

Modification of Exempt Form

1. Purpose & Policy

1. Goal: Defines when the IRB accepts changes to previously "Exempt" studies.
2. Rule: Modifications are permitted only if they do not increase risk or disqualify the study from its specific exemption category.

2. Changes Requiring Submission (Modification Application)

You must submit a request for administrative review before implementing these changes:

1. Key personnel: Changing any key personnel listed on the protocol.
2. Funding: Adding or changing funding sources (especially federal).
3. Instruments: Minor additions to surveys/interviews.
4. Recruitment: Minor edits to ads or flyers.
5. Enrollment: Increasing sample size without changing the population or scope.

3. Changes NOT Requiring Submission

These can be documented internally by the PI without notifying the IRB:

1. Editorial: Typos, formatting, or clarifications that don't change meaning.

4. Review Process

1. Submission: PI submits the request form.
2. Review: IRB Staff determines if the study remains Exempt.
3. Outcome:
 - a. Approved: Cayuse HE Modification protocol approval letter issued.
 - b. Rejected/IRB Reviewer comments: Cayuse HE Modification protocol rejected; PI must submit appropriate changes to the application to proceed with application.