Washington University in St. Louis
SCHOOL OF MEDICINE

Department of Pediatrics Clinical Trials Sponsor Site Visit Policy

1.0 Purpose: The purpose of this policy is to provide guidelines and requirements for **Sponsor Representative** site visits (Pre-Study Site Visits (PSSV), Site Initiation Visits (SIV), Interim Monitoring Visits (IMV), Close-Out Visits (COV), or Audit Visits) within the Patient Oriented Research Unit (PORU) in the Department of Pediatrics.

2.0 Responsibility: The **Study Investigator** has overall responsibility for the conduct of sponsor visits.

3.0 Procedures:

3.1 **Scheduling:**

3.1.1 The **Study Coordinator** is responsible for scheduling all site visits with PORU administration by contacting the **Clinical Research Resource Coordinator (CRRC)** at least two weeks before the visit. Study visits are to be conducted during regular business hours.

3.1.2 When the **Study Coordinator** is contacted by the **Sponsor Representative** to schedule a site visit the following information will be obtained:

- Name(s), phone number(s), and email address(es) of the sponsor representative(s) attending the visit
- The sponsor name and, if applicable, the Contract Research Organization (CRO) name
- The protocol number and title of the research study related to the visit
- Name of PI and clinical research staff related to the visit
- Purpose of Visit (PSSV, SIV, IMV, COV, Audit)
- Date(s) and time(s) requested for visit
- Records and equipment required for visit
- Other areas to be visited (e.g. patient care area(s), pharmacy, etc.). **NOTE**: If Sponsor Representatives will be visiting a patient care area between October 1st and March 31st they must complete the WUSM Visitor Policy Questionnaire and present documentation of an influenza vaccine for that current season.

3.1.3 The **Study Coordinator** should advise the **Sponsor Representative** not to finalize travel plans until their visit is confirmed.

3.1.4 The **Study Coordinator** is responsible for emailing the **Clinical Research Resource Coordinator** the information obtained (3.1.2) and request the work space the **Sponsor Representative** will occupy during the visit. Work space is limited and will be assigned in the order requests are received.

3.1.5 The **Clinical Research Resource Coordinator** is responsible for scheduling the visit on the PORU Site Monitor Calendar.

3.1.6 Visit requests are only considered confirmed upon receipt of an email confirmation from the **Clinical Research Resource Coordinator** to the **Study Coordinator**. The **Study Coordinator** is responsible for notifying the **Sponsor Representative** that the visit date(s) has been confirmed.

3.2 **Documentation Requirements for Sponsor Representative's Initial Visit to the PORU**

3.2.1 The **Clinical Research Resource Coordinator** will forward the following documents to the **Sponsor Representative(s):**

- If applicable, Washington University School of Medicine Visitor Policy Questionnaire and Influenza Vaccination Request
- Directions to the PORU
- Local lodging information

3.2.2 The **Clinical Research Resource Coordinator** will complete the PORU Sponsor Representative Data Form and forward to the **Study Investigator** for approval.

4.0 Guidelines for General Conduct During Visits:

4.1 The **Sponsor Representative** should contact the **Study Coordinator** (or other previously arranged staff) of their arrival to the NWT 10th Floor so they may enter the PORU.

4.2 The **Study Coordinator** (or other previously arranged staff) will escort the **Sponsor Representative** to the **Clinical Research Resource Coordinator** (or Administrative Coordinator designee) for sign in on the Site Monitor Visit Log. All **Sponsor Representatives** will receive a Site Monitor ID Badge that allows access to the PORU. The badge must be turned in daily to the **Study Coordinator**.

4.3 At the time of departure on the final day of the visit, the **Sponsor Representative** will turn in the assigned Site Monitor ID Badge to the **Study Coordinator**. To conclude the visit the **Study Coordinator** will return the Badge to the **Clinical Research Resource Coordinator** (or Administrative Coordinator designee) and will sign out the **Sponsor Representative**.

4.4 **Sponsor Representatives** are not permitted access to the patient care areas unless approved in advance. Note: see 3.1.2 regarding influenza vaccine.

4.5 **Sponsor Representatives** are expected to maintain a professional demeanor while visiting our site.

5.0 Guidelines for Review of Source Documents:

5.1 **Sponsor Representatives** are not permitted unsupervised or direct access to electronic medical records.

5.2 Source documents can be printed from the electronic medical records by study staff or the **Sponsor Representative** can review the required elements of the electronic medical record under the direct supervision of the **Study Coordinator.**

5.3 **Sponsor Representatives** cannot review documents or records for any other protocol other than the one(s) identified at the time of scheduling the visit.

6.0 Non-Compliance:

6.1 Non-compliance with any of the above mentioned guidelines may result in immediate action by the Unit and Department Administration.

Approval Date _____**8/8/13**_____
Effective Date _____**8/8/13**_____
Revision Date _____**4/6/15**_____

Signature