

VCU IRB Guidelines and Best Practices for Researchers and IRB Staff for Cold Call Phone Recruitment

1. Introduction and Types of Phone Recruitment

The purpose of this document is to offer guidance to investigators and research staff regarding the use of phone recruitment procedures for research projects. The term “phone recruitment” encompasses all recruitment procedures that happen via telephone. Common types of phone recruitment include “cold calling” as well as returning phone calls that were initiated by potential participants. This guidance will only address cold calling methods of phone recruitment.

In general, the VCU IRB (along with most other institutions: [McHugh 2018](#)) discourages any use of cold calling as a recruitment strategy. Due to their potentially vulnerable nature, the VCU IRB is very unlikely to approve cold calling children (individuals under 18 who are not emancipated) and decisionally-impaired adults.

Other methods of recruitment have concerns and considerations as well, but this guidance is specific to cold calling. This guidance is not trying to prevent people from being approached by researchers; it is intended to give guidelines about when and how it can be done well. It will help investigators select the recruitment methods that are both effective and respectful.

2. Definition of “cold calling”

“Cold calling” is defined by the VCU IRB as the act of researchers calling potential participants on the phone without providing them with prior information about the study before contact. Prior information could include letters mailed, emails, or other information provided from someone they already have a relationship with.

When cold calling individuals, it is likely the first time the person will have heard about the study. This makes cold calling different from a “warm call” where there is prior permission given for a researcher to contact a potential participant or a prior relationship in another setting with the researcher. It is also different from a registry/repository calling their participants to let them know of another research opportunity.

3. Reasons why cold calling is discouraged by the VCU IRB

Privacy Concerns

People are more likely to perceive cold calls as an invasion of their privacy (46.111 #7) than with other methods of recruitment. Such unsolicited calls raise questions about what other private information the researcher was able to access without the knowledge or permission of the individual, and this could undermine the trust individuals and

communities have in research, the investigators and institutions. The study staff will need to be prepared to honestly explain how they got the phone number and to respect requests for the study to not call again or to destroy contact information/data.

The granting of a partial waiver of HIPAA authorization to obtain contact information from health records does not eliminate these privacy concerns because this waiver does not mean that the potential participant would necessarily agree with the release of their information. The IRB/HIPAA Privacy Board only grants partial waivers when there are no other practicable methods to obtain contact information and when there are only minimal risks (not that there are no risks) to privacy. The privacy risks still exist, and proper, respectful recruitment methods (such as those outlined in this guidance) must still be used to minimize the risks as much as possible.

Phone calls “enter” the person’s home or personal life, and may be perceived as disrupting their right to have their private life. They will not know it is a researcher when they answer the phone since they will receive a call “out of the blue”. People have more control over their interactions with other methods of recruitment because they are more likely to know the researcher in another relationship/context or they will be able to know in advance that they will be speaking to a researcher.

Risks and Discomforts

Cold calling is also discouraged by the IRB because the operational procedures for placing the call, when not done well, can increase the probability and magnitude of discomfort to the potential participant (46.111 #1). Calling someone about research on a sensitive topic (e.g. sexual health, substance use, mental health, etc.) could be embarrassing to them if it is not done with the utmost tact and respect. Similarly, information in a voicemail might violate a person’s privacy and damage relationships if someone else were to hear the message.

The phone number the researcher uses to place the call may mislead and potentially irritate people or create undue anxiety. For example, people might become concerned when receiving an unexpected call placed from a VCU Health phone, thinking it is from the hospital, the Emergency Department, their doctor, or other person or office in the hospital that they might be expecting or need to interact with.

Some people will get upset about being contacted for research, no matter what methods of contact are used. However cold-calling increases the probability of this happening.

VCU has about 2,000 to 3,000 active research studies, and if multiple studies were to be using cold calling methods to the same people, this could make people feel confused, harassed or coerced. It might erode the public trust in VCU. Websites are more effective ways to inform people of all potential research opportunities so that they can have the time and space to choose among all their options.

Bias and equitable subject selection

Finally, cold calling may introduce bias into the research sample, which compromises the scientific integrity and scientific benefit of the study ([45 CFR 46.111 #1 & 2](#)).

Although cold calling may make it easier to target a specific population, subject selection becomes less equitable because of the bias in the sampling ([46.111 #3](#)). All recruitment strategies have limitations and potential bias, but phone recruitment in particular is known to be heavily biased toward older, retired, white people.

There may be bias introduced through the following factors, including but not limited to:

- a. Populations who own a phone vs those who do not. Those who have a phone (landline or cell) have the resources to pay monthly bills, while lower income and transient populations would be less reachable.
- b. Populations who might be more likely to answer unsolicited phone calls (older people, older phones without caller ID, etc.) vs those who might not answer calls as readily. Although phone calls may be faster to do, the response rates are known to be lower than mailed solicitation.
- c. Populations called on a landline phone number vs. a cell phone number. Some localized exceptions may exist in rural areas without good cell service, but rural areas are generally older and whiter.
- d. Populations whose phone might be answered by someone else vs. those who are more likely to answer their own phone. There may be gender, age, language, or cultural factors that contribute to who answers the phone and is willing to interact with the researcher.

4. When cold calling should or shouldn't be used

Cold-calling, without any prior attempt at other research methods or a "warm handoff", is rarely justifiable due the reasons outlined above. Cold-calling should not be used to avoid inconvenience or expense of other forms of communication, and it should not be used simply because contact information is available from another professional context.

To create a "warm handoff", an emailed or mailed flyer/letter should be sent well in advance of the initial phone call. Best practices for this procedure are as follows:

- e. Send a flyer/letter from the individual's physician, someone who has a current relationship with the individual, or other steward/gate keeper of the data to inform the individual of the research opportunity and better prepare them to expect a phone call from researchers.
- f. The flyer/letter should let people know that researchers will be attempting to call them, and should contain instructions for how to opt out of the research prior to receiving the phone call from researchers.
- g. Potential participants should be provided an adequate amount of time to receive and respond to the opt out instructions.
- h. The flyer/letter may need to be written in a vague manner as to not disclose any private or sensitive information about the individual. The flyer/letter should not

disclose information related to the individual's care or services that are provided by the organization as this could disclose Protected Health Information.

Cold-calling should only be considered in very specific situations where researchers can justify not attempting other methods of recruitment. For example, there may be pressing time limitations that preclude more passive initial efforts, such as mailing letters or posting flyers. There may be circumstances where it is more respectful to contact potential subjects by phone during a less stressful or fraught time, and there is not time to send a letter or email first. Another example may be situations where the population is very difficult to reach, there are no other viable means to reach them, and contact information is publicly available.

5. Best practices and guidelines

- a. Create a script for staff who will perform the calls and ensure staff will be prepared to explain how the researchers obtained the individual's contact information.
 - i. Also consider preparing FAQ's so that staff will be prepared with appropriate responses to anticipated questions.
 - ii. Anticipate who could answer the phone and plan whether the study team will identify themselves before or after confirming that they are speaking with the intended individual.
 - iii. Develop a process for verifying the identity and/or age of the potential participant so that only adults are being contacted.
 - iv. Research is not telemarketing, and there should not be a goal of keeping people on the phone to convince them to participate.
- b. Specify how many calls/attempts will be made and the time between the calls so that the process remains respectful of the individuals. The following guidelines are generally acceptable:
 - i. Average number of attempts may be 4-6 calls, and no more than 10 total unless otherwise justified.
 - ii. No more than once per day. Generally, every other day is more acceptable.
 - iii. Attempts to contact a single individual should span a time period of no longer than 4 weeks. This could be negotiated with the IRB depending on the calling frequency.
- c. The research team should keep good documentation in the study files of what occurred during the calls, and it is recommended that a log be used to record specific details about individual phone calls. For instance:
 - i. Track the schedule and frequency of calls to each individual to ensure compliance with the approved protocol, and avoid over-calling the same individual(s).
 - ii. Develop a process that allows people to opt out of further phone calls for the current research study.

- iii. Track and abide by refusals and opt-out requests.
- iv. The research team must track all complaints about calls and report participant complaints at the time of IRB continuing review.
- d. Some research teams may need to think about having safety procedures for study staff. While many safety procedures that apply to research staff are not necessarily within IRB purview, the IRB is aware of rare situations where problems have been encountered.
 - i. Consider how you would handle a situation where someone aggressively calls back or tries to track down the researcher's location.
 - ii. Consider if the study staff should refrain from using their full name when performing calls and from using personal phone numbers to contact potential participants.
 - iii. Some research personnel who are making the phone calls may wish to use pseudonyms, as an additional protection for their identity. This should be explained in the IRB submission, and researchers would need to make sure not to choose the name of another individual who may be employed with VCU.

6. How the IRB will review proposals for cold calling

The VCU IRB will review the use of phone recruitment procedures with particular attention to considerations for privacy and confidentiality within the context of the study. In addition, the VCU IRB will consider the impact of phone recruitment on the equitability of subject selection. Given concerns about the representativeness of phone recruitment samples, the VCU IRB must determine if proposed phone recruitment strategies will inappropriately target or exclude certain populations. Finally, the VCU IRB will also take into consideration whether consent or HIPAA authorization is required for any given phone recruitment strategy.

7. Template Scripts from Other Universities

Purdue University's guidelines:

[https://www.irb.purdue.edu/docs/Guidance Recruitment of Human Participants.pdf](https://www.irb.purdue.edu/docs/Guidance%20Recruitment%20of%20Human%20Participants.pdf)

UCSF's script: <https://irb.ucsf.edu/recruitment>

OSU's script: <https://rcs.uoregon.edu/content/sample-recruitment-and-consent-materials>

UMBC's script: <https://research.umbc.edu/telephone-recruitment-screening-scripts/>

UVA's scripts: <https://research.virginia.edu/irb-hsr/advertising-human-research-study-subjects>

8. References

[Boise State University's Guidelines for Investigators Using Snowball Sampling Recruitment Methods](#)

Personal communication from Jim Ellis, Director of Design and Methodology, Survey and Evaluation Research Laboratory, Virginia Commonwealth University (5/11/2020)

McHugh, K. R., Swamy, G. K., & Hernandez, A. F. (2018). Engaging patients throughout the health system: A landscape analysis of cold-call policies and recommendations for future policy change. *Journal of clinical and translational science*, 2(6), 384–392.
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