

**LURN Organ-Based Pilot SAE Form**

1. Date of this report: □□ / □□ / □□□□

2. Start Date of Event: □□ / □□ / □□□□

3. End Date of Event: □□ / □□ / □□□□

4. ICD-10 Code: \_\_\_\_\_

5. Severity of event (assessed by PI):

Mild

Moderate

Severe

6. Pattern of event:

Single episode

Intermittent

Continuous

7. Relatedness of event to study procedure:

Unrelated

Remote

Possible

Probable

Related

8. If related, possible related, probably related, or remotely related, which study procedure?

\_\_\_\_\_

9. Action(s) taken (check all that apply):

- None
- Additional meds
- Additional therapy
- Additional lab tests
- Hospitalization required
- Prolonged hospitalization required

10. SAE condition (check all that apply):

- Death
- Life-threatening
- Inpatient/prolonged hospitalization
- Congenital anomaly or birth defect
- Persistent/significant disability or incapacity
- Medically important condition

11. Is this an expected SAE? --

- No
- Yes

12. Has the principal investigator reviewed this report? --

- No
- Yes

13. Date of PI review:  /  /