

Calling potential VA subjects without first sending a notification in person or through mail or email for the purpose of VA research recruitment is NOT permitted outside of this ORD approval process unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study as per VHA Office of Research and Development (ORD) policy in VHA Directive 1200.05, Requirements for the Protection of Human Subjects in Research.

The acting Under Secretary of Health (USH) signed a policy memorandum on June 29, 2021 allowing for the proactive calling of VA subjects, sometimes referred to as “cold calling”, as a recruitment strategy for VA human subject research studies using an ORD approval process. Any request for proactive calling for subject recruitment in a VA study **must be submitted and approved through this ORD process**. ORD approvals are specific to the individual research study submitted with the request.

Criteria

Specific criteria must be met as evaluated by ORD for approval to a VA study requesting proactive calling. **The following criteria must be met** with all questions addressed in the application. **Have all the information ready prior to beginning the application process.**

1. The research must be an exempt or non-exempt study.
2. The research must involve an intervention or interaction impacting the prevention or treatment of a disease or condition.
3. The application must include justification of why proactive calling must be used instead of using in person or mail notifications as the initial contact. Please include in the justification time-sensitivity associated with recruitment if applicable.

Additional Information

A common misconception regarding the current ORD policy is that the potential VA subject has to “opt in” to receive a telephone call after a letter or email is sent. A reviewing IRB may require “opt in” as an IRB requirement per the IRB policies and procedures, but it is not an ORD national policy requirement. However, if the reviewing IRB requires an “opt in”, the reviewing IRB policy applies because it is not in conflict with ORD national policy. The reviewing IRB policy is more stringent. Please consider this and your reviewing IRB policy, as you decide whether to apply for this permission.

Submission of a request for ORD approval of proactive calling for a VA study does not equate to ORD approval. ORD’s approval process for proactive calling for VA subject recruitment does not replace all other required research regulatory committee approvals specific to the study,

4. The research must describe a verification process for how the disease or condition is verified prior to proactively calling the potential subject.
5. The research must describe:
 - a. how the potential subject's primary clinical care team will be contacted prior to the proactive call for study recruitment, or
 - b. a justification of why the primary clinical care team will not be contacted until after the potential subject has received a proactive call for study recruitment.
6. The application must include:
 - a. confirmation that calls made by the VA study team are from a non-blocked, VHA number,
 - b. confirmation that a copy of the script used for contacting the subject will be submitted to the IRB of Record for the study, and
7. The approximate number of calls over the described time period for each potential subject.
8. The application must describe how the telephone numbers will be obtained (e.g., source).
9. If the study proposes to leave a message on the potential subject's phone:
 - a. confirmation that a script of the proposed message will be submitted for review to the IRB of Record for the study,
 - b. confirmation that any message left on the potential subject's phone will not include Protected Health Information (PHI).

including IRB and Research & Development (R&D) Committee approval.

Application Submission Instructions

To submit a request for proactive calling for a VA study, please **complete all fields** in the request application located **below**.

Once the request is submitted, it will be reviewed by ORD. ORD's evaluation of the request will be sent electronically to the requester and the VA Facility's ACOS/R&D. Expected ORD evaluation time from receipt of application to written communication of the evaluation is 5 to 10 business days.

A copy of the ORD final evaluation (approval or disapproval) must be kept with the VA Principal Investigator's study file.

If further information is needed, contact ORD at vhacoordregulatory@va.gov with the term "Proactive Calling" in the subject line.

To make a new request, click on the "+New" button under the sub header "Recruitment Request".

To make an edit/update to a previous request, click on the "ID" number in the list below.

Recruitment Request



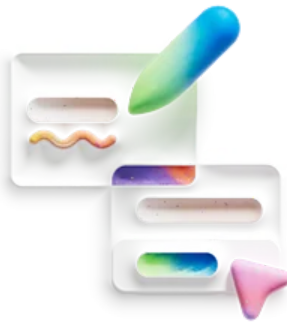
① ID

📎 Attachments

📅 Request Cr... ↓

👤 Created By

≡ Name of Study



Welcome to your new list

Select the New button to get started.