

Umbrella Institutional Review Board Protocol Guidance

1. Overview and Definitions

An umbrella protocol is a single IRB application allowing multiple related sub-studies under one approval, provided they share purpose, methodology, and risk level.

Examples:

- A faculty member overseeing multiple student survey projects using the same instrument
- Longitudinal analysis of a single dataset across several related research questions
- Surveys, Interventions, etc., with related research questions and design.

2. Purpose and Appropriate Use

Umbrella protocols improve efficiency while maintaining compliance. They are appropriate only when studies are closely aligned and introduce minimal variation.

Allowed Use	Not Allowed Use
Repeated surveys with same design	Different methodologies across studies
Minor population differences	Introducing new risks or interventions
Shared dataset analysis	Combining unrelated research topics

Examples:

- Multiple semesters of the same classroom-based survey study
- Analyzing different variables within one institutional dataset

3. Principal Investigator Responsibilities

The Principal Investigator (PI) retains full responsibility for all research conducted under an approved umbrella protocol and must ensure ongoing compliance with all Institutional Review Board (IRB), Human Research Protection Program (HRPP), federal, state, and institutional requirements.

The PI must ensure that all sub-studies are conducted in accordance with the approved protocol and that the rights, safety, and welfare of research participants are protected at all times.

Management Plan Requirement

The PI must provide a written certification statement within the umbrella protocol application confirming that appropriate oversight and management processes are in place.

The certification must affirm that the PI will:

- Review and approve each sub-study prior to IRB submission to ensure it falls within the approved scope
- Maintain a comprehensive tracking system for all sub-studies, including study status, personnel, and enrollment
- Ensure consistency in study procedures, documentation, and participant protections across all sub-studies
- Monitor ongoing sub-study activities to ensure continued compliance with IRB/HRPP requirements

Status Reporting Requirement

The PI is required to maintain accurate, current information regarding the status of all sub-studies and must promptly update the IRB/HRPP as study status changes occur. At a minimum, the PI must report when a sub-study:

- Has been completed and all research activities have concluded
- Is no longer enrolling participants
- No longer involves direct interaction or intervention with participants
- Has transitioned to data analysis only (with no further participant involvement)
- Is suspended, terminated, or otherwise inactive

All status updates must be submitted in accordance with IRB/HRPP reporting requirements and timelines. Failure to maintain current study status information may result in noncompliance determinations.

4. Protocol Structure and Organization

Applications must clearly separate shared procedures from study-specific elements and ensure consistent organization.

Shared Elements	Study-Specific Elements
Recruitment method	Population differences
Consent template	Study timeline
Data storage plan	Specific instruments used

Examples:

- One consent form template reused across studies with minor edits
- Standard survey method applied to different participant groups

5. Study Submission, Labeling, and Organization Requirements

All sub-studies must be submitted, labeled, and organized in a standardized and consistent manner to ensure efficient IRB review and ongoing oversight.

Submission expectations include:

- Each sub-study must be submitted as a clearly distinct package within the umbrella protocol, with all required materials included at the time of submission.
- Submissions must include sufficient detail for reviewers to evaluate whether the study falls within the approved umbrella scope and does not introduce new risks.

Labeling conventions must ensure clarity and consistency:

- Each study must be assigned a sequential identifier (e.g., Study 1, Study 2, Study 3) that remains consistent across all documents.
- All documents must include the study identifier and a clear document title (e.g., 'Study 2 – Consent Form', 'Study 2 – Recruitment Flyer').
- Version numbers and dates must be included on all materials to support version control and audit readiness.

Organization requirements include:

- Shared materials (e.g., templates, general procedures) should be grouped in a central section of the protocol and not repeated unnecessarily.
- Study-specific materials must be grouped by sub-study and clearly separated from other studies.
- Files and sections must be arranged so reviewers can easily navigate between shared content and individual sub-study components.

Well-Organized Submission	Poorly Organized Submission
Study 1 materials grouped together and labeled consistently	Mixed documents from different studies without identifiers
Clear naming (Study 3 – Survey Instrument v2, dated)	Generic file names like 'survey_final'

Shared consent template referenced once centrally	Repeated or inconsistent consent documents across studies
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Examples:

- A submission where each study has its own clearly labeled folder or section with recruitment, consent, and instruments
- A protocol where shared survey methods are described once, and each study only includes what differs

6. Submission, Amendments, and Documentation

All umbrella protocol applications must be submitted through the IRB system with complete, accurate, and internally consistent materials.

Requires Amendment	Requires New Protocol
Adding a new sub-study within scope	Changing overall study design
Updating recruitment materials	Introducing new risk level research
Adding personnel	Expanding to unrelated research areas

Examples:

- Submitting a new student project under the same survey framework
- Updating consent language across all studies