Algorithm for Reporting Unanticipated Problems, Adverse Events, and Deviations

**Incident, experience, or outcome**

- Unexpected given known risks to subjects?  
  - yes  
  - no

- Related or possibly related to participation?  
  - yes  
  - no

- Suggests greater risk of harm to subjects or others?  
  - yes  
  - no

- Deviation?  
  - no  
  - yes

- MAJOR Deviation (effect on subjects or data)?  
  - no  
  - yes

- Adverse Event or Serious Adverse Event?  
  - no  
  - yes

- Report to IRB at Continuing Review
  - Attach to Progress Report:
    - If have DSMB report  
      - attach to Section 4
    - Otherwise,  
      - attach AE/SAE/Minor deviation summary to Section 5

- Submit on Reportable Events and New Information form
  - within 2 days if fatal or life-threatening event
  - within 7 days otherwise