



Title:	Sponsored Research		
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1 Purpose

It is the University of North Carolina at Chapel Hill (UNC-Chapel Hill) policy that any sponsored research conducted under the auspices of the Organization is conducted in accordance with federal guidelines and ethical standards.

The following describe the procedures required to ensure that all sponsored research meets this requirement.

2 Procedure

2.1 Definitions

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

Sponsored research. Sponsored research means research funded by external entities (public, industry, or private) through a grant or contract that involves a specified statement of work (e.g., the research proposal), including clinical trials involving investigational drugs, devices or biologics.

2.2 Responsibility

Sponsor grants, contracts, and other written agreements will be reviewed for the following by the Office of Sponsored Research and/or the Office of Industry Contracting, including consultation with the IRB, as necessary:

1. All sponsor contracts have a written agreement with the Sponsor that addresses medical care for research participants with a research-related injury, when appropriate including who will provide care and who is responsible to pay for it.
2. In studies where Sponsors conduct research site monitoring visits or conduct monitoring activities remotely, the sponsor contracts have a written agreement with the Sponsor that the Sponsor promptly (no longer than within 30 days) reports to the UNC-Chapel Hill findings that could affect the safety of participants, influence the conduct of the study, or alter the IRB's approval to continue the study.

3. When the Sponsor has the responsibility to conduct data and safety monitoring, the sponsor contracts have 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 UNC-Chapel Hill. 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. Investigators or the organization conducting the research are required to forward this information to the IRB.
4. Sponsor contracts have a written agreement with the Sponsor about plans for disseminating findings from the research and the roles that investigators and Sponsors will play in the publication or disclosure of results.
5. When participant safety could be directly affected by study results after the study has ended, the sponsor contracts have a written agreement with the Sponsor that the investigator or the UNC-Chapel Hill will be notified of the results in order to consider informing participants. Contracts or other funding agreements specify a timeframe after closure of the study during which the sponsor will communicate such findings (e.g., two years). This should be based on the appropriate timeframe for each individual study.
6. Payment in exchange for referrals of prospective participants from investigators (physicians) (“finder’s fees”) is not permitted. Similarly payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (“bonus payments”) are also not permitted.