

July 9, 2009

Dear Colleagues:

Please be aware there are two policies (see links below) from NewYork-Presbyterian Hospital (NYP) which describe the adverse events which must be reported to the Hospital per NYS and other regulatory mandates. You are advised that these policies also apply to patients who are in a research study whether they are an inpatient at NYP or are an outpatient in the hospital's Ambulatory Care Network (ACN) at the time any such event occurs.

Links:

<http://infonet.nyp.org/QA/HospManual/IncRpt/I125IncidentReportingToNYDOH.pdf>  
<http://infonet.nyp.org/QA/HospManual/IncRpt/S120SentinelEvent.pdf>

To make a report of such events or occurrences you should immediately:

1) Notify Patient Services Administration at the appropriate site by telephone, Monday - Friday 9AM - 5PM:

NYP/CUMC and MSCHONY extension 5-5904;  
Allen Pavilion, extension 4-4321;  
NYP/WCMC, extension 6-4293;  
Payne Whitney/Westchester, extension 5920.

All other times, please contact the Administrator-on-Call through the page operator. At Payne Whitney/Westchester, contact the Doctor-on-Call at 914 682-9100.

2) Enter the event into the Hospital's on-line Medical Event Reporting System (MERS-th) the link is: <https://www.mers-th.org/mers-th/main>

For any questions regarding NYPH reporting policies, please call:

Rose Ann Cannon  
Corporate Director,  
Patient Services Regulatory Affairs  
New York Presbyterian Hospital  
177 Fort Washington Avenue  
New York, NY 10032  
Office: 212-305-5904  
Fax: 212-305-5826

Unanticipated problems involving risks to subjects or others that may occur in any study conducted by Columbia faculty or NYPH staff that is reviewed by the Columbia IRB must also be reported in RASCAL in accordance with the Columbia IRB policy found at:  
<http://www.cumc.columbia.edu/dept/irb/policies/documents/UnanticipatedProblemSPolicy.FINALVERSION.012408.pdf>

Sincerely,

George Gasparis  
Executive Director, Columbia Human Research  
Protection Program/IRB