Levels of IRB Review

All research involving humans that falls under the jurisdiction of the IRB for review and approval must meet the criteria for one of the following methods for review:

⇒ Exempt from IRB Committee Review
⇒ Expedited Review
⇒ Full Review

No Human participants may be enrolled or recruited prior to receipt of written final approval of the study from the IRB.

Exempt Review

Exemption does not mean "Do nothing."

In each instance, the investigator will make the initial request for exempt status and the IRB Chair will make the final determination. If the research is submitted by the IRB Chair, the Vice Chair the Vice Chair will review this determination. Neither the Chair nor the Vice Chair may review for approval research studies submitted for exempt or expedited review from their respective departments or divisions (for larger departments). The exemption status must be approved by the IRB Chair or IRB Vice Chair, or an experienced member designated by the Chair. If upon this review the determination of exemption is not upheld, the investigator will be informed and provided with the reasons for denial of exemption. The protocol will then be submitted for either expedited or full review, as appropriate to the level of risk, by the IRB.

The institution retains the option under the assurance to not claim the options provided for exempt status, but instead choose to require IRB review. Documentation for all exemptions will include citation of the specific category justifying the exemption.

In addition, for studies subject to the 2018 Common Rule, the IRB will conduct a limited review of the research as required. Limited IRB review is a new requirement created under the revised DHHS regulations, and is unique to DHHS regulations. Limited IRB review will not be conducted by staff, but by a member of the IRB (IRB Chair or Vice-Chair or an experienced IRB member designated by the IRB Chair).

Research that is determined to be exempt from IRB review is not exempt from protection of human subjects. All exempt research is subject to all human subject protections and ethical standards. Studies submitted requesting exempt status will be reviewed by the Chair or Vice Chair to determine whether the research fulfills the organization’s ethical standards. The standards are as follows:

1. The research holds out no more than minimal risk to the participants.

2. The selection of participants is equitable.
3. If the study includes recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.

4. *If the study includes interactions with participants, there is a consent process that discloses such information as
   
   a. that the activity involves research
   b. a description of the procedures
   c. that participation is voluntary
   d. the name and contact information for the investigator

5. The research has adequate provisions to maintain the privacy interests of participants.

6. For studies subject to limited review, information about risk of loss of confidentiality.

*In limited circumstances, the IRB Chair may determine that this requirement is not appropriate. Contact the IRB staff for questions.

For VA studies: For exempt research activities involving the Investigator interacting with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions, the following information must be given to the prospective human subject as applicable in writing or orally: (1) The activity is research; (2) Participation is voluntary; (3) Permission to participate can be withdrawn; (4) Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and (5) Contact information for the VA Investigator.

If the Chair or Vice Chair identifies ethical concerns in the research submitted for exemption, the study will not be exempted.

**Under the 1991 Common Rule,**

Only studies that meet the six specific categories of exempt activities as delineated by HHS Regulations 45 CFR 46 (101) (b) are eligible to be given exempt status. **NOTE:** These categories do not apply to prisoners and categories 1-5 do not apply to FDA regulated research.

1. 45 CFR 46.101 (b)(1): Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   
   a. research on regular and special education instructional strategies, or
   b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. 45 CFR 46.101 (b)(2): Research involving the use of educational tests, (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   b. 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 or insurability.

For 45 CFR 46 (101) (b)(2), the exemption for research involving survey or interview procedures or observations of public behavior DOES NOT apply to research covered by 45 CFR Part 46, Subpart D (Additional DHHS Protections for Children Involved as Subjects in Research), except for research involving observation of public behavior where the investigators do not participate in the activities being observed.

3. 45 CFR.46.101(b)(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 45CFR 46.101(b)(2)) if:
   a. the human subjects are elected or appointed public officials or candidates for public office, or
   b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. 45 CFR 46.101(b)(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.

To qualify for the above 45 CFR 46 (101) (b) category 4 exemption, data, documents, records or specimens must already exist at the time the research is proposed.

5. 45 CFR 46.101(b)(5): 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:
   a. Public benefit or service programs;
   b. procedures for obtaining benefits or services under those programs;
c. possible changes in or alternatives to those programs or procedures; or

d. possible changes in methods or levels of payment for benefits or services under those programs. To qualify for Exemption 5 for Public Benefit Projects, which is for projects conducted by or subject to approval of federal agencies, the following criteria must be satisfied:

a) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive or nutrition services as provided under the Older Americans Act)

b) The research or demonstration project must be conducted pursuant to specific federal statutory authority

c) There must be no statutory requirement that the project be reviewed by an IRB

d) The project must not involve significant physical invasions or intrusions upon the privacy of participants

e) Authorization or concurrence by funding agency

For VA studies, the determination of exempt status for research and demonstration projects meeting the criteria in this category must be made by the Under Secretary for Health on behalf of the Secretary of VA, after consultation with Office of Research and Development (ORD), Office of Research Oversight (ORO), Office of General Counsel (OGC), and other experts, as appropriate.

6. 45 CFR 46.101(b)(6) and 21 CFR 56.104(d): Taste and food quality evaluation and consumer acceptance studies,

a. if wholesome foods without additives are consumed or

b. 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 US Department of Agriculture

For studies subject to the Common Rule:

Only research activities in which the only involvement of human subjects will be in one or more of the six specific categories of exempt activities as delineated by HHS Regulations 45 CFR 46 (1041) (db) are eligible to be given exempt status. ETSU has determined to not allow exemptions under category 7 or 8.

Categories 1-5 and 7-8 do not apply to FDA-regulated research.
Subpart B (pregnant women, fetuses and neonates): Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

Subpart C (prisoners): The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Subpart D (children): The exemptions at paragraphs (d)(1), (4), (5), (6), (7- not allowed at ETSU), and (8- not allowed at ETSU) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

Transnational: Laws and regulations in some countries do not allow exemptions. If the research is not eligible for an exemption under the laws of that country, even though the research may be covered by DHHS regulations, ETSU will not allow an exemption for research.

The six categories are:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most 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.

   The exemption at Category 1 may be applied may be applied to research with children (research subject to subpart D) if the conditions of the exemption are met.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

   (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, 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, educational advancement, or reputation; or
(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § (insert reference)_111(a)(7).

Children (research subject to Part D):

Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) 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, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § (insert reference)_111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Benign behavioral interventions are:
• Brief in duration.

• Harmless

• Painless

• Not physically invasive

• Not likely to have a significant adverse lasting impact on the participants.

• The researcher has no reason to think the subjects will find the interventions offensive or embarrassing

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(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 (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and 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. Such projects 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, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

For VA studies, the determination of exempt status for research and demonstration projects meeting the criteria for exempt category 5 must be made by the Under Secretary for Health on behalf of the Secretary of VA, after consultation with Office of Research and Development (ORD), Office of Research Oversight (ORO), Office of General Counsel (OGC), and other experts, as appropriate.

(6) 45 CFR 46 and 21 CFR 56.104(d): Taste and food quality evaluation and consumer acceptance studies,

a. if wholesome foods without additives are consumed or

b. 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 US Department of Agriculture.

If the proposed research activities do not meet the criteria for exemption, the IRB will promptly correspond with the investigator outlining any additional information needed and proper type of review (e.g., expedited or full)

**Modifications:** Any proposed changes to an exempt study must be submitted to the IRB for review and approval prior to implementation. Some modifications to the research may change the review status and require the investigator to submit an application for expedited or full review. (Refer to modification policy)
Expedited Review

Expedited review does not mean “fast” but rather, certain research, meeting the specified criteria, may be reviewed by the IRB Chairperson, Vice Chair or two or more IRB members who have been selected based on their expertise and experience, not at a convened Committee meeting.

For studies subject to the 1991 Common Rule, expedited review **MAY NOT** be used if:

- research is minimal risk but does not appear in one of the listed categories

- research involves greater than minimal risk.

- research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

- research is classified and involves human subjects.

**Categories for Expedited Approval:** HHS Regulations at 45CFR.46.110(b)(1) limit the use of expedited review procedures to specific research categories published in the Federal Register at 63 FR 60364-60367. The following categories of research may be reviewed by the IRB through an expedited review procedure:

Only those research activities that:

A. present no more than minimal risk to human subjects **AND**

B. involve only procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   b) Research on medical devices for which

      (i) an investigational device exemption application (21 CFR Part 812) is not required; or
(ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b) from other adults and children\(^2\), considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

a) hair and nail clippings in a nondisfiguring manner

b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction

c) permanent teeth if routine patient care indicates a need for extraction

d) excreta and external secretions (including sweat)

e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue

f) placenta removed at delivery

g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor

h) supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques

i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings

j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

   a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy

   b) weighing or testing sensory acuity

   c) magnetic resonance imaging

   d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography

   e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

   a) Where
(i) the research is permanently closed to the enrollment of new subjects;

(ii) all subjects have completed all research-related interventions; and

(iii) the research remains active only for long-term follow-up of subjects; or

b) where no subjects have been enrolled and no additional risks have been identified; or

c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

2 Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

For studies subject to the revised Common Rule:

HHS Regulations at 45CFR.46.110(b)(1) limit the use of expedited review procedures to specific research categories published in the Federal Register at 63 FR 60364-60367. The following categories of research may be reviewed by the IRB through an expedited review procedure:

b)(1) An IRB may use the expedited review procedure to review the following:

(i) Some or all of the research appearing on the list described below, unless the reviewer determines that the study involves more than minimal risk;

(ii) Minor changes in previously approved research during the period for which approval is authorized; or

(iii) Research for which limited IRB review is a condition of exemption under §__.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8).

Only those research activities that

(1) present no more than minimal risk to human subjects

AND

(2) involve only procedures listed in one or more of the following categories
may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110.

For research subject to the revised Final Rule, research appearing on the list of expedited review categories is deemed to be no more than minimal risk. Research that falls within the list of categories is presumed to be minimal risk unless the IRB determines and documents that the research involves more than minimal risk. [§ .110(b)(1)(i)] If the reviewer determines that the research involves more than minimal risk, it will be referred for review by the convened IRB.

If a reviewer finds that research appearing on the expedited review list is greater than minimal risk, the reviewer must document the rationale for this determination and the rationale for review by the convened IRB or EC.

Expedited review MAY NOT be used if:

X research is minimal risk but does not appear in one of the listed categories

X research has been determined by reviewer to involve greater than minimal risk.

X research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

X research is classified and involves human subjects.

The activities listed below are not considered to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. The categories in this list apply regardless of the age of subjects, except as noted.

Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

The IRB shall apply the most current list of categories of research published in the Federal Register that may be reviewed using expedited review procedures [§ .110(a)].

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

2 Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

Expedited reviews should be conducted with the same depth as reviews conducted by the convened board. Research materials submitted must include sufficient detail for the reviewer(s) to determine the study meets criteria 45 CFR 46.111, 21 CFR 56.111 and 38 CFR 16.111, if applicable, for approval.

Expedited reviewers may approve research, require modifications in order to secure approval, or defer the proposal to the convened board. Protocols are also referred to the convened board if the investigator does not concur with the requested modifications.
For studies subject to 1991 Common Rule and FDA studies, if the proposal is approved or approved with stipulations, reviewers also decide on the interval for the ongoing review of the study based on the degree of risk to human subjects. Continuing reviews for approval beyond the initial year will be annual reviews or other predefined review periods not to exceed one (1) year.

For studies subject to the 2018 Common Rule, the IRB will conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in § __.109(f).

Unless an IRB determines otherwise, continuing review of research is not required in the following circumstance: Research eligible for expedited review in accordance with § __.110, (Research meets one or more categories of research that qualify for expedited review). If the expedited reviewer determines that continuing review of an expedited study is necessary, the reviewer must explicitly justify why continuing review would enhance protection of research subjects (§ ll.109(f)(1)(i) and § ll.115(a)(3)).

The full Committee is advised of research proposals/activities that have been approved through the expedited review procedure.

In determining which studies require review more often than annually, the IRB will consider:

- (A) The nature of and any risks posed by the clinical investigation.
- (B) The degree of uncertainty regarding the risks involved.
- (C) The vulnerability of the participants.
- (D) The experience of the clinical investigator in conducting clinical research.
- (E) The IRB’s previous experience with that researcher or sponsor (e.g., compliance history, previous problems with the researcher obtaining informed consent, prior complaints from participants about the researcher).
- (F) The projected rate of enrollment.
- (G) Whether the study involve novel therapies
- (H) other reasons as determined by IRB

**Full Reviews**

For Initial Full reviews, see Full Review Section of this handbook.