



**Clinical Research Center  
Standard Operating Procedure**



Section Clinical Research Center

Date Created: November 15<sup>th</sup>, 2016

Title: Opted-in To Be Contacted for Research Process

Date Reviewed/Modified: -

SOP Number: SOP-51

Version Number: -

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:**

- x 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.
  - o Voicemail information should follow the guidelines below
  - o If no voicemail, call once, then after 48 hours, and lastly after 72 hours.
- x 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:**

- x ~~SOPDWOVVREGEHQERORSHWQSDWQP~~PHDQDGGHVVDQHEDO  
return address
- x If postcard format is appropriate, the postcard must fold and seal to cover any medical/trial information

**E-mail:**

- x All e-mail communications must go through the OneChart Applications Training Lead

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- 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).

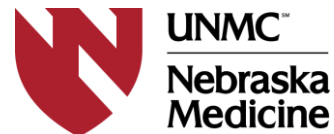
Would you be interested in learning more about this study?

- 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 [dmeyerk@unmc.edu](mailto:dmeyerk@unmc.edu) for documentation purposes.
  - **If the patient is generally irate or says we violated a HIPPA rule, please e-mail Deb Meyer at [dmeyerk@unmc.edu](mailto:dmeyerk@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.

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**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

Signed

  
Associate Vice Chancellor for Clinical Research