Clinical Research Center
Standard Operating Procedure

Section: Clinical Research Center  Date Created: November 15th, 2016
Title: Opted-in To Be Contacted for Research Process
Date Reviewed/Modified: November 15, 2019
SOP Number: SOP-51  Version Number: 2

**Purpose:** This Standard Operating Procedure (SOP) outlines the basic steps when requesting patient information in relation to research recruitment using the opt-in database. This database consists of patients who signed the Conditions of Treatment 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 opt-in database including study personnel, IRB personnel, EHR personnel, and all others who may have or want access to the information.

**Personnel Responsible:** Director of Electronic Health Record Access Core, Research Subject Advocate, Director of Clinical Research Operations, Associate Vice Chancellor for Clinical Research, 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 Director of Electronic Health Record Access Core (9-3845) 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 opted-in patients in the Electronic Health Records (EHR) system. No individual patient information will be provided, only the total number of patients who satisfy the specified criteria will be provided.

   “The Request for Electronic Health Data Form” (Attachment A) can be found at: https://unmcredcap.unmc.edu/redcap/surveys/?s=94TLJCCAAT

**Identified Information: for recruitment purposes**

You must have approval from the Associate Vice Chancellor for Clinical Research and the IRB to obtain a patient list with contact information or other protected health information based upon the Conditions of Treatment Form designation. Patients that have opted-in 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 Associate Vice Chancellor for Clinical Research for initial approval using the COT Database Recruitment Request Form (Attachment B). The study staff will need to fill out the “Request for Electronic Health Data Form” via https://unmcredcap.unmc.edu/redcap/surveys/?s=94TLJCCAAT
to gain an initial patient feasibility assessment if not already completed. This request form will later be used for identified lists if approved.

2. Once approved by the Associate Vice Chancellor for Clinical Research, 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. Prior to initiating any contact all personnel who will contact potential subjects must complete training by scheduling a time with the Research Recruitment Specialist in the Clinical Research Center.

4. The Director of Electronic Health Record Access Core 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 UNMC/NM computer. The list must be deleted/destroyed once it is no longer in use. See Nebraska Medicine policy IM14-Destruction of Confidential Information for more details.
   b. No list should be kept for more than 3 months at a time.

Phone/Mail Guidelines

There should be no more than 3 direct contact attempts 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 patient 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 patient.

First Class Mail:

- All materials should be in an envelope with only patient’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

E-mail:

- All e-mail communications must go through the OneChart Applications Training Lead
• E-mails will be sent via a central address (ClinicalResRecruit@unmc.edu)
• For a detailed list of guidelines, see Attachment C: Email Patient Recruitment Guidelines

Recorded Messages/Text Messaging:
• All recorded messages and text messages must follow the Telephone Consumer Protection Act (Attachment D).

Phone Script
Can I please speak with Mr./Ms.____________?
• If patient is not available or busy, ask for a good time to call back or leave your name and call back number.
• If patient answers, proceed to the following script:
Hello Mr./Ms.__________, my name is __________ from the University of Nebraska Medical Center/Nebraska Medicine. 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 patient to Patient Access Services in order to remove their name. Transfer the call to 402-559-4222 and email Deb Meyer the patients name and MRN # to dmeyrerk@unmc.edu for documentation purposes.
  ◦ If the patient is generally irate or says we violated a HIPPA rule, please e-mail Deb Meyer at dmeyrerk@unmc.edu with this information along with your call back number. Deb will notify the compliance team/IRB and they may contact you for additional information.

Voicemail Script
Hello Mr./Mrs.__________________, my name is ____________________ from the University of Nebraska Medical Center/Nebraska Medicine. 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:

Request for Electronic Health Data Form: See Attachment A

COT Database Recruitment Request Form: See Attachment B

Email Patient Recruitment Guidelines: See Attachment C

Telephone Consumer Protection Act: See Attachment D

Staff Accountability:

Developed By: Clinical Research Outreach Coordinator
Director of Clinical Research Operations

Reviewed By: Director of Clinical Research Operations
Associate Vice Chancellor for Clinical Research, Clinical Research Center

Department Approval

Signed

Director of Clinical Research Operations

Associate Vice Chancellor for Clinical Research

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