PRE-SCREENING POTENTIAL SUBJECTS TO DETERMINE ELIGIBILITY [REDCap Instructions]

Pre-screening of potential subjects to determine initial eligibility and interest in a study is considered part of the recruitment process and therefore requires Institutional Review Board (IRB) review.

Pre-screening may be done over the phone with interested candidates, in person, or online. Only information directly related to the potential participant's eligibility and suitability for the study should be collected (e.g., basic inclusion/exclusion criteria, ability to travel to the site for research visits). The investigator must protect the privacy of the potential subject and the confidentiality of information collected.

Using REDCap to administer a pre-screening questionnaire (survey) can be efficient for the investigator and convenient for the potential participant. Links to the survey may be added to recruitment material or placed in ResearchMatch communications.

To use REDCap to administer a pre-screening survey follow these steps:

- 1. Include a copy of the survey in your IRB application.
- 2. Describe the recruitment method in the IRB Research Description (Form B). See <u>sample description</u>.
- Since pre-screening collects self-disclosed information from potential study participants before informed consent for study participation. Since the information is retained in REDCap, begin the survey with informed consent from the potential participant. See sample consent language.
- 4. Since the on-line consent process does not involve obtaining the potential participant's signature, submit the IRB Request for Waiver of Documentation of Informed Consent (Form F). The IRB may waive the requirement for obtaining a signed consent (documentation), if the research activity presents no more than minimal risk and involves no procedure for which written consent is normally required.
- Obtain permission to contact the potential participant if eligible for the study, and if applicable, obtain permission to contact him/her with future study opportunities. See <u>sample questions</u>.

SAMPLE Research Description if using REDCap for pre-screening eligibility survey:

The study will employ a pre-screening eligibility survey to determine if a volunteer meets basic inclusion/exclusion criteria (see Appendix _). We built and will administer the eligibility survey on UK's REDCap which provides HIPAA compliant storage on UK servers and encrypted transmission of survey responses. The portable devices do not download the data, it is directly stored into the secure web based connection (https) behind the firewall. All files are password protected once entered into the system. All project data is stored and hosted locally. A link to the eligibility survey will be provided in recruitment materials. The link will also be included in study information sent to ResearchMatch participants who have indicated interest in the study. Before redirecting the volunteer outside of ResearchMatch and to the REDCap survey, the volunteer is once again asked to confirm their interest in completing the pre-screening survey.

The REDCap survey includes an on-line consent process with consent indicated by selecting the "submit" button. Since no signature is obtained we are requesting a waiver of documentation for the pre-screening survey. The volunteer may skip questions or discontinue the survey at any time. All respondents will be asked permission for investigator to retain information and contact individual with future study opportunities

Sample REDCap Eligibility Survey Consent:

You are invited to complete this pre-screening survey is to see if you might be a good fit for the ______ research study. ______ (principal investigator) is conducting the ______ research study at the University of Kentucky. The pre-screening survey will ask general information and health questions. Your answers gives us an idea whether or not you meet some of the basic criteria for the study. Completing this screening survey does NOT obligate you to participate in the ______ research study. If your answers show that you might qualify, we will (contact you/meet with you) to explain the ______ research study further. There may be no direct benefit to you for completing the screening survey.

Only complete the pre-screening survey if you choose to do so. You may also skip any questions or quit the survey at any time.

Your response to the survey will be kept confidential to the extent allowed by law. This survey is on the University of Kentucky web-based tool called REDCap. REDCap has features to help keep your information secure. However, as with anything involving the Internet, we can never guarantee the complete confidentiality of the information.

If you have questions about this pre-screening survey or the ______ research study, please feel free to ask. You may contact the study team at ______. If you have complaints, suggestions, or questions about your rights as a research volunteer, contact the University of Kentucky Office of Research Integrity at 859-257-9428 or toll-free at 1-866-400-9428.

The survey will take about ____ minutes to complete. By clicking the [submit] button below you are indicating that you understand the information and agree to begin the pre-screening survey.

Permission to contact survey questions:

• Agreement to be contacted:

If you appear to meet the criteria for the ______ study and you wish for a member of ______ (principle investigator)'s study team to contact you, include your name and preferred contact information below:

| Name: | | | | |
|--------------------|---|------------------|--------|--|
| (first) | | (middle) | (last) | |
| Daytime phone: () | - | . Email address: | | |

Permission for investigator to retain information and contact individual with future study opportunities (include if applicable):

 Do you give your permission for ________(insert investigator or staff) to keep your answers on file and contact you regarding your willingness to participate in future research studies about ________(insert name of disease, condition, or topic area)?

□ Yes, _____ may keep my answers and contact information and contact me with future study opportunities.

□ No. I would like my answers and contact information destroyed when the _____ research study is over.

Jointly prepared by the UK Office of Research Integrity (ORI), UK Institutional Review Board (IRB) and the UK Center for Clinical and Translational Science (CCTS)

J:\Belinda S\Subject Recruitment and SOCIAL MEDIA\Prescreening using REDCap.docx 5/25/2023 updated weblinks