UNIVERSITY OF SOUTH ALABAMA

IRB SOP 1005
Multi-Site Industry Sponsored Studies: Supporting Documents That Do Not Require IRB Review

Purpose

The purpose of this policy is to identify and govern the handling of supporting documents and supplementary materials in multi-site, industry-sponsored studies that do not require IRB review. By identifying non-regulatory study materials, this policy streamlines the research approval process and removes administrative burdens while upholding all federal and institutional compliance standards.

Scope: This policy applies to multi-site industry sponsored clinical trials, regardless of site location.

Policy

The following documents do not require IRB review. These documents do not alter participant risk, clinical procedures, or study safety profiles. Additionally, documents that contain only operational, logistical, or financial details (administrative nature) do not qualify for review.

- Centralized recruitment campaign materials
  - Local IRB may rely directly on commercial IRB approved campaign materials
  - USA site utilizing their own (customized) internal campaign materials must seek local IRB approval
- Labels (for IP, chart labels)
- Financial and contract documents
  - Clinical Trial Agreements
  - Budget Documents
- Certified questionnaires and surveys
- Professional communications exclusively for health professionals

- Sponsor newsletters
- Operational and study management documents
    - Delegation Logs
    - Case Report Forms
    - Procedure Manuals
    - Laboratory Manuals
    - Medication/Pill Diaries, Diary Cards

The IRB reserves the right to request any study document when necessary to evaluate participant protections, regulatory compliance and/or institutional requirements.