



MEMO

To: PREVENT Site Teams

From: Project PREVENT Coordinating Center
Nick Mohr, MD
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Date: March 16, 2021

RE: Protocol Change – Replacement of participants who do not complete baseline survey

This memo details a change that will permit replacement of consented participants who do not complete their baseline survey within 7 days.

Which consented HCP should be replaced?

Any HCP who does not complete their baseline survey after (1) at least **7 days and** (2) at least **3 attempted contacts** may be replaced. The REDCap system automatically sends the participant 2 follow-up reminder emails at day 2 and day 4 after they consent to participate if they haven't completed the baseline survey. These count as 2 of the 3 attempted contacts, so the site team will make the 3rd contact attempt preferably using alternative means, such as by text or telephone to maximize response. Both criteria must be met to classify a participant as non-responsive and eligible for replacement.

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

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

Should I replace 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 participants?

Yes, your site should continue to follow your site-specific procedures for contacting consented participants who have not completed surveys.

How do I indicate in REDCap that a consented participant has been replaced?

You do not need to do anything to indicate you replaced them. The DCC will mark any consented participant who doesn't complete their baseline survey 60 days after their test date as "lost to follow-up."

Does this change apply to cases or just controls?

This change only applies to control enrollment, since there are no leftover cases.

Should I go back and invite replacements for prior weeks?

Yes. This change takes effect immediately, and it should be applied retrospectively. Sites with consented but non-responsive HCP from prior weeks should select and invite a replacement HCP from the same week that the non-responsive control participant was tested. Remember that we can only enroll HCP who were tested in the last 60 days, so those tested in early January no longer qualify.

What if I do not have any replacement HCP from that prior week that the non-responsive participant was tested?

Then you cannot replace, in this case. Do not replace with controls who were tested in other weeks. Keep trying the non-responsive participant!

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.