What is an exempt review process?

An exempt review procedure consists of a review by the IRB chairperson. Studies that are determined to meet exempt status are not exempt from human subject protections and ethical principles.

What qualifies for exempt review?

Only studies that meet the six specific categories of exempt activities as delineated by HHS Regulations 45 CFR 46 (101) (b) are eligible to be given exempt status.

Studies can NOT be exempt if either of the following is true:
   a. the research includes prisoners
   b. the research is regulated by the FDA (categories 1-5)

How do I submit a request for exempt review?

The principal investigator may make an initial request for study exemption by submitting a completed new protocol submission xForm in IRBManager. The IRB Chair (or designee) will make the final determination for exemption status.

There are 6 Exempt Categories:

1. 45 CFR 46.101 (b)(1): Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   a. research on regular and special education instructional strategies, or
   b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. 45 CFR 46.101 (b)(2): Research involving the use of educational tests, (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
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a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

b. 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, or reputation, or insurability.

For 45 CFR 46 (101) (b)(2), the exemption for research involving survey or interview procedures or observations of public behavior DOES NOT apply to research covered by 45 CFR Part 46, Subpart D (Additional DHHS Protections for Children Involved as Subjects in Research), except for research involving observation of public behavior where the investigators do not participate in the activities being observed.

3. 45 CFR 46.101(b)(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 45CFR 46.101(b)(2) if:
   a. the human subjects are elected or appointed public officials or candidates for public office, or
   b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. 45 CFR 46.101(b)(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.

To qualify for the above 45 CFR 46 (101) (b) category 4 exemption, data, documents, records or specimens must already exist at the time the research is proposed.

5. 45 CFR 46.101(b)(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:
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a. Public benefit or service programs;
b. procedures for obtaining benefits or services under those programs;
c. possible changes in or alternatives to those programs or procedures; or
d. possible changes in methods or levels of payment for benefits or services under those programs.

To qualify for Exemption 5 for Public Benefit Projects, which is for projects conducted by or subject to approval of federal agencies, the following criteria must be satisfied:

- The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive or nutrition services as provided under the Older Americans Act)
- The research or demonstration project must be conducted pursuant to specific federal statutory authority
- There must be no statutory requirement that the project be reviewed by an IRB
- The project must not involve significant physical invasions or intrusions upon the privacy of participants
- Authorization or concurrence by funding agency

6. 45 CFR 46.101(b)(6) and 21 CFR 56.104(d): Taste and food quality evaluation and consumer acceptance studies,
   a. if wholesome foods without additives are consumed or
   b. 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 US Department of Agriculture.