INTERNAL DEATH REPORT

POLICY: All internal deaths (regardless of attribution) MUST be reported to the IRB within 10 working days of the study team's knowledge of the event. An internal event represents an event that happened to a subject who was enrolled at a Piedmont Healthcare site and for which Piedmont Healthcare IRB is the IRB of record.

Deaths must be reported **INDEPENDENT** events (not in conjunction with an adverse event) using this form. **Attach all relevant/supporting documents along with the consent version in effect at time of event.**

IRBNet ID | Participant ID | Enrollment date

Report date | Event date | Date event known

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1. Relationship of death to study participation:
- ☐ related
- ☐ possibly related
- ☐ unrelated **(choose one)**
- ☐ * unknown

***NOTE:** by selecting 'unknown' you attest that no other clarifying information can be obtained.

2. The death was: ☐ expected ☐ unexpected ☐ reported to sponsor and/or FDA

3. Do you recommend informed consent changes due to this death?
- ☐ Yes **(choose one)**
- ☐ No

If yes, submit a revised informed consent document to the IRB separately using the Request for Modification form found in the Library Manager section in IRBNet or via the research website at: https://www.piedmont.org/research/research-eforms-and-systems.

4. If the death was unexpected **AND** related **OR** possibly related to participation in the study, does the death suggest that the research places others at a greater risk of harm than was previously known or recognized?
- ☐ Yes **(choose one)**
- ☐ No

If yes, in the space below, please provide details and provide safety measures to be put into place to protect subjects:

5. Instructions for providing event details in the space below:

a. Use lay language to fully describe the circumstances of the death.
b. Submit de-identified documentation pertaining to the death. Include a death certificate and/or obituary when possible.
c. Do not hold report past the 10 working days of knowledge of event. If this report is awaiting medical records or other documentation for completion beyond the mentioned time period, please add that your narrative below and indicate that follow up documentation on the event will be forthcoming.

Enter study title below:

PI or designee signature Date