



Sponsor Liability in Clinical Trials

OHSU policy requires that research subjects be provided any and all medical treatment reasonably necessary for any injury sustained as a direct result of research procedures. Sponsors of clinical research must reimburse OHSU for any losses sustained and costs incurred in providing research subjects with medical treatment reasonably necessary for any injury sustained as a direct result of research procedures performed in accordance with the protocol that would not be expected from the standard treatment using currently approved therapies. It is not acceptable for the sponsor to require billing of third party insurance companies or research subjects for treatment required for these injuries.

Sponsor liability statements that include exculpatory statements such as "the sponsor will not pay" must be deleted prior to submission of the Consent Form to the IRB. If the sponsor does not provide a liability statement, there is a default liability statement provided in the Sample Consent Form:

<http://www.ohsu.edu/research/rda/forms.shtml#hss>

A diagram outlining the flow of how charges for services in the context of a research study should be directed is attached.

