



INSTRUCTIONS FOR REASON FOR STUDY WITHDRAWAL FORM RSW, VERSION 2.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Reason for Study Withdrawal form is completed when a participant decides to withdraw from SPIROMICS or when a participant is deceased or when the lost to follow-up protocol has yielded a lost to follow-up withdrawal status.

Header Information: The header information consists of key fields which uniquely identify each recorded instance of a form. For the Event field, record if this is happening at Visit 5 or another event.

0a. Date of Collection: Record the date the data was collected or abstracted. Select the date from the pop-up calendar in the data management system (DMS) or type the date in the space provided. Dates should be entered in the mm/dd/yyyy format.

0b. Staff Code: Record the SPIROMICS staff code of the person who collected or abstracted the data. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SPIROMICS data, please contact the GIC in order to receive your own individual staff code.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

Item 1. **Note:** Question 1 has been removed.

Item 2. **Date of Study Withdrawal** Record the date the subject withdrew from the study. Select the date from the pop-up calendar in the data management system (DMS) or type the date in the space provided. Dates should be entered in the mm/dd/yyyy format.

Item 3. **Reason for Withdraw** Select only one option among the six possible choices.

- Select participant no longer wishes to participate; withdrawal of consent if the subject no longer wishes to participate and withdrew consent.
- Select participant is too sick to participate if the subject is too sick to participate.
- Select participant is lost to follow-up if the subject is lost to follow-up.
- Select participant died if the subject died.
- Select participant failed to complete baseline visit if the subject failed to complete baseline visit.
- Select other if none of the above answers fit the participant's reason to withdrawal from the study.
 - If other, specify in Item 3a.

Item 4. **Description of Reason for Study Withdrawal** Use the textbox provided to describe the reason for study withdrawal in detail. For participants who are withdrawn due to death, please include the date of death, if known, in the description.

Item 5. **Participant's Wishes Regarding Study Data Post Withdrawal** Select only one option among the four possible choices.

- Select no change, leave already collected data and specimens in repositories if the participant wishes no change and to leave already collected data and specimens in repositories.

- Select keep collected medical records data, but remove all specimens from repositories if the participant wishes to keep collected medical records data, but remove all specimens from repositories.
- Select participant is lost to follow-up if the subject is lost to follow-up.
- Select remove all data collected and remove all specimens from repositories if the subject wishes to remove all data collected and remove all specimens from repositories.

Save and close the form.