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.

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Signature

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