Penn
University of Pennsylvania
Human Research Protections Program

Recruiting Human Research Subjects: Guidance and Requirements

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Introduction

The Institutional Review Board is responsible for reviewing study recruitment plan procedures and materials to ensure protection of the rights and welfare of human subjects and equitable subject selection into research [21 CFR 56.107(a), 56.111(a)(3)]. *Any method of advertisement must be approved by the IRB before it is used with human subjects*. All advertisements must comply with informed consent and subject selection regulations pursuant to 21 CFR 50.20, 50.25, and 56.11(a)(3) as well as the institutional policy described in this document.

Recruitment Plan Content Guidance

A plan for identifying and recruiting participants should be outlined for the IRB's review and approval. A general recruitment plan may be outlined in a multi-site protocol. However, when the local site is involved in recruitment, the general plan may be insufficient. In these cases, a supplemental recruitment plan is needed to specify and outline what will happen at the local site.

The protocol or the application should clearly note the following:

- **How** participants will be identified;
- **Who** at the local site will approach potential participants;
- **What** information will be presented to potential participants (i.e., use of any recruitment materials) prior to beginning the consent process;
- **When** recruitment will happen (i.e., context);
- **Where** recruitment will happen (i.e., setting);

The recruitment plan should ensure equitable subject selection, minimize undue influence or coercion to participate, and maintain potential participants privacy and confidentiality. In alignment with equitability, research teams should also assess how their recruitment plan will allow them to obtain a diverse and representative sample.

Methods of recruitment should be outlined in the recruitment plan. Methods may include one or more of the following methods:

- Direct potential participant approach (e.g., in-person visit)
- Phone calls ('cold calls')
- Direct messaging
- Social Media
- Advertising / Marketing

When direct messaging is used, **potential participants must be given an explanation on how to opt out.** Recruitment plans should **specify the number of messages**, mailings, emails, etc. that will be sent to potential participants **within the recruitment plan.**

Recruitment Material Content Guidance

Recruitment materials must be submitted prior to their implementation to the IRB for review. This may be done with the initial protocol submission, or as an amendment for review through an expedited mechanism.

Below are types of recruitment materials the IRB would expect to be submitted for IRB review and approval.

- Recruitment phone scripts
- 'Dear Physician' letters
- Direct messaging such as messages to patients via My Penn Medicine (MPM) portal
- Emails or letters
- Interactions via Social Media direct messages or posts
- Non-interactive posts or advertisements on social media accounts
- Flyers / brochures / posters
- Text or script of paid advertisements such as newspapers, magazines, tv, radio, Craigslist, public transit, billboards, You tube, etc.
- Text from any internet postings such as department/Center website
- Publicized Research Participant Interview Script, if used for recruitment purposes (e.g., CureTalks)

NOTE: Penn Medicine does not allow texting for *recruitment* of patients. It is not HIPAA secure. If an exception is being requested, it may not be used as first line choice for recruitment AND rationale for its use must be included in the IRB application or standalone protocol.

Email is also not recommended for direct patient contact as it is not HIPAA secure. My Penn Medicine is the preferred direct message medium for recruiting participants.

As technology evolves, this list may become incomplete. If in doubt, please reach out to the IRB to determine whether submission is required. Postings on federally maintained sites such as clinicaltrials.gov do not need prior IRB approval.

Recruitment materials must not be coercive, must not promise a possibility of benefit beyond what is outlined in the consent and the protocol, must portray accurate information, and must direct potential subjects to personnel approved to conduct recruitment for further information. This is particularly important when a study involves subjects who may be vulnerable to undue influence. [21 CFR 50.20, 50.25, 56.111(a)(3), 56.111(b) and 812.20(b)(11).]

Recruitment materials should include the following information:

- Name of the institution, center/department, and PI conducting the research
- The word "research"
- Condition/ topic being studied and brief description of the purpose of the research
- A brief list of the major research procedures involved
- A brief summary of the eligibility criteria
- A statement of the approximate time commitment required, if appropriate
- A brief description of the compensation/reimbursement,
- Contact for further information, with telephone number or **Penn** email address

If the material involves direct messaging (e.g., email, MPM message, letter, etc.)

- ***Information on how to opt-out***
- How the potential participant was identified for potential participation

Recruitment materials should NOT include:

- ***Protected Health Information (PHI) when utilizing direct messaging outside of the patient medical record* (e.g., emails and letters to patients).** Email address, physical address, and name are considered HIPAA identifiers. Hence, a statement such as, "We are contacting you because you have a diagnosis of lupus and may be eligible for a research study" constitutes PHI when accompanied by name, address, or email address.
- Exculpatory language such as "you give up rights to…"
- Any language that would contribute to therapeutic misconception (research subject's belief that enrolling in study will contribute to direct therapeutic benefit) for example: the use of the words "new treatment," "new medication," or "new drug."
- Claims about the efficacy, safety, or superiority of investigational agents, or the security of confidential information
- Enticing or inducing terms such as "free," "new," "exciting," "opportunity," "limited

opportunity," "you deserve to feel better."
- A promise of free treatment when the intent is that participants will not be charged for taking part in the research.
- Inducing phrases such as "limited enrollment," "call today" or "study ends soon"
- Overemphasis on compensation but should not emphasize the payment or the amount to be paid by such means as larger or **bold type**. If the payments will be prorated, the ad should make this clear. For example, instead of stating, "$300 compensation," the ad should state that subjects will receive $50 for each of six completed visits.
- Compensation for participation in a trial offered by the sponsor to involve a coupon for a discount on the purchase price of the product once it has been approved for marketing.
- Links to sites/resources that are not IRB approved.

Penn Medicine Requirements for Direct Recruitment of Patients

Contacting patients for recruitment purposes is permissible under the federal HIPAA regulations and is described in the Notice of Privacy Practices (NPP) that Penn Medicine patients acknowledge before clinical care is delivered.

It is standard practice for clinical and research teams within Penn Medicine to communicate with patients in various ways including, but not limited to; via patient portal (MPM) messages mobile health devices, by phone, electronic surveys, in person at the time of in-clinic visits or hospital admissions, or indirectly via a clinician in another practice or specialty.

Regarding contact for research recruitment, the IRB may seek advice and guidance from other PSOM central support offices, such as the Office of Clinical Research (OCR) and the Office of Audit Compliance and Privacy (OACP), when assessing feasibility, appropriateness and privacy considerations.

When investigators are writing their recruitment plan in their protocol, they must describe the eligibility characteristics of the study population, along with where, when, and how the participants will be recruited. This ensures that an assessment by both the investigator and the IRB can be done that will ensure recruitment practices are ethical, equitable, and minimally intrusive.

Penn Medicine guiding principles for engagement with patients directly for research participation must be routinely practiced and include the following:
- Consider the optimal population to target those who are most likely interested in participation while ***minimizing the number of unsolicited contacts.***
- Consider the sensitivity of the patient data being accessed to conduct the study and the patient population being recruited. For example, ***a research team should not contact a patient directly for studies involving mental health***

information, HIV status, infertility, genetic information, substance abuse.

- **Consider using**, whenever possible, **more secure modes of contact or recruitment** such as MPM messaging, best practice advisory alerts, and volunteer registries ***where consent to contact has already be obtained.***
- Consider if it is important for the health and welfare of the patient that their care provider is involved.
- **In some studies, the patient's provider should be contacted in advance of outreach to the patient** and /or should communicate clinically relevant information during study execution.
- Provider contact may not be necessary in minimal risk studies, for example studies in which phone calls or MPM messaging would not be unexpected (sleep study, smoking cessation study in otherwise healthy population).
- Provider contact may also not be necessary or practical in certain studies, for example a study seeking patients with eczema where the patients might be under the care of several providers

- **Do not reach out to patients who have opted out of being contacted for research studies.** The DAC will not provide patient information for those patients who have opted out. **It is important for teams to not maintain their own lists of eligible patients since someone may opt out at any time. If you are unsure if someone has opted out you may check the FYI flag in their PennChart record or consult with the Office of Clinical Research (OCR).**

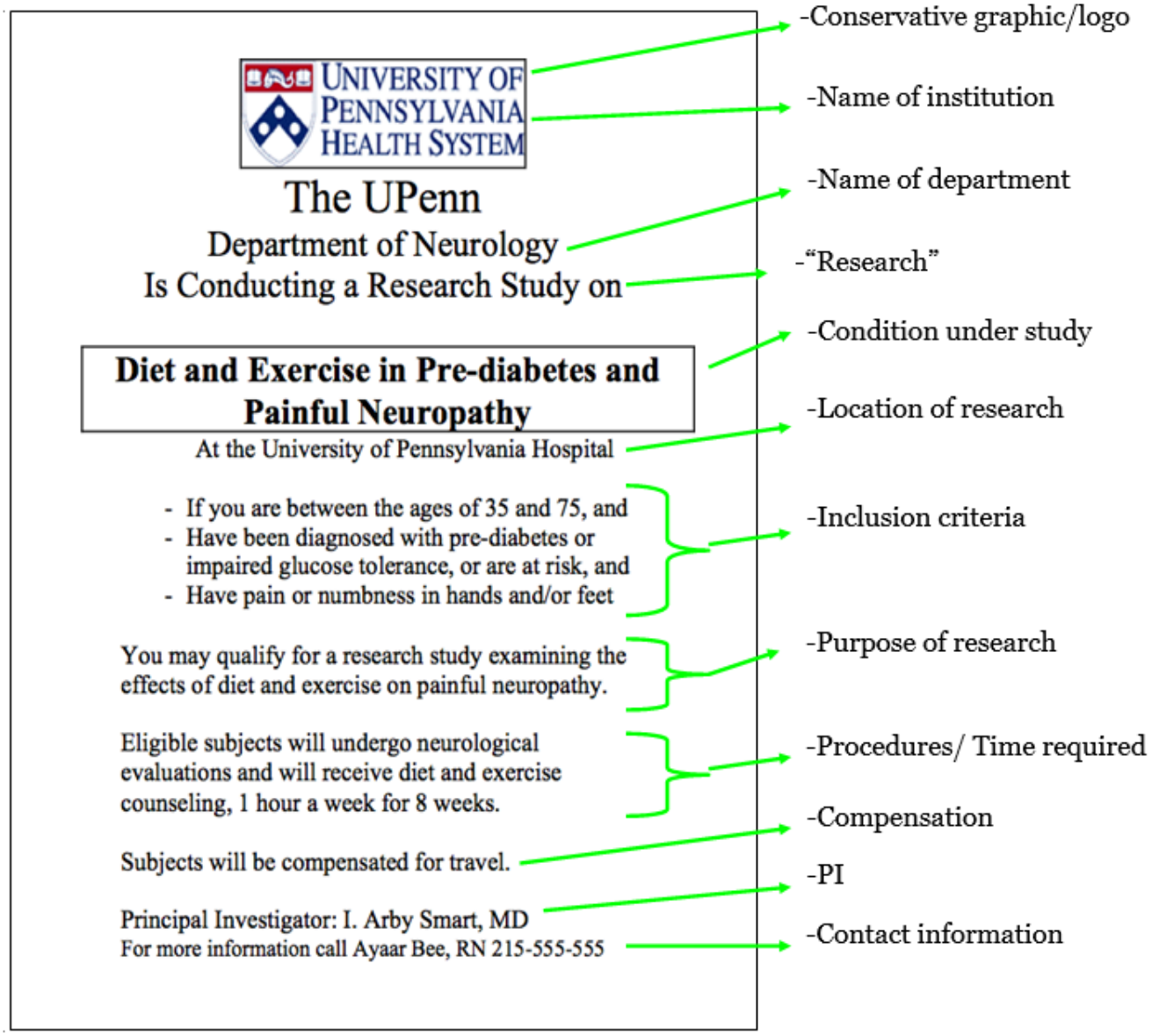
- **Inform patients of how they were identified and provide the ability to opt out of future research contact or create a volunteer profile.**

Penn Medicine Resources and Guidance

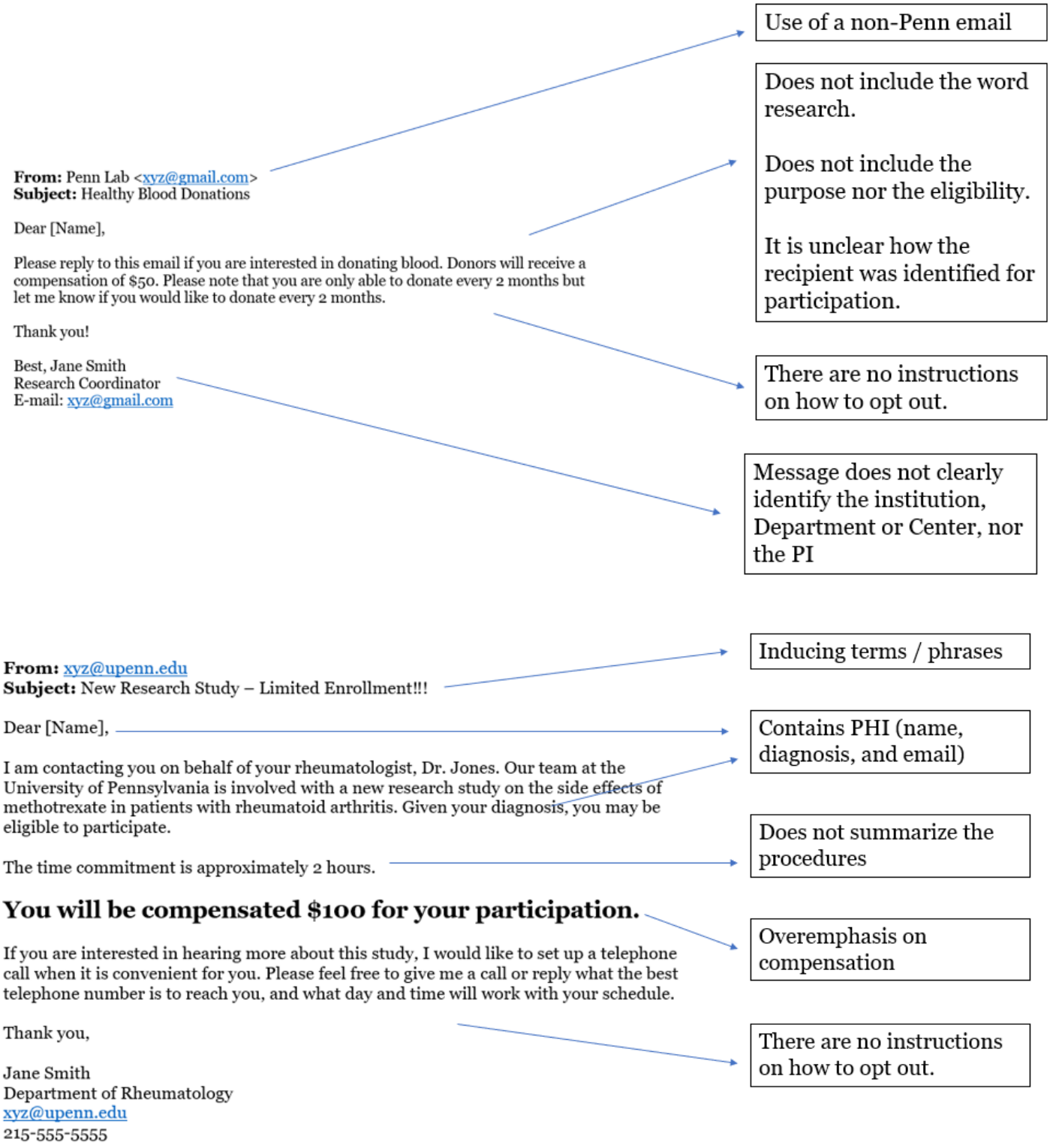
- **Email Guidance**: Avoid and Minimize PHI in Email and Use of Email During the Conduct of Research
- **Text Messaging Guidance**: Penn Medicine Guidance for Text Messaging and Research
- **Office of Clinical Research Templates:** www.med.upenn.edu/ocr/secure/forms-tools-templates.html
- **Penn Manual Advertising Options:** www.med.upenn.edu/pennmanual/secure/advertising-venues.html
- **Social Media Tips**: www.med.upenn.edu/ocr/social-media
- **Telemedicine Guidance:** www.med.upenn.edu/ocr/faq.html

Sample Recruitment Materials

Example of an Acceptable Flyer



Examples of Unacceptable Direct Messages



Acceptable Direct Message

RE: Research Study Opportunity

Greetings,

Dr. Jones and the Department of Rheumatology at the University of Pennsylvania is conducting a research study on the side effects of methotrexate. You may be eligible to participate if you have taken methotrexate within the past 6 months and suffer from chronic pain.

Study participation involves a brief research interview, a blood draw, and an MRI scan. Total duration of participation should be approximately 2 hours. Compensation of $100 is offered.

If you are interested in hearing more about this study, I would like to set up a telephone call with you to determine if you are eligible to participate. Please feel free to give me a call or reply what the best telephone number is to reach you, and what day and time will work with your schedule.

Note: If you would prefer to not be contacted about this research or any research in the future, please reply and I will take care of that for you.

Thank you,

Jane Smith
Department of Rheumatology
xyz@upenn.edu
215-555-5555

Language is neutral and polite

Name and diagnosis are not used, but the potential participant is given some indication that this study is related to their condition. It also doesn't directly infer that they take methotrexate

Department, PI, and Institution are clear

Content aligns with IRB guidance and doesn't overemphasize compensation.

Patients are told how to opt out