SOP 406: Studies Initially Approved Before January 2019

Terms and Abbreviations

IRB: Institutional Review Board
IRB office staff: the IRB Manager, IRB Administrator, and any other IRB office staff, either collectively or individually
OHRP: Office of Human Research Protections; a division of the federal Health and Human Services department (HHS) that oversees human subjects research
Pre-2018 regulations: Regulations governing all research that was approved prior to January 21, 2019. The regulation changes were originally slated to go into effect January 2018 (hence "pre-2018"), but the implementation was delayed for a year.
UWM: University of Wisconsin – Milwaukee

Overview

In 2017 OHRP issued new federal regulations governing human subjects research, which went into effect on January 21, 2019. Under the regulations, institutions were allowed to decide whether studies approved before the effective date would continue to be reviewed and administered under the previous version of the federal regulations or be transitioned to the new regulations. At UWM, previously approved studies continue to be governed by the pre-2018 regulations, and only new studies that receive initial approval on or after January 21, 2019 follow the 2018 regulations.

At UWM, studies reviewed and approved under the pre-2018 regulations differ from newer studies in the following areas:

- continuing review requirements
- exempt categories
- required elements of informed consent
- clinical trials

SOPs governing those areas apply to new (2019 onwards) studies only, and the processes governing older studies are outlined in this document. Any process not outlined here is identical to the process followed by all new studies, and the appropriate SOP for that process should be referenced for details.

Details and Procedures

Continuing Reviews

All expedited and full board studies are required to undergo a continuing review not less than annually. Continuing reviews are submitted to the IRB in advance of the study expiration date. IRB office staff perform the review and may assign the continuing review to a reviewer for expedited review or send to the full board, depending on the level of risk.

Exempt Review Categories

The exempt categories under the pre-2018 regulations are as follows:

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

(2) Research that involving the use of interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(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 (b)(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 that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or 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.

Required Elements of Informed Consent

Basic elements:

- Statement that the study involves research and an explanation of the purposes of the research
- The expected duration of the subject's participation
- Description of the procedures to be followed and identification of any procedures which are experimental
- Description of any reasonably foreseeable risks or discomforts to the subject
- Description of any benefits to the subject or to others which may reasonably be expected
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- Statement describing the extent to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained
- Research, Rights or Injury: An explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury
- Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

Additional elements, as appropriate:

- Statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- Statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject

- The approximate number of subjects involved in the study

Clinical Trials

New regulations require that the consent form for federally funded clinical trials be posted to a website that is publicly accessible. This is not required in the pre-2018 regulations.

References

45 CFR 46 (pre-2018)

SOP 401 Review of Research

SOP Appendix 401.1 Exempt Review Categories

SOP 402 Informed Consent

SOP 404 Continuing Review & Study Closure

Revision History

Version	Date	Summary of Changes
1	2 Jul 2020	Initial version