

## 20 Sponsored Research

It is University of Virginia 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.

### 20.1 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.

### 20.2 Responsibility

Sponsor grants, contracts, and other written agreements will be reviewed for the following by the Office of Sponsored Programs, with consultation with the IRB, as necessary:

1. All industry contracts have a written agreement with the Sponsor that addresses medical care for research participants with a research-related injury, when appropriate, or lack of research-related injury has been reviewed and approved by the appropriate representative of the Dean's Office in the school.
2. Where appropriate, 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 reports to the University of Virginia findings that could affect the safety of participants or influence the conduct of the study, or lack of such provision has been reviewed and approved by the appropriate Dean's representative.
3. Where appropriate, 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 University of Virginia, or lack of such provision has been reviewed and approved by the appropriate Dean's representative.
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, where appropriate the sponsor contracts have a written agreement with the Sponsor that the investigator or University of Virginia will be notified of the results in order to consider informing participant, or lack of such provision has been reviewed and approved by the appropriate Dean's representative.

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.