

Benign behavioral interventions: interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing.

Exempt Research

3. Policy

All research activities involving human subjects must receive IRB review prior to initiation, including human research activities that may qualify for exempt determination. Requests for IRB review are submitted through Cayuse. KSU IRB Office staff are responsible for making exempt determinations.

3.1. For a study to qualify for an exempt determination, the research must pose no more than minimal risk to participants, and all research activities involved must be eligible for at least one of the exempt categories. If any of the research activities involved are not eligible for an exempt determination, the research must receive IRB review.

- 3.12. Changes related to study personnel must be submitted as a Modification for IRB review and approval before initiation of the changes.
- 3.13. Investigators must notify the IRB when the study is complete by submitting a closure request.

include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act.

(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

(d) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or 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.

Pre-Common Rule Exemption

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(5) Research and demonstration projects which are conducted by or subject to the approval of