

INFORMED CONSENT CHANGES

ID NUMBER:									
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FORM CODE: **ICC**
 VERSION: **1.0 01/28/2025**

Event: _____

0a) Date of Change: / /

0b) Staff Code:

Instructions: This form should be completed when a participant indicates a change, at any point, in their initial response to specific items collected during initial informed consent via the Informed Consent Tracking (ITF) form.

Note: This form does not apply to a change in response to ITF item 1. If there is a change in response to ITF item 1, please enter the Reason for Study Withdrawal (RSW) form according to protocol.

1) Is the participant requesting a change to ITF item 2? *“Participant agrees to allow the collection, storage, use, and sharing of their data, images, and biospecimens, including DNA and RNA, with commercial entities (e.g., for profit organizations such as pharmaceutical companies), including those who are not working for the National Heart, Lung, and Blood Institute or on studies not funded by the institution, for research purposes.”*

No₀ → **Go to 2**
 Yes₁

1a) New response. Participant agrees to allow the collection, storage, use, and sharing of their data, images, and biospecimens, including DNA and RNA, with commercial entities (e.g., for profit organizations such as pharmaceutical companies), including those who are not working for the National Heart, Lung, and Blood Institute or on studies not funded by the institution, for research purposes.

No₀
 Yes₁

2) Is the participant requesting a change to ITF item 3? *“Participant agrees to allow important findings regarding their health from the SPIROMICS III study tests and examinations to be shared with their personal health care provider.”*

No₀ → **Go to 3**
 Yes₁

2a) New response. Participant agrees to allow important findings regarding their health from the SPIROMICS III study tests and examinations to be shared with their personal health care provider.

No₀
 Yes₁

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3) Is the participant requesting a change to ITF item 4? *“Participant agrees to allow the SPIROMICS III study team to contact them via unencrypted text messaging and/or email that may include personal and study related information such as results, reminders, prompts, and notifications.”*

No₀ → **Go to 4**

Yes₁

3a) New response. Participant agrees to allow the SPIROMICS III study team to contact them via unencrypted text messaging and/or email that may include personal and study related information such as results, reminders, prompts, and notifications.

No₀

Yes₁

3b) Please confirm. Changes were put in place, including updates in Mosio, to reflect the participant’s current wishes regarding being contacted via unencrypted text messaging and/or email that may include personal and study related information.

No₀ → **Please ensure appropriate changes are put in place**

Yes₁

4) Is the participant requesting a change to ITF item 5? *“Participant agrees to allow SPIROMICS study staff and investigators to contact them about participating in additional assessments, procedures, and studies in addition to the SPIROMICS studies.”*

No₀ → **Go to END**

Yes₁

4a) New response. Participant agrees to allow SPIROMICS study staff and investigators to contact them about participating in additional assessments, procedures, and studies in addition to the SPIROMICS studies.

No₀

Yes₁

END OF FORM