**PLEASE NOTE: The following is an example of a SUSAR report submission when DUHS is not the IRB of record, and the SUSAR directly impacted DUHS participants, agents, or occur at DUHS as a site, consistent with guidance in the DUHS IRB 1400 Promptly Reportable Information Policy, (09/01/2026). This should only be used as a reference to provide form logic and guidance.

DUHS IRB SAE/AE form (Version 2.0)

1.0 Duke Health Safety Event Form

1.1 Protocol Information

Principal Investigator:

Cassandra Myers

Protocol Title:

TEST

Date Form Created:

08/24/2026

2.0 IRB of Record

2.1 Is Duke the IRB of record?

○ Yes ◉ No

Before continuing with this submission, report to your IRB-of-record. Once you have the external IRB's information, complete the following:

2.2 Provide External IRB's determination:

The [INSERT IRB OF RECORD] IRB of record has made a determination of [INSERT UPIRTSO, SERIOUS AND/OR CONTINUING NONCOMPLIANCE] for DUHS, or This is reportable per DUHS IRB's Other Reportable Information.

PLEASE NOTE: IF THE IRB OF RECORD HAS NOT MADE A DETERMINATION OF UPIRTSO, SERIOUs AND/OR CONTINUING NONCOMPLIANCE FOR DUHS AS A SITE ("DIRECTLY IMPACTS DUHS PARTICIPANT MEANS IT INVOLVED A DUHS PARTICIPANT, AGENT, SITE"), OR OTHERWISE LISTED UNDER "OTHER REPORTABLE INFORMATION PER POLICY 1400, IT IS NOT REPORTABLE, THE DUHS IRB WILL WITHDRAW THE SUBMISSION.

2.3 Upload documentation from external IRB:

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
1.0		Advarra UPIRTSO Determination Letter	Outcome Letter				9.15 KB

*As a reminder we are unable to review without the reviewing IRB's letter, unless otherwise reportable information

3.0 Safety Event Type

3.1 **Select the Safety Event type:**

- (•) Adverse Event
- ( ) Protocol Deviation/Violation/PHI Disclosure
- ( ) Correspondence
- ( ) Other Problem/Event Requiring Prompt Reporting

3.2 **Name of the problem or event:**

List the terms that most accurately characterize the problem/event. List the most important terms first.

DUHS Participant Experienced a SUSAR-REPORT #343347 INITIAL.

3.3 **Brief description of the problem or event:**

Provide a brief overview of the SUSAR the DUHS participant experienced, and their status up to the date of this report being submitted, please do not copy and paste from the SUSAR report. Please confirm this has been reported to the sponsor.

As a reminder if this is a SUSAR report that didn't impact a DUHS participant, where DUHS is not the IRB of record, these do not need to be submitted.

3.4 **Is this an internal problem/event?**

(An internal problem/event is one that occurs at a Duke site or to a participant enrolled by a Duke Investigator.)

(•) Yes ( ) No *If not an internal problem and we are not the IRB of record, we do not need to receive these, unless it otherwise meets the "Other Reportable Information

4.0 Adverse Event Evaluation

In the judgement of the Duke PI, answer the questions below for this adverse event:

4.2 **Was the problem/event related or possibly related (more likely related than unrelated) to the research?**

(•) Yes ( ) No * If this is being reported to the sponsor as a SUSAR and the IRB of record already determined its a UPIRTSO, SNC, or CNC, this already meets the criteria for "Yes" in 4.2, 4.3,, and 4.5

4.3 **Was the problem/event unexpected?**

(●) Yes ( ) No

4.5 **Has the research or problem/event placed, or possibly placed, participants or others at a greater risk of physical, psychological, economic or social harm than was previously known or recognized?**

(●) Yes ( ) No

4.6 **Categorize the seriousness of the event:**

Select the most serious outcome of the event. Items are listed in order of seriousness.

( ) Death (indicate date of death below)
( ) Life-threatening (placed the participant at immediate risk of death from the event as it occurred)
(●) Resulted in inpatient hospitalization (initial or prolonged)
( ) Resulted in a persistent or significant disability/incapacity
( ) Resulted in a congenital anomaly/birth defect
( ) Required immediate medical or surgical intervention
( ) None of the above (not a serious event)

5.0 Reportable Problem/Event

5.1 **Categorize the event by selecting all that apply below:**

☑ Adverse reaction to study drug/device/biologic
☐ A drug interaction causing an adverse reaction or failed therapeutic effect
☐ Medication error (prescribing, dispensing, administration, or monitoring)
☐ Device malfunction
☐ Error or product defect in manufacture of drug/device/biologic
☐ Study activity missed or completed out of window
☐ Compromise or breach of confidentiality or privacy
☐ Other

5.2 **Categorize the harm resulting from the event in more detail by selecting any that apply below:**

Outcome:

☑ Resulted in prolongation of existing hospitalization
☐ Resulted in emergency department visit
☐ Resulted in clinic visit
☐ Will require additional or ongoing medical or surgical care or intervention
☐ Resulted in psychological harm
☐ Resulted in economic harm
☐ Resulted in social harm

☐ Resulted in a compromise or breach of confidentiality or privacy
☐ Other

5.3 Date the problem/event occurred:

Date the problem/event occurred is defined as the date on which the problem first occurred, even if the problem was not detected until later.

06/15/2026

5.4 Date the PI at Duke recognized/learned of the problem or event:

06/18/2026

5.5 Is this an Initial Report?

◉ Yes ○ No

5.6 Sponsor Report Number:

Reference number or participant code that links the safety event to a participant or document.

43468848-Initial

5.7 Participant Number:

57264

5.8

For Industry Sponsored Studies:

In the judgment of the sponsor, what is the likelihood that this problem/event was related to the research?

◉ More likely related than unrelated
○ More likely unrelated than related
○ Relatedness not specified by the sponsor (include the sponsor's evaluation below)

Sponsor's Evaluation:

As SUSAR's must be reported to the sponsor and the IRB of record, this information should be available after a determination has been made by the IRB of record, and provided to DUHS IRB as the site where the event occurred.

6.0 Study Information

6.1 What is the status of study and recruitment?

- ○ Study initiation is pending (not yet open for enrollment of new participants)
- ○ Open for enrollment of new participants
- ○ Closed to enrollment of new participants but some enrolled participants are still receiving study drug or other interventions that are more than minimal risk
- ○ Closed to enrollment of new participants but some enrolled participants are still receiving study interventions that are minimal risk
- ◉ Closed to enrollment of new participants; all enrolled participants have completed the study but some participants continue for observation or follow up
- ○ All study enrollment and participant involvement is complete but data analysis is ongoing
- ○ Ongoing retrospective research with no direct participant contact
- ○ Closed with the IRB

7.0 Internal Problem/Event

7.1 Is the problem/event resolved?

◉ Yes ○ No

7.2 Has the PI's final determination been reported to a sponsor or any federal officials?

- ◉ Yes
- ○ No
- ○ N/A

7.3 For problems/events affecting, or with the potential to affect, patient care, has the problem/event been reported to the Duke University Health System Safety Reporting System?

◉ Yes ○ No

8.0 Other Relevant Information

8.1 Use this section to describe any other information relevant to this problem/event that should be reported to the IRB. If your study has a Data Safety Monitoring Board (DSMB/DSMC) indicate if they were convened to review this event. If so, upload the report and any supporting documents at the end of this submission form.

NA

9.0 Corrective Action

9.1 Will any corrective action be taken in response to this safety event?

(•) Yes ( ) No

What corrective actions or substantive changes have been or will be taken to minimize the likelihood of future events? (select all that apply):

- [ ] Changes to the research protocol initiated by the investigator prior to obtaining IRB approval to eliminate apparent immediate hazards to participants
- [ ] Modify inclusion or exclusion criteria
- [x] Implement additional monitoring procedures
- [ ] Modify or delete study procedures, interventions or interactions
- [ ] Withdrawal of participant
- [ ] Suspend enrollment of new participants
- [ ] Suspend research procedures in currently enrolled participants
- [ ] Modify informed consent documents
- [x] Provide additional information to previously enrolled participants
- [ ] Re-consent participants
- [ ] Other

Describe how the corrective actions indicated above will decrease the likelihood of future problems:

*Since this is only for DUHS SUSAR events this should be what was approved by the IRB of record, and if there is any additional CAPA activities, as DUHS IRB is not the IRB of record, this is more about ensuring that institutionally we have taken care of our DUHS participants as part of our institutional oversight, and not "IRB approval"

We have continued to monitor the impacted participant, and at this time all AE's are resolved, the participants blood pressure returned to normal. We are currently waiting for the sponsors revision to the consent form, but will verbally notify any participants who are still receiving study drug of the increased risk for hypertension, and document in their medical record. As this is expected to not increase risk to participants who no longer are receiving the study drug, we will not be notifying them.

PLEASE NOTE: THE CORRECTIVE AND PREVENTATIVE ACTION SHOULD INCLUDE BOTH HOW THE IMPACTED PARTICIPANT WILL BE MONITORED, BUT ALSO TAKE INTO ACCOUNT STUDY DESIGN, CURRENT ENROLLMENT, AND EXPECTED IMPACT TO IDENTIFY IF ANY ADDITIONAL ACTIVITIES INCLUDING RECONSENT OR PROVIDING ADDITIONAL INFORMATION IS REQUIRED.

10.0 Document Attach

10.1 Please attach new documents below.

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							