Standard Operating Procedures

Great Plains IDeA-CTR Regional Registry

Purpose: This Standard Operating Procedure (SOP) outlines the basic steps when requesting participant information in relation to research recruitment using the Great Plains IDeA-CTR Regional Registry. This database consists of participants who signed the Adult Consent Form indicating their willingness to participate in clinical research. The process to obtain this information while upholding HIPAA and security regulations can be found below.

Scope: This SOP applies to all personnel involved in the process of gathering, analyzing, and evaluating patient information using the Great Plains IDeA-CTR Regional Registry including study personnel, IRB personnel, EHR personnel, and all others who may have or want access to the information.

Personnel Responsible: Principal Investigator, the requestor, and other study personnel.

Procedures:

De-identified: for feasibility purposes

1. Investigator and/or Study Coordinator may submit an application to the Registry Administrator to obtain the total number of patients that may be eligible internally based on criteria set forth by the requestor. Search will be applied to all participants in the Great Plains IDeA-CTR Regional Registry. No individual patient information will be provided, only the total number of patients who satisfy the specified criteria will be provided.

Identified Information: for recruitment purposes

You must have approval from the IRB to obtain a patient list with contact information or other protected health information. Participants that have consented to be contacted for research are the only ones that will be included in this search.

1. The requestor develops a recruitment plan to submit to the Registry Administrator for initial approval using the Registry Database Recruitment Request Form.
2. Once approved by the Registry Administrator, the study personnel can add this documentation to their IRB submission showing approval. The IRB application must define the recruitment methods to be used during the study.
3. The Registry Administrator must be given a copy of the IRB approval letter in order to provide the requested patient information.

a. Once the list is provided, it must be kept on a secure computer. The list must be deleted/destroyed once it is no longer in use.
b. No list should be kept for more than 3 months at a time.

Phone/Mail Guidelines

There should be no more than <u>3 direct contact attempts</u> made between all media channels (phone, mail, e-mail, etc.). For example, if you send 1 letter, you may not make more than 2 calls thereafter.

Phone only:

- If participant does not answer on first call, leave a voicemail. You may try again after a minimum of 6 hours. If no return call after 72 hours, call again and leave a reminder voicemail. Do not call thereafter unless otherwise approved.
    - Voicemail information should follow the guidelines below
    - If no voicemail, call once, then after 48 hours, and lastly after 72 hours.
- The voicemail will not give description of the trial and any information given over the phone must ONLY be given directly to the specified participant.

First Class Mail:

- All materials should be in an envelope with only participant's name and address and general return address
- If postcard format is appropriate, the postcard must fold and seal to cover any medical/trial information

Phone Script

Can I please speak with Mr./Ms._____?

- If participant is not available or busy, ask for a good time to call back or leave your name and call back number.
- If participant answers, proceed to the following script:

Hello Mr./Ms._____, my name is _____ from the (insert University or Clinic). You agreed to let us contact you about potential research studies and we have found that you may be eligible for a study that is looking at (insert one-line description). Would you be interested in learning more about this study?

- If yes, give a brief explanation of the study, purpose, and consenting process.
- If no, ask them if it is okay to call them in the future if we find out they may be eligible for a different study. If they answer yes, thank them for their time. If they decline, inform them that you will transfer the Registry Administrator in order to remove their name. Transfer the call to 402-836-9283 and email Emily Frankel the patients name and phone number to emily.frankel@unmc.edu for documentation purposes.

Voicemail Script

Hello Mr./Mrs. _____, my name is _____ from the (insert University of Clinic). I am calling you today about a research study for which you may be eligible. If you would like to learn more, please call _____, otherwise, we will attempt to contact you one additional time. Thank you for your time.

Resources:

- Contacting Registry Participants Training Sheet
- Email Participant Recruitment Requirements
- Registry Database Recruitment Request

Registry Administrator:

Emily Frankel
emily.frankel@unmc.edu
402-836-9283