



Sponsored Research – Standard Operating Procedures

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1. Overview

It is Drexel University policy that any sponsored research conducted under the auspices of Drexel University is conducted in accordance with federal guidelines and ethical standards.

These procedures describe the processes required to ensure that all sponsored human subjects research meets University requirements.

2. Subject Injury Language

Informed consent documents for Drexel University clinical trials must contain subject injury language. Subject injury language must be reviewed by Drexel University's Office of Sponsored Programs (OSP). Drexel University investigators must contact OSP for subject injury language review and upload a copy of OSP's subject injury language approval when submitting an initial IRB application. IRB reviewers are responsible for reviewing the subject injury language approval documentation to ensure that the informed consent document includes subject injury language that is consistent with that in the OSP approval documentation in initial applications, modifications, and renewals. If subject injury language in the consent document is inconsistent with that in the OSP approval documentation, Drexel University investigators must either update the consent document or obtain and provide updated documentation from OSP.

3. Other Contractual Obligations

Sponsor grants, contracts, and other written agreements will be reviewed for the following by the Office of Sponsored Programs, 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 Drexel University 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 Drexel University. 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 Drexel University 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

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which the sponsor will communicate such findings (e.g., two years). This should be based on the appropriate timeframe for each individual study.

4. Finder’s Fees and Bonus Payments

Payment in exchange for referrals of prospective participants from investigators (“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.

5. Responsibilities

5.1 Office for Research & Innovation and Human Research Protections Responsibilities

The Office of Research & Innovation and Human Research Protections Office are responsible for maintaining these procedures, applicable tools, and training. For inquiries regarding these procedures, please contact the Executive Director for Human Research Protections, as part of the Office for Research & Innovation (ORI).

5.2 Principal Investigator and Faculty Mentor Responsibilities

The Principal Investigator (and Faculty Mentor as applicable) is ultimately responsible for the conduct and oversight of the project. Please refer to ORI-002, Principal Investigator Eligibility and Responsibilities, for a listing of the PI and Department Responsibilities. The PI is responsible for following these procedures, ensuring appropriate approvals and oversight prior to performing study procedures, and complying with sponsor contractual obligations.

6. Revision

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