

3.6 Subject Recruitment Through Direct Invitation

Last Revised: 3/12/2025

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

It is the policy of the Organization that

- 2.1. All direct recruitment materials must be reviewed and approved by the IRB or ORA before they can be used to recruit potential subjects.
 - 2.2. Recruitment materials must be clear, promote equitable enrollment and not represent undue influence or coercion.
 - 2.3. Direct recruitment of subjects to research must be respectful of the privacy of potential subjects.
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3.0 Definitions

- 3.1. Opt-In (in the context of invitation to participate in research) refers to agreement by the patient to have records reviewed (prior to explicit informed consent) to determine eligibility for possible inclusion in research.
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4.0 General Prohibitions

- 4.1. Direct invitations may not include any of the following:
 - 4.1.1. Statements implying a certainty of a favorable outcome or other benefits beyond those described in the consent document and the protocol.

- 4.1.2. Claims, either explicit or implicit, that the research procedures and/or the test article (drug, biologic or device) are safe or effective for the purposes under investigation.
 - 4.1.3. Claims, either explicit or implicit, that the research procedures are known to be equivalent or superior to other interventions off-study.
 - 4.1.4. Terms such as “new treatment”, “new medication”, or “new drug”.
 - 4.1.5. Promises of “free medical treatment” regardless of whether the treatment will be provided without charge.
 - 4.1.6. The amount of compensation for participation (monetary or related to free or reduced price for services).
 - 4.1.7. Any exculpatory language.
 - 4.1.8. Claims, either explicit or implicit, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling.
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5.0 Invitations to Patients

- 5.1. This section applies to patients (present and former) associated with NM (including hospital and/or clinics), Bellevue Medical Center, or CN (including Children’s Physicians Clinics).
 - 5.1.1. Potential Subject Lists may be obtained either (1) based on clinical databases or prior research subject databases, or (2) status of EPIC “Opt-In” flag (subsequently referred to “Opt-In Status”). Once potential subjects have been identified they may be contacted as per processes described in sections 4.5 through 4.8 below.
- 5.2. Potential Subject Lists based on Clinical Databases or Prior Research Subject Databases
 - 5.2.1. Potential subjects listed in these databases 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 (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.
- 5.3. Potential Subject Lists based on “Opt-In Status”)
 - 5.3.1. Potential Subject list will be prepared by the READi (Research Education Administration Development for Health Informatics) Core.
 - 5.3.2. The READi core will generate the List based on the inclusion and exclusion criteria requested by the investigator and approved by the IRB.
 - 5.3.3. Contact with potential subjects based on the List will not occur until IRB review and approval is complete.
 - 5.3.4. Only patients who have opted-in to be contacted for research may be included in this search.
 - 5.3.4.1. Patients who have opted-out 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 (as per section 4.2 above).
 - 5.3.5. If there is a Potential Subject List that is shared with investigators, it will be stored on HIPAA compliant data sharing software (such as SharePoint), and control of the list will be maintained by the VCR Clinical Recruiting team or READi Core.

- 5.3.6. When the data request expires, or the protocol is completed by the investigator, or suspended or terminated by the IRB or institution, the VCR Cores (READi or the VCR Clinical Recruiting team) will remove access to Potential Subject List.
- 5.3.7. The READi Core and/or the VCR Clinical Recruiting team will assure that investigators have completed mandatory training on data confidentiality, as per their policies, prior to release of information to the investigator.
- 5.4. No more than three invitation attempts between all media channels (phone, mail, e-mail or OneChart patient portal) for any specific study may be made from any Potential Subject List described above unless specific approval is given by the IRB. The timeframe over which these invitation attempts can be made must be specified by the investigator in the IRB application, and must be approved by the IRB.
- 5.5. Contacting Patients by Email via MS Outlook (or future email system supported by the Organizations)
 - 5.5.1. 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.
 - 5.5.2. Emails must contain minimal PHI, limited to (a) Patient name, and (b) email address.
 - 5.5.3. The subject line must clearly identify "UNMC Research Opportunity" or "Children's Nebraska Research Opportunity" (as appropriate). PHI or study information must not be contained in the subject line.
 - 5.5.4. The sender of the email must be clearly identified as affiliated with the Organization.
 - 5.5.5. The text of the email must include the following items:
 - 5.5.5.1. Name of the PI and associated institution.
 - 5.5.5.2. A clear statement that activity is research.
 - 5.5.5.3. Purpose of the research.
 - 5.5.5.4. IRB number (in the format XXXX-XX-XX).
 - 5.5.5.5. An invitation to contact the study team for more information, with telephone number and/or email address if applicable.
 - 5.5.5.6. An explanation of how the patient's name and contact information were available to the investigator (for example, because they had chosen to opt-in to be contacted for research on their Conditions of Treatment Form, or because he/she had previously participated in research and had agreed to be contacted regarding additional research studies).
 - 5.5.5.7. If the patient had chosen to opt-in to be contacted for research on their Conditions of Treatment Form, information on how to change their research recruitment option.
 - 5.5.6. The text of the email may include the following items, as appropriate:
 - 5.5.6.1. A brief description of major relevant eligibility criteria (specifically, why a person might believe they are a potential subject)
 - 5.5.6.2. Time or other commitments required from the subject, including the duration of the person's participation in the study.
 - 5.5.6.3. A brief description of potential benefits to the subject, and of reasonably foreseeable risks and discomforts, if any. If potential benefits are stated in the email, then a brief description of the risks must also be included.
 - 5.5.6.4. As applicable, a statement that compensation is available; however, this information may not be in any font, font size, color, or other manner that is intended to draw attention to the value or availability of compensation.

- 5.5.6.5. Location where the research activities will take place.
 - 5.5.7. The email may not include any other information, unless specifically approved by the Office of Regulatory Affairs.
 - 5.5.8. Email invitations to potential subjects identified through the Potential Subject List will be sent from a central recruiting email address, unless a different process is specifically authorized by the IRB.
 - 5.5.9. The recruitment email invitation may be sent to potential subjects no more often than weekly unless specifically authorized by the IRB.
 - 5.5.10. If a potential subject declines participation in a specific study, no further recruitment emails may be sent regarding that study.
- 5.6. Contacting Patients by Nebraska Medicine “OneChart Patient Portal” or Children’s Nebraska “Children’s Connect”
 - 5.6.1. The subject line must clearly identify "UNMC Research Opportunity" or "Children’s Nebraska Research Opportunity" (as appropriate). PHI or study information must not be contained in the subject line.
 - 5.6.2. The text of the Patient Portal message must include the following items:
 - 5.6.2.1. Name of the PI and associated institution.
 - 5.6.2.2. A clear statement that activity is research.
 - 5.6.2.3. Purpose of the research.
 - 5.6.2.4. IRB number (in the format XXXX-XX-XX).
 - 5.6.2.5. An invitation to contact the study team for more information, with telephone number and/or email address if applicable.
 - 5.6.2.6. An explanation of how the patient’s name and contact information were available to the investigator (for example, because they had chosen to opt-in to be contacted for research on their Conditions of Treatment Form, or because he/she had previously participated in research and had agreed to be contacted regarding additional research studies).
 - 5.6.2.7. If the patient had chosen to opt-in to be contacted for research on their Conditions of Treatment Form, information on how to change their research recruitment option.
 - 5.6.3. The text of the message may include the following items, as appropriate:
 - 5.6.3.1. A brief description of major relevant eligibility criteria (specifically, why a person might believe they are a potential subject)
 - 5.6.3.2. Time or other commitments required from the subject, including the duration of the person’s participation in the study.
 - 5.6.3.3. A brief description of potential benefits to the subject, and of reasonably foreseeable risks and discomforts, if any. If potential benefits are stated in the email, then a brief description of the risks must also be included.
 - 5.6.3.4. As applicable, a statement that compensation is available; however, this information may not be in any font, font size, color, or other manner that is intended to draw attention to the value or availability of compensation.
 - 5.6.3.5. Location where the research activities will take place.
 - 5.6.4. The message may not include any other information, unless specifically approved by the Office of Regulatory Affairs.
 - 5.6.5. If a potential subject declines participation in a specific study, no further recruitment emails may be sent regarding that study.
- 5.7. Contacting Patients by Phone
 - 5.7.1. Telephone script must be approved by the IRB prior to use.
 - 5.7.2. The text of the script must include the following items:
 - 5.7.2.1. Name of the PI and associated institution.

- 5.7.2.2. A clear statement that activity is research.
- 5.7.2.3. Purpose of the research.
- 5.7.2.4. An invitation to contact the study team for more information, with telephone number and/or email address if applicable.
- 5.7.2.5. An explanation of how the patient's name and contact information were available to the investigator (for example, because they had chosen to opt-in to be contacted for research on their Conditions of Treatment Form, or because he/she had previously participated in research and had agreed to be contacted regarding additional research studies).
- 5.7.3. The text of the script may include the following items, as appropriate:
 - 5.7.3.1. A brief description of major relevant eligibility criteria (specifically, why a person might believe they are a potential subject)
 - 5.7.3.2. Time or other commitments required from the subject, including the duration of the person's participation in the study.
 - 5.7.3.3. A brief description of potential benefits to the subject, and of reasonably foreseeable risks and discomforts, if any. If potential benefits are stated in the email, then a brief description of the risks must also be included.
 - 5.7.3.4. As applicable, a statement that compensation is available; however, this information may not be presented in any manner that is intended to draw attention to the value or availability of compensation.
 - 5.7.3.5. Location where the research activities will take place.
- 5.7.4. The message may not include any other information, unless specifically approved by the Office of Regulatory Affairs.
- 5.7.5. Calls must originate from a UNMC/NM or CN telephone number, unless specifically approved by the IRB.
- 5.7.6. 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.
- 5.7.7. If a potential subject declines participation in a specific study, no further recruitment phone calls may be made regarding that study.
- 5.7.8. All recorded messages must comply with the Telephone Consumer Protection Act (TCPA) (47 U.S.C. § 227; 47 CFR 64.1200).
- 5.8. Contacting Patients by Mail
 - 5.8.1. Letters must contain minimal PHI, limited to (a) Patient name and (b) address.
 - 5.8.2. 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.
 - 5.8.3. If postcard format is appropriate, the postcard must fold and seal to cover any medical/trial information.
 - 5.8.4. The text of the letter must include the following items:
 - 5.8.4.1. Name of the PI and associated institution.
 - 5.8.4.2. A clear statement that activity is research.
 - 5.8.4.3. Purpose of the research.
 - 5.8.4.4. IRB number (in the format XXXX-XX-XX).
 - 5.8.4.5. An invitation to contact the study team for more information, with telephone number and/or email address if applicable.
 - 5.8.4.6. An explanation of how the patient's name and contact information were available to the investigator (for example, because they had chosen to opt-in to be contacted for research on their Conditions of Treatment Form, or because

they had previously participated in research and had agreed to be contacted regarding additional research studies).

- 5.8.4.7. If the patient had chosen to opt-in to be contacted for research on the Conditions of Treatment Form, information on how to change their research recruitment option.
- 5.8.5. The text of the letter may include the following items, as appropriate:
 - 5.8.5.1. A brief description of major relevant eligibility criteria (specifically, why a person might believe they are a potential subject)
 - 5.8.5.2. Time or other commitments required from the subject, including the duration of the person's participation in the study.
 - 5.8.5.3. A brief description of potential benefits to the subject, and of reasonably foreseeable risks and discomforts, if any. If potential benefits are stated in the email, then a brief description of the risks must also be included.
 - 5.8.5.4. As applicable, a statement that compensation is available; however, this information may not be in any font, font size, color, or other manner that is intended to draw attention to the value or availability of compensation.
 - 5.8.5.5. Location where the research activities will take place
- 5.8.6. The message may not include any other information, unless specifically approved by the Office of Regulatory Affairs.
- 5.8.7. The recruitment letter may be sent to potential subjects no more often than weekly unless specifically authorized by the IRB.
- 5.8.8. If a potential subject declines participation in a specific study, no further recruitment letters may be sent regarding that study.

6.0 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 Nebraska (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 School of Medicine students); cultural, ethnic or religious groups (e.g., Sudanese immigrants, members of a particular church); trades or professions (e.g., farmers, physicians, prison guards).

- 6.1. Creation of Potential Subject Lists
 - 6.1.1. In most cases, unless the investigator has ethical access to names of potential subjects, or the names are obtained from publicly available databases, the potential subject 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.

- 6.1.2. 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:
 - 6.1.2.1. 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
 - 6.1.2.2. There are adequate safeguards to minimize the risk of disclosure beyond the investigator and study personnel, and
 - 6.1.2.3. There are adequate provisions to protect the privacy of subjects.
- 6.1.3. If the potential subject 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.
- 6.1.4. 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 99).
- 6.1.5. No more than three invitation attempts between all media channels (phone, mail, or e-mail) for any specific study may be made from any potential subject list unless specific approval is given by the IRB. The timeframe over which these invitation attempts can be made must be specified by the investigator in the IRB application and must be approved by the IRB.
- 6.2. Contacting Prospective Subjects by Email
 - 6.2.1. 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 CN Outlook account.
 - 6.2.2. 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.
 - 6.2.3. The subject line must clearly identify UNMC, UNO or CN "Research Opportunity". Study information must not be contained in the subject line.
 - 6.2.4. The group sending the email must be clearly identified.
 - 6.2.5. The affiliation of the investigator with the Organization must be clearly stated in the email.
 - 6.2.6. The text of the email must include the following items:
 - 6.2.6.1. Name of the PI and associated institution.
 - 6.2.6.2. A clear statement that activity is research.
 - 6.2.6.3. Purpose of the research.
 - 6.2.6.4. IRB number (in the format XXXX-XX-XX).
 - 6.2.6.5. An invitation to contact the study team for more information, with telephone number and/or email address if applicable.
 - 6.2.6.6. A description of why the prospective subject's name and contact information were available.
 - 6.2.7. The text of the email may include the following items, as appropriate:
 - 6.2.7.1. A brief description of major relevant eligibility criteria (specifically, why a person might believe they are a potential subject)

- 6.2.7.2. Time or other commitments required from the subject, including the duration of the person's participation in the study.
- 6.2.7.3. A brief description of potential benefits to the subject, and of reasonably foreseeable risks and discomforts, if any. If potential benefits are stated in the email, then a brief description of the risks must also be included.
- 6.2.7.4. As applicable, a statement that compensation is available; however, this information may not be in any font, font size, color, or other manner that is intended to draw attention to the value or availability of compensation.
- 6.2.7.5. Location where the research activities will take place.
- 6.2.8. The email may not include any other information, unless specifically approved by the Office of Regulatory Affairs.
- 6.2.9. The recruitment email invitation may be sent to potential subjects no more often than weekly unless specifically authorized by the IRB.
- 6.3. Contacting Prospective Subjects by Phone
 - 6.3.1. Telephone script must be approved by the IRB prior to use.
 - 6.3.2. The text of the script must include the following items:
 - 6.3.2.1. Name of the PI and associated institution.
 - 6.3.2.2. A clear statement that activity is research.
 - 6.3.2.3. Purpose of the research.
 - 6.3.2.4. An invitation to contact the study team for more information, with telephone number and/or email address if applicable.
 - 6.3.2.5. A description of why the prospective subject's name and contact information were available.
 - 6.3.3. The text of the script may include the following items, as appropriate:
 - 6.3.3.1. A brief description of major relevant eligibility criteria (specifically, why a person might believe they are a potential subject)
 - 6.3.3.2. Time or other commitments required from the subject, including the duration of the person's participation in the study.
 - 6.3.3.3. A brief description of potential benefits to the subject, and of reasonably foreseeable risks and discomforts, if any. If potential benefits are stated in the email, then a brief description of the risks must also be included.
 - 6.3.3.4. As applicable, a statement that compensation is available; however, this information may not be presented in any manner that is intended to draw attention to the value or availability of compensation.
 - 6.3.3.5. Location where the research activities will take place.
 - 6.3.4. The message may not include any other information, unless specifically approved by the Office of Regulatory Affairs.
 - 6.3.5. Calls must originate from a UNMC/NM, UNO or CN telephone number, unless specifically approved by the IRB.
 - 6.3.6. 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.
 - 6.3.7. All recorded messages must comply with the Telephone Consumer Protection Act (TCPA) (47 U.S.C. § 227; 47 CFR 64.1200).
- 6.4. Contacting Prospective Subjects by Mail
 - 6.4.1. 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 potential subject list.

- 6.4.2. The affiliation of the investigator with the Organization must be clearly stated in the letter.
- 6.4.3. The mail must include an explanation why the prospective subject's name and contact information were available.
- 6.4.4. The text of the letter must include the following items:
 - 6.4.4.1. Name of the PI and associated institution.
 - 6.4.4.2. A clear statement that activity is research.
 - 6.4.4.3. Purpose of the research
 - 6.4.4.4. IRB number (in the format XXXX-XX-XX).
 - 6.4.4.5. An invitation to contact the study team for more information, with telephone number and/or email address if applicable.
 - 6.4.4.6. A description of why the prospective subject's name and contact information were available.
- 6.4.5. The text of the script may include the following items, as appropriate:
 - 6.4.5.1. A brief description of major relevant eligibility criteria (specifically, why a person might believe they are a potential subject)
 - 6.4.5.2. Time or other commitments required from the subject, including the duration of the person's participation in the study.
 - 6.4.5.3. A brief description of potential benefits to the subject, and of reasonably foreseeable risks and discomforts, if any. If potential benefits are stated in the email, then a brief description of the risks must also be included.
 - 6.4.5.4. As applicable, a statement that compensation is available; however, this information may not be in any font, font size, color, or other manner that is intended to draw attention to the value or availability of compensation.
 - 6.4.5.5. Location where the research activities will take place.
- 6.4.6. The message may not include any other information, unless specifically approved by the Office of Regulatory Affairs.
- 6.4.7. The recruitment letter may be sent to potential subjects no more often than weekly unless specifically authorized by the IRB.

DOCUMENT HISTORY:

? Written: 8/23/2018 (Approved: 8/23/2018) - original author not recorded

? Revised: 9/25/2024 - Revised definition of "Opt-In" (section 3.1); deleted definition of Honest Broker since not used in policy; clarified how distribution list obtained, processed and used (sections 4.1.1 and 4.3); clarified and simplified method of contact of potential patient subjects thru OneChart Patient Portal or Children's Connect (section 4.6); provided regulatory reference for TCPA (sections 4.7.5 and 5.3.3); specified that phone calls must originate from a UNMC/NM, CN or UNO telephone number, unless specifically approved by the IRB (section 4.7.2 and 5.3.2).

? Revised: 3/5/2025 - Reformatted and revised to make requirements consistent for all routes of contact with potential subjects; clarified information that must, may, and may not appear in recruitment materials; specified IRB number format; stylistic changes.

? Revised: 3/12/2025 – clarified that advertisements must include contact information for the study team (not necessarily the PI).