DATAFORM 5
ADE and Near Miss Incident Classification Form

1. Study ID Number:  __________

1. Rx ID Number:  __________

2. Case Number:  __________

3. Reviewer Initials:  __________

4. Classification of incident (Choose only one)
   1. ADE
   2. Near Miss
   3. Medication Error
   4. Exclusion

5. Confidence regarding above judgement?  __________
   1. Little or no evidence
   2. Modest confidence
   3. Medium confidence
   4. Strong confidence
   5. Very certain confidence

6. Severity of ADE or PADE (Choose only one)
   1. Fatal
   2. Life-threatening
   3. Serious
   4. Significant
   5. Not an ADE or Near Miss

7. Preventability—Implicit (choose only one)
   1. Error intercepted
   2. Definitely preventable
   3. Probably preventable
   4. Probably not preventable
   5. Definitely not preventable
8. Could this event have been prevented by any of the following checks?  
(Choose all that apply)

1. Computerized physician order entry (basic design which ensure complete field legibility and signature)
2. CPOE with drug decision support
   2a. Drug-weight or drug dose check (guided dose algorithms)
   2b. Drug-allergy check
   2c. Drug-drug check
   2d. Drug-lab check
   2e. Drug frequency check
   2f. Drug-route check
   2g. Drug-pt. characteristic check: renal function
   2h. Drug-pt. characteristic check: age
   2i. Drug-pt. characteristic check: pregnancy
   2j. Drug-pt. characteristic check: other, specify: 
   2k. Drug duration
3. Electronic transmission of prescription
4. Clinical pharmacist
   4a. Discussing ordering
   4b. Discussing administration/monitoring
   4c. Monitoring/dispensing
5. Changes in staffing for:
   5a. Physicians
   5b. Nurses
   5c. Pharmacists
   5d. Other, specify: 
6. Changes in training for:
   6a. Physicians
   6b. Nurses
   6c. Pharmacists
   6d. Other, specify: 
7. Changes in hours for:
   7a. Physicians
   7b. Nurses
   7c. Pharmacists
   7d. Other, specify: 
8. Changes in communication between:
   8a. Physicians and patients
   8b. Nurses and patients
   8c. Physicians and pharmacists
   8d. Physicians and RNs, PAs, NPs, etc.
   8e. Parents and other caregivers (babysitter, school)
   8f. Other, specify: 
   8g. Pharmacists and patients
9. Other, specify: 
10. None
11. Drug specific guidelines
12. Pre printed template
9. Complete the following table

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.1 Are there any previous reports of this reaction in the Literature to your knowledge?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>9.2 Was the condition present before the administration of the drug in question?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>9.3 Could a non-pharmalogical clinical condition explain the change noted?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>9.4 Was the amount of the drug used too much for this patient?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>9.5 Is there objective evidence of toxicity (eg. from body fluids, biopsy, blood levels, but NOT rash or vital signs)?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>9.6 Did the patient receive an antagonist to the drug?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>9.7 Was the antagonist effective?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>9.8 Did the patient undergo therapy other than the antagonist directed at the condition in question?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>9.9 Was the therapy effective?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>9.10 Does the patient have a known allergy or intolerance to the drug?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>9.11 Was this reaction a rash, hives, itching, or anaphylaxis?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
<tr>
<td>9.12 Was this reaction a commonly reported sensitivity to this medication (eg. Nausea to opiates)?</td>
<td>Y</td>
<td>N</td>
<td>U</td>
</tr>
</tbody>
</table>

10. Was the event ameliorable?  
   1. Yes  
   2. No