Human Research Protection Committee

Exempt Status

The regulations recognize that certain items should not require IRB oversight and are therefore exempt from review. This standard will outline what types of items qualify for exemption from review and how it is determined if a study is exempt. At Cox College/CoxHealth, the HPRC will determine and approve projects that qualify for exempt status. Regulations DHHS 45 CFR 46.101(b), 21 CFR 56.104, and 21 CFR 56.105 are followed.

I. 5 categories of research qualify for exemption according to FDA regulation (21 CFR 56.104 and 21 CFR 56.105)
   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 our 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
   E. On the application of a sponsor or sponsor-investigator, the Food and Drug Administration may waive any of the requirements contained in these regulations, including the requirements for IRB review, for specific research activities or for classes of research activities, otherwise covered by these regulations.

II. 6 categories of research qualify for exemption according to OHRP regulation (45 CFR 46.101(b))
   A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
      1. Research on regular and special education instructional strategies, or
      2. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
   B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
      1. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
      2. 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, or reputation.
   C. 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:
      1. The human subjects are elected or appointed public officials or candidates for public office; or
      2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
   D. 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.

1. Special Note: an investigator may obtain identifiable information (e.g. medical record number to access records) to collect other data necessary for the research as long as the data collected is not recorded in a manner in which the data may again be linked to the identifiable information.

E. 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:
   1. Public benefit or service programs;
   2. Procedures for obtaining benefits or services under those programs;
   3. Possible changes in or alternatives to those programs or procedures; or
   4. Possible changes in methods or levels of payment for benefits or services under those programs.

F. Taste and food quality evaluation and consumer acceptance studies:
   1. If wholesome foods without additives are consumed or
   2. 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.

III. Cox College/CoxHealth also recognizes the following does not qualify as research requiring oversight
   A. Research in quality improvement of treatment or organizational processes so long as the research is organized in such a way that subjects are not placed at medical risk, risk of adverse financial or social consequences, or risk of release of personally identifiable information and is for the sole purpose of internal quality improvement.

IV. Exceptions to these categories
   A. Research involving children
      1. 46.101(b)(2), II.B. in this standard,is only allowed to include children if the investigator(s) do not participate in the activities being observed.
   B. Research involving prisoners
      1. 46.101(b) is not allowed for prisoners.

V. Checklist for Exempt Research to aid in decision making
   A. It is clear that the nature of the proposed research fits one of the exempt categories listed in this policy.
   B. No implications for criminal or civil liability, employability, or damage to subject's financial standing or reputation would exist if data were known outside of the study.
   C. Does the research employ a protected group as subjects (for example: minors).
   D. The study does not present more than MINIMAL RISK to the subjects.
   E. The study does not involve DECEPTION.
   F. Appropriate informed consent procedures will be followed.
   G. It is clear that the research includes human subjects.

VI. Authority to determine exemption status and notification to the Committee and investigator
   A. Because Exempt research does not require IRB over site, the HRPC will make the determination, according to regulation, if proposed research is exempt from the human subject regulations.
      1. A decision will be determined within a reasonable time.
      2. An investigator must submit a written description of the protocol with complete detail of the purpose, procedures of the project, how consent of participants (if applicable) will be obtained, what the intent of the project is, and how the results will be used.
   B. The Committee will review the applications for exempt status at the monthly meeting. If approved, a recommendation will be send to the CoxHealth Institutional Official responsible for oversight

of ethical research.

C. A letter will be sent to the investigator within approximately 10 business days of the exemption status and will include what category of exemption the decision is based upon.
    1. This letter should include how the decision was made and instructions that if any aspect of the project changes the HRPC should be notified for determination if the study still qualifies for exemption under these regulations and policies.
D. Even if proposed research is deemed to be exempt from IRB review it may be required to be followed by CoxHealth to ensure the protection of participants. Such oversight may include:
    1. The requirement of informed consent
    2. Department Head of where research taking place agreement of responsibility