start of the predictive testing process will be excluded from the study. A positive psychiatric history is defined by a suicide attempt and/or psychiatric hospitalization.

iv) **Procedures:**

This study will be conducted by interviewing participants via audio or audio and video platforms. The invitation to participate is distributed via the HDSA and their following platforms: the survey section of the HDSA's website, the HDSA research blog, www.HDTrialfinder.org, social media outlets for the National Youth Alliance, and email to gene-negative members of the global research advocacy organization – HD-COPE. Individuals who wish to participate will be directed to a webpage that holds the consent form. They will be asked to read and acknowledge that they understand all information pertaining to the study. Once subjects voluntarily consent to participate in the study, they will schedule an interview with the primary investigator by clicking on a Calendly link. No names need to be provided when booking the interview. Interviews will be listed in the Eastern Time Zone. The interviews will take place via Zoom. The participant will need to enter their personal email address at the time of booking the interview. Participants will receive a confirmation email with the Zoom link and verification of the time/date of the interview. At the time of the interview, participants will be directed to a virtual waiting room and be let in by the host. The participant will have the option to turn their video camera on/off to ensure the privacy and confidentiality of the subject. It is also optional for the participant to have their name present on the Zoom screen. The interviews will last approximately thirty minutes (one hour maximum). The interviews will be recorded audio-only and transcribed through the Zoom Cloud platform.

v) Potential Risks:

Participants of this study are not at risk for any financial or legal implications. Participants may be at minimal risk of emotional, physical, or sociological effects due to participation in the study, as they will be interviewed about their personal experiences. If a participant experiences significant emotional discomfort due to the interview session, the respondent may cease participation in the study at any time. Should participants require additional counseling support, they are supplied with contacts for the following national counseling services: HDSA helpline - call (800)-345-HDSA; Crisis Call Center - call 800-273-8255 or text CARE to 839863, and Crisis Text Line - text HOME to 741741.

vi) Potential Benefits:

Subjects will not gain any direct benefit from participating in this study. However, this study presents educational benefits as it aims to give more knowledge about the psychosocial effects

of predictive testing for individuals who test gene-negative for HD. Since there is limited literature investigating this topic, this study will address this knowledge gap. Learning more about these individuals' experiences will provide insight to the genetic counseling profession as well as other medical professions who work with the HD predictive testing population. Ultimately, the major benefit of this study is to learn how to better support individuals who test negative. It will also bring awareness to the need for more explicit guidelines of support in the predictive testing process.

vii) Financial Obligation:

There will be no financial obligation to the respondent.

viii) Compensation/Treatment:

There is no compensation for participation in this study.

ix) Confidentiality:

A number will be assigned to each participant to ensure de-identification. No identifying information will be associated with the interview session transcripts. Each participant will use a personal email address to schedule the interview/access the Zoom link to the session, but the personal email will not be associated with the interview transcript. To protect the privacy of the participant, demographic information will not be provided prior to the interview session. It will be asked only in the beginning of the interview session, to ensure that there are no predisposed biases or known information.

x) Participation:

Participation in this research is completely voluntary. The participant may withdraw from the study at any time.

Questions/Comments:

If there are any questions or concerns, please contact the primary investigator or the faculty adviser. The Kean University IRB can also be contacted if there are any questions regarding rights as research participants.

Contact Information

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