

Institutional Review Board & Human Subjects Office

Umbrella Project Policy and Procedures 3/18/19

Introduction

An umbrella project is a HawkIRB application that seeks approval for multiple sub projects that follow a common pattern or paradigm and are conducted by multiple researchers. The umbrella project Principal Investigator (PI) creates a New Project Application in HawkIRB, outlining the parameters and providing template documents for the sub projects. Once the project is approved, the PI can then submit HawkIRB Modification forms to add team members, abstract forms and other documents related to new sub projects. These team members and materials are removed via a HawkIRB Modification form when the sub-study is complete.

Overall umbrella project approval is at the discretion of the IRB. Contact the [Human Subjects Office](#) for assistance with establishing a new Umbrella Project or managing an existing one.

[Note: A series of studies cannot be grouped into an umbrella project if the Principal Investigator (PI) plans to conduct variations of the study design in separate waves by making slight changes to stimuli or other study procedures.]

Umbrella Project Policy

The [IRB Standard Operating Procedures and Researcher Guide](#) (Section I, Part 17) outlines the conditions that apply to umbrella projects.

Examples of Umbrella Projects

Umbrella Projects can involve retrospective review, secondary data analysis or prospective data collection. Here are some examples of Umbrella Projects:

Retrospective Medical Reviews in Radiology

Many trainees in Radiology (students and residents) conduct retrospective medical record reviews with a standard and consistent research question: how well does a particular imaging test perform in predicting specific disorders, as confirmed by later clinical course or other diagnostic studies? These studies always meet the criteria for expedited review, waiver of consent, and waiver of HIPAA authorization. As individual trainees develop sub projects, they complete a one-page abstract form which provides specific details for the sub project, including a specific hypothesis/research question, the date the review of records will begin and end, the earliest and latest date of the data being

accessed, and the number of records to be reviewed. All records reviewed for the sub project must exist at the time the HawkIRB Modification form is submitted to add the sub project, to be consistent with the regulatory requirements for waiver of consent for the review of “retrospective” data. Note that the latest date the data is accessed will be after the date the New Project form for the umbrella project was originally submitted to the IRB.

Marketing Research in the College of Business

A professor in the College of Business has an umbrella project primarily for students to conduct research about consumer behavior and decision-making. Subjects come from a pool of students in the College who receive course credit for participating in research studies. Subjects complete surveys on paper, in a computer lab or online. Depending on the nature of the questions, studies like this may qualify for a waiver of documentation of consent (no subject signature required on the consent document) or exempt status (subjects receive an exempt information sheet prior to participating in the survey). The exact questions posed to the students vary, but the general theme is that students are given certain choices from which to choose. No personal information is sought and the student’s individual results are not linked to the student’s identity.

Checklist for Umbrella Project HawkIRB Applications

Use the following checklists to prepare HawkIRB forms.

New Project Form

1. Section I.1 - Select IRB-01 or IRB-02, as appropriate. Researchers applying through IRB-03 cannot create an umbrella project.
2. Section I.2 or I.3 - Include the word “umbrella” in the Project Title or the Short Title.
3. Section I.4 - Describe how the umbrella project PI will oversee the project (See item #8 in the policy, [IRB Standard Operating Procedures & Researcher Guide](#), Section I, Part 17)
4. Section I.5 – Include a general hypothesis or research question that sets the parameters for all sub project hypotheses. State that the specific hypothesis/research question will be included in the abstract form for each sub project.
5. Section I.6 – For background and significance the PI should state the value of the general study design used by all sub projects.
6. Section I.7 – It is okay to state “not applicable” for literature citations for umbrella projects. Citations may be included in the abstract forms, but this is not an IRB requirement.
7. Section II – The umbrella project PI must be a UI faculty or staff member. Sub project investigators must be UI faculty, staff or student. Faculty Advisors of students/trainees must be UI faculty or staff. Adjunct and Emeritus Faculty may not serve as the Faculty Advisor for a student or trainee sub project. The umbrella project PI may serve as the Faculty Advisor for a student or trainee sub project.
8. Section IV.1 – The PI should request [“Regular Review” or “Exempt Status.”](#) as appropriate.
9. Section IV.3 – For umbrella projects that involve a retrospective record review, the PI should request a waiver of consent, either for all subjects or for some subjects, and provide a justification for the waiver in Sections IV.4-IV.19. Selecting a waiver of consent “for all subjects”

will close other sections of the HawkIRB application that do not apply to retrospective record reviews. For umbrella projects that only involve prospective data collection, mark “No” for waiver of consent and Sections IV.4-IV.19 will not open.

10. Section IV.5 – For a retrospective review, it is not necessary to provide subjects with “additional pertinent information after participation.”
11. Section IV.9 – The HawkIRB application may specify the earliest (beginning) date of the data sub projects will access for a retrospective review under a waiver of informed consent. Or, the abstract form may include a field for this date to be specified for each sub project.
12. Section IV.10 – The latest (ending) date of the data sub projects will access for a retrospective review will not be specified (enter “Specified on abstract forms”). The actual date must be provided in the abstract form for each sub project. Data must exist before the HawkIRB Modification form is submitted for an individual sub project.
13. Section IV.12 – Make sure the list includes the medical record number (MRN) or other subject identifiers if the researcher plans to collect/record them. Confidentiality protections described in Section IV.18, plans for removing identifiers in Section IV.19 and data analysis plans described in Section XI.1 should be appropriate to the identifiers that will be recorded.
14. Section VII.A.1 – List all possible location for study procedures. This section may need to be updated in the Modification forms to add new sub projects.
15. Section VII.D – For studies that do not have a waiver of consent, the PI should describe all possible recruitment methods and procedures for obtaining informed consent. The completed abstract forms may include the specific recruitment and consent procedures for each sub project.
 - a. Section VII.D.1 – Include a list of all possible recruitment methods.
 - b. Section VII.D.29 – Describe the following: (1) how all recruitment methods will be used, (2) how the consent process will be conducted, and (3) how all sub project investigators will minimize coercion or undue influence in the consent process. Specify in this response whether sub projects will use the standard umbrella project consent document or if they will edit a template consent document for each sub project.
16. Section VII.E – For studies that do not have a waiver of consent, the PI should describe all possible study procedures. Abstract forms should describe specific study procedures and refer by name to study data collection tools and other documents to be used for the sub project.
17. Throughout the HawkIRB application - Specify in the HawkIRB application that sub project-specific descriptions will be included on the abstract form.
18. Template Abstract Form – The IRB provides template abstract forms for retrospective and prospective data collection. (Contact the [Human Subjects Office](#) to request a template.) The template should include -
 - a. Names of everyone involved with conducting the project
 - b. Sub project start and end date
 - c. Number of subjects to be enrolled or records to be reviewed
 - d. All information the HawkIRB application states will be provided on the abstract form (hypothesis/research question, earliest and latest date of data to be reviewed, recruitment methods, consent procedures, study procedures, etc.).
 - e. A list of sub project qualifiers that are specific to this umbrella project application. It should be formatted as a bulleted list where the PI and sub project investigator

signatures indicate that the sub project fits under the umbrella application. Some older abstract forms will have the sub project investigator initial each item on this list.

- f. Sub project investigator name and signature
- g. Umbrella project PI name and signature
- h. For student/trainee sub projects: The faculty advisor assurances, with the faculty advisor signature indicating agreement to oversee the research activity of the student or trainee.

19. Informed Consent Documents – For studies that involve obtaining informed consent, the PI should attach a standard Informed Consent Document that will be used as-is for all sub projects or a template consent document that will be modified for each sub project. Guidance for the Informed Consent Document:

- a. Study Title – The consent document should include the full title of the umbrella project, as indicated in Section I.2 of the HawkIRB application. The sub project investigator may add a sub title on the Informed Consent Document that indicates the topic of the sub project.
- b. Listing the PI, Sub Project Investigator, Contact Person – Typically the Informed Consent Document used for the umbrella project lists the PI of the umbrella project as the PI and the name and contact information of the sub project investigator as the “Contact Person.” However, if the sub project investigator is the instructor of a course in which subjects are recruited, the investigator name must be included in the document but there should be a separate contact person who recruits subjects, answers questions and gathers data, keeping the instructor blinded to student participation in the research. The consent document should include a statement about these procedures and explain that the course instructor/sub project investigator will not know who participates in the study or have access to study data until grades are posted. Add a heading for “Sub Project Investigator” between the PI name and the Contact Person name.
- c. Filename – Use a standard naming convention for all sub study consent documents. Indicate if the document is a template or include the sub project investigator name.

20. Tracking Log – The umbrella project PI must keep track of all sub studies conducted under the umbrella. Attach a template tracking log to the New Project application and then modify it every time a sub project begins or ends. At a minimum, the tracking log should include the following:

- a. Name of sub project investigator
- b. Start and end date of the project
- c. Number of subjects enrolled or records reviewed
- d. The title or topic of the sub project

21. Survey Documents – The IRB must review the survey questions and the actual web-based survey presented to subjects.

- a. Include the link to any web-based surveys in the attached document with the survey questions. The instructions and questions must be the same in the web-based survey and the attached survey document.
- b. If survey questions will be presented in a random order, indicate this in Section VII.E.4 of the HawkIRB application but turn this feature off for the IRB review process.
- c. Most researchers protect subject privacy by allowing them to skip questions in a survey. Make sure the survey is set up to allow this.

- d. If the Exempt Information Sheet or Consent Letter will be provided at the beginning of the survey, include the content in the survey document.
 - e. Follow the file naming convention specified in the umbrella project management plan (as stated in Section I.4 of the HawkIRB application).
22. Other Documents – All other documents related to the sub projects should be attached in the appropriate attachment category (recruitment materials, interview guides, member checking emails, miscellaneous attachments, etc.). Follow the file naming convention specified in the umbrella project management plan (as stated in Section I.4 of the HawkIRB application).

Modification Form

Adding a sub project

1. Add all team members who will interact with subjects or have access to identifiable data (including coded data for which there is a link between the ID code and subject identifying information).
2. Attach the completed and signed abstract form and all other documents related to each new sub project.
3. Use a consistent naming convention for all documents attached so the PI and the IRB can tell which documents go with each sub project.
4. Use the Edit function to add all new sub projects to the tracking log.

Removing a sub project

1. Remove all team members working on the completed sub project(s), unless they are working on another ongoing sub project.
2. Remove the abstract form and any other documents related to the completed sub project(s).
3. Use the Edit function to update the tracking log to indicate the sub project end date and how many subjects were enrolled or records reviewed.

Continuing or Biennial Review

Umbrella Projects will have a [Continuing Review](#) for the first year. After that the project may qualify for a [Biennial Review](#). At the time of either type of review, the PI should update the HawkIRB application regarding the active and inactive sub projects, and the total enrollment or total number of records reviewed for each sub project.

Reporting Enrollment

Umbrella projects that include obtaining informed consent should report the total number of subjects enrolled to date, including a breakdown of males and females. The umbrella project PI must obtain the number of subjects enrolled to date for all ongoing sub projects. The umbrella project PI will need to submit a HawkIRB Modification form at the time of the Continuing Review to update the tracking log to report total enrollment to date for all ongoing or completed sub projects.

Reporting Number of Records Reviewed

Umbrella projects that involve retrospective record reviews must report the total number of records reviewed to date for all ongoing and completed sub projects in the umbrella project tracking log. Submit a Modification form at the time of the Continuing Review and use the Edit function to update the tracking log.

Current Sub Projects

Submit a HawkIRB Modification form to remove abstract forms and other attachments (if applicable) for sub projects that have been completed.