UNIVERSITY OF SOUTH ALABAMA

CT-203 CONFLICT OF INTEREST

EFFECTIVE DATE: May 2023

Purpose

The purpose of this Standard Operating Procedure is to support the USA Conflict of Interest in Research Policy and the USA Conflict of Interest in Research Procedures within clinical trials as well as applicable federal regulations such as 21 CFR 54. It is meant to provide appropriate institutional safeguards to sustain an environment where sponsored projects, dedicated gifts, research, scholarship, entrepreneurial endeavors, and technology transfer are carried out responsibly, and in so doing foster a culture of transparency and integrity.

Scope

This policy and procedures applies to PIs, Sub-Is, or other research personnel working on studies under the purview of the Clinical Trials Office. Personnel have a responsibility to disclose financial conflict of interest involving human subject's research. Conflict of interest could pertain to a sponsor, CRO, and/or product under investigation.

Definitions

All language contained within this document are defined within the USA Conflict of Interest in Research Policy.

Policy

The Clinical Trials Office and all staff should be familiar with and follow the USA Conflict of Interest in Research Policy and Procedures. All procedures listed herein are intended to support these policies within the setting of a clinical trial. If there is a discrepancy among these policies, the University Policies will prevail.

When a person's professional or financial interests could lead that investigator to prefer one outcome to another, a conflict of interest may exist. Conflicts of interest include commitments of financial support unrelated to the study in question, financial incentives, serving as a paid consultant or speaker on behalf of a commercial sponsor, as well as less obvious ones such as non-monetary inducements or rewards to investigators or their family members.

Procedures

1. Research personnel shall carefully consider and disclose the potential for a conflict of interest in the outcome of any clinical trial they are considering initiating or taking part in.

2. The USA Institutional Review Board (IRB) requires a protocol-specific disclosure of any relationships or financial holdings, which could give the appearance of a Financial Conflict of Interest as provided in the IRB application. If a conflict exists, it must be reported to the USA IRB even if it is not the IRB of record. The Office of Research Compliance and Assurance (ORCA) has developed a management plan template for use when potential conflicts arise from conducting human subject's research. In addition, the USA IRB provides recommended language for conflicts disclosure in informed consent available on the Human Subjects website. The USA IRB will take these circumstances into consideration when evaluating the protocol, and will refer any concerns about potential Financial Conflict of Interests or Conflict of Commitment to the Office of Research Compliance and Assurance.

3. Financial Disclosure Forms (FDF) are to be completed by all research personnel listed on the study 1572 or Investigator Agreement at the beginning of the study and at timepoints as requested by the study sponsor.

    3.1. A FDF must be completed and submitted to appropriate parties if the financial interest of research personnel changes during the course of the study.

Additional Resources

RELATED FORMS:

- **REGULATORY BINDER CHECKLIST AND ORGANIZATIONAL FORMAT**

RELATED POLICIES:

USA CONFLICT OF INTEREST IN RESEARCH POLICY
USA CONFLICT OF INTEREST IN RESEARCH PROCEDURES.

History

N/A

Next Review Date

January 2026

Responsible Party

Director, Clinical Trials Office