

<b>Policy Number:</b>	204	<b>Version Number:</b>	5.0
<b>Approval Date:</b>	February 14, 2020		
<b>Title:</b>	Modifications		

**Purpose**

To provide a policy for the Princeton University research community and the Princeton University Institutional Review Board (IRB) for review of modifications to previously approved research.

**Scope**

This policy applies to all investigators, including students, conducting human subjects research under the jurisdiction of the Princeton IRB.

**Regulatory Background**

Federal regulations require that changes in approved research, during the period for which IRB approval has already been given, are not initiated by the investigator without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject. An IRB may use the expedited review procedure to review minor changes in previously approved research during the period (of one year or less) for which IRB approval is authorized. In addition, IRB staff must have a mechanism to ensure prompt reporting to the IRB of changes in research activities.

**Responsibilities**

**Principal Investigator:** Responsible for obtaining IRB approval for modifications to approved research prior to implementation of the modification. Please see Princeton University IRB SOP 207 for the complete list of principal investigator obligations.

**IRB Chair or Designated Reviewer:** reviews modifications that are eligible for expedited review.

**Convened IRB:** reviews modifications that are not eligible for expedited review.

**Definitions**

**Modification:** A change to research activity which was previously approved by the IRB. Modifications are reviewed under expedited review or at a convened Board meeting.

**Minor change:** for a modification to be considered a minor change, one of the following sets of criteria must be met:

1. Set #1:
  - a. The modification does not affect the design of the research
  - b. and the modification adds no more than minimal risk to subjects

c. and all added study procedures (if applicable) fall into one or more of the expedited review categories established by OHRP.

2. Set #2:

- a. The research activities (or remaining research activities) present no more than minimal risk to subjects
- b. and identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will not reasonably place them at risk of criminal or civil liability or be damaging to the their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk
- c. and all added study procedures (if applicable) fall into one or more of the expedited review categories established by OHRP.

**Policy**

- 1. Investigators must submit a modification request form to the IRB via eRIA.
- 2. The investigator must include any new documents and any previously approved documents that are affected by the modification, e.g., initial review application that serves as the protocol; consent form; recruitment materials; survey, questionnaire, interview guide, etc. Clean and tracked change versions must be submitted, which will allow the IRB to identify the changes.
- 3. Minor changes are reviewed via expedited review by the IRB Chair or a designated reviewer. The IRB Chair or a designated reviewer determines whether the modification is a minor change and is eligible for expedited review. The IRB Chair or a designated reviewer may approve or require revisions to the modification. The IRB Chair or designated reviewer cannot disapprove a modification.
- 4. Modifications that do not meet the definition of minor change are reviewed at a convened IRB meeting.
- 5. After the IRB approves the modification, the investigator can implement the change.
- 6. The IRB will require that an investigator re-consent subjects if the modification may affect the subjects' willingness to continue participation.
- 7. If the IRB approves the modification via expedited review, IRB staff will report the modification's approval to the IRB via the expedited review report. The expedited review report is part of each IRB meeting's agenda materials.

**References**

45 CFR §46.103 (4) (iii)

45 CFR §46.110 (a) (b)

45 CFR §46.116 (b) (5)

**Version History**

Version Number	Revision Date	Revision Description
1.0	N/A	Initiation
2.0	6/17/2013	Editorial revisions
3.0	10/1/2016	Minor changes
4.0	10/1/2017	Edited to reflect the use of eRIA
5.0	2/14/2020	Revised to reflect RIA policy template