Research Recruitment Guidelines: Frequently Asked Questions
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General Questions/Definitions

1. What is HIPAA?

HIPAA stands for the Health Information Portability and Accountability Act of 1996. As used in this document, references to HIPAA also include the regulations issued under this legislation. HIPAA sets forth requirements to protect the privacy and security of health information. HIPAA applies to health care providers such as NMHC and SRAlab. HIPAA requirements are separate and distinct from other rules governing research (e.g., the Common Rule and FDA regulations). Accordingly, when researchers conduct recruitment on behalf of NMHC or SRAlab, they must abide by both research regulations and the requirements set forth in this document which reflect HIPAA requirements.

2. What is a Covered Entity?

Under HIPAA, a Covered Entity includes (1) health plans, (2) health care clearinghouses, and (3) health care providers that electronically transmit health information in certain formats as specified by the Department of Health and Human Services. NMHC and SRAlab are Covered Entities. With some exceptions, Northwestern University is not a Covered Entity. Northwestern University must follow other laws and institutional policies governing privacy, including access to electronic medical records while conducting research (e.g., NMHC’s Research Privacy and Confidentiality policy).

3. What is Protected Health Information or PHI?

PHI stands for Protected Health Information. PHI is any health information that includes any of the 18 elements identified by HIPAA or any information that can be reasonably used to identify a person. (See General Questions/Definitions #4.A. below for the list of 18 elements.)

4. What is de-identified PHI? How can I de-identify health information?

De-identified data means health information that does NOT CONTAIN ANY of the 18 identifying elements under HIPAA. While information not containing identifiers such as name or date of birth may not be identifiable to you, if ANY of the 18 elements are present or there is a reasonable basis to believe that the information can be used to identify an individual, HIPAA considers it identifiable and thus PHI. If health information is de-identified, it is no longer considered PHI and is not subject to HIPAA.
Health information may be de-identified by one of two methods:

A. All of the following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

i. Names;
ii. All geographic subdivisions smaller than a State, including: street address, city, county, precinct, zip codes and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly-available data from the Bureau of the Census: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and (2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
iii. Telephone numbers;
iv. Fax numbers;
v. E-mail addresses;
vi. Social Security numbers;
 vii. Medical record numbers;
viii. Health plan beneficiary numbers;
ix. Account numbers;
x. All elements of dates (except year) for dates related to an individual, including: birth date, admission date, discharge date, date of death, all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
xii. Certificate/license numbers;
 xiii. Vehicle identifiers and serial numbers, including license plate numbers;
xiv. Device identifiers and serial numbers;
xv. Web Universal Resource Locators (URLs);
xvi. Internet Protocol (IP) address numbers;
xvii. Biometric identifiers, including finger and voice prints;
xviii. Full face photographic images and any comparable images; and
xviii. Any other unique identifying numbers, characteristics, or codes.

B. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
i. applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

ii. documents the methods and results of the analysis that justify such determination.

**NMHC**: To utilize this second method with NMHC data, prior approval from the NMHC Data Steward is required.

**SRAlab**: To utilize this second method with SRAlab data, prior approval from the SRAlab Corporate Compliance Office is required.

5. What activities does Recruitment include?

Recruitment means reviewing PHI, such as information from the medical record or Enterprise Data Warehouse (EDW), for the purpose of both identifying individuals potentially eligible for a research study and contacting individuals to seek their participation in the research study.

6. How do Preparatory to Research activities differ from Recruitment activities?

Covered entities, such as NM, may permit a researcher to review PHI Preparatory to Research. These reviews allow the researcher to determine, for example, whether there is a sufficient number or type of records to support research. Additionally, these reviews may aid in study recruitment by allowing the researcher to identify, but not contact, potential study participants. Prior to conducting a review Preparatory to Research, the research is required to make the following representations: (i) the use or disclosure is sought solely to review PHI as necessary to prepare the research protocol or other similar preparatory purpose; (ii) no PHI will be removed from the covered entity during the review; and (iii) the PHI that the researcher seeks to use or access is necessary for the research purposes.

In short, researchers cannot contact patients through the preparatory to research provision nor can researchers download, email, or remove the information from NMHC property or servers. (See Identifying Potential Study Participants #1 for more information.)
7. What is the Enterprise Data Warehouse (EDW)?

The EDW is a comprehensive and integrated electronic repository of most clinical and research data sources at NMHC and Northwestern University Feinberg School of Medicine (FSM). It is designed to facilitate research, clinical quality, healthcare operations and medical education. The EDW can provide reports and other data tools to support research. To obtain more information contact nmedw@northwestern.edu.

SRAlab also maintains an EDW. For more information on the use of the SRAlab EDW for research purposes, contact the SRAlab Office of Research Administration.

8. Who is considered a researcher? Who is on the research team or qualifies as authorized research personnel for a study?

The term researcher in this document refers to employees of NMHC and SRAlab, Northwestern University researchers from the Feinberg School of Medicine, Northwestern University researchers from areas outside of the Feinberg School of Medicine (e.g., Kellogg), and researchers from institutions other than Northwestern University. The research team or authorized research personnel may consist of all individuals listed on the authorized personnel list for a study. This may also apply to exempt research or research that does not involve human subjects.

### Obtaining Information Needed for Recruitment

1. How do I obtain patient information necessary for any type of Recruitment?

**NMHC:** All researchers must obtain patient information needed for recruitment (e.g., patient lists) from the NM Enterprise Data Warehouse (EDW) in accordance with the FSM policy, [FSM Research Use of Electronic Medical Record Data](#). The EDW staff must provide the minimal information needed to contact the patient and to assess eligibility for the research study. Researchers may contact the EDW directly for report requests at nmedw@northwestern.edu.

In general, the research team is obtaining patient contact information for purposes of asking the patient to sign an informed consent that contains a HIPAA-authorization since the research team is seeking to acquire further NMHC patient information (e.g., clinical information) for purposes of the research study. There are, however, situations where a researcher is requesting patient contact information so the researcher can send a survey or questionnaire. The study participants will not complete a HIPAA authorization. In these
situations, the researcher must provide a waiver (or partial waiver) of HIPAA authorization in order for NMHC to provide patient contact information to the researcher.

**SRAlab:** All SRAlab researchers must obtain information necessary for recruitment from SRAlab’s Information Systems department in accordance with SRAlab’s policy, [Research Subject Recruitment](#).

2. Are there situations where I am allowed to directly access the electronic medical record for purposes of recruiting patients?

**NMHC:** You may directly access the electronic medical record for purposes of recruitment only in the following situations:

a. **Where an exception is granted:** If the EDW staff determine the information necessary to assess eligibility and contact the patient cannot be provided via an EDW report, an exception may be granted allowing researchers to access patient information directly from the medical record.

   **Example:** Direct access may be granted where eligibility for a research study is dependent upon a dynamic presentation (e.g., studies recruiting intensive care unit patients based on specific clinical criteria within short recruitment windows) or where a patient may be discharged prior to the information showing in the EDW (e.g., an emergency room study).

b. **Where a treatment relationship exists:** If the Principal Investigator (PI) or co-investigator is the potential participant’s clinical provider, then the PI or co-investigator, or the research team working with them, may obtain information for assessing eligibility and contacting the patient directly from the medical record.

**SRAlab:** A researcher may be granted direct access only if SRAlab has issued a written exception confirming that recruitment directly from the medical record is necessary and that information required for recruitment is not available from SRAlab Information Systems.

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**Identifying Potential Study Participants**

1. May I identify potential study participants—even though I’m not yet ready to contact them? (See General Questions Definitions #6 above for more information.)
Under HIPAA’s Preparatory to Research exception, a Covered Entity may share PHI with researchers for the purposes of identifying potential study participants. Under this exception, a researcher may identify—but not contact—potential study participants. In addition, the researcher may not remove PHI from the Covered Entity.

**Example:** Suppose you want to identify NMHC or SRAlab patients who might qualify for a study, but you are doing so as a preliminary step and are not yet ready to contact individuals. You may receive this information under HIPAA’s Preparatory to Research exception. However, because you cannot remove the information from the Covered Entity, you must view reports within the EDW portal (i.e. for NMHC patients) or on the respective Covered Entity server and may only download the information to servers or other locations approved by the Covered Entities. Researchers should work with the affected NMHC or SRAlab clinical department for any download of information. Researchers may not download data to a Northwestern University server or to personal accounts. Nor may researchers email the data outside of the Covered Entity or print the data and remove it from Covered Entity premises.

**Contacting Individuals for Recruitment**

1. **May I contact individuals who respond directly to study recruitment materials?**

   A researcher may choose to develop recruitment materials (e.g., flyers, advertisements) addressing potential participants. If interested, an individual may contact the research team directly. A researcher may contact a potential study participant who responds *directly to the researcher* through an advertisement or who completes a research study contact form left in a physician’s office. Information obtained directly from individuals through this route is not considered PHI.

2. **Once I have identified potential study participants from either NMHC’s or SRAlab’s patient populations, may I contact them?**

   **NMHC:**

   a. **Where a treatment relationship exists:** If the Principal Investigator (PI) or co-investigator is the potential participant’s clinical provider, then the PI or co-investigator, or the research team working with them, may contact the patient in-person, electronically (e.g., via email or MyChart), by phone, or by letter to discuss participation in the study.
Where no treatment relationship exists: If the potential participant is not a patient of the PI or co-investigator, then the PI or co-investigator or a member of their research team may contact the patient in-person to discuss participation in the study. In addition, the PI or co-investigator, or a member of their research team, may also contact the patient by phone, email or letter to discuss participation in the study. However, where no treatment relationship exists and where the contact is either by phone, email or letter (“cold contact”), then the researcher must ensure that the patient has not opted out of being contacted for research. If the contact information is obtained from the EDW, then the contact list will not contain the names of individuals who have opted out. However, if, pursuant to an exception, the research team may directly access the medical record for contact information, then the research team member, prior to contacting the patient, is responsible to verify that the patient has not opted out of being contacted for research. Instructions on how to conduct this verification are set forth on Appendix A.

Guidelines for In-Person Cold Recruitment are set forth in Appendix B.

SRAlab: Please see the SRAlab Research Subject Recruitment policy for more information on contacting potential research participants.

3. Do I need to obtain permission from a patient’s treating provider in order to recruit the patient?

Researchers are not required to secure permission from a patient’s treating clinician prior to recruiting potential participants. However, we encourage researchers to make arrangements with clinic department administrators if the researchers plan to conduct in-person recruitment on site at the Covered Entity.

NMHC Example: If a researcher works for Dr. Smith, a Principal Investigator from the Department of Urology at Northwestern Medical Group (NMG), and is recruiting study subjects for a urological study, the researcher may contact not only Dr. Smith’s patients who meet eligibility criteria, but also the patients of Dr. Green, another physician in NMG’s Urology Department, as well patients of Dr. Jones, an NMG dermatologist. The researcher does not need to secure the permission from Dr. Green or Dr. Jones in order to recruit qualifying patients.

SRAlab Example: If an SRAlab researcher works for Dr. Ryan, a Principal Investigator from the Legs + Walking Lab, and is recruiting subjects across all research labs, the SRAlab researcher may contact patients that are part of the Legs + Walking Lab and any other lab (e.g., Think + Speak Lab, etc.).
4. May I discuss research opportunities face-to-face with patients?

Yes. Treating clinicians at NMHC and SRAlab may inform patients about research opportunities. In addition, other authorized research personnel may approach patients on site at the Covered Entity and discuss the individual’s participation in the study. Researchers must clearly state that they are recruiting for “X” study on behalf of either NMHC or SRAlab, as appropriate. Again, we encourage researchers to make arrangements with clinic department administrators if the researchers plan to conduct in-person recruitment on site at the Covered Entity.

5. May I contact patients by letter, email, or phone?

a. **Letter or Email**: You may send a letter or email to patients who potentially qualify as for a study. **Remember**: when you send the letter or email, you are doing so **on NMHC’s or SRAlab’s behalf**.

   i. For paper letters, researchers must use either NMHC’s or SRAlab’s letterhead compliant with applicable branding standards. For NMHC letterhead, please click [here](#), if you don’t have access to Northwestern Medicine Intranet, contact research@nm.org. For SRAlab letterhead, please contact Melissa Mitchell mmitchell2@sralab.org.

   ii. If email is used, the email must be sent from a clinical affiliate email address. If you do not have an NM.org email address, please contact accesspr@nm.org to start the process of gaining access or to request an NM.org email. If you do not have a sralab.org email address, please contact the SRAlab Office of Research Administration.

   iii. The communication must state that the patient is being contacted "on behalf" of the affected Covered Entity. The purpose of this communication is to inform the recipient about a study and ask him or her to contact the researcher for purposes of securing a HIPAA-compliant research authorization and research informed consent. The communication should specify if the researcher will follow-up with a phone call. Click [here](#) for a sample NMHC letter.

b. **Phone**: You may also call potential study participants. Again, please communicate that you are conducting recruitment on behalf of either NMHC or SRAlab.
6. I am a treating clinician. May I inform my patients about studies?

Absolutely. Treating clinicians at NMHC and SRAlab may discuss study participation, which may include participating in a clinical trial, with their patients as part of the patients’ treatment. Treating clinicians may also call or send a letter or email their patients.

Patient Request to Not be Contacted as Part of Research Recruitment

1. What if a patient says that he or she does not want to be contacted now or in the future about participating in research?

**NMHC:** If a patient indicates that he or she does not want to be contacted for recruitment purposes, then the patient should be instructed to call the NMHC Office of Research: 630-933-6528. The research team may also make this request by calling the same phone number. The NMHC Office of Research will set the “do not contact” flag in EPIC, and the EDW staff will not release the patient’s name to researchers for recruitment purposes.

**SRAlab:** If a patient indicates that he or she does not want to be contacted for recruitment purposes, the patient should be instructed to call the SRAlab Office of Research Administration: 312-238-5195. If a patient has indicated that he or she does not want to be contacted by researchers, the SRAlab Office of Research Administration will set the “Opt Out From Future Research Studies” flag in the electronic medical Record, and the SRAlab Information Systems staff will not release the patient’s name to researchers for recruitment purposes by phone, email, or letter.

If a patient has indicated that he or she is not interested in participating in your specific study, the research team must document this internally and ensure that the patient is not contacted again.

Patient Authorizations for Research

1. As part of recruitment, I am gathering the patient’s informed consent and HIPAA authorization. How do I know if the authorization is compliant with HIPAA?

Patient authorization is the means by which a study participant agrees that a Covered Entity may disclose the individual’s Protected Health Information to researchers. Only HIPAA-compliant authorizations must be used for research. Elements of a HIPAA-compliant authorization include the following items. All elements must be included in the authorization, unless there is an alteration approved by the IRB or Privacy Board. Failure
to include all elements will result in the need to obtain a new authorization from the patient. The NU IRB informed consent template includes all the elements and instructions for modifying language based on the specifics of the study. Be sure to carefully read the directions in the template to ensure all elements are present.

- A specific description of the PHI that will be used and/or disclosed;
- The names of persons or organizations that may use or disclose the PHI;
- The names of persons or organizations to whom the PHI will be disclosed;
- A statement of the purpose of the use and/or disclosure;
- A statement of how long the use and/or disclosure will continue (no expiration date is permitted for research purposes, however this must be specifically stated in the authorization form and justification must be provided in the protocol);
- A statement that the subject can revoke his or her authorization;
- A statement regarding the potential for re-disclosure to others not subject to the HIPAA Privacy Rule;
- A notice that the covered entity either may or may not condition treatment or payment on the individual’s signature;
- The individual’s signature and the date.

**NOTE:** In addition to the above requirements, state law or other federal law may also require that certain items be included in the authorization form. For example, if the study involves the use of mental health, developmental disabilities or genetic counseling information of Illinois residents, then the authorization must have a witness signature, include a calendar date for expiration, allow the study participant to inspect and copy the PHI that was provided to the researcher, and specifically describe the information to be disclosed. Again, follow the instructions contained within the Northwestern University IRB informed consent template.

2. Where should I keep HIPAA authorizations?

**NMHC:** Research personnel must ensure that all HIPAA-compliant research authorizations (whether stand-alone or as part of an informed consent document) are placed in Study Tracker and retained for at least six years. This includes initial authorizations and any subsequent authorizations.

**SRAlab:** Research personnel must follow all internal SRAlab Policies on retention of HIPAA Authorizations and related study documentation. Contact the SRAlab Office of Research Administration for further information.
Privacy Violations

1. What is a privacy violation?

A privacy violation occurs when the health information you receive from the Covered Entities for purposes of recruitment is used by or disclosed to an unauthorized or incorrect person. Consider the following examples:

- Your computer—which includes information received from the Covered Entity for recruitment purposes (e.g., a contact list) is stolen or lost.
- You email a recruitment communication to the wrong patient.
- You email a recruitment communication to a patient and accidentally include other patients or individuals on the communication.

2. What do I do if I become aware of a privacy violation?

Any actual or suspected data breach (including unauthorized access to or compromise of data, theft or removal of equipment, papers, storage media, etc.) must be reported immediately to: FSMIT-Policy@northwestern.edu. University staff will contact NMHC or SRAlab, as appropriate, regarding violations involving their respective PHI.
## Assistance

1. Who do I contact for guidance?

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<thead>
<tr>
<th>NMHC</th>
<th>SRAlab</th>
<th>Northwestern University</th>
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<tbody>
<tr>
<td>Rayan Venkatesh</td>
<td>Tim McKula</td>
<td>Abby Cosentino-Boehm</td>
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<tr>
<td>Corporate Compliance &amp; Integrity</td>
<td>VP, Chief of Research Operations</td>
<td>Director, Clinical Research Operations</td>
</tr>
<tr>
<td>Northwestern Memorial HealthCare</td>
<td>Shirley Ryan AbilityLab</td>
<td>Northwestern University</td>
</tr>
<tr>
<td>(312) 926-4800</td>
<td>(312) 238-5195</td>
<td>Feinberg School of Medicine</td>
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<tr>
<td>or</td>
<td>or</td>
<td>Office for Research</td>
</tr>
<tr>
<td>Megan Carney</td>
<td>Melissa Mitchell</td>
<td>(312) 503-2306</td>
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<tr>
<td>Office of Research</td>
<td>Chief Compliance and Privacy Officer</td>
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<tr>
<td>Northwestern Memorial HealthCare</td>
<td>Shirley Ryan AbilityLab</td>
<td>Joseph Kline</td>
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<tr>
<td>(630) 933-6527</td>
<td>(312) 238-7032</td>
<td>Associate General Counsel</td>
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<tr>
<td>or</td>
<td>or</td>
<td>Northwestern University</td>
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<tr>
<td>Mary Lucie or Meghan Archdeacon</td>
<td>Laurie Tenzer</td>
<td>(847) 467-2045</td>
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<td>Office of General Counsel</td>
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<td>Northwestern Memorial HealthCare</td>
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<td>(312) 926-4040</td>
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1. What additional resources are available?

You may find the following documents helpful:

APPENDIX A

Do not contact flags in Epic

As part of the consent patients sign prior to getting care at Northwestern Medicine, patients are made aware that we are an organization that participates in research and are given the opportunity to indicate he or she does not want to be contacted to participate in research. The NMHC Office of Research tracks the patient’s wishes in their Epic chart.

Reports obtained from the EDW for the purposes of recruitment will not contain patients who have chosen not to be contacted or “opted out.” When an exception has been granted to recruit potential subjects directly from the medical record, researchers must verify the patient has not opted out prior to contact.

From within a patient’s chart in Epic researchers must check for the “Research Opt Out” flag. In the below screenshot you will see a yellow banner over FYI in the upper right corner. It is outlined in red in the screenshot to help you identify it. If the patient does not have any FYI flags on his or her record, the yellow FYI banner will not appear. Please note, there are other types of FYI flags a patient could have on his or her chart. You will have to click on the banner to determine if the Research Opt Out flag is one of them.

Click on the yellow banner and the FYI box will open. A list of FYI flags on that patient’s record will appear. If the “Research Opt Out” flag appears, the patient does not wish to be contacted for research and the research team must not solicit the patient for recruitment into the study.

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The below screen shot shows the flag.
APPENDIX B

Guidelines for In-Person Cold Recruitment

Overview:
Researchers at Northwestern Medicine may employ recruitment strategies that include approaching patients in person for whom the investigator or research team does not already have an existing clinical relationship. For the purposes of this document, we are defining that as in-person cold recruitment. When utilizing methods to cold recruit patients for research in NM space, investigators should follow these guidelines. Of note, all methods used to recruit individuals in a research study must first be described in your IRB approved protocol.

Prior to initiating any in-person cold recruitment, the research team should engage with the leaders of the NM area in which this activity will occur. The research team and the area leaders may consider the following elements when determining a recruitment plan; factors specific to the type of patient population, causing minimal disruption to the operations of the area, protecting the privacy of the patient related to conversations in public, etc. If the research team is unsure whom to contact in the NM area, they should reach out to the NMHC Office of Research at research@nm.org.

At all times during in-person cold recruitment at NMHC, members of the research team should conduct themselves professionally and show respect for the patient and their families. Members of the research team should be mindful that many individuals receiving care at Northwestern Medicine may be under stress. Patients or family members who at any time demonstrate or express they are not interested in discussing the research should be thanked for their time, if appropriate, and not further approached.

Template Script:
The following script should be followed as a template as it relates to the specific study.

Step 1
Introduce yourself with your name and association to research. Tell the person about how much time it will take to describe the research, and ask the individual if they are willing to learn more about the research study.

Step 2
If willing, provide a brief statement of the purpose of the research or what the research is hoping to accomplish. Ask the individual if they would like to hear more.

Step 3
If willing, tell the individual you will ask for their consent to participate and go on to describe what is expected of the individual with their participation in this study. Explain that participation is voluntary.

Step 4
Ask the individual if they are interested in the next steps to participating, i.e., reviewing consent, screening, setting up a follow up time.

Example Study Script:

1. Hi, my name is Elizabeth and I am a research coordinator at Northwestern Medicine. Can I have 5 minutes of your time to tell you about the HEAL research study?
2. Many medical centers across the U.S. are working together to understand how the hospital environment affects levels of stress hormones in patients. By understanding this we hope to guide improvement in the environment to support healing. We are looking for individuals who are currently hospitalized to participate by providing blood samples and responding to a couple surveys. Are you interested in hearing more?

3. We would ask for your consent to participate in the study and then take blood samples at 3 different time points during your hospitalization. We would also ask for permission to gather information about your health and your hospitalization from your medical record. Finally, we would ask you to complete 2 surveys now and those same surveys in 6 months. Whether or not you want to participate is entirely up to you and will not affect the care you are already getting at Northwestern Medicine.

4. If you are interested, could I provide you with a copy of the consent to review and set up time with you tomorrow to go through the document and answer any questions?
APPENDIX C

Recruitment Letter Template-Northwestern Medicine

<<NOTE: NM Letterhead must be used>>

Dear: <<Potential Participant>>

Hello, my name is _________________ and I am the <<insert title>> for a research study being conducted by <<Name of researcher>> with Northwestern University<< Feinberg School of Medicine>>. I am contacting you on behalf of Northwestern Medicine as someone who may be interested in participating in a research study. We ask that you please review the << insert short title>> study description and see whether you may be interested in participating.

[Name of Study]: IRB approval # STUxxxxxx

[OPTIONAL INFO BELOW—take from IRB approved protocol]

Information about the study:

What is the study about?

What is involved?

Who is conducting the study?

Who can participate?

If you have any questions, would like more information about our research, or would like to speak to a member of the study team, please reply to this email or contact XXXXX.

Thank you,

XXXX
<<insert staff title>>
Northwestern University

XXX
Principal Investigator, <<insert rank>> at Northwestern University