Specifications for Completion of the Adverse Events for NIH-Sponsored Clinical Trials (RAE)

The Report of Adverse Events for NIH-Sponsored Clinical Trials (RAE) is to be completed for all serious adverse events that may be a result of the screening procedures performed as part of the Lung Screening Study. The following adverse events are considered serious:

- Death
- Life threatening event
- Inpatient hospitalization
- Persistent or significant disability/incapacity
- Medical or surgical intervention to prevent one of the above outcomes.

The specifications for completing each question are listed below:

1. **Name of Center**: Enter the name of the Screening Center where the participant was enrolled at the time of the event.

2. **Date the event occurred**: Enter the date in MM/DD/YYYY format. This should be the date that the participant received the screening exam that is considered the cause of the event.

3. **Category of event**: Check all categories that describe the event.

    - Death: This category should be used if the participant died as a result of his/her participation in the Lung Screening Study.

    - Life threatening event: This category should be used if the participant experiences events such as cardiac/respiratory arrest, cardiac arrhythmia, significant blood loss, etc.

    - In-patient hospitalization: This category should be used if the event required the participant to be hospitalized. This would include visits to the emergency room during which the participant was admitted to the hospital.

    - Persistent or significant disability/incapacity: This category includes events that caused the participant a significant reduction in daily functioning and activities. This would include any paralysis or loss of organ function.

    - Medical or surgical intervention to prevent one of the above outcomes: This category should be used if the participant required a major medical or surgical intervention as a result of the event. This would include surgery performed or medication given to repair internal injury or organ damage caused by the participant's involvement in the Lung Screening Study.

    - Other: If none of the above categories describe the event, this "other" option should be used. The SC should enter a more appropriate category on the line. Questions 5 and 6 ask for a description of the event and its outcome so there is no need to include a lengthy description on this specify line.

4. **Brief description of research participant who experienced the adverse event:** Include items such as gender, age and race. It is also important to note any other characteristics of the participant that may have played a role in the event, such as comorbidities or medications. Note: please be sure that this description does not contain any participant identifiers such as name and address.

5. **Brief description of the event**: This item should give a description of the participant's experiences that may have led to the adverse event. Report symptoms, the timing of the onset of these symptoms, and the manner in which the SC became aware of the event.

6. **Description of the outcome of the event**: This should be a description of any medical interventions that the participant received and their outcome. Any persistent or significant disability/incapacity (as described above) should be described here as well.

7. **Do you believe that the adverse event was study related?**: The SC Principal Investigator should decide whether or not the event reported by the participant was related to their involvement in the Lung Screening Study. The four responses are:

    - Yes, study related: This should be used if the PI feels certain that the event occurred as a result of the participant's screening exam.

    - Possibly study related: This means that the PI is not certain that the event occurred as a result of the participant's involvement but it is likely.

    - Not study related: This should be used if the PI feels certain that the event did not occur as a result of the participant's screening exam.

    - Unknown: If the PI is unsure if the event was related to the screening exam, this response should be used.

8. **Do you feel revision to the informed consent document is necessary?**: The SC PI should decide whether or not the event warrants revision of the consent form to mention it as a possible danger. The four responses are:

    - Yes, revision of the informed consent document is necessary: This should be used if the PI feels certain that all participants should be made aware of the potential danger.

    - Revision of the informed consent may be necessary: This means that the PI is not certain that all participants should be made aware of the potential danger but it may be necessary.

    - No revision of the informed consent document is necessary: This should be used if the PI feels certain that the event does not warrant announcement in the informed consent document.

    - Unknown: If the PI is unsure whether or not the event warrants announcement in the informed consent document.

After these questions are completed, the PI is required to sign and date the form as well as print his/her last name and first initial below the signature. At this time the SC should keep a copy of the form for their files and forward the original to Westat. The SC may also attach any relevant exam forms or other documentation regarding the event. If any other documentation is attached, the SC should be sure that no personal identifying information is present.