

## UMBRELLA PROTOCOL SUBMISSION GUIDANCE

An *umbrella project* is an administrative term used to describe a research study in which a single investigator submits an IRB application that will cover multiple sub-projects which have a common hypothesis, set of investigators, or data set and for which details of the study procedures will only change minimally. Note: Overall umbrella project approval is at the discretion of the IRB; studies must be no more than minimal risk. Examples of typical umbrella projects are provided in the last section of this guidance.

### CONDITIONS THAT APPLY TO UMBRELLA PROJECTS:

- 1) All sub-projects covered under the umbrella protocol must meet the regulatory definition of ***minimal risk human subjects research*** (45 CFR 46.102(i)). The risks to subjects, from study procedures or the use of private identifiable information, should not exceed the risks that subjects encounter in their daily life or in the conduct of routine physical or psychological examinations.
- 2) The studies described within the submitted Umbrella Protocol will be *overseen by a Principal Investigator*. The Principal Investigator must be a Wright State University faculty member. The Principal Investigator will ultimately be responsible for the protection of human subjects, for compliance with applicable regulations and Wright State policies.
- 3) The Umbrella Protocol PI must include an oversight/management plan within the IRB application for the umbrella protocol. This plan should contain:
  - a. Description of the process to review and evaluate each new sub-project as being appropriate under the umbrella. IRB suggest use of a protocol form for each sub-study.
  - b. Plans for tracking enrollment/records accessed for each sub-project and for reporting these numbers to the IRB at continuation.
  - c. The naming convention for all sub-project documents.
  - d. Plan for retaining study documentation for auditing purposes. This includes, but is not limited to, all study-specific records and analyses that are conducted in accordance with the procedures and provisions described in the approved umbrella application. Additionally, regulatory and study-specific documentation (i.e., HRPP/IRB-approval letters, consent documentation, case report forms, questionnaires, etc.) should be retained for each sub-study as you would for any IRB-approved protocol.
- 4) The IRB application for umbrella protocols should include a general hypothesis or research question that sets the parameters for all sub projects. The main study's research design and procedures should also be described in the IRB application.
- 5) An amendment should be submitted to add each sub-study to the umbrella protocol along with their respective research personnel prior to beginning any research-related activities. All research personnel need to meet Wright State credentialing requirements.
  - a. Documents to include with the amendment:
    - i. Separate local protocol should be submitted for each sub-study describing the research procedures for each sub-study.
    - ii. Sub-project specific SFI form
    - iii. Recruitment documents/scripts
    - iv. Consent forms (see note in next item)
    - v. Surveys/questionnaires/interview questions specific to the sub-project
    - vi. Anything else that will be viewed by the subject



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- 6) Consent Document and Process - If sub-projects require a consent process and/or consent document, the umbrella project PI should construct a generic consent document that would adequately describe and could be used for all sub-projects. Alternatively, the umbrella project PI could create a template consent document that could be modified for each sub project under the umbrella.
- 7) Each sub-study needs to meet all appropriate HIPAA and FERPA regulations.
- 8) An umbrella project may involve retrospective record review for minors. But research requiring parental permission for minor subjects may not be conducted under an umbrella project.
- 9) Umbrella projects may not have any federal funding sources.
- 10) Umbrella projects must not involve prisoner populations.
- 11) Umbrella projects should not primarily target pregnant women (incidental participation is acceptable).
- 12) Umbrella projects should not involve FDA-regulated products.

### EXAMPLE UMBRELLA PROJECTS:

- 1) Retrospective Medical Reviews in Radiology: A Principal Investigator, along with trainees in Radiology, 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 diagnostic studies? These studies always meet the same criteria for review, waiver of consent, and waiver of HIPAA authorization. The research objectives and research design for these studies covered under the umbrella protocol are the same.
- 2) 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 complete online surveys. No personal information is sought and the individual results are not linked to the subject's identity. The exact questions posed to the subjects vary, but the research hypotheses and research design is the same for all studies.
- 3) Pedagogical Research: A department establishes an umbrella protocol to cover all pedagogical research in their department. During each course, instructors/researchers will explain to students that they will be conducting research on student learning in their section of the course. They will be told that the purpose of this research is to demonstrate the effectiveness of different pedagogical strategies. Students will be told that the activities are no different from activities they would otherwise experience during the course; the difference is that instructors/researchers will be collecting effectiveness data and data from students on their perspectives relative to the innovations implemented by their instructors.
- 4) Course Assignment Related Research: A course instructor requires a research project as a class assignment and the goal of the project is to provide generalizable data. All students within the course are following the same or similar research protocol. A single IRB application form can be submitted by the instructor to cover all student projects.