INSTRUCTIONS FOR CANCER ABSTRACTION FORM - ENDPOINTS
CAF, VERSION 2.0 QUESTION BY QUESTION INSTRUCTIONS (QxQ)

I. GENERAL INSTRUCTIONS

Data collected on this form are derived from the medical records received.

Header Information: The header information consists of key fields which uniquely identify each recorded instance of a form.

0a. Date of Collection: Record the date the data was collected. 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. Reviewer Code: Record the SPIROMICS staff code of the person who collected 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

Please answer every question on this form.

A. GENERAL INFORMATION

Item 1. **Event Information:** Select only one option among the three possible choices.
- Select 'In hospital only' if the event was in the hospital only.
- Select 'Emergency Dept. visit only (ED) if the event was an ED visit only.
- Select 'Both ED and in hospital' if the event was both ED and in hospital.

Item 2. **Date of admission:** Enter the date of admission.

Item 3. **Date of discharge:** Enter the date of discharge.

Item 4. **Primary admitting diagnosis code:** Enter the primary admitting diagnosis code.

Item 5. **Primary discharge diagnosis code:** Enter the primary discharge diagnosis code.

B. CANCER OUTCOMES

Item 6. **Was there a primary cancer diagnosis:** Select only one option among the two possible choices.
- Select No if the participant has not been diagnosed with a primary cancer. [Go to Q13]
- Select Yes if the participant has been diagnosed with a primary cancer.

Item 7. **Date of diagnosis:** Enter the date of primary cancer diagnosis.

Item 8. **Type of cancer:** From the options provided, select only ONE type of cancer as the primary cancer diagnosis. (Please select ONLY one)

Item 8a. **Other type of cancer:** Please specify the primary cancer diagnosis if it was not an option in Item 8.

Item 9. **Tumor behavior:** Select only one option among the four possible choices.

- Select 'Invasive; malignant; infiltrating; micro-invasive' if the tumor behavior was invasive; malignant; infiltrating; micro-invasive.
- Select 'In situ; intraepithelial; non-infiltrating; non-invasive; intraductal' if the tumor behavior is in situ; intraepithelial; non-infiltrating; non-invasive; intraductal.
- Select 'Borderline malignancy; low malignant potential; uncertain if benign or malignant' if tumor behavior was borderline malignancy; low malignant potential; uncertain if benign or malignant.
- Select 'Unknown' if tumor behavior was unknown.

Item 10. **Diagnostic confirmation status:** Select only one option among the six possible choices. (Please select ONLY one. If more than one applies, select the **first and primary** applicable category.)

- Select 'Positive histology (pathology)' if the diagnostic confirmation status was positive histology (pathology).
- Select 'Positive cytology, no positive histology' if the diagnostic confirmation status was positive cytology, no positive histology.
- Select 'Positive histology (pathology), regional or distant metastatic site only' if the diagnostic confirmation status was positive histology (pathology), regional or distant metastatic site only.
- Select 'Positive microscopic confirmation, method not specified' if the diagnostic confirmation status was positive microscopic confirmation, method not specified.
- Select 'Clinical diagnosis only' if the diagnostic confirmation status was clinical diagnosis only.
- Select 'Unknown' if the diagnostic confirmation status was unknown.

Item 11. **Laterality:** Select only one option among the six possible choices. (Please select ONLY one)

- Select 'Not a paired site' if laterality was not a paired site.
- Select 'Right origin of primary' if laterality was right origin of primary.
- Select 'Left origin of primary' if laterality was left origin of primary.
- Select 'One side involved, right or left origin unspecified' if laterality was one side involved, right or left origin unspecified.
- Select 'Bilateral involvement, lateral origin unknown; stated to be a single primary' if laterality was bilateral involvement, lateral origin unknown; stated to be a single primary.
- Select 'Unknown' if laterality was unknown.

Item 12. **Summary stage:** Select only one option among the five possible choices. (Please select ONLY one)

- Select 'In situ' if the summary stage was in situ.
- Select 'Localized' if the summary stage was localized.
- Select 'Regional' if the summary stage was regional.
- Select 'Distant' if the summary stage was distant.
- Select 'Unknown' if the summary stage was unknown.

C. LUNG CANCER

Item 13. **Lung cancer diagnosis:** Select only one option among the two possible choices.

- Select No if the participant does not have a lung cancer diagnosis. [Go to Q20]
- Select Yes if the participant does have a lung cancer diagnosis.

Item 14. **Site of lung cancer:** From the options provided, select only ONE site of the lung cancer. (Please select ONLY one)

Item 15. **Type of lung cancer:** Select only one option among the four possible choices.
- Select 'Non-small cell lung cancer' if the type of lung cancer was non-small cell lung cancer. [Go to Q15b]
- Select 'Small cell lung cancer' if the type of lung cancer was small cell lung cancer. [Go to Q16]
- Select 'Type unknown' if the type of lung cancer was unknown. [Go to Q16]
- Select 'Other' if another type of lung cancer is specified.

Item 15a. **Other type of lung cancer:** Please specify the other type of lung cancer.

Item 15b. **Type of non-small cell lung cancer:** Select only one option among the four possible choices.
- Select 'Adenocarcinoma' if the type of non-small cell lung cancer was adenocarcinoma.
- Select 'Squamous/epithelioid carcinoma' if the type of non-small cell lung cancer was squamous/epithelioid carcinoma.
- Select 'Large cell carcinoma' if the type of non-small cell lung cancer was large cell carcinoma.
- Select 'Unspecified' if the type of non-small cell lung cancer is unspecified.

Type of Lung Cancer Treatment

Item 16. **Surgery:** Select only one option among the two possible choices.
- Select No if the participant did not have surgery as lung cancer treatment.
- Select Yes if the participant did have surgery as a lung cancer treatment.

Item 17. **Chemotherapy:** Select only one option among the two possible choices.
- Select No if the participant did not have chemotherapy as lung cancer treatment. [Go to Q18]
- Select Yes if the participant did have chemotherapy as lung cancer treatment.

Item 17a. **Type of chemotherapy:** Select only one option among the two possible choices.
- Select 'Neoadjuvant' if the type of chemotherapy was neoadjuvant.
- Select 'Adjuvant' if the type of chemotherapy was adjuvant.

Item 18. **Radiation:** Select only one option among the two possible choices.
- Select No if the participant did not have radiation as lung cancer treatment.
- Select Yes if the participant did have radiation as lung cancer treatment.

Item 19. **Targeted drug treatment:** Select only one option among the two possible choices.
- Select No if the participant did not have targeted drug treatment as lung cancer treatment. [Go to Q20]
- Select Yes if the participant did have targeted drug treatment as lung cancer treatment.

Type of Targeted Lung Cancer Drug Treatment

Item 19a. **Bevacizumab (Avastin):** Select only one option among the two possible choices.
- Select No if the participant did not have Bevacizumab (Avastin) as targeted lung cancer drug treatment.

- Select Yes if the participant did have Bevacizumab (Avastin) as targeted lung cancer drug treatment.

Item 19b. **Crizotinib (Xalkori):** Select only one option among the two possible choices.
- Select No if the participant did not have Crizotinib (Xalkori) as targeted lung cancer drug treatment.
- Select Yes if the participant did have Crizotinib (Xalkori) as targeted lung cancer drug treatment.

Item 19c. **Erlotinib (Tarceva):** Select only one option among the two possible choices.
- Select No if the participant did not have Erlotinib (Tarceva) as targeted lung cancer drug treatment.
- Select Yes if the participant did have Erlotinib (Tarceva) as targeted lung cancer drug treatment.

Smoking Status

Item 20. **Former smoker:** Select only one option among the two possible choices.
- Select No if the participant was not a former smoker. [Go to Q21]
- Select Yes if the participant was a former smoker.

Item 20a. **Pack years:** Select only one option among the four possible choices.
- Select '10 or less' if the pack years was 10 or less.
- Select '10 to 20' if the pack years was 10 to 20.
- Select '20 or more' if the pack years was 20 or more.
- Select 'Unknown' if the pack years was unknown.

Item 21. **Current smoker:** Select only one option among the three possible choices.
- Select No if the participant was not a current smoker.
- Select Yes if the participant was a current smoker.
- Select Unknown if it is unknown if the participant was a current smoker.

Item 22. **Lung transplant:** Select only one option among the three possible choices.
- Select No if the participant did not receive a lung transplant. [Go to END]
- Select Yes if the participant did receive a lung transplant.
- Select Unknown if it is unknown if the participant received a lung transplant. [Go to END]

Item 22a. **Area of lung transplant:** Select only one option among the three possible choices.
- Select 'Single Right' if the area of lung transplant was single right.
- Select 'Single Left' if the area of lung transplant was single left.
- Select 'Bilateral' if the area of lung transplant was bilateral.

Save and close the form.