ALABAMA A&M UNIVERSITY
OFFICE OF RESEARCH COMPLIANCE
IRB APPLICATION FORM

Approval of Research Projects Involving Human Subjects IRB# _____

SECTION A

I, _____, submit to the Institutional Review Board (IRB) this IRB Form along with a copy of my research project/proposal and a copy of a one-page abstract in lay terminology and the informed consent document. I have also attached a copy of my CITI Human Subjects Training Certification. ***Note**: I understand that my IRB application **WILL NOT** be accepted/reviewed without the Human Subjects Training Certification.*

By certifying below, the Principal Investigator (PI)/Researcher affirms the following:

- I will personally conduct or supervise this research study.
- I will ensure that this study is performed in compliance with all applicable laws, regulations and university policies regarding Human Subjects research.
- I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects.
- I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations.
- I will obtain informed consent of subjects who are to participate in this research project.
- I will make sure that all collaborators, students and employees assisting in this research study have completed the CITI Human Subject Training.
- I will cooperate with the continuing review of this research project by submitting annual reports and a final report.
- I will obtain prior approval from the IRB before amending or altering the project or implementing changes in the approved consent form.
- I will maintain all documentation such as consent forms, progress reports, data as required by the institution and Federal Regulations.

All information given in this form is accurate and complete. ***I acknowledge that this study proposes research that has been determined to include Security Level 2 data security requirements***.

I agree to accept responsibility for managing these risks appropriately in consultation with departmental and/or campus security personnel. The Data Security requirement addendum can be reviewed here.

Note: If PI is a student or Trainee Investigator, the Faculty advisor also certifies the following: *I accept ultimate responsibility for ensuring that this study complies with all the obligations listed above for the PI/Researcher.*

☐ I certify and attest that all the above statements are true.

Signature: **Date:**

Please E-mail completed IRB Form and supporting documents to: *Research.Compliance@aamu.edu*
Attached: 45 CFR 46, Subpart A: Federal Policy for the Protection of Human Subjects

SECTION B
PROJECT INFORMATION AND SCREENING

STUDY IS PART OF: **Choose an item** Other:

PROJECT TITLE

Choose an item

PRINCIPAL INVESTIGATOR **COLLEGE/PROGRAM**

Campus (Building #) or Street Address Phone Number

City State Zip E-mail Address

KEY PERSONNEL AND TRAINING (students must include the faculty member overseeing the research)

CITI: *Social & Behavioral Research – Basic/Refresher* completed through the CITI portal is the **ONLY training that will be accepted. **

Name	Role on Project	AAMU Affiliated (Yes/No)? (If no, please list affiliation)	CITI Training completion date

*Key personnel are any individuals considered engaged in research. Examples include obtaining consent, recording private behavior, analyzing identifiable data, etc. ANY changes in personnel during the project requires written notification to and approval from the Institutional Review Board.

SECTION B
PROJECT INFORMATION AND SCREENING

POTENTIAL CONFLICT OF INTEREST *Required*

Do any investigators or key personnel in this research now have, or expect to have during the term of the project, any financial or other conflicting interest in a business entity that could reasonably be expected to bias the activities described in this application, or that could create a perception of bias? **NO** ☐ **YES** ☐ *If "Yes," describe:*

EXTERNAL FUNDING ☐ **No** ☐ **Yes.** If yes, provide:

- Funding Source: ☐ Awarded ☐ Submitted
- Effective Date: University Account Number:
- Exact Application Title:

CONTROLLED SUBSTANCES

Does this project require procurement, administration, or laboratory testing of controlled substances? ☐ **No** ☐ **Yes**

- Name of the person who is or will be licensed to obtain controlled substances:
- Alabama Controlled Substances License # (if still in process, type "pending"):
- US Drug Enforcement Agency Registration # (if still in process, type "pending"):

PARTICIPANT INFORMATION

- Approximate number of anticipated participants:
- Participant age range:
- Approximate date when participants will be contacted:
- Approximate ending date of participant involvement:

Initial contact date MUST be a future date allowing adequate time for IRB review

PARTICIPANT TIME COMMITMENT (Frequency and Duration)

Research Method (type of interaction with participant)	**Choose an item**	**Choose an item**	**Choose an item**
Number of Sessions (How often the PI will interact with the participant)			
Average Duration of Each Session (How long each session lasts, for example 10 minutes)			
Total average time required (number of sessions multiplied by average duration of each session)			

SPECIAL REQUIREMENTS

- Will participants be photographed or recorded? ☐Yes ☐No ☐Audio ☐Video ☐ Still Photo
- Are you planning to solicit subjects by email? ☐Yes ☐No
- Will you access protected health information? ☐Yes ☐No
- Will you access educational records? ☐Yes ☐No
- Will non-English materials be used? ☐Yes ☐No

SECTION B
PROJECT INFORMATION AND SCREENING

The following questions will help you determine which additional sections of the IRB application require completion and assist the IRB in assigning a review level. Most submissions only require the addition of Section C. If you answer "yes" to question eight, please complete Section D (Section D submissions may also require completion of Section C if you are collecting new human subjects data in conjunction with existing secondary data).

Question	Yes	No
1. Does this project involve minors (less than 18 years of age) as subjects, other than to study typical educational practices (e.g., instruction, classroom management) in an established educational setting?	☐	☐
2. Does this project involve prisoners or incarcerated persons as subjects?	☐	☐
3. Does this project involve persons with diminished mental capacity (e.g. intellectual, neurological, psychiatric, or related disability) as subjects?	☐	☐
4. Does this project involve persons in a residential program (e.g. hospital, developmental center, group home) as subjects?	☐	☐
5. Does this project involve clients of a human service program (e.g. counseling center or clinic) as subjects?	☐	☐
6. Does this project involve using deception (intentionally withholding from or giving false or misleading information to subjects)?	☐	☐
7. Does this project involve more than minimal risk (i.e. will/might/can the research activities cause any degree of physical, emotional, and/or psychological discomfort that is greater than those ordinarily encountered in everyday life?)	☐	☐
8. Does this project involve existing data/biospecimens? *If yes, you must complete Section D.*	☐	☐

Most submissions only require the addition of Section C. If you answer "yes" to question eight, please complete Section D (Section D submissions may also require completion of Section C if you are collecting new human subjects data in conjunction with existing secondary data).

Application Tips: When submitting your full application, please include all necessary supporting documents. Examples of supporting documents include consent and recruitment forms, as well as any relevant study materials. Study materials should be submitted in Word or PDF format. If you are conducting an electronic survey, please provide a test link. ***When submitting documents to the IRB, students must copy the faculty member overseeing their research project.***

SECTION C
APPLICATION FOR NEW HUMAN SUBJECTS DATA COLLECTION
Projects Collecting New Data

1. State the purpose of the study.

2. Describe the potential subject pool, including a justification (when applicable) for the inclusion of any vulnerable populations (e.g., minors, persons with diminished mental capacity, persons who are incarcerated or whose liberty is otherwise restricted, and persons who are pregnant).

3. How will you obtain contact information for your potential subjects? *If obtaining contact information from private sources, include a signed approval from the designated authority*.

4. How will you recruit subjects? (e.g. email, verbal script, flyer, MTurk or Prolific, SONA, social media posts, etc.)

5. Where is the location of the research? (e.g., subject's home, during organized workshop, via mail, via Zoom, online survey). *If using an online survey, include the survey link for review*.

6. If conducting research with students in their classroom or clients in their human service delivery setting, will it require any activity that is not part of normal class delivery or provider services?
   ○N/A ○Yes ○No *If "Yes," explain:*

7. Is there a pre-existing dual relationship between the researcher and subject (e.g., teacher-student, counselor-client)? ○Yes ○No *If "Yes," explain the nature of the relationship and arrangements for a third party to solicit subjects for participation:*

8. Will a consent form be provided to participants? ○Yes ○No (attaching consent form for board review required) *If "No," provide a justification for your request*:

SECTION C
APPLICATION FOR NEW HUMAN SUBJECTS DATA COLLECTION

9. Will participants receive compensation (e.g., money, extra credit toward grades)? ◯Yes ◯No *If "Yes," describe the incentive amount:*

10. If offering extra course credit to students, describe the alternate assignment for students who opt out of research participation. *Alternative assignments should require similar effort and time.* ☐N/A

11. If the project involves recording (audio, video, or still photos), explain why recording is necessary, the intended uses of the recording(s), and who will have access to recording(s). ☐N/A

12. Describe, if applicable, any equipment that will be connected to, or used by, the subjects, how safety (including sanitation) checks are performed, the qualifications of the person overseeing safety, and any safety measures that will be used to protect participants from harm. *For certain equipment, the IRB might request proof of maintenance or certification of equipment safety.* ☐N/A

13. Describe any risks to the subject that might arise from participation in the study and the steps you will take to minimize risk and inform participants of possible risks. *Categories of risk include physical, psychological, social, economic, legal, loss of confidentiality, etc.*

14. If the project involves procedures that are more than minimal risk (e.g., obtaining blood samples, treatment involving drugs/biologicals or devices, psychological manipulation, more than moderate exercise, etc.), describe the qualifications/certification of the person(s) who are administering/assisting with the data collection. ☐N/A

15. Describe how you will record data to ensure anonymity/confidentiality of participants (e.g. substituting numbers for names, using anonymous data collection, not identifying individuals in reports, etc.). *Do not confuse confidentiality with anonymity. Anonymity applies only when participant identities are not known, even to the researcher.*

16. Describe where data will be stored and who will have access to identifiable data. *The IRB encourages the use of your AAMU-issued OneDrive for electronic data storage.*

SECTION C
APPLICATION FOR NEW HUMAN SUBJECTS DATA COLLECTION
Projects Collecting New Data

17. Upon study completion, will you destroy or delete any materials (e.g., code lists, audio/video recordings, other data)? Note: research records must be retained for at least 3 years after the study ends. Some granting agencies may require longer retention.
☐ Yes ☐ No *If "Yes" indicate method and timeframe of destruction. If "No," explain why not.*

18. Describe procedures IN DETAIL. Begin with the process of recruitment, followed by how you will gain participant consent. Then describe participant interactions with any measurements, interventions, etc. employed in this protocol. *When submitting your application, include copies of any materials that will be used during the research study (e.g., recruitment scripts, consent forms, questionnaires, interview protocols, surveys, etc.).*

SECTION C
APPLICATION FOR NEW HUMAN SUBJECTS DATA COLLECTION
Projects Collecting New Data

Additional space, **if needed**, to elaborate on Section C responses. If using this extra space, please also include the corresponding question number:

SECTION D
APPLICATION TO USE EXISTING HUMAN SUBJECTS RESEARCH DATA
Projects Using Secondary Data

Question	Yes	No
1. Will information or biospecimens be obtained by intervention or interaction with a human subject? * *If yes, you must complete Section C.*	☐	☐
2. Will this project involve existing information or biospecimens from prisoners?	☐	☐
3. Will this project involve existing information or biospecimens from school records?	☐	☐
4. Will this project involve existing information or biospecimens from medical records? * *If you plan to access private medical information, you must comply with the Health Insurance Portability and Accountability Act (HIPAA). You should contact the medical facility where the records are kept and ask about special requirements for accessing their medical records.*	☐	☐
5. Will information or biospecimens contain any information that could directly identify individual subjects? * *If yes, you must complete Section C.*	☐	☐
6. Will information or biospecimens be obtained from a publicly available source? (e.g., access is available without need for a password or agreement, from the Census Bureau, or public court records)	☐	☐
7. Will any information or biospecimens be obtained from a source that is not publicly available? * *If yes, a letter granting you permission to use the information or biospecimens must be attached.*	☐	☐
8. Will this project involve the physical handling of previously collected human tissue and/or body fluids? * *If yes, approval must be obtained from the Institutional Biosafety Committee and attached*	☐	☐

1. State the purpose of the study.

2. What is the original source of data? If from a data repository include the data set name/number. If from a previous AAMU IRB approved study, include the protocol PI name and protocol number.

3. What permission(s) do you have to access and analyze the data? *Note: All data collected by someone other than you (except publicly available data) requires a permission letter or data use agreement.*

SECTION D
APPLICATION TO USE EXISTING HUMAN SUBJECTS RESEARCH DATA
Projects Using Secondary Data

4. What types of participant information does the data contain? (e.g., age, sex, test scores, number of arrests, number of children, etc.).

5. Do the data contain participant identifiers and/or is a participant code list in existence? ☐Yes ☐No
If "Yes," explain the nature of identifiers. For code lists, explain who has access.

Additional space, ***if needed***, to elaborate on Section D responses If using this extra space, please also include the corresponding question number:

***Criteria for IRB approval of research:**

- risks to subjects are minimized;
- risks are reasonable in relation to anticipated benefits;
- selection of subjects is equitable;
- informed consent is sought from each subject;
- informed consent is appropriately documented.

Institutional Review Board (IRB) Action:

IRB Review: ☐ Exempt ☐ Expedited ☐ Full

☐ 1. Exempt according to category number **DG** listed in Appendix 1 **
☐ 2. Expeditable according to category number _____ listed in Appendix 2 **
☐ 3. Other and must be reviewed by the IRB.
☐ 4. Not regulated and does not have to be reviewed by the IRB.

☐ Application Approved.*

☐ Application denied at this time. Additional information requested and consists of the following:

☐ Application denied

Signature:

_____ **34**

IRB Chair **Date**

APPENDIX 1

RESEARCH ACTIVITIES THAT MAY BE EXEMPT FROM IRB REVIEW AND APPROVAL

§46.104 Exempt research.

(**a**) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

(**b**) *Use of the exemption categories for research subject to the requirements of subparts B, C, and D.* Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

(1) *Subpart B.* Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) *Subpart C*. 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.

(3) *Subpart D*. The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) 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.

(c) [Reserved.]

(**d**) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:

(**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.

(**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 §46.111(a)(7).

(**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 §46.111(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.

(**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.

(ii) [Reserved]

(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.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

APPENDIX 2

ACTIVITIES THAT MAY BE REVIEWED THROUGH EXPEDITED REVIEW PROCEDURES

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(**a**) The Secretary of HHS has established, and published as a Notice in the *Federal Register*, a list of categories of research that may be reviewed by the IRB through an expedited review procedure.

Applicability

A. 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. The activities listed should not be deemed 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.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used 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 subjects= 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.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

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

Research Categories

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

(**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 in paragraph (a) of this section, 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 §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (d)(8)

(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in. §46.108(b)

(**c**) Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that have been approved under the procedure.

(**d**) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.