

HAC Policies and Procedures for HAC Members and OHRP Staff

Exempt Protocols

How are Exempt Projects Reviewed?

Projects reviewed by the exempt procedure require a complete application and are conducted by the HAC Chairperson, or by one or more experienced reviewers who have been voting members for more than one year and have expertise in the area being considered. The HAC Chairperson will designate the individual.

What Tools are Available to the HAC Reviewer for Exempt from Full Review?

The HAC Chairperson or designee use the Exempt Review checklist to review the packet of information submitted by the Principal Investigator. The HAC Chairperson or designee must confirm that the protocol may be reviewed under the exempt from full review criterion:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, reputation or lead to loss of insurability.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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Can the HAC Chairperson Approve Research Protocols if they Qualify for Exempt from Full Review?

Yes. The HAC Chairperson may approve research protocols if the protocol qualifies for exempt from full review.

Can the HAC Chairperson Disapprove a Protocol Regardless of Level of Review?

No. The HAC Chairperson may not disapprove a protocol. All disapprovals, regardless of level of review, must be determined by the full committee.