# Adverse Event Reporting

Site PIs are required to immediately report any and all breaches of confidentiality, adverse events (AEs), or serious adverse events (SAEs) that they deem possibly, probably, or definitively related to a patient's, PICU doctor's, or child abuse consultant's active participation in the CDR implementation trial. Such reports should be directed to the Study PI (kphymel@gmail.com), to the Chair of the Data Safety Monitoring Board (ehalstead@hmc.psu.edu), AND to your local IRB (in accordance with your IRB's institutional reporting policy). Site PIs can use this form to facilitate documentation and reporting of such events.

Name of the participating site:

Is this site participating as an *intervention* site or as a *control* site?

Name of the Site PI making this report:

Email address of the Site PI making this report:

Phone number(s) of the Site PI making this report:

Date of this report:

Date of the suspected breach, AE or SAE:

Site PI's characterization of the event (check one):

□ A suspected *breach of confidentiality*
□ A suspected *adverse event* [an expected side effect that is of a serious nature, or an unexpected side effect/event regardless of severity]
□ A suspected *serious adverse event* [an event that meets any of the following criteria: (1) fatal or life-threatening, (2) requires or prolongs inpatients hospitalization, (3) results in persistent or significant disability/incapacity, or (4) an important medical event that may jeopardize the patient or require intervention to prevent a serious outcome]

Site PI's estimation of person(s) harmed or potentially harmed by the event (check all that apply):

□ A patient
□ The patient's family member(s)
□ A PICU provider
□ A child abuse consultant
□ Other(s):

Site PI's characterization of the event's "relatedness" to trial participation (check one):

□ *Possibly* related to trial participation
□ *Probably* related to trial participation
□ *Definitively* related to trial participation

[NOTE: Events that you deem to be unrelated to trial participation do NOT need to be reported.]

The Site PI’s description of the breach or adverse event:

The Site PI’s description of local actions taken to address the breach:

Date when the Study PI was first informed about the breach, AE, or SAE:

Date when the DSMB chair was first informed about the breach, AE, or SAE:

Date when the local IRB was first informed about the breach, AE, or SAE: