Research participants have the right to withdraw from participation in research at any time (45 CFR 46.116(a)(8)), either completely or partially.

If a study participant decides to completely withdraw from all aspects of a research study, the investigator must immediately discontinue all research-related activities for that participant, including all research-related interactions, interventions, and collection of participant study data or identifiable private information.[[1]](#footnote-1)

A participant may only withdraw from the primary intervention of a study, but still allow other research activities described in the IRB- approved protocol and informed consent document to continue, including obtaining participant data through interaction (e.g., follow- up interviews, physical exams, blood tests, or imaging) or obtaining identifiable private information from medical, educational, or social service records and/or providers.

|  |  |  |  |
| --- | --- | --- | --- |
| **Participant Initials:** |  | **Participant Number:** |  |
| **Type** | Withdrawal (by participant)1  Withdrawal (by investigator)1, [[2]](#footnote-2) | | |
| **Scope** | Complete Withdrawal: All study procedures/components  Partial Withdrawal: Primary intervention only (i.e., continued follow-up of associated clinical outcomes allowed)[[3]](#footnote-3) | | |
| **Reason[[4]](#footnote-4)** | Lost to follow-up (or cannot be located)  Refused further participation (or withdrew consent)  Concerned about risks  Experienced AE/SAE  PI withdrew, non-compliance  PI withdrew, safety concern  Study terminated/cancelled  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Additional Information** |  | | |
| **Staff Signature** |  | **Date** |  |

1. For clinical trials evaluating the safety of an intervention, the Investigator should express to the participant the importance of performing and obtaining follow-up safety assessments and data. [↑](#footnote-ref-1)
2. Investigator should explain to participants the reason(s) for withdrawal and, as appropriate, other treatment options. [↑](#footnote-ref-2)
3. Additional consent may be required for limited follow-up. [↑](#footnote-ref-3)
4. Reason(s) should be document *if known and/or provided by participant*. However, participants do not need to provide reason(s) for study withdrawal. [↑](#footnote-ref-4)