

## **Recruitment (HRPP 3.6)**

### **Description:**

This policy describes UNMC's requirements for subject recruitment through direct invitations to participate.

### **Definitions:**

**Honest Broker:** a person designated by the Organization certified to collect specified health information from the tissue or data bank, remove all identifiers, and provide **de-identified** health information or tissue to research teams or healthcare workers.

**“Opt-In”:** an agreement by the patient to be contacted for possible inclusion in biomedical research based on information in the patient's electronic medical record (EMR).

### **Inviting Patients Associated with UNMC/NM, BMC, or CHMC:**

#### Using **Clinical Databases** or **Prior Research Subject Databases:**

- Potential subjects must be one of the following:
  - A current or former patient of an investigator.
  - Patient to whom the investigator has ethical access (HRPP Policy 3.12).
  - Previous research subject who has given express permission (usually during the consent process) to be listed in the database for future research studies.
  - No more than 3 invitation attempts total per subject for any specific study (unless IRB approval given).

#### Using the **OPT-IN Method:**

- After IRB approval, the Director of EMR Access Core will authorize an Honest Broker to generate the list.
- Once the list is provided, it must be kept on a secure/encrypted UNMC/NM computer for no more than 3 months.
  - After 3 months, the list must be re-generated.
- The list must be destroyed when no longer in use.
- No more than 3 invitation attempts total per subject for any specific study (unless IRB approval given).

## Contacting Patients by **Email**:

- Must use the blind copy function if sending to multiple recipients.
- Must contain minimal PHI, limited to patient name and email address.
- The subject line should clearly identify “UNMC (or other Organization) Research Opportunity”.
  - No PHI or research information should be in the subject line.
- The sender of the information must be clearly identified as affiliated with the Organization.
- The **text of the email must include the following**:
  - Name and email address of the PI and associated institution
  - Clear statement that the activity is research
  - Purpose of the research
  - IRB number
  - An invitation to contact the investigator for more information, with a phone number if applicable.
  - **If recruiting through the Opt-In method**:
    - An explanation that the patient’s name and contact information were available because they’d chosen to opt-in to be contacted for research on the Conditions of Treatment Form.
    - Information on how to change their research recruitment option in the Conditions of Treatment Form and the contact information of the Research Subject Advocate.
- **For opt-in method**: the email must also be sent to the Clinical Research Outreach Coordinator (or equivalent position).
- **For CHMC patients**: the Pediatric Research Office must send the email.
- Emails may be sent no more often than weekly (unless given specific approval by the IRB).
- If a potential subject declines, no more emails may be sent regarding that specific study.

## Contacting Patients by **EPIC Email through OneChart**:

- The subject line should clearly identify “UNMC (or other Organization) Research Opportunity”.
  - No PHI or research information should be in the subject line.
- The reply back to sender will be set to return all replies to the investigator with ethical access.
- **The text of the email MUST include**:
  - Name and email address of the PI and associated institution
  - Clear statement that the activity is research
  - Purpose of the research
  - IRB number
  - An invitation to contact the investigator for more information, with a phone number if applicable
- Emails may be sent no more often than weekly (unless given specific approval by the IRB).
- If a potential subject declines, no more emails may be sent regarding that specific study.

### Contacting Patients by **Phone**:

- The telephone script must be approved by the IRB prior to use.
- Recorded voice messages must go through the Clinical Research Outreach Coordinator (or equivalent position).
- The frequency and number of calls must be specified in the application and approved by the IRB.
- VOICEMAIL- the message may only state that the call is about a research study the patient may be eligible for and offer a callback number.
  - No details regarding the study or reasons the patient is eligible should be given.
- If a potential subject declines, no more calls may be made regarding that specific study.

### Contacting Patients by **Mail**:

- Must contain minimal PHI, limited to patient name and mail address.
- Materials should be in an envelope with only the patient's name and address.
  - The return address must include the organization name but no specific department.
- If a postcard format is appropriate, the postcard must fold and seal to cover any medical/trial information.
- **Letters MUST include the following:**
  - Name and email address of the PI and associated institution
  - Clear statement that the activity is research
  - Purpose of the research
  - IRB number
  - An invitation to contact the investigator for more information, with a phone number if applicable
  - **If recruiting through the Opt-In method:**
    - An explanation that the patient's name and contact information were available because they'd chosen to opt-in to be contacted for research on the Conditions of Treatment Form.
    - Information on how to change their research recruitment option in the Conditions of Treatment Form and the contact information of the Research Subject Advocate.
- Letters may be sent no more often than weekly (unless given specific approval by the IRB).
- If a potential subject declines, no more letters may be sent regarding that specific study.

## Inviting Non-Patients:

### Creation of **Distribution Lists**:

- Unless the investigator has ethical access (HRPP Policy 3.8) to names of potential subjects or the names are obtained from publicly available databases, the distribution list must remain within the group that generates the list. The invitation should come from the group that generates the list.
- In certain circumstances, the IRB may approve the list be transferred to the investigator if they're satisfied that:
  - Risks of disclosure of contact information constitutes no more than minimal risk
  - Adequate safeguards are put in place to minimize the risk of disclosure beyond the investigator and study personnel
  - Adequate provisions are in place to protect the privacy of subjects
- If the list is provided to the investigator, it must be kept on a secure computer for no more than 3 months.
  - The list must be destroyed when it is no longer in use

### Contacting by **Email**:

- Must use the blind copy function if sending to multiple recipients
- The subject line should clearly identify "UNMC (or other Organization) Research Opportunity".
  - No PHI or research information should be in the subject line
- The group sending the email must be clearly identified
- **The text of the email must include the following:**
  - Name and email address of the PI and associated institution
  - Clear statement that the activity is research
  - Purpose of the research
  - IRB number
  - An invitation to contact the investigator for more information, with a phone number if applicable
  - An explanation why the prospective subject's name and contact information were available
  - The affiliation of the investigator with the Organization
- Emails may be sent no more often than weekly (unless given specific approval by the IRB)

### Contacting by **Phone**:

- The telephone script must be approved by the IRB prior to use
- The frequency and number of calls must be specified in the application and approved by the IRB
- VOICEMAIL- the message may only state that the call is about a research study the patient may be eligible for and offer a callback number.
  - No details regarding the study or reasons the patient is eligible should be given
- All recorded messages must follow the Telephone Consumer Protection Act

Contacting by **Mail**:

- Materials should be in an envelope with only the patient's name and address.
  - The return address must include the organization name but no specific department
- **Letters MUST include the following:**
  - Name and email address of the PI and associated institution
  - Clear statement that the activity is research
  - Purpose of the research
  - IRB number
  - An invitation to contact the investigator for more information, with a phone number if applicable
  - A description of why the subject's name and contact information were available
  - The affiliation of the investigator with the organization
- Letters may be sent no more often than weekly (unless given specific approval by the IRB)

## Finder's Fees/Recruitment Bonuses (HRPP 3.7)

**Definitions:**

**Finder's Fees:** fees paid to investigators, investigator's staff, or any representative of the organization, for referring research subjects.

**Recruitment Bonus:** payment, merchandise, or other gift or service offered by a sponsor as an incentive or reward to an organization, investigator, or investigator's staff designed to accelerate recruitment that is tied to enrollment rate, timing, or numbers.

Finder's fees and recruitment bonuses are NOT permitted.

Finder's fees paid to non-research personnel or research subjects are generally not permitted UNLESS, under limited circumstances, the IRB approves payment of small amounts as necessary to recruit a population of subjects that would potentially benefit from the research but would otherwise be difficult to recruit.