

Withdrawal of Consent Worksheet

Instructions: The study site completes the WOC Form to document participant and investigator-initiated study withdrawals. As addressed in the study consent, participants are free to withdraw from the study at any time. That said, the level of withdrawal a participant desires can vary, which may result in confusion regarding the participant's intention. Therefore, since there are various degrees of withdrawal, it is important to initiate a discussion and ask questions to determine (1) the degree of withdrawal the participant desires and (2) whether some level of contact can be agreed upon – such as an annual phone call or a call/letter at the end of the study to "check in with them and see how they are", allowing determination of vital status. This discussion will help the study team avoid having to make their own interpretation as to the participant's choices regarding study participation. **With this in mind, refusal of a study activity (biospecimen collection, imaging, etc.) should not be interpreted as refusal of all future study activities or withdrawal from the study.** Refusal of a study activity should be documented on a PR. Furthermore, the issue of withdrawal should not be confused with participants considered Non-responders, Lost, or Lost to Followup; withdrawal involves an active, explicit request by the participant. Documentation of the WOC conversation (participant letter, chart notes, etc..) will be required to be uploaded in the Rave form.

1. Date of Withdrawal _____ - _____ - _____ *MMM dd yyyy*

2. Reason for withdrawal (select all that apply):

- | | | |
|--|---|--|
| <input type="checkbox"/> Transportation Problems | <input type="checkbox"/> Concerned about medical costs responsibility | <input type="checkbox"/> Family responsibilities |
| <input type="checkbox"/> Concerned about privacy | <input type="checkbox"/> Concerned about health care effects | <input type="checkbox"/> Work demands |
| <input type="checkbox"/> Physical illness/cognitive impairment | <input type="checkbox"/> Participating in other research study | <input type="checkbox"/> Loss of interest in Study |
| <input type="checkbox"/> Out of area | <input type="checkbox"/> Dissatisfied with study | <input type="checkbox"/> No Reason Given |
| <input type="checkbox"/> Other, specify: _____ | | |

3. Level of Participant Withdraw (select only one (1, 2, or 3) , and then provide details in sub questions):

- (1) Participant elected to cease one or more study procedures

Indicate the level of withdrawal for each:

Biospecimen collection

- Participant did not withdraw consent for biospecimen collection
- Participant refuses upcoming biospecimen collection and would like to be contacted to decide on future collections
- Participant agrees to only partial biospecimen collection
- Participant refuses all future biospecimen collection

PFT

- Participant did not withdraw consent for PFT
- Participant refuses upcoming PFT and would like to be contacted to decide on future collections
- Participant refuses all future PFTs

CT Imaging

- Participant did not withdraw consent for CT Imaging exams
- Participant refuses upcoming CT Imaging exams and would like to be contacted to decide on future collections
- Participant refuses all future CT Imaging exams

- (2) Participant refuses further active study participation, but will allow continued vital and disease status collection

Indicate if contact is allowed for vital status:

- Yes
- No

If yes, indicate the timeframe:

- Yearly
- Other, specify: _____

- (3) Participant explicitly withdraws study consent/authorization

Signature of Site PI

_____ *mmm-dd-yyyy*
Date Form Completed