UNIVERSITY OF OREGON
RESEARCH COMPLIANCE SERVICES

Modification Requirements and Submission Guidance

Scope: This document is intended to guide researchers when considering changes to previously approved research to determine review and submission requirements.

I. General Considerations

In general, changes to previously approved research require review by RCS and/or the IRB prior to implementation to determine the study continues to comply with regulatory requirements. The first section of this guidance helps an investigator determine whether a modification or a new study may be appropriate for the proposed changes. The second section of this guidance helps an investigator determine the submission and review requirements for a modification based on the level of review.

If a change requires either a modification or a new study, approval for the changes must be secured prior to implementing changes.

If you must make a change to an approved protocol to eliminate immediate potential hazards to participants, you may do so without prior approval. If you make changes to eliminate immediate potential hazards, contact RCS as soon as possible for further instructions.

II. Modifying a Protocol vs. Submitting a New Protocol

When proposing changes to an existing study, it is important to consider whether the changes may warrant submission of a new protocol rather than a modification. It is a misconception that adding a modification to an existing study will be easier and faster than submitting a new application. RCS and the IRB must examine any modification using the same review criteria and standards as a new submission. A modification that results in an overly long application with many inconsistencies and/or the inclusion of information and documents that are no longer relevant can be confusing to reviewers. In some cases, a new application which is current and consistent will be easier to review and faster to approve.

When deciding whether to submit a modification or submit a new protocol, consider the following:

- *Do the proposed changes alter the research hypotheses? Is there a change in the study purpose and/or aims?*
    - If the basic research question remains intact, then a new application may not be warranted.

- If the focus or research question has changed, even if it builds on the knowledge learned in an existing study, then a new application may be warranted.
    - The IRB must assess the risks and benefits of the research and balance the risks of the research against the benefits. If the research question has changed then the benefits are likely to have changed. A new application may be warranted to evaluate the balance of risks against the benefits.

- *How will the procedures/methods change?*
    - If the procedures/methods to be used remain essentially the same, then a new application may not be warranted.
        - For example, if the only changes involve substituting one questionnaire another similar questionnaire or adding different stimuli of the same type, then submitting a modification is likely to be the best course of action.
    - If the new procedures/methods deviate substantially from those proposed in the original research plan, then a new application may be warranted.
        - If the changes to the procedures/methods result in a study that is substantially different from the one(s) originally proposed, studies can become unwieldy with multiple study add-ons, can blur the focus of the research, and can affect data quality. This can cause confusion and errors among research team members and lead to non-compliance with the approved protocol and/or impact risks to participants. Submitting a new study may be more appropriate.
        - If the changes result in a "menu" of procedures that may be used, it may become difficult for the IRB to assess the risks of the research to individual participants. Reviewers will need to consider all possible combinations of materials and experimental procedures for all possible participants. In this case, a new application would be the best course as submitting a modification could lead to multiple rounds of revisions.

- *How long has the study been open?*
    - If the protocol is intended as a longitudinal study or is operating within the planned study timeline and if changes are otherwise closely related to the previously approved study, then submitting a modification is likely appropriate.
    - If the protocol is not intended as longitudinal research and has been active for several years, the information within the protocol can become inaccurate as institutional policies, lab settings, and research personnel change. A new application may be appropriate.
        - Protocols that have been open for an extended period may include irrelevant information as portions of the research may be complete and this can create confusion about what activities are ongoing.
        - As new information on risks becomes available, studies that have been ongoing may not reflect the most current information and potentially exposes participants to unnecessary risk. A new application would allow

the protocol to be refined to meet the aims of the current research objectives, ensuring that the study is being conducted consistent with the approved protocol, and that it will reach completion.

- *Will the study utilize new funding?*
  - If new funding is awarded to support the research as currently approved, then a modification application to associate the funding is appropriate.
  - If new funding points to new directions for the research and the aims and research design need to change, a new application can cleanly delineate this new focus and ensure an approved protocol is accurate and relevant to the planned research.

➢ **Contact RCS with any questions about whether it is best to submit a new protocol for review or modify an existing study.**

III. Determining Review Requirements

Review requirements depend on the level of review a protocol initially received. To identify your protocol's level of review—Exempt, Expedited, or Full Board—refer to the information in the most recently issued approval or determination letter for your study. Review the modification criteria below based on the level of review and nature of the change.

Upon review of the proposed changes, RCS and the IRB may determine an alternative path of review is necessary to satisfy regulatory requirements and to protect the rights and welfare of participants.

A. Exempt Protocols

Investigators must self-assess that the proposed changes to a study previously determined to qualify for exemption continues to qualify for exemption. Minor changes are likely to qualify for exemption and more substantive changes have the potential to no longer meet the conditions of exemption. Therefore, some changes to Exempt protocols will require review by RCS to verify the self-assessment of exemption ***prior to implementing changes***. If the study no longer qualifies for exemption with the proposed changes, the study will require review by the IRB using the expedited or full board review procedures; this would require submission of a new initial application for IRB review.

Use the RCS Exempt Self-Assessment Tool to evaluate whether the modified study continues to meet exemption criteria.

1. Minor Changes to Exempt Research

Minor changes to studies previously determined exempt are likely to continue to qualify for exemption. The investigator must self-assess that the study continues to qualify for exemption and whether further submission to RCS is required based on the types of changes detailed below. If the investigator self-assesses that the study no longer qualifies for exemption or if you have questions about the eligibility of a minor change, contact RCS for further instruction.

- *Minor changes include:*
  - Editorial changes that clarify but do not alter the existing meaning of a document

    e.g., grammatical corrections, wordsmithing, addition of clarifying questions, addition of very similar questions to those previously approved, or deletion of questions.
  - Minor revisions to recruitment materials and methods.

    e.g., a change to a phone number, or the addition of a newspaper ad.
  - Minor revisions to survey, interview, or focus group instruments that do not fall outside the scope of the originally described instruments.

    e.g., wordsmithing, addition of clarifying questions, addition of very similar questions to those previously described, or deletion of questions

- *Submission Requirements for Minor Changes to Exempt Research*

  Use the self-assessment tool to evaluate if the study is still exempt.

  → IF STILL EXEMPT, do NOT submit for RCS review. Investigators are responsible for documenting in their research records that the changes made to the protocol were self-assessed as continuing to qualify for exemption and that further submission to RCS was not necessary.

  → IF UNCERTAIN IF STILL EXEMPT, contact RCS to discuss the proposed changes.

  → IF NO LONGER EXEMPT, contact RCS for further instruction as it may be necessary to prepare an initial protocol submission for IRB review.

2. Substantive Changes to Exempt Research

Substantive changes to studies previously determined exempt may continue to qualify for exemption but will require a modification be submitted to RCS for review to verify continued eligibility for exemption or determine if IRB review is required. The investigator must self-assess that the study continues to qualify for exemption prior to submitting a modification. If the investigator self-assesses that the study no longer qualifies for exemption, an initial application for IRB review may be necessary.

- *Substantive changes include but are not limited to:*
  - Adding or removing study personnel.
  - Changing the funding source.
  - Changing the study purpose or procedures.

    e.g., adding a new method, adding a survey on a different topic than previously described, new data collection, etc.
  - Changes to the study population targeted for recruitment.

e.g., increasing number of participants, adding a new population or substantively revising the inclusion/exclusion criteria for the current population.

- Changing the identifiability of the research data you will receive or record.

  e.g., your exempt application states that you will not collect names with the surveys, but you now want to, or you now want to record identifiable data from an existing dataset.

- Changes that alter the risks involved in the study.

- *Submission Requirements for Substantive Changes to Exempt Research*

  Use the self-assessment tool to evaluate if the study is still exempt.

  → IF STILL EXEMPT, prepare an Exempt Modification using the Exempt Review Application and submit to RCS for verification of continued exemption. For studies that were initially granted exemption prior to January 2019, the Modification Review Application may be used to request changes; include any previously reviewed protocol materials impacted by the changes.

  → IF UNCERTAIN IF STILL EXEMPT, contact RCS to discuss the proposed changes.

  → IF NO LONGER EXEMPT, contact RCS for further instruction as it may be necessary to prepare an initial protocol submission for IRB review.

B. Expedited Protocols

Any proposed change to research previously approved using an Expedited Review procedure requires review and approval by the IRB ***prior to implementation***. The modification will be reviewed by at least one member of the IRB. The proposed changes to the protocol will be assessed to determine if the study continues to satisfy IRB approval criteria and if the study continues to qualify for Expedited review.

- *Submission Requirements for Changes*

  Prepare a modification Application and include all applicable materials. At least one member of the IRB will conduct the review.

  → IF STILL EXPEDITED, at least one member of the IRB will conduct the review and RCS will communicate any additional requirements to secure approval.

  → IF NO LONGER EXPEDITED, the modification will be reviewed by the fully convened IRB. RCS will communicate next steps to the investigator.

C. Full Board Protocols

Any proposed change to research previously approved by the fully convened IRB requires review and approval by the IRB ***prior to implementation***. Minor changes must be reviewed by at least one member of the IRB and may not require consideration by the fully convened IRB. Substantive changes will require review by the fully convened IRB.

1. Minor Changes to full board research

Minor changes to studies previously determined to require Full Board review are likely to qualify for an expedited review procedure.

- *Minor changes typically include:*
  - Administrative changes such as editorial changes, wordsmithing, addition of clarifying questions, addition or deletion of similar questions to those previously approved.
  - Revisions to recruitment & consent materials/methods that are similar to previously approved such as a new advertisement using similar language previously approved or adding a clarifying statement in the consent form.
  - Revisions to study instruments or other materials that do not fall outside the scope of the original approved instruments and do not alter risks to participants.
  - Adding or changing study personnel
  - Adding a new study site (most cases)

- *Submission Requirements for Minor Changes*

  Prepare a modification Application and include all applicable materials. At least one member of the IRB will conduct the review and determine if the proposed changes are minor and if IRB approval criteria are still satisfied.

  → IF CHANGEs DETERMINED MINOR AND QUALIFY FOR EXPEDITED REVIEW, at least one member of the IRB will conduct the review and RCS will communicate any additional requirements to secure approval.

  → IF CHANGES DETERMINED TO NOT BE MINOR, the modification will be reviewed by the fully convened IRB. RCS will communicate next steps to the investigator.

2. Substantive Changes to Full Board Research

Substantive changes to studies previously determined to require Full Board review will require review by the fully convened IRB.

- *Substantive changes include but are not limited to:*
  - Changes that adversely affect the risk/benefit ratio of the study or specifically increase the risk to subjects.
  - Changes that significantly alter the risk to benefit assessment or affect the safety of subjects.
  - Changes that involve the addition of procedures, interactions or interventions that add significant physical, social, or psychological risks.
  - Changes that significantly alter the hypothesis or research design.
  - Changes in inclusion/exclusion criteria.

- Changes to a study population.
- Changes that involve the addition of invasive procedures.
- Significant changes in study design.
- New or revised financial conflict of interest disclosures and/or management plans.

- *Submission Requirements for Substantive Changes*

  Prepare a modification Application and include all applicable materials. -The proposed changes will be reviewed by the fully convened IRB to determine if the study continues to satisfy the IRB approval criteria. RCS will communicate next steps to the investigator.