**Instructions:** This form is used to report an unanticipated problem, adverse event involving risk to a human subject or others, or noncompliance with the approved protocol or TBR IRB procedures or requirements. Fill out this form as soon as possible in the event of an unanticipated problem, adverse event, or incident of noncompliance, and submit it to the TBR IRB and the TBR Academic Affairs leadership at [IRB@tbr.edu](mailto:IRB@tbr.edu). The TBR IRB will determine whether to make a report to the Office for Human Research Protections or other regulatory agency. Attach any relevant documentation and correspondence related to the unanticipated problem, adverse event, or incident of noncompliance. Consolidate all supporting documentation into a single PDF document, but please submit Form E as a signed PDF document separately.

**Note**: The TBR IRB will determine whether the event constitutes an unanticipated problem, adverse event, or serious or continuing noncompliance and whether any further actions are necessary, including, but not limited to, modifications to the study protocol or informed consent documents, suspension or termination of the study, or reporting to regulatory agencies. After review and assessment, the TBR IRB will inform the TBR Chancellor or designee of any unanticipated problem, adverse event involving risk to a human subject, or incident of noncompliance. Additional information may be requested from the Principal Investigator.

**Project Title**:

**Principal Investigator**:

**Date of the initial TBR IRB approval**:

**TBR IRB Approval Number**:

**Date of occurrence**:

**Date reported**:

**Location of incident and number of participants involved**

**Event type as assessed by PI** (can select more than one):

Unanticipated problem involving risk to subjects or others

Unanticipated adverse event

Data breach or unintentional information disclosure

Protocol deviation or other noncompliance

Other

**Based on your assessment of the unanticipated problem or adverse event, do the current project activities need to be put on hold until the problem is resolved?**

Yes

No

**Provide the rationale for either answer here**:

**Description of the problem/event**:

**Assessment of potential harm or risk to participants**:

**Cause of the problem/event** (if known):

**Immediate actions to address the problem/event and minimize risk to participants**:

**Follow-up measures to prevent recurrence:**

**Parties notified or to be notified**:

**Additional comments** (if applicable):

**Documentation attached**:

**Principal Investigator:**

Typed Name:

Signature/ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**IRB Actions [to be filled out by the TBR IRB Chair]:**

**Proposed actions to address the problem/event**:

**Proposed modifications to study procedures / documents / informed consent process**:

**TBR IRB Chair:**

Typed Name:

Signature/ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_