

## FAQs: Exempt Research Determination

**These Frequently Asked Questions (FAQs) apply to research that is conducted or supported by the Department of Health and Human Services (HHS)**

**Question 1:** [Who may determine that research is exempt?](#)

**Question 2:** [Must there be review by someone other than the investigator before a research study is determined to be exempt?](#)

**Question 3:** [What should investigators do when considering changes to an exempt study that could make it nonexempt?](#)

**Question 1:** Who may determine that research is exempt?

**Answer 1:** The regulations do not specify who at an institution may determine that research is exempt under [45 CFR 46.101\(b\)](#). However, OHRP recommends that, because of the potential for conflict of interest, investigators not be given the authority to make an independent determination that human subjects research is exempt. (For more on this issue, see also [FAQ #2](#) “Must there be review by someone other than the investigator before a research study is determined to be exempt?”). Institutions should implement exemption policies that most effectively address the local setting and programs of research. OHRP recognizes that this may result in a variety of configurations of exemption authority, any of which are acceptable assuming compliance with applicable regulations.

In developing policies and procedures addressing exemption, OHRP recommends that institutions consider the following:

- Persons making an exemption determination should have access to sufficient information to make a correct determination. Evaluation tools and resources may take a variety of forms, including but not restricted to: checklists, Standard Operating Procedures, or specialized training for individuals authorized by the institution to make an exemption determination.
- When an exemption determination is made, the specific exemption category or categories should be included in the record and this information should be available for oversight and audit purposes.
- Institutional policies and procedures should identify clearly who is responsible for making exemption decisions. This may be done in a variety of ways, including delegation by name, role, or position.
- Institutions should make policy and procedure information addressing exemption determination readily accessible to investigators and others involved in the conduct and administration of human subjects research.
- Regarding the possibility of exemption determinations being made without review by someone other than the investigator, please also see [FAQ #2](#), “Must there be review by someone other than the investigator before a research study is determined to be exempt?”

OHRP notes that the HHS retains final authority as to whether a particular human subjects research study conducted or supported by HHS is exempt from the HHS regulations ([45 CFR 46.101\(c\)](#)).

**Question 2:** Must there be review by someone other than the investigator before a research study is determined to be exempt?

**Answer 2:** No, the regulations do not require that someone other than the investigator be involved in making a determination that a research study is exempt. What they do require is that there be accurate determinations so that non-exempt research ends up being reviewed by an IRB. Because of the potential for conflict of interest in this situation, OHRP's long-standing recommendation is that investigators not be given the authority to make an independent determination that human subjects research is exempt.

OHRP recognizes that some institutions will wish to take advantage of the regulatory flexibility so that exemption determinations can be made in a manner that minimally delays research, while at the same time not diminishing human subject protections. While an institutional policy that allowed investigators to make their own exemption determinations, without additional protections, would likely risk inaccurate determinations, institutions may be able to craft policies that build in protections which lead to accurate determinations by appropriately dealing with investigator conflicts of interest and lack of detailed knowledge of the regulations.

For example, an institution might craft a checklist for certain exemption categories, with questions that are easily answered "yes" or "no" by an investigator, with certain answers leading to a clear conclusion that the study is exempt. The institution might allow a researcher to immediately begin a study after having completed such a checklist and filed it, together with accompanying documents, with an appropriate institutional office, without waiting for or requiring any prior review of that filing. Similarly, a web-based form might be created that served the same purpose, allowing the researcher to begin the research immediately after submitting the required information using the web form. In both instances, the key issue would be whether these procedures lead to correct determinations that studies are exempt.

OHRP notes that the HHS retains final authority as to whether a particular human subjects research study conducted or supported by HHS is exempt from the HHS regulations ([45 CFR 46.101\(c\)](#)).

**Question 3:** What should investigators do when considering changes to an exempt study that could make it nonexempt?

**Answer:** Investigators should consult with the appropriate institutional authority whenever questions arise about whether planned changes to an exempt study might make that study nonexempt human subjects research. OHRP recommends that institutions have policies in place to define how proposed changes to exempt research will be evaluated. The person(s) authorized to make this determination should have access to sufficient information to make a correct determination. In addition, the institution should ensure the appropriate communication of such a policy to all investigators.