Report of Adverse Events for NIH-Sponsored Clinical Trials (RAE)

Participant ID Label

1. Name of Center: _____

2. Date the event occurred: _____/_____/_____

3. Category of event (check all that apply):

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

4. Description of participant who experienced the adverse event, such as gender, age, etc. (no identifiers please):
_____
_____
_____
_____

5. Brief description of event: _____
_____
_____
_____
_____

6. Description of the outcome of the event: _____
_____
_____
_____
_____
_____

7. Using your best judgement, do you believe that the adverse event was study related?

- Yes, study related
- Possibly study related
- Not study related
- Unknown

8. Do you feel revision to the informed consent document is necessary?

- Yes, revision of the informed consent document is necessary
- Possible revision of the informed consent document may be necessary
- No revision of the informed consent document is necessary
- Unknown

Investigator's Signature and Date: _____

Investigator's Printed Last Name and Initial: _____

(Please attach copies of any relevant exam forms or other documentation regarding the event)