



MEMO

To: PREVENT Site Teams

From: Project PREVENT Coordinating Center
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Date: February 5, 2021

RE: Protocol Change – Replacement Procedures

Thank you for your hard work in running Project PREVENT. We have had a great start to enrollment. This memo details a protocol change that will impact all sites.

In the Manual of Procedures (MOP), sites are directed to replace control participants who are ineligible or decline participation (Section 4.0), but not those who do not respond to the invitation. **This memo details a change that will permit replacement of healthcare personnel (HCP) who do not respond to the invitation to participate.**

Which non-responsive HCP should be replaced?

Any HCP who does not respond to the recruitment invitation after (1) at least **7 days and** (2) at least **3 attempted contacts** may be replaced. Attempted contacts may be by e-mail, telephone, or alternative means, as approved at each site, and the method of contact should be selected to maximize response. Both criteria must be met to classify an invited participant as non-responsive and eligible for replacement.

What if a replaced participant responds after they have been replaced?

If an HCP is classified as non-responsive and another HCP is invited as a replacement, the invitation to participate for the first HCP is still active. If that person responds to the project team, he/she may still be enrolled.

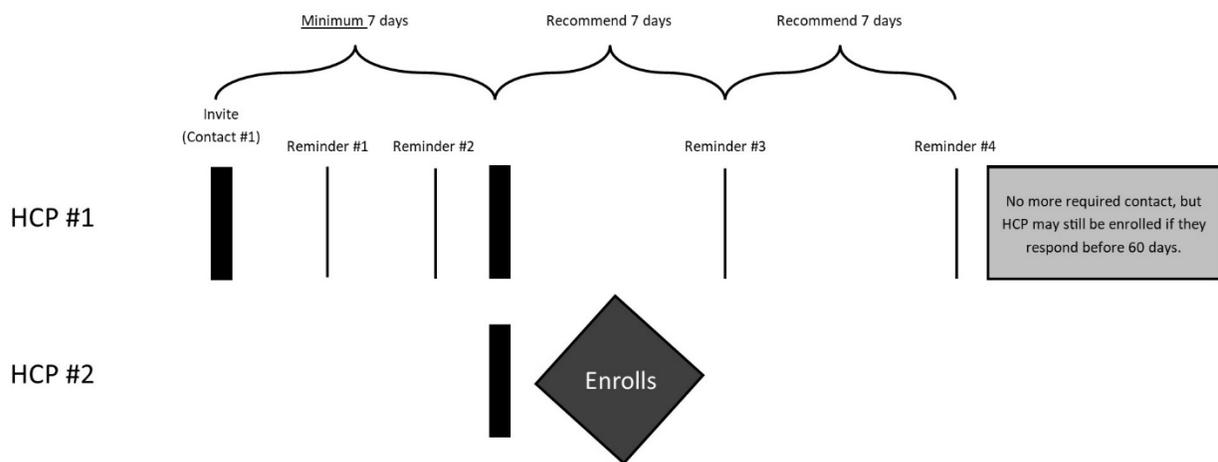
Should I replace a participant who responds after 7 days but before I invite a replacement?

No. If a participant is non-responsive after 7 days, but responds and agrees to participate before you invite a replacement, he/she should not be replaced.

Should I continue to contact replaced HCP?

Yes. Every HCP invited to participate should be contacted a minimum of 5 times. Even though you are permitted to replace that participant after 3 contacts in 7 days, you should continue to follow up for at least 2 more contacts. The schedule for ongoing contact is left to the discretion of sites, but we recommend 2 additional contacts at one-week intervals. This schedule is designed so that if a prospective participant were hospitalized (and, thus, could not respond), we can still permit enrollment after hospital discharge.

The following timeline summarizes contact points. Please note that each invited HCP (1) will have 5 attempted contacts, (2) will be replaced only after 3 contacts and 7 days, and (3) will have the opportunity respond and enroll within 60 days of the test *even if he/she has been replaced already*.



How do I indicate on my screening log that an HCP has been replaced?

Please include a column on your screening log to indicate that an invited HCP has been replaced. These data should be tracked at sites, but they need not be reported to the coordinating center.

Does this change apply to cases or just controls?

Since all cases are already being enrolled, this change only applies to control recruitment.

Should I go back and invite replacements for prior weeks?

Yes. This change takes effect immediately, and it should be applied retrospectively. Sites with non-responsive HCP from prior weeks should invite a replacement HCP selected from the week of the non-responsive HCP control.

This change will be incorporated into the next revision of the MOP. In the interim, please consider this memo as an addendum to the MOP.

Thank you for your hard work on PREVENT enrollment. Please contact the project team at emergencyidnet-prevent@uiowa.edu if you have questions.