

HAC Policies and Procedures

Subject Injury and Financial Responsibility

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Who is Financially Responsible for Subject Injury?

Many research studies involve potential physical risks to the subjects, including the need for medical treatment and/or hospitalization. It is a requirement of contracts and agreements with outside sponsors that they agree to pay the costs of research-related injuries if they initiate the study protocol. However, such risks may also be present in externally sponsored, investigator-initiated studies where the sponsor will not agree to be responsible for research-related injury costs, as well as in non-sponsored studies.

There are no mechanisms available to pay costs of research-related injuries under current institutional policies and procedures. Those studies with no outside indemnification of the institution must inform the subjects of the potential risks, and that the costs associated with such injuries, will have to be borne by the subjects or their third party payer. The subjects must also be informed of the approximate costs (a dollar amount) of such treatments and that the third party may not pay for treatment of research-related injuries.

It is recognized that use of this language may cause potential subjects to be reluctant to participate as well as cause investigators to feel ethically bound to provide a mechanism to pay for the costs of research-related injuries. Therefore, the investigator must provide a realistic assessment of the potential risks as part of the risk/benefit analysis required for each protocol. It is suggested that a mechanism be described to pay for such treatments and that this be included as part of the analysis.

If funds are available to pay these costs, the ICD may be modified to reflect this. The payments may not come from state funds. Legitimate sources include residual grant funds, incentive funds, and similar sources. Department chairs must ensure that the monies are available and that the proposed mechanisms for such payments are consistent with state and institutional policies.

Is There Suggested Language For The ICD If There Are No Funds Available To Pay Costs Of Research-Related Injuries?

Yes. Please refer to the section on Informed Consent.

Who Do I Contact if I Have Any Questions?

For additional guidance, contact the HAC Administrative Office at HAC@mcg.edu or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

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Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.