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 an OHSU researcher has designed the study being conducted and is collecting the study data and conducting the primary analysis of study data.

Non-industry study: A study which is funded by a non-industry entity, e.g. federal grant, foundation, etc.

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:

PI/Study Team:
1. Immediately upon becoming aware of a suspected injury, contact the study sponsor and inform them of the injury, copying the Clinical Trials Office (browjacq@ohsu.edu) and the Clinical Research Billing Support Office (crbo@ohsu.edu).
2. Direct the study sponsor to contact crbo@ohsu.edu to obtain information relating to subject’s Medicare status. Any requests received from the study sponsor requesting information related to the subject’s Medicare status should be forwarded to crbo@ohsu.edu.
3. If the injury was potentially caused or exacerbated by OHSU personnel or facilities, separately inform Risk Management (riskmgmt@ohsu.edu) and the Clinical Trials Office (browjacq@ohsu.edu). Indicate that this is an industry sponsored study, describe the events and OHSU’s contribution to the event, and attach the study informed consent form.
4. Email crbo@ohsu.edu with the patient’s medical record number and the any dates of service related to the evaluation and treatment of the injury.
5. Once charges are identified and transferred to study account, invoice study sponsor and provide instructions for payment to the OGA study account. If required, a detailed charge listing can be obtained by emailing crbo@ohsu.edu.
Clinical Research Billing Support Office (CRBO):
1. Provide HB and PB with the subject’s MRN and dates of service related to the evaluation and treatment of the subject’s injury and request that charges be directed to study industrial account.
2. Upon request, provide PI/Study Team with detailed charge listing.

Hospital Billing/Professional Billing (HB/PB):
1. Transfer relevant charges to the study industrial account in Epic.

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

Injuries in Non-Industry and Investigator Initiated Studies:

PI/Study Team:
1. Immediately inform Risk Management (riskmgmt@ohsu.edu) stating the study is investigator initiated, describing the injury, and attaching the study informed consent form.

Risk Management:
1. 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.