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 specific 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 allow their medical record to be reviewed (prior to giving full informed consent) for the purpose of determining eligibility for possible inclusion in a research study.

General Prohibitions:

Direct invitations to potential research subjects **must NOT include** the following:

- Any guarantees or suggestions of a certain positive outcome or benefits beyond what's in the consent form or study protocol
- Claims of safety or effectiveness (explicit or implied) regarding the research procedures or study drug/device
- Suggestions that the study intervention is equal or superior to other available treatments
- Use of promotional terms such as "*new treatment*", "*new medication*", or "*new drug*"
- Promises of "*free medical treatment*", even if treatment is provided at no cost
- The amount of compensation for participating (including financial payment or free/reduced-cost services)
- Exculpatory language, which attempts to waive legal rights or release the research team from liability
- Any claims about the study drug, biologic, or device that are inconsistent with FDA labeling (approved usage)

Invitations to PATIENTS

This section applies to recruiting current or former patients associated with Nebraska Medicine, Bellevue Medical Center, and Children's Nebraska.

Eligible Sources for Potential Subject Lists:

- **Clinical Database/Prior Research Subject Database:** includes
  - Current or former patients of the investigator
  - Patient to whom the investigator has ethical access (HRPP Policy 3.12)
  - Previous research participants who gave permission (usually during consent process) to be contacted for future research studies
- **Opt-In Status via EPIC:**
  - Lists created by the READi Core
  - Contact with potential subjects based on the list will not occur until IRB review and approval is complete
  - Only patients who've opted-in to be contacted may be included in this search

Contact LIMITATIONS:

- **Maximum 3 contacts** (total across all platforms) per study, unless IRB approves more
- Contact frequency and methods must be defined in the IRB application

EMAIL:

- Must use blind copy (bcc) for group emails
- **Subject line:** *"UNMC Research Opportunity", "Children's Nebraska Research Opportunity", etc.*
  - No PHI or research information should be in the subject line
- The sender must be clearly identified as affiliated with the Organization
- **REQUIRED CONTENT:**
  - PI name and institution
  - Clear statement that the activity is research
  - Purpose of the research
  - IRB number (xxxx-xx-xx)
  - Study team contact information
  - Explanation of how potential subject information was obtained

    - **If opted-in:** information on how to change their research recruitment option
- **Optional content:**
    - Brief eligibility criteria
    - Time or other commitments
    - Risks/benefits
        - If potential benefits are stated, then risks must also be included
    - Location where research activities will take place
    - A statement that compensation may be available
- **If opted-in:** emails must be sent from a central recruiting address (unless otherwise approved by the IRB)
- **No more than one email per week**
- **If a potential subject declines participation,** no further emails for that study may be sent

PATIENT PORTAL MESSAGES (OneChart/Children's Connect):

- **Subject line:** *"UNMC Research Opportunity", "Children's Nebraska Research Opportunity", etc.*
    - No PHI or research information should be in the subject line
- **REQUIRED CONTENT:**
    - PI name and institution
    - Clear statement that the activity is research
    - Purpose of the research
    - IRB number (xxxx-xx-xx)
    - Study team contact information
    - Explanation of how potential subject information was obtained
    - **If opted-in:** information on how to change their research recruitment option
- **Optional content:**
    - Brief eligibility criteria
    - Time or other commitments
    - Risks/benefits
        - If potential benefits are stated, then risks must also be included
    - Location where research activities will take place
    - A statement that compensation may be available

- **If a potential subject declines participation,** no further messages for that study may be sent

PHONE CALLS:

- IRB-approved script required
- **REQUIRED CONTENT:**
    - PI name and institution
    - Clear statement that the activity is research
    - Purpose of the research
    - Study team contact information
    - Explanation of how potential subject information was obtained
- **Optional content:**
    - Brief eligibility criteria
    - Time or other commitments
    - Risks/benefits
        - If potential benefits are stated, then risks must also be included
    - Location where research activities will take place
    - A statement that compensation may be available
- Calls must come from official UNMC/NM or CN numbers
- Voicemails must be minimal; just study opportunity and callback information
- **If a potential subject declines participation,** no further calls for that study may be sent
- Must comply with TCPA regulations

POSTAL MAIL:

- Only include potential subject name and address as PHI
- Return address must include Organization name, but no specific department or office
- Postcards must be sealed to cover any medical/trial information
- **REQUIRED CONTENT:**
    - PI name and institution
    - Clear statement that the activity is research
    - Purpose of the research

    - IRB number (xxxx-xx-xx)
    - Study team contact information
    - Explanation of how potential subject information was obtained
    - **If opted-in:** information on how to change their research recruitment option
- **Optional content:**
    - Brief eligibility criteria
    - Time or other commitments
    - Risks/benefits
        - If potential benefits are stated, then risks must also be included
    - Location where research activities will take place
    - A statement that compensation may be available
- **Letters may be sent no more than weekly**
- **If a potential subject declines participation,** no further letters for that study may be sent

Invitations to Non-Patients

Examples of prospective subject populations:

- Students *(e.g. UNO, UNMC, trade schools)*
- Religious or cultural groups
- Occupational groups *(e.g. farmers, teachers, guards)*

Creation of Potential Subject Lists:

- **Default Rule:** investigators must not receive direct access to names unless
    - They have ethical access, or
    - The names are from publicly available databases
- **Preferred Approach:** the group that created the list sends the invitation. If they cannot or will not, the IRB may specifically approve that the list be transferred to the investigator, provided that the following conditions are met:
    1) Minimal risk of disclosure *(e.g. no harm to reputation, employability)*, and
    2) Adequate safeguards for limiting access, and
    3) Privacy protections in place

- **If the list is provided to the investigator:**
    - it must be kept on a secure computer for no more than 3 months and must be destroyed once no longer in use, and
    - all information provided must comply with applicable privacy laws and regulations *(e.g. FERPA)*
- No more than 3 contact attempts (via any media) per study without IRB approval
    - Timeframe and contact method must be defined in the IRB application

EMAIL:

- **Sender:** group that created the list OR an investigator (with IRB permission)
- Must use UNMC/NM/UNO/CN Outlook account
- Use BCC for group messages
- **Subject line:** Must include *"Research Opportunity"* and institution, no study details
- **REQUIRED CONTENT:**
    - PI name and institution

- Clear statement that the activity is research
- Purpose of the research
- IRB number (xxxx-xx-xx)
- Study team contact information
- Explanation of how potential subject information was obtained

- **Optional Content:**
  - Brief eligibility criteria
  - Time or other commitments
  - Risks/benefits
    - If potential benefits are stated, then risks must also be included
  - Location where research activities will take place
  - A statement that compensation may be available
- **No more than one email per week**

PHONE CALLS:

- IRB-approved script required
- **REQUIRED CONTENT:**
  - PI name and institution
  - Clear statement that the activity is research
  - Purpose of the research
  - Study team contact information
  - Explanation of how potential subject information was obtained
- **Optional content:**
  - Brief eligibility criteria
  - Time or other commitments
  - Risks/benefits
    - If potential benefits are stated, then risks must also be included
  - Location where research activities will take place
  - A statement that compensation may be available
- Calls must come from official UNMC/NM, CN, or UNO numbers
- Voicemails must be minimal; just study opportunity and callback information
- Must comply with TCPA regulations

POSTAL MAIL:

- Only include potential subject name and address
- Return address must include Organization name or the name of the group supplying the potential subject list
- **REQUIRED CONTENT:**
    - PI name and institution
    - Clear statement that the activity is research
    - Purpose of the research
    - IRB number (xxxx-xx-xx)
    - Study team contact information
    - Explanation of how potential subject information was obtained
- **Optional content:**
    - Brief eligibility criteria
    - Time or other commitments
    - Risks/benefits
        - If potential benefits are stated, then risks must also be included
    - Location where research activities will take place
    - A statement that compensation may be available
- **Letters may be sent no more than weekly**

Finder's Fees/Recruitment Bonuses (HRPP 3.7)

Definitions:

Finder's Fees: fees paid to investigators, study staff, or any representative of the Organization for referring research participants.
Example: A physician receives $100 for every patient they refer to a clinical trial.

Recruitment Bonus: a reward (monetary or non-monetary) offered by a sponsor to the organization, investigator, or study staff tied to recruitment performance, such as enrollment rate, timing, or numbers.
Example: A research site gets an extra $5,000 if it enrolls 50 participants within the first 2 months.

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.