



**INSTITUTIONAL REVIEW BOARD
Guidance and Requirements for
Recruitment Letters and Emails for
Potential Human Subjects Identified
from Electronic Health Records**

When recruiting human subjects identified from electronic health records, investigators must consider the perspectives of the people being recruited. Potential participants will have many questions, including the following:

- Why were they recruited? Does the recruitment reflect or imply an identified health condition? Has the invitation invaded their privacy?
- Who are the people contacting me? What is their relationship to USC and their health care providers? Who authorized their recruitment activity?
- What are the consequences of participation in a study for themselves?
- How was their information obtained? What is the relationship between being a patient in an academic medical center and being contacted as a potential participant in a clinical study?
- Where is the information saved? Is it saved in a secure server?

A high-quality recruitment letter or email should provide accurate information to give potential participants confidence that their recruitment was ethical and appropriate and give them information to guide their decision as to whether to respond to the invitation. It also should not alarm them or create concerns. Therefore, the content, tone, and format of the recruitment letter/email/telephone script are all important considerations.

Letter/Email/Phone Script Content

Letters, emails, and where appropriate, phone scripts should contain the information below.

Sections shown in bold are essential.

1. Appropriate salutation (e.g., Dear X).
2. **Identify both who is responsible for the study, along with the unit of the university where that person is employed** (e.g., “On behalf of Keck Medicine of USC...”). **The person responsible must be a USC faculty member and must sign the invitation letter or email.**
 - a. If the study is conducted by students (under required faculty supervision), the invitations must communicate the relationship of the study to the degree process (e.g., “This survey is a component of the doctoral dissertation of USC student, NAME OF STUDENT, who is conducting this study under the supervision of faculty member NAME OF FACULTY MEMBER at the University of Southern California.”).

- b. If the patient’s clinician is a collaborator on the study, name the collaborator, as this may affect potential participants’ interest in the study. Consider working with clinicians so that potential participants are familiar with an investigator on the study.
 - c. **Explain why you are reaching out to the potential participant** (e.g., “We would like to tell you about [our study], underway here at USC.”).
 - d. **Provide a general explanation of the purpose of the research or the condition under study** (e.g., “We want to learn about the way our differences might affect our health) and how the study’s purpose explains the invitation to participate (e.g., “That is why we are inviting you to participate in this study.”).
- 3. Do not disclose the potential participant’s personal health or sensitive information, and do not suggest or imply that this person has a health condition.**
- a. This can be worded in a generic manner. For example, “This letter does not contain information related to sensitive personal health information and does not imply that you have a health condition.”
4. **Explain that participation is voluntary.** Consider including instructions on how to opt out of any future contact about the study and be certain to follow through if offered.
5. Clearly state the eligibility criteria.
- a. May include general information such as age range or gender but not too detailed to avoid implying or indicating a medical condition.
6. Explain what participants will be asked to do as a part of participation (e.g., “You will be asked to ...”), how much time is required or other commitments that will be necessary.
7. Explain if compensation is being offered and the amount and form of the compensation (e.g., “\$25 gift card and parking validation for the study visit”). Note the compensation cannot stand out from the surrounding font.
8. Provide the location and address of the research.
9. **Identify the person or way to find out further information using a USC email address or site whenever possible** (e.g., “For more information contact [name and telephone number]” or “If you would like to learn more, visit [link] or read about us [link]!”).
10. Thank the recipient (e.g., “Thank you for being one in a million. The future of health begins with you.”).
- 11. Provide the name and contact information of the principal investigator.**

Tone

Just as important as the content of your recruitment letter/email/phone script is the tone and the format. Be sure that you strike a tone that is respectful and inviting. Similarly, you should

consider whether the recipients will be surprised to receive a letter/email/phone call that identifies them by name (if that is the case), especially if they have not knowingly volunteered their names and contact information for research solicitation purposes. You should also ensure that you are culturally responsive both in tone and content. In other words, consider whether there are different cultural expectations on the part of the recipient and if those different expectations have implications for tone, format, or content. You should also consider the readability of the letter/email or academic language in the phone script. Consider that 43% of adults in the US have “basic” or “below basic” literacy skills and texts directed at this portion of the population should be written at the 6th grade level or lower. For the general public, an 8th grade level of text is appropriate.

Formatting

- 1. Use appropriate letterhead (if sending a letter).**
- 2. Use an official USC email address** (<https://policy.usc.edu/employee-email/> requires that employees use USC email exclusively to conduct official university business).
- 3. Never send information about others who are being invited to participate in a recruitment letter. Make sure the communication goes only to the intended recipient. It is never acceptable to list multiple email addresses in the “to” or “cc” fields to recruit.**
4. For clarity, spell out all acronyms in first use (e.g., University of Southern California (USC)).
5. Format the document consistently, using the same font, space breaks between paragraphs, etc. throughout.
6. Be careful about grammar, formatting, and email addresses. Poor grammar, unusual formatting, and non-USC email addresses (not permitted) may create suspicions about the authenticity of the email.
7. Make sure that the text is culturally appropriate, written at an appropriate grade level, and if appropriate, translated into a language other than English based on the target population.
8. Consider whether your recipient might be surprised to receive a letter/email or phone call directed at them. If you believe that someone will be surprised, take that into consideration as you draft your message (in terms of tone and content).

IRB Role in Reviewing Letters

Recruitment letters/emails are reviewed by the IRB for expedited and full board studies, but not for exempt studies. It is incumbent on every PI, and especially PIs of exempt studies, to ensure that recruitment letters/emails abide by these guidelines to ensure ethical practices, and to align

with the Belmont Report and Federal Regulations. Misleading letters/emails or phone scripts may lead to a reportable event and risk study activities (e.g., your study may be suspended).

If you have questions about your recruitment materials, feel free to reach out to OPRS at oprs@usc.edu. You may also reach out to CTSI at ctsi@usc.edu or (323) 442-2872.