

Umbrella Project Educational Tool

Institutional Review Board and Human Subjects Office

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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.

Use of the umbrella project model 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: If the Principal Investigator (PI) plans to conduct variations of the study in separate waves by making slight changes to stimuli or other study procedures, this is NOT considered an Umbrella Project.]

[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 (students, residents, postdoctoral fellows/scholars) conduct retrospective medical record reviews with a standard and consistent research question. (Example: how well does a particular imaging test perform in predicting specific disorders, as confirmed by later clinical course or other diagnostic studies?) If submitted after the new HawkIRB form was released in January 2022, retrospective record reviews or secondary data analysis may qualify for Exempt Status, with waiver of consent and waiver of HIPAA authorization. As individual trainees develop sub projects, they complete an 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. 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: Unlike individual HawkIRB applications for retrospective record review, it is acceptable for the latest date that data will be accessed for a sub project to be after the date of submission for the Umbrella Project New Project form.

[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 Exempt Status or for Regular Review with a waiver of documentation of consent (no subject signature required on the consent document). 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 individual results are not linked to the student’s identity.

[Checklists for Umbrella Project HawkIRB Applications](#)

Use the following checklists to prepare HawkIRB forms for Umbrella Projects.

[New Project Form Checklist](#)

All Umbrella projects must meet the regulatory definition of minimal risk ([45 CFR 46.102\(j\)](#)). Umbrella Projects have a unique study design. An umbrella project involves sub projects conducted by faculty, staff, student or trainee researchers. Projects where the study PI plans to make slight changes to stimuli or study design in different waves of the study do not qualify as an umbrella project.

1. Section I.1 - Select IRB-01 or IRB-02, as appropriate. Umbrella Projects cannot be conducted at the VA Health Care System under IRB-03.
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 also item #8 in the policy, [IRB Standard Operating Procedures & Researcher Guide](#), Section I, Part 17).
 - a. Describe the review of sub project proposals to make sure they fit under the umbrella.
 - b. Describe the plan to submit modifications to add/remove sub project team members, abstract forms and any other documents AND update the tracking log when a sub project begins/ends.
 - c. Describe the role of anyone named on the research team who is not directly involved with conducting one or more of the sub projects.
 - d. State that sub project researchers may not share data collected under the Umbrella Project outside the UI. [**Note:** A sub project researcher taking data with them is NOT considered “sharing data” with a non-UI entity. Neither is publication of results of a sub project.]

If there is an intent to share data externally, whether or not it contains personally identifying information, it is not eligible for review under the Umbrella Project. A separate IRB application would be required. Section I.4 Example regarding data sharing outside the UI: *Sub project researchers may not share data collected under this Umbrella Project outside the University of Iowa. If there is an intent to share data outside of the University of Iowa, whether it contains personally identifying information or not, it would not be eligible for review under this umbrella Project. A separate IRB application is required.*

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.
 - a. Sub project investigators may be UI faculty, staff, residents, fellows or students.
 - b. 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 – Waiver of Consent
 - a. For a retrospective record review submitted prior to January 2022, 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.
 - b. For 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 with Regular Review and a waiver of consent, it is not necessary to provide subjects with “additional pertinent information after participation.”

11. Section IV.9 – The HawkIRB application specifies the earliest (beginning) date of the data sub projects will access for a retrospective review under a waiver of informed consent. 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 prospective data collect, 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 – Select 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 prospective data collection, 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. Section X.5 and Section X.6 – If sub project researchers could take data with them when they leave the UI, select “No” in Section X.5. Answer the follow up question in Section X.6 to indicate whether they will remove identifiers associated with the data. Also state that sub project researchers who take data with them will work with the Division of Sponsored Programs to establish a Data Use Agreement before they leave the UI. The Data Use Agreement will document approval from the following entities (as applicable) to take data from the UI: the Department, Registrar, funding source, and/or the UI HIPAA Privacy Officer. [Note: A sub project researcher taking data with them or publishing results is NOT considered “sharing data” with a non-UI entity.]

Section X.6 Example: Sub project researchers may take data with them when they graduate or leave the University of Iowa. Data will be completely deidentified. Sub project researchers will work with the Umbrella Project PI and the Division of Sponsored Programs to establish a Data Use Agreement before they leave the UI. The Data Use Agreement will document permission the Registrar, a funding source if any, and/or the UI HIPAA Privacy Officer (as applicable) to take data from the UI.

18. Throughout the HawkIRB application - Specify in the HawkIRB application that sub project-specific descriptions will be included on the abstract form.
19. Attachments - Use a standard naming convention for all files/documents attached to the Umbrella project. Indicate if the document is a template or include the sub project investigator name according to the naming convention.

20. Template Abstract Form – Contact the [Human Subjects Office](#) to request a template abstract form for retrospective or prospective data collection. The template should include -
- a. Sub project start and end date
 - b. Number of subjects to be enrolled
 - c. Number of records to be reviewed (only for retrospective record review Umbrella Projects approved prior to January 2022 with a Regular Review and a waiver of consent)
 - 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. (This is not required by the IRB and could be updated for the signature below to indicate agreement to the list of sub project qualifiers.)
 - 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.
21. 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.
22. Tracking Log – The umbrella project PI must keep track of all sub studies conducted under the umbrella. Contact the [Human Subjects Office](#) to request a template tracking log. 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
23. 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).
24. 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, survey instruments, 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 Checklist

Add 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.

Remove 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 may be approved for [Continuing Review](#) or [Biennial Review](#). At the time of the Continuing 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. It is not possible to submit a Modification form at the same time as a Biennial Review, so modifications will need to be submitted separately.

Continuing Review Submission Requirements

Most Umbrella Projects qualify for Biennial Review, but those that have a Continuing Review should do the following:

- Report 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.
- Report Number of Records Reviewed - Umbrella projects that involve retrospective record reviews approved under Regular Review and a waiver of informed consent (Section IV) 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.

Biennial Review Submission Requirements

The Biennial review form submission is required every two years. The PI remains responsible for maintaining accurate enrollment, records reviewed, and all sub projects as required in the continuing review submission requirements however it is not possible to submit this information in the Biennial Review form. Any updates to the Umbrella Project must be submitted in a separate Modification form, before or after submission of the Biennial Review form. Records related to sub projects must be available to the IRB upon request.