



Guidelines & Template Consent Language for Recontacting Participants Post-Study Completion

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Overview

MarkVCID sites are requested to obtain consent to recontact study participants for future studies. This will enable sites to contact and consent participants for additional follow up beyond the initial study period, and allow for the collection of extended longitudinal data and the assessment of long-term outcomes, should additional NIH funding be awarded.

For sites that do not already have participant consent to recontact, the Coordinating Center (CC) has provided sample language below that may be incorporated into the informed consent form (ICF). Once approved by the local IRB, the site must recontact each participant prior to their study completion and enter the participant's response into the data system.

Please send an updated and approved version of your ICF to Carissa Tuozzo (carissa.tuozzo@mgh.harvard.edu).

Informant interviews will remain an essential source of information for capturing participant cognitive and behavioral changes longitudinally. While many sites do not obtain formal consent from informants, some may need to obtain it in accordance with local policies. To accommodate this variation, the CC will include a field in the EDC to indicate whether informants consented to being recontacted (yes/no/not applicable). "Not applicable" should be selected only when local policy does not require consent for recontact or if the participant did not have an informant.

The example consent language provided below includes language related to informants. Please remove those references or develop separate consent language as needed to comply with your local requirements.

Once the participant and informant (if necessary) have been approached, please fill out the Consent for Future Contact Form in the MarkVCID Electronic Data Capturing System.

Template language

Permission to Be Recontacted After Study Completion

- 1) In this scenario, participants are not required to provide a separate response regarding recontact; their consent to the study includes permission to be recontacted.

Example Language

We may contact you and your informant(s) in the future to gather additional information or ask if you are interested in joining other research studies.

- 2) In this scenario, participants are given a choice within the consent document regarding recontact.

Example Language

You and your informant(s) may be contacted after the study ends to gather additional information, share study results, or invite you to participate in additional studies. You may withdraw this permission at any time by notifying the study team. We will only reach out to you through the methods you have allowed (e.g., phone, email, mail).

Please indicate your preference below:

- ☐ I agree to be contacted after the study ends.
- ☐ I do not agree to be contacted after the study ends.