3.6 Subject Recruitment Through Direct Invitation

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for subject recruitment through direct invitations to participate.
Subject recruitment through advertisements is described in HRPP policy 3.5.

2.0 Policy

- **2.1.** It is the policy of the Organization that all direct recruitment materials must be reviewed and approved before they can be used to recruit potential subjects.
- **2.2.** It is the policy of the Organization that recruitment materials be clear, promote equitable enrollment and not represent undue influence or coercion.
- **2.3.** It is the policy of the Organization that direct recruitment of subjects to research be respectful of the privacy of potential subject.

3.0 Definitions

- **3.1.** ***"Opt-In"*** designation refers to agreement by the patient to be contacted for possible inclusion in biomedical research based on information in the patient's EMR, as reflected in the UNMC/Nebraska Medicine [UNMC/NM] "Conditions of Treatment Form" (or, when available, the Children's Hospital Medical Center [CHMC] "Conditions of Treatment Form").
- **3.2.** ***Honest Broker*** refers to a person, appropriately trained and designated by the Organization, whose responsibility is to de-identify protected health information and provide that de-identified information to investigators, in accordance with UNMC policy 6074.

4.0 Invitations to Patients

- **4.1.** This section applies to patients (present and former) associated with UNMC/NM (including hospital and/or clinics), Bellevue Medical Center, or CHMC (including Children's Physicians Clinics).
- **4.2.** Distribution Lists based on Clinical Databases or Prior Research Subject Databases
  - **4.2.1.** Potential subjects listed in these databases are either: (1) current or former patients of the investigator; or (2) patients to whom he/she has ethical access per HRPP policy 3.12 (Ethical Access); or (3) previous research subjects who have given express permission (usually as part of an IRB approved consent process) to be listed in the database for the purpose of being contacted for future research studies.
- **4.3.** Distribution Lists based on the Conditions of Treatment Form designation ("opt-in" designation)
  - **4.3.1.** The Associate Vice Chancellor must approve subject recruitment plans, which include directed invitations to former or present patients based on the Conditions of Treatment Form designation ("opt-in designation) for Clinical Research.
  - **4.3.2.** Once approved by the Associate Vice Chancellor for Clinical Research, the study personnel can add this documentation to their IRB submission.
  - **4.3.3.** After review and approval by the IRB, the Director of Electronic Health Record Access Core will authorize an "honest broker" to generate the distribution list based on the inclusion parameter defined in the Request for Electronic Health Data Form.
  - **4.3.4.** Only patients who have opted-in to be contacted for research on his/her Conditions of Treatment Form may be included in this search.
  - **4.3.5.** Once the distribution list is provided, it must be kept on a secure/encrypted UNMC/NM computer (reference End User Device Security procedure or IM16 End User Device Policy) for no more than 3 months. After that time, the distribution list must be re-run to validate the opt-in recruitment status.
  - **4.3.6.** The list must be deleted/destroyed once it is no longer in use (Nebraska Medicine policy IM14-Destruction of Confidential Information).
  - **4.3.7.** Patients who have opted-out based on the Conditions of Treatment Form designation may still be contacted if they are either: (1) current or former patients of the investigator, or (2) patients to whom the investigator has ethical access per HRPP policy 3.12 (Ethical Access); or (3) previous research subjects who have given express permission to be contacted for future research studies.
  - **4.3.8.** Note that currently CHMC and Children's Physicians clinics do not utilize an "opt-in" designation on the Conditions of Treatment form; therefore Distribution Lists based on the

Conditions of Treatment Form designation described in this section (3.1) do not apply for potential subjects from those sites.

- **4.4.** No more than three invitation attempts between all media channels (phone, mail, e-mail) for any specific study may be made from any Distribution List described above unless specific approval is given by the IRB or by the expedited reviewer as applicable. Specific parameters regarding frequency are noted below.
- **4.5.** Contacting Patients by Email via MS Outlook (or future email system supported by the Organization)
  - **4.5.1.** If multiple recipients are included on the same email, the blind copy email function must be used to prevent recipients from seeing the email address of another subject or potential subject.
  - **4.5.2.** Emails must contain minimal PHI, limited to (a) Patient name, and (b) email address.
  - **4.5.3.** The subject line must clearly identify "UNMC/Nebraska Medicine (or CHMC) Research Opportunity". PHI or study information must not be contained in the subject line.
  - **4.5.4.** The sender of the email must be clearly identified as affiliated with the Organization
  - **4.5.5.** The text of the email must include only the following items:
    - **4.5.5.1.** Name and email address of the PI and associated institution.
    - **4.5.5.2.** A clear statement that activity is research.
    - **4.5.5.3.** Purpose of the research.
    - **4.5.5.4.** IRB number.
    - **4.5.5.5.** An invitation to contact the investigator for more information, with telephone number if applicable.
    - **4.5.5.6.** An explanation that the patients name and contact information were available because they had chosen to opt-in to be contacted for research on his/her Conditions of Treatment Form.
    - **4.5.5.7.** Information for the patient on how to change their research recruitment option in the conditions of treatment form and the contact information for the Research Subject Advocate.
  - **4.5.6.** Email invitations to UNMC/NM or BMC patients obtained through the Conditions of Treatment Distribution lists must be sent by the Clinical Research Outreach Coordinator (or equivalent position), via a central email address.
  - **4.5.7.** The Pediatric Research Office (PRO), via a central email address, must send email invitations to CHMC patients.
  - **4.5.8.** The reply back to sender will be reviewed by the Clinical Research Outreach Coordinator or the PRO coordinator, and then forwarded to research staff if appropriate.
  - **4.5.9.** The recruitment email invitation may be sent to potential subjects no more often than weekly unless specifically authorized by the IRB.
  - **4.5.10.** If a potential subject declines participation in a specific study, no further recruitment emails may be sent regarding that study.
- **4.6.** Contacting Patients by EPIC Email through One Chart
  - **4.6.1.** The subject line must clearly identify "UNMC/Nebraska Medicine (or CHMC) Research Opportunity". PHI or study information must not be contained in the subject line.
  - **4.6.2.** The reply back to sender will be set to return all replies regarding recruitment to the investigator with ethical access.
  - **4.6.3.** The text of the email must include only the following items:
    - **4.6.3.1.** Name and email address of the PI and associated institution.
    - **4.6.3.2.** A clear statement that activity is research.
    - **4.6.3.3.** Purpose of the research.
    - **4.6.3.4.** IRB number.
    - **4.6.3.5.** An invitation to contact the investigator for more information, with telephone number if applicable.
  - **4.6.4.** The recruitment email invitation may be sent to potential subjects no more often than weekly unless specifically authorized by the IRB.
  - **4.6.5.** If a potential subject declines participation in a specific study, no further recruitment emails may be sent regarding that study.
- **4.7.** Contacting Patients by Phone
  - **4.7.1.** Telephone script must be approved by the IRB prior to use.
  - **4.7.2.** Recorded voice messages must go through the Clinical Research Outreach Coordinator (or equivalent position).
  - **4.7.3.** Frequency and number of calls must be specified by the investigator in the IRB application, and must be approved by the IRB.
  - **4.7.4.** If voicemails are left the message may only state that the call is about a research study for which the patient may be eligible and offer a call back number. The voicemail must not provide any additional details regarding the trial or the reason a patient may be eligible.
  - **4.7.5.** If a potential subject declines participation in a specific study, no further recruitment phone calls may be made regarding that study.
  - **4.7.6.** All recorded messages must follow the Telephone Consumer Protection Act.
- **4.8.** Contacting Patients by Mail
  - **4.8.1.** Letters must contain minimal PHI, limited to (a) Patient name and (b) address.
  - **4.8.2.** All materials should be in an envelope with only patient's name and address; the return address must include the Organization name, but no specific medical or surgical department.
  - **4.8.3.** If postcard format is appropriate, the postcard must fold and seal to cover any medical/trial information.
  - **4.8.4.** The text of the letter must include only the following items:
    - **4.8.4.1.** Name and email address of the PI and associated institution.

        - **4.8.4.2.** A clear statement that activity is research.
        - **4.8.4.3.** Purpose of the research.
        - **4.8.4.4.** IRB number.
        - **4.8.4.5.** An invitation to contact the investigator for more information, with telephone number if applicable.
        - **4.8.4.6.** An explanation of how the patients name and contact information were available to the investigator (for example, because they had chosen to opt-in to be contacted for research on his/her Conditions of Treatment Form, or because he/she had previously participated in research and had agreed to be contacted regarding additional research studies).
        - **4.8.4.7.** If the patient had chosen to opt-in to be contacted for research on his/her Conditions of Treatment Form, information on how to change their research recruitment option, and the contact information for the Research Subject Advocate.
    - **4.8.5.** The recruitment letter may be sent to potential subjects no more often than weekly unless specifically authorized by the IRB.
    - **4.8.6.** If a potential subject declines participation in a specific study, no further recruitment letters may be sent regarding that study.

5.0 Invitations to Prospective Subjects who are not Patients

This section applies to prospective subjects who may be eligible for participation in research but who are not primarily eligible because they have a disease or condition being diagnosed or treated at UNMC/Nebraska Medicine (including hospital and/or clinics), Bellevue Medical Center, or Children's Hospital & Medical Center (including Children's Physicians Clinics). They may be patients or former patients, but that is not the primary reason they may be eligible.

Note: Examples of this subject population would be public or private school students; college, trade or professional school students (e.g., UNO freshman, enrollees at a particular trade school, UNMC SOM students); cultural, ethnic or religious groups (e.g., Sudanese immigrants, members of a particular church); trades or professions (e.g., farmers, physicians, prison guards).

- **5.1.** Creation of Distribution Lists
    - **5.1.1.** In most cases, unless the investigator has ethical access to names of potential subjects, or the names are obtained from publicly available databases, the distribution list must remain within the group, which has generated the list (that is, the investigator should not have access to the names or contact information on the list). The invitation to participate should come from the group, which generated the list.
    - **5.1.2.** In certain circumstances, when the group supplying the list cannot or will not be responsible for sending the invitation, the IRB may specifically approve that the list be transferred to the investigator. In making this exception, the IRB must be satisfied that:
        - **5.1.2.1.** The risks of disclosure of the contact information constitutes no more than minimal risk to potential subjects (for example, disclosure would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation), and
        - **5.1.2.2.** There are adequate safeguards to minimize the risk of disclosure beyond the investigator and study personnel, and
        - **5.1.2.3.** There are adequate provisions to protect the privacy of subjects.
    - **5.1.3.** If the distribution list is provided to the investigator, it must be kept on a secure computer for no more than 3 months. The list must be deleted/destroyed once it is no longer in use (Nebraska Medicine policy IM14: Destruction of Confidential Information).
    - **5.1.4.** All information distributed to the investigator must be in compliance with applicable privacy laws and regulations, including The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99).
- **5.2.** Contacting Prospective Subjects by Email
    - **5.2.1.** As noted above, in most cases the invitation to participate should come from the group, which generated the list. If the invitation comes directly from the investigator (as per section 5.2.2 above) emails must be sent from a UNMC/Nebraska Medicine, UNO, or CHMC, Outlook account.
    - **5.2.2.** If multiple recipients are included on the same email, the blind copy email function must be used to prevent recipients from seeing the email address of another potential subject.
    - **5.2.3.** The subject line must clearly identify UNMC, UNO or CHMC "Research Opportunity". Study information must not be contained in the subject line.
    - **5.2.4.** The group sending the email must be clearly identified.
    - **5.2.5.** The affiliation of the investigator with the Organization must be clearly stated in the email.
    - **5.2.6.** The email must include an explanation why the prospective subject's name and contact information were available.
    - **5.2.7.** The text of the email must include only the following items:
        - **5.2.7.1.** Name and email address of the PI and associated institution.
        - **5.2.7.2.** A clear statement that activity is research.
        - **5.2.7.3.** Purpose of the research.
        - **5.2.7.4.** IRB number.
        - **5.2.7.5.** An invitation to contact the investigator for more information, with telephone number if applicable.

        - **5.2.7.6.** A description of why the prospective subject's name and contact information were available.
    - **5.2.8.** The recruitment email invitation may be sent to potential subjects no more often than weekly unless specifically authorized by the IRB.
- **5.3.** Contacting Prospective Subjects by Phone
    - **5.3.1.** Telephone script must be approved by the IRB prior to use.
    - **5.3.2.** Frequency and number of calls must be specified by the investigator in the IRB application, and must be approved by the IRB.
    - **5.3.3.** If voicemails are left, the message may only state that the call is about a research study for which the patient may be eligible and offer a call back number. The voicemail must not provide any additional details regarding the trial or the reason a prospective subject may be eligible.
    - **5.3.4.** All recorded messages must follow the Telephone Consumer Protection Act.
- **5.4.** Contacting Prospective Subjects by Mail
    - **5.4.1.** All materials should be in an envelope with only prospective subject's name and address; the return address must include the Organization name (if sent by the investigator), or the name of the group supplying the distribution list.
    - **5.4.2.** The affiliation of the investigator with the Organization must be clearly stated in the letter.
    - **5.4.3.** The mail must include an explanation why the prospective subject's name and contact information were available.
    - **5.4.4.** The text of the letter must include only the following items:
        - **5.4.4.1.** Name and email address of the PI and associated institution.
        - **5.4.4.2.** A clear statement that activity is research.
        - **5.4.4.3.** Purpose of the research
        - **5.4.4.4.** IRB number
        - **5.4.4.5.** An invitation to contact the investigator for more information, with telephone number if applicable.
        - **5.4.4.6.** A description of why the prospective subject's name and contact information were available.
    - **5.4.5.** The recruitment letter may be sent to potential subjects no more often than weekly unless specifically authorized by the IRB.

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