IRB RESEARCH REVIEW CATEGORIES

The extent of the IRB review will depend upon the nature of the research.
There are three research review categories: Exempt Research, Expedited Review, And Full Review.

7.1 Exempt Research

7.1.1 Certain categories of research are exempt from the Protection of Human Subjects policy in the Code of Federal Regulations 45 CFR 46. The IRB Chair will determine, based on the federal guidelines, whether a research activity qualifies for exemption. Although exempt research is not regularly reviewed by the IRB, the exempt research form (and the informed consent form, if applicable) must be on file with the IRB, and the research may be reviewed at the committee’s discretion. If the committee deems necessary, it may require a full review.

7.1.2 Unless otherwise required by federal departments or agencies, research activities in which the only involvement of human subjects will be in one or more of the following categories are generally exempt from full review by the IRB:

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

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

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 the previous paragraph, 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 by or subject to the approval of federal department or agency heads, and that are designed to study, evaluate, or otherwise examine:
   i. public benefit or service programs;
   ii. procedures for obtaining benefits or services under these programs;
   iii. possible changes in or alternatives to those programs or procedures; or
   iv. possible changes in methods or levels of payment for benefits or services under those programs.

7.1.3 Research involving special or protected populations, such as children, the elderly, prisoners, pregnant women, and the handicapped, is subject to full review.

7.2 Expedited Review
**7.2.1** Expedited review procedures are available for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. Specifically, research is eligible for expedited review if it involves no more than minimal risk (see 45 CFR as amended) to the subjects and the only involvement of human subjects will be in one or more of the categories listed below:

1. Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
2. Collection of excreta and external excretion including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve the input of matter or significant amounts of energy into the subject or an invasion of the subject’s privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, X-rays, microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older who are in good health and not pregnant.*
5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Voice recording made for research purposes such as investigation of speech defects.
7. Moderate exercise of healthy volunteers.**
8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subjects’ behavior and the research will not involve stress to the subjects.
10. Research on drugs and devices for which an investigational new drug exemption or an investigational device exemption is not required.
11. Any other category specifically added to this list by HHS and published in the Federal Register.

* Subjects must be informed orally of the risk of bruising and infection.

** Moderate exercise does not include stress testing.

**7.2.2** Informed consent is required, but the requirement to obtain a signed consent form may be waived if:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

**7.2.3** In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

**7.3** **Full Review**
All those projects not exempt or qualifying for expedited review shall be subject to full review by the IRB.