



Template Protocol and Consent Language for Follow-Up Visit Completion After 36M

v. 5.20.26

Overview

MarkVCID sites are requested to obtain IRB approval and participant consent to conduct two follow-up visits over three years (54- and 72-months). These timepoints were proposed in the R01 application submitted by the Coordinating Center (CC) in February 2026. Across the consortium, 54-month visits are expected to begin in June 2026, with the last 72-month visit expected in July 2030.

The CC has provided sample language below that may be incorporated into the protocol and informed consent form (ICF), if sites do not already have the ability to conduct both proposed follow-up visits. Once approved by the local IRB, the site must re-consent each participant before conducting additional follow-up visit procedures with them.

Please send an updated and approved version of your ICF to [Carissa Tuozzo](#).

Template language

Study Protocol

Study participants will be asked to complete up to two additional follow-up visits over an extended two-year period. During each visit, participants may receive a clinical exam, cognitive testing, MRI scan including the Cerebrovascular Reactivity (CVR) task, and a blood draw.

Commented [CT1]: This language is intentionally broad to allow for flexibility.

Informed Consent Form

You will be asked to complete **two additional follow-up visits for this study**. Like your previous study visits, you will complete the same questionnaires, physical exams, cognitive testing, and blood tests. At the first additional follow-up visit, participants will be chosen at random to have an MRI scan with a breathing task (Cerebrovascular Reactivity). Having MRI scans in about half of participants gives the study team enough information to meet the goals of the study while reducing the number of study activities some participants complete. All participants will have an MRI scan with the breathing task at the second additional follow-up visit.

Commented [CT2]: IRB requirements for describing the follow-up period or number of visits vary across sites.

See the Overview section above for more information about the consortium-wide follow-up visit period or refer to your individual site's follow-up visit period as required by your IRB.

We will also contact your informant(s) to gather additional information about how you have been doing at each follow-up visit.