

AAHRPP ELEMENTS:

CTA

Research Related Injury- AAHRPP Element I.8.A.

- “Sponsor shall be responsible for payment, to all necessary providers, of the actual [can accept “necessary”] and reasonable medical charges incurred in diagnosing and treating any injury, illness, or adverse reaction of a study subject that results from the participation in the study.”

Monitoring- AAHRPP example for Elements I.8.B. (Site Monitoring), I.8.C. (Data Monitoring) AND I.8.E (Report of Findings):

- “Sponsor shall promptly report to the Institution and Investigator: (a) any finding that Sponsor becomes aware of, including the Study results, or finding from a site monitoring visit, that could directly affect the safety or appropriate medical care for past or current Study subjects, and (b) any findings that could affect the willingness of Study subjects to continue participation in the Study, influence the conduct of the Study, or alter the IRB's approval to continue the Study. Sponsor agrees to notify Investigator and Site after the study has ended of any results that could affect the study participant's safety in order to inform study participants as appropriate.”

ICF

Subject Injury:

If you are injured or become ill as a direct result of a [insert as appropriate: study procedure or the study drug or study device], please contact the study doctor who will provide or assist with arranging reasonable, necessary, and customary (usual) medical care.

If you have followed the instructions of the study staff and [main and/or co-study doctor or main and/or co-researcher] and have an illness, injury, or complication that the Sponsor and main study doctor determines is a result of you being in this research study, the Sponsor will pay for this medical treatment and neither you nor your insurance will be billed for the cost of treatment. There is no extra compensation for costs such as lost wages, travel, or expenses, other than the medical treatment. Neither the Sponsor, your researcher, Texas Health Resources, or [insert name of THR hospital or other facility] agree to give compensation for any injury from being in this study.

[Include the following if a Pregnant partner consent will be used: There is no cost to you for authorizing the collection of the relevant medical information about your pregnancy, its outcome, and the birth and health of your baby. Any medical care costs related to your pregnancy and childbirth will be billed to you and/or your health insurance in the usual way. You will not be paid for the release or collection and use of your medical information.]

By signing this consent, you do not give up any legal rights associated with your participation in this research study.