INSTRUCTIONS FOR CLINICALLY SIGNIFICANT FINDINGS FORM
CSF, VERSION 1.0, QUESTION BY QUESTION (QxQ)

I. GENERAL INSTRUCTIONS

The Clinically Significant Findings Form is filled out by the study coordinator out for findings that require more urgent follow-up and therefore would need to be communicated by phone or equivalent method to allow for close follow-up with the participant's healthcare team to evaluate these findings. If there are other relevant findings that need to be communicated to the participant less urgently and not included here and not deemed to require urgent follow-up, other methods of contact could be employed such as a letter or message, as deemed necessary by the site PI/ IRB.

This form is to be completed at Visit 5.

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. **Blood Abnormalities** Select only one option among the two possible choices.

- Select No if the subject does not have either or both of the listed blood abnormalities that requires immediate contact by phone or equivalent. [GO TO Q2]
- Select Yes if the subject does have either or both of the listed blood abnormalities that requires immediate contact by phone or equivalent.

Item 1a-b. **Blood Abnormalities.** If Yes to Item 1, check all blood abnormalities that apply.

Item 1c. **Contact with the subject.** Select only one option among the two possible choices.

- Select No if the site PI or other study staff did not make contact with the participant about these values and convey plans to provide a copy of abnormal values to participant and medical provider.

  Item 1c1 If No to 1c, specify in Item 1c1.

- Select Yes site PI or other study staff successfully made contact with the participant about these values and convey plans to provide a copy of abnormal values to participant and medical provider.

  Item 1c2 If Yes to 1c, record the date the participant was contacted. 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 2. Greyed out on paper form and fields disabled in CDART.

Item 3. **CT findings** Select only one option among the two possible choices.

- Select No if the subject does not have CT findings that require immediate contact by phone or equivalent. [GO TO Q4]
- Select Yes if the subject has CT findings that require immediate contact by phone or equivalent.

Item 3a-f. **CT findings.** If Yes to Item 3, check all CT findings that apply.

Item 3g. **Contact with the subject.** Select only one option among the two possible choices.

- Select No if the site PI or other study staff did not make contact with the participant about these values and convey plans to provide a copy of abnormal values to participant and medical provider.

Item 3g1 If No to 3g, specify in Item 3g1.

- Select Yes site PI or other study staff successfully made contact with the participant about these values and convey plans to provide a copy of abnormal values to participant and medical provider.

Item 3g2 If Yes to 3g, record the date the participant was contacted. 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 4. **Other findings.** Select only one option among the two possible choices.

- Select No if the subject does not have other findings that require immediate contact by phone or equivalent. [GO TO Q5]
- Select Yes if the subject has other findings that require immediate contact by phone or equivalent.

Item 4a. **Other findings.** If Yes to Item 4, list all other findings in Item 4a1-3.

Item 4b. **Contact with the subject.** Select only one option among the two possible choices.

- Select No if the site PI or other study staff did not make contact with the participant about these values and convey plans to provide a copy of abnormal values to participant and medical provider.

  Item 4b1 If No to 4b, specify in Item 4b1.

- Select Yes if the site PI or other study staff successfully made contact with the participant about these values and convey plans to provide a copy of abnormal values to participant and medical provider.

  Item 4b2 If Yes to 4b, record the date the participant was contacted. 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 5. **PI review and sign off.** Select only one option among the two possible choices.

- Select No if the PI did not review or sign off on the form.
- Select Yes if the PI reviewed and signed off on the form.

Item 5a-b **PI Signature and date:** If Yes to Item 5, enter the PI's electronic signature in Item 5a and the date in Item 5b.

Save and close the form.