



INSTRUCTIONS FOR EVENT REVIEW FORM - ENDPOINTS ERF, VERSION 2.0 QUESTION BY QUESTION INSTRUCTIONS (QxQ)

I. GENERAL INSTRUCTIONS

The Event Tracking Form is to be used by SPIROMICS assigned event reviewers to classify the event using the information provided on the Event Summary Report.

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

0a. Date of Completion: Record the date the form was completed. 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.

- Item 1. **Type of review:** Select only one option among the three possible choices.
- Select 'Original' if this is the original review.
 - Select 'Adjudication' if this an adjudication review.
 - Select 'Special Review' if this is a special review.
- Item 2. **Primary cause of death:** Select only one option among the five possible choices, then proceed to the next question as indicated.
- Select 'Respiratory' if the primary cause of death was respiratory. [Go to Q2a]
 - Select 'Cardiovascular' if the primary cause of death was cardiovascular. [Go to Q2b]
 - Select 'Cancer' if the primary cause of death was cancer. [Go to Q2c]
 - Select 'Other, known' if the primary cause of death is known but other than a cause previously listed. [Go to Q2d]
 - Select Unknown if the primary cause of death is unknown. [Got to Q2e]
- Item 2a. **Respiratory cause of death:** Select only one option among the four possible choices.
- Select 'COPD Exacerbation with pneumonia' if the respiratory cause of death was COPD exacerbation with pneumonia.
 - Select 'COPD Exacerbation without pneumonia' if the respiratory cause of death was COPD exacerbation without pneumonia.
 - Select 'COPD without exacerbation' if the respiratory cause of death was COPD without exacerbation.
 - Select 'Other respiratory cause of death' if the respiratory cause of death was other than a cause previously listed.
- Item 2a1. **Other respiratory cause of death:** Specify the other respiratory cause of death.
- Item 2b. **Cardiovascular cause of death:** Select only one option among the five possible choices.

- Select 'Myocardial infarction' if the cardiovascular cause of death was myocardial infarction.
- Select 'Heart failure' if the cardiovascular cause of death was heart failure.
- Select 'Stroke/aneurysm' if the cardiovascular cause of death was stroke/aneurysm.
- Select 'DVT/PE' if the cardiovascular cause of death was DVT/PE.
- Select 'Other heart problem' if the cardiovascular cause of death was other than a cause previously listed.

Item 2b1. **Other heart problem:** Specify the other heart problem cause of death.

Item 2b2. **Type of cardiovascular death:** Select only one option among the three possible choices.

- Select 'Sudden Death' if the type of cardiovascular cause of death was sudden death. (Sudden death is defined as death that occurs within 24 hours of being observed alive and without evidence of a deteriorating medical condition).
- Select 'Sudden Cardiac Death' if the type of cardiovascular cause of death was sudden cardiac death. (Sudden cardiac death is defined as death that occurs within 1 hour of being observed alive and without evidence of a deteriorating medical condition).
- Select 'Neither of the above' if the type of cardiovascular cause of death was neither sudden death nor sudden cardiac death.

Item 2c. **Cancer cause of death:** Select only one option among the two possible choices.

- Select Lung if the cause of death was lung cancer.
- Select 'Other cancer' if the cause of death was a cancer other than lung cancer.

Item 2c1. **Other cancer causing death:** Specify the other type of cancer causing death.

NOTE: If cancer is the cause of death complete Cancer Abstraction Form (CAF) once this form is completed.

Item 2d. **Other, known cause of death:** Record the other, known cause of death.

Item 2e. **Reason for Unknown cause of death:** Select only one option among the two possible choices.

- Select 'Information is inadequate' if inadequate information is the reason for the cause of death being unknown.
- Select 'Indeterminate' if information is available, but the cause of death is unclear.

Item 3. **Belief that diagnosis of COPD contributed to death:** Select only one option among the two possible choices.

- Select No if you do not believe that a diagnosis of COPD contributed to the death of this individual.
- Select Yes if you do believe that a diagnosis of COPD contributed to the death of this individual.

Item 4. **SPIROMICS Endpoints Committee Review:** Select only one option among the two possible choices.

- Select No if this case should not be reviewed by the SPIROMICS Endpoints Review Committee.
- Select Yes if this case should be reviewed by the SPIROMICS Endpoints Review Committee.

NOTE: Question 5 must be answered for the form to be considered complete.

Item 5. **Comments:** Enter final comments.

Save and close the form.