All human subject research subject to HRPP Manual Section 4-1, Applicability, that may generate a billable event, regardless of funding source, must be billed appropriately and in compliance with relevant billing laws and regulations. A billable event is an event that could generate a charge (e.g., clinic visits, procedures, blood draws, labs, or radiology) to a patient or their insurance carrier. Any research related billing must be documented, coded, and charged based on actual services rendered; must be allowable by regulations governing medical billing practices; must be consistent with any applicable contractual provisions; and must be consistent with the informed consent signed by the research subject.

MSU requires that all studies with a billable event follow the Compliance office review process to ensure that clinical research expenses are prospectively allocated appropriately, a coverage analysis is performed and that third party payers are not billed for services for which the study Sponsor is responsible and/or that are provided free of charge. See HRPP Manual Section 7-8-A, Clinical Research Billing Compliance Coverage Analysis and 8-10, Research Site Visits.

Individuals (e.g. faculty, providers and staff) must work together to ensure that clinical services associated with a research study are billed appropriately and in compliance with relevant laws and regulations.