Research Subject Injury Reporting Procedure

**Purpose:** To ensure all required steps are taken for compliant billing and reporting of research subject information to a study sponsor, if applicable, when a subject is injured due to participation in a clinical trial.

**Definitions:**

Industry sponsored study: A study in which a company has designed the study being conducted and is collecting the study data and conducting the primary analysis of study data. In general, the industry sponsor would be responsible for injuries to subjects enrolled in these studies (see Payment for Subject Injuries).

Investigator initiated study: A study in which a researcher has designed the study being conducted and is collecting the study data and conducting the primary analysis of study data.

**Procedure:** If a research subject is injured and a determination has been made, or is anticipated to be made, that the injury is due to research participation, the following steps should be followed:

**Injuries in Industry Sponsored Studies:**
1. Immediately upon becoming aware of a suspected injury, the study team will contact the study sponsor, and inform them of the situation, copying the Clinical Trials Office (browjacq@ohsu.edu), the appropriate IRB analyst for the study, and the Clinical Research Billing Compliance Office (crbo@ohsu.edu).

2. If the injury was potentially caused or exacerbated by OHSU personnel or facilities, separately inform Risk Management (riskmgmt@ohsu.edu), the Clinical Trials Office (browjacq@ohsu.edu), the appropriate IRB analyst for the study, and the Clinical Research Billing Compliance Office (crbo@ohsu.edu), including that this is an industry sponsored study, describing the events and OHSU’s contribution to the event, and attaching the study informed consent form.

3. The CRBO will contact the study coordinator to obtain the medical record number and dates of service related to the injury, copying Risk Management (riskmgmt@ohsu.edu).

4. The CRBO will contact the sponsor to notify them that CRBO@ohsu.edu is the appropriate contact for obtaining the subject’s Medicare status in accordance with MMSEA requirements and will respond to sponsor inquiries requesting that information. Any requests from the study sponsor for information related to the subject’s Medicare status should be forwarded to the CRBO (crbo@ohsu.edu).
5. The CRBO will notify Hospital Billing (HB) and Professional Billing (PB) to move charges related to the subject’s injury to the research industrial account in Epic. HB and PB will provide the study coordinator with a detailed listing of charges transferred to the study industrial account, and the study team will provide the study sponsor with the charge information and instructions for payment to the OGA study account.

If a study sponsor refuses to pay the charges associated with the subject injury, contact the Clinical Trial Contracting Office (browjacq@ohsu.edu).

Injuries in Investigator Initiated Studies:

1. The study team should immediately inform Risk Management (riskmgmt@ohsu.edu), the appropriate IRB analyst for the study, and the Clinical Research Billing Compliance Office (crbo@ohsu.edu), stating the study is investigator initiated, describing the injury, and attaching the study informed consent form.

2. The CRBO will contact the study coordinator to obtain the medical record number and dates of service related to the injury, copying Risk Management (riskmgmt@ohsu.edu).

3. Risk Management will determine whether OHSU will cover any charges generated from the injury, will communicate to the study team the appropriate steps for communication with the patient and will work with CRBO to direct charges appropriately, if necessary.