13 Sponsored Research

These procedures apply to clinical research trials of drugs and medical devices that are conducted according to FDA regulations.

CMU Office of Sponsored Programs (OSP) will not enter into sponsored research agreements to conduct clinical trials that require Investigational New Drug Exemptions (INDs). As appropriate (*ie*, if trained investigators and adequate facilities are available), then OSP may enter into sponsored agreements to conduct research on approved drugs and on medical devices.

13.1 Definitions

Sponsor – The company, institution, individual donor, or organization responsible for the initiation, management, or financing of a research study.

Sponsored research – Research funded by external entities through a grant or contract that involves a specified statement of work (e.g., the research proposal) with a related transfer of value to the sponsor, including clinical trials involving investigational drugs, devices, or biologics.

13.2 Contracts

1. OSP will negotiate contracts for research involving human subjects, and OSP and the Office of Research Compliance (ORC) will share information as necessary to ensure that protocol, consent, and contract language are consistent.
2. Contracts for sponsored research involving human subjects will be reviewed for the following provisions by both OSP and ORC:
   a. All sponsor contracts will indicate that the CMU investigator will follow the protocol, applicable regulations, and applicable ethical standards.
   b. All sponsor contracts will define who will provide care for research-related injuries and who will pay for it.
   c. If the sponsor will monitor the conduct of the research, the contract will be required to state that if the study monitor uncovers information that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB's approval to continue the study, the sponsor will make sure that the information is promptly (no longer than 30 days) communicated to the IRB.
   d. Contracts or other funding agreements require the sponsor to send data and safety monitoring plans and reports to the organization. Contracts or other funding agreements specify the time frame for providing routine and urgent data and safety monitoring reports to the organization as indicated in the data and safety monitoring plan approved by the IRB. (See Sec 3.6.4 for further details regarding safety monitoring.)
   e. If the sponsor discovers results that could affect the safety or medical care of subjects or others involved in the study, the sponsor will make sure the IRB is notified. This requirement survives for a period following closure of a study to be determined on a case-by-case basis (e.g., two years).

f. Payment arrangements among sponsors, organizations, investigators, and those referring research participants may place participants at risk of coercion or undue influence or cause inequitable selection. Payment (i.e., "finder's fees") in exchange for referrals of prospective participants from researchers (e.g., physicians) is not permitted. Similarly, payments designed to accelerate recruitment that is tied to the rate or timing of enrollment ("bonus payments") are also not permitted.