

STANDARD I-8: The organization works with public, industry, and private sponsors to apply the requirements of the Human Research Protection Program to all participants.

ELEMENT I.8.A.: The organization has a written agreement with the sponsor that addresses medical care for research participants with a research-related injury, when appropriate.

ELEMENT I.8.B.: In studies where sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the organization has a written agreement with the sponsor that the sponsor promptly reports to the organization findings that could affect the safety of participants or influence the conduct of the study.

ELEMENT I.8.C.: When the sponsor has the responsibility to conduct data and safety monitoring, the organization has a written agreement with the sponsor that addresses provisions for monitoring the data to ensure the safety of participants and for providing data and safety monitoring reports to the organization.

ELEMENT I.8.D.: Before initiating research, the organization has a written agreement with the sponsor about plans for disseminating findings from the research and the roles that researchers and sponsors will play in the publication or disclosure of results.

ELEMENT I.8.E.: When participant safety could be directly affected by study results after the study has ended, the organization has a written agreement with the sponsor that the researcher or organization will be notified of the results in order to consider informing participants.