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| Johns Hopkins Bayview Medical Center | |
| GENERAL CLINICAL RESEARCH CENTER | Policy No.: 102 Original Date: 10/97 Previous Date: 06/03 Revised Date: 03/06 |
| Adverse Event, Exception to Protocol | |

Purpose: To define the terms “adverse event”, and “exception to protocol” and provide guidelines for subject care, documentation and follow-up.

Definition: An adverse event is any event which occurs during the subject’s participation in a research protocol which: (1) warrants medical evaluation, (2) interrupts the subject’s participation in study procedures, or (3) is of such a nature that it requires immediate emergency care or hospitalization. Adverse events that occur when a subject is participating in investigational drug research protocols differ from the above in that they have reporting mechanisms that are protocol-specific and regulated by the Food and Drug Administration.

A *serious adverse event* in a research protocol enrolling subjects at a Johns Hopkins site is defined as any event that is fatal or life-threatening, that is permanently disabling, requires or extends hospitalization, that represents a significant overdose or breach of protocol, or any event that suggests that a drug, device, or procedure used in a research protocol has produced a congenital anomaly or cancer.

A *non-serious adverse event* in a research protocol enrolling subjects at a Johns Hopkins site is defined as any event that does not meet the definition of a serious adverse event.

An exception to protocol is any deviation from IRB approved protocol procedures.

Procedures:

In the event of an **Adverse Event**, the GCRC staff member will:

1. *For serious adverse events*, the staff will notify the GCRC study coordinator, Research Subject Advocate, Patient Care Manager and the Physician on call for the study and/or the Principal Investigator of the nature of the adverse event.
2. For subjects in an investigational drug trial, the staff will follow any sponsor protocol-specific guidelines regarding an adverse event.
3. The GCRC staff will complete a “GCRC Serious Adverse Experience (SAE) Notification Form”, by completing Part I (Items 1-3). The person responsible for study medical coverage, the Principal investigator or the study physician, will be requested to complete Part II (Items 4-9). The completed form will be forwarded to the GCRC Nurse Study Coordinator. Copies will be forwarded to the Patient Care Manager, the Research Subject Advocate, and any other designated personnel. If appropriate a JHBMC Occurrence Report form will be completed as per JHBMC Patient Care policy, O-8.
4. Document the event in the medical record and include the following:

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- A. a description of the event
 - B. the date and time the event began
 - C. the degree of severity of the event, i.e., mild, moderate, or severe, depending upon the extent to which the event affects the subject's ability to continue in the study or is life-threatening.
 - D. procedures used to ameliorate the event.
 - E. the date and time the event stopped.
 - F. the name of the person(s) notified of the event.
5. The Research Subject Advocate, or designated person in the Research Subject Advocate's absence, will notify the GCRC Program Director and /or Associate Director, and Manager or Director of the core service, of any serious adverse event.
 6. The Investigator is accountable for:
 - a. Assuring that medical evaluation is performed if indicated.
 - b. Reporting any serious adverse events, i.e., those that are life threatening or require hospitalization, in writing according to IRB policy and providing a copy of this report to the GCRC study coordinator and the Research Subject Advocate.
 7. Fatal and/or life-threatening adverse events which are reported to the IRB will be reviewed by the GAC at the next scheduled meeting. The Research Subject Advocate will summarize all other reportable adverse events at regular intervals for review by the GAC.
 8. For non-serious adverse events, the GCRC staff will document the event in the medical record as previously outlined. The staff will complete a "GCRC Adverse Event Log" and follow up either by phone or at the next visit as directed by the Research team or the Research Subject Advocate.
 9. The Patient Care Manager will share trended information regarding non-serious adverse events with the Program Director and /or Associate Director, the Research Subject Advocate, or designated person in the Research Subject Advocate's absence, and any other designated personnel.
 10. The Research Subject Advocate will summarize non-serious adverse events at regular intervals for review by the GAC.
 11. In the event that a protocol is terminated by the IRB, GAC or an outside agency due to subject risks or

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safety, the offices of JH Legal and JHBMC Risk Management will be notified through the appropriate channels.

In the event of an **Exception to Protocol**, the GCRC staff will:

1. In an anticipated exception to protocol, the GCRC staff will obtain a physician order to cover the protocol change, such as, changing an angiocath size to a smaller gauge needle.
2. For unplanned exceptions to protocol, the staff will complete a GCRC Protocol Deviation and Exception Report Form that includes a rationale for the protocol deviation. If appropriate, a JHBMC Occurrence Report form will be completed as per JHBMC policy.
3. Notify the GCRC study coordinator or the Patient Care Manager in the coordinator's absence of the exception to protocol.
4. Document the exception to protocol in the medical record.
5. The Patient Care Manager will share trended information regarding Exceptions to Protocol with the Program Director and/or Associate Director and Research Subject Advocate, or designated person in the Research Subject Advocate's absence, and any other designated personnel.

Originator: GCRC Patient Care Manager

Reviewed by : JHBMC Risk Management

References: Johns Hopkins Bayview Medical Center Patient Care Practices
Guidelines of the Johns Hopkins Medicine Institutional Review Boards for Human Subject Research

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