ID:	
Notes:	

Is research exempt?[1,2]

One or more the following categories must be met:

☐ The research has to follow the <Original Rule>

<Revised Rule> Category

1. ☐ Education
   - 1.1. ☐ The research is conducted in established or commonly accepted educational settings
   - 1.2. ☐ The research 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[3]
   - 1.3. ☐ The research is NOT FDA-regulated
   - 1.4. ☐ The research does NOT involve <Prisoners> as subjects except for research aimed at involving a broader population that only incidentally includes <Prisoners>
   - 1.5. ☐ The research is NOT <Classified Research> conducted or supported by DOE
   - 1.6. ☐ The research is consistent with the ethical principles in the Belmont Report
2. ☐ Interactions
   - 2.1. ☐ The research only includes interactions involving educational tests[4], survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)
   - 2.2. ☐ One of the following is true:
     - 2.2.1. ○ 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
     - 2.2.2. ○ 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
     - 2.2.3. ○ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
   - 2.3. ☐ The research does NOT involve <Children> as subjects
   - 2.4. ☐ One of the following is true:
     - 2.4.1. ○ The research does NOT involve <Children> as subjects
     - 2.4.2. ○ The research is limited to educational tests and observation of public behavior where the investigator(s) do NOT participate in the activities being observed
   - 2.5. ☐ The research is NOT FDA-regulated
   - 2.6. ☐ The research does NOT involve <Prisoners> as subjects except for research aimed at involving a broader population that only incidentally includes <Prisoners>
   - 2.7. ☐ The research is NOT <Classified Research> conducted or supported by DOE
   - 2.8. ☐ The research is consistent with the ethical principles in the Belmont Report

3. ☐ Behavioral Interventions

3.1. ☐ The research involves behavioral interventions in conjunction with the collection of information through verbal or written responses (including data entry) or audiovisual recording

3.2. ☐ Subjects will prospectively agree to the intervention and information collection

3.3. ☐ The research does NOT involve <Children> as subjects

3.4. ☐ The behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects

3.5. ☐ The investigator has no reason to think the subjects will find the interventions offensive or embarrassing[5]

3.6. ☐ One of the following is true:

3.6.1. ○ 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

3.6.2. ○ 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

3.6.3. ○ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

3.7. ☐ One of the following is true:

3.7.1. ○ The research does NOT involve deceiving the subjects regarding the nature or purposes of the research

3.7.2. ○ The subject will be informed that he or she will be unaware of or misled regarding the nature or purposes of the research and will authorize the deception through a prospective agreement to participate

3.8. ☐ The research is NOT FDA-regulated

3.9. ☐ The research does NOT involve <Prisoners> as subjects except for research aimed at involving a broader population that only incidentally includes <Prisoners>

3.10. ☐ The research is NOT <Classified Research> conducted or supported by DOE

3.11. ☐ The research is consistent with the ethical principles in the Belmont Report

4. ☐ Secondary Research Without Consent
   - 4.1. ☐ The research involves the use of <Identifiable Private Information> or <Identifiable Biospecimens>
   - 4.2. ☐ One of the following is true:
     - 4.2.1. ○ The <Identifiable Private Information> or <Identifiable Biospecimens> are publicly available
     - 4.2.2. ○ 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
     - 4.2.3. ○ 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 §§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)
     - 4.2.4. ○ 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
   - 4.3. ☐ The research is NOT FDA-regulated
   - 4.4. ☐ The research does NOT involve <Prisoners> as subjects except for research aimed at involving a broader population that only incidentally includes <Prisoners>
   - 4.5. ☐ The research is NOT <Classified Research> conducted or supported by DOE
   - 4.6. ☐ The research is consistent with the ethical principles in the Belmont Report
5. ☐ Federal Demonstration Projects
   - 5.1. ☐ The research or demonstration project is 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)
   - 5.2. ☐ The research or demonstration project is 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[6,7]
   - 5.3. ☐ The research or demonstration project will be published on a list of research and demonstration projects exempted under this category prior to commencing the research
   - 5.4. ☐ The research is NOT FDA-regulated
   - 5.5. ☐ The research does NOT involve <Prisoners> as subjects except for research aimed at involving a broader population that only incidentally includes <Prisoners>
   - 5.6. ☐ The research is NOT <Classified Research> conducted or supported by DOE
   - 5.7. ☐ The research is consistent with the ethical principles in the Belmont Report

6. ☐ Taste and Food

6.1. ☐ The research involves taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or 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

6.2. ☐ The research does NOT involve <Prisoners> as subjects except for research aimed at involving a broader population that only incidentally includes <Prisoners>

6.3. ☐ The research is NOT <Classified Research> conducted or supported by DOE

6.4. ☐ The research is consistent with the ethical principles in the Belmont Report

7. ☐ Collection of Data for Secondary Research With Consent

7.1. ☐ The research involves storage or maintenance of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) for potential secondary research use

7.2. ☐ One of the following is true:

7.2.1. ○ No change is being made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained

7.2.2. ○ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

7.3. ☐ The investigator will obtain the legally effective informed consent of the subject or LAR

7.4. ☐ The investigator will seek informed consent only under circumstances that provide the subject or LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence

7.5. ☐ The information given to the subject or LAR will be in language understandable to the subject or the legally authorized representative

7.6. ☐ The subject or LAR will be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information

7.7. ☐ Informed consent does NOT disclose any exculpatory language through which the subject or LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence

7.8. ☐ The consent will disclose:

7.8.1. ☐ Risks
7.8.2. ☐ Benefits
7.8.3. ☐ Confidentiality
7.8.4. ☐ Investigator contact
7.8.5. ☐ Independent contact
7.8.6. ☐ Injury contact
7.8.7. ☐ Voluntary
7.8.8. ☐ Refusal
7.8.9. ☐ Withdrawal
7.8.10. ☐ Types of research
7.8.11. ☐ What might be used
7.8.12. ☐ Duration
7.8.13. ☐ Details of research
7.8.14. ☐ Return of results

7.9. ☐ When appropriate, the consent will disclose:

☐ A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit

☐ For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing[8]

7.10. ☐ One of the following is true:

7.10.1. ○ Consent will be documented in writing in accordance with "WORKSHEET: Criteria for Approval (HRP-400)"

7.10.2. ○ Written documentation of consent is waived in accordance with "CHECKLIST: Waiver of Documentation of Consent (HRP-303)"

7.11. ☐ The research is NOT FDA-regulated

7.12. ☐ The research does NOT involve <Prisoners> as subjects except for research aimed at involving a broader population that only incidentally includes <Prisoners>

7.13. ☐ The research is NOT <Classified Research> conducted or supported by DOE

7.14. ☐ The research is consistent with the ethical principles in the Belmont Report

8. ☐ Use of Data for Secondary Research With Consent

8.1. ☐ Consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with <Revised Rule> Category #7

8.2. ☐ One of the following is true:

8.2.1. ○ Consent was documented in writing in accordance with "WORKSHEET: Criteria for Approval (HRP-400)"

8.2.2. ○ Written documentation of consent was waived in accordance with "CHECKLIST: Waiver of Documentation of Consent (HRP-303)"

8.3. ☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

8.4. ☐ The research to be conducted is within the scope of the consent

8.5. ☐ The investigator does not include returning individual research results to subjects as part of the study plan[9]

8.6. ☐ The research is NOT FDA-regulated

8.7. ☐ The research does NOT involve <Prisoners> as subjects except for research aimed at involving a broader population that only incidentally includes <Prisoners>

8.8. ☐ The research is NOT <Classified Research> conducted or supported by DOE

8.9. ☐ The research is consistent with the ethical principles in the Belmont Report

<Original Rule> Category

1. ☐ Education

1.1. ☐ The research is conducted in established or commonly accepted educational settings and involves normal educational practices[3]

1.2. ☐ The research is NOT FDA-regulated

1.3. ☐ The research does NOT involve <Prisoners> as subjects

1.4. ☐ The research is NOT <Classified Research> conducted or supported by DOE

1.5. ☐ The research is consistent with the ethical principles in the Belmont Report

2. ☐ Interactions
   - 2.1. ☐ The research involves the use of educational tests[4], survey procedures, interview procedures or observation of public behavior
   - 2.2. ☐ One of the following is true:
     - 2.2.1. ○ 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
     - 2.2.2. ○ 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
   - 2.3. ☐ One of the following is true:
     - 2.3.1. ○ The research does NOT involve <Children> as subjects
     - 2.3.2. ○ The research is limited to educational tests and observation of public behavior where the investigator(s) do NOT participate in the activities being observed
   - 2.4. ☐ The research is NOT FDA-regulated
   - 2.5. ☐ The research does NOT involve <Prisoners> as subjects
   - 2.6. ☐ The research is NOT <Classified Research> conducted or supported by DOE
   - 2.7. ☐ The research is consistent with the ethical principles in the Belmont Report
3. ☐ Interactions that place subjects at risk
   - 3.1. ☐ The research involves the use of educational tests[4], survey procedures, interview procedures or observation of public behavior
   - 3.2. ☐ The research is NOT exempt under <Original Rule> Exempt Category #2
   - 3.3. ☐ One of the following is true:
     - 3.3.1. ○ The subjects are elected or appointed public officials or candidates for public office
     - 3.3.2. ○ Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter
   - 3.4. ☐ The research is NOT FDA-regulated
   - 3.5. ☐ The research does NOT involve <Prisoners> as subjects
   - 3.6. ☐ The research is NOT <Classified Research> conducted or supported by DOE
   - 3.7. ☐ The research is consistent with the ethical principles in the Belmont Report
4. ☐ Existing Data
   - 4.1. ☐ The research involves the collection or study of existing[9] data, documents, records, pathological specimens, or diagnostic specimens
   - 4.2. ☐ One of the following is true:
     - 4.2.1. ○ 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
     - 4.2.2. ○ The sources are publicly available
   - 4.3. ☐ The research is NOT FDA-regulated
   - 4.4. ☐ The research does NOT involve <Prisoners> as subjects
   - 4.5. ☐ The research is NOT <Classified Research> conducted or supported by DOE
   - 4.6. ☐ The research is consistent with the ethical principles in the Belmont Report

5. ☐ Federal Demonstration Projects

5.1. ☐ The research or demonstration project is conducted by or subject to the approval of Department or Agency heads

5.2. ☐ The research or demonstration project is designed to study, evaluate, or otherwise examine public benefit or service programs, 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

5.3. ☐ The program under study delivers 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)

5.4. ☐ The research or demonstration project is conducted pursuant to specific federal statutory authority

5.5. ☐ There is no statutory requirement that the project be reviewed by an IRB

5.6. ☐ The research involves involves no significant physical invasions or intrusions upon the privacy of participants

5.7. ☐ The research is NOT FDA-regulated

5.8. ☐ The research does NOT involve <Prisoners> as subjects

5.9. ☐ The research is NOT <Classified Research> conducted or supported by DOE

5.10. ☐ The research is consistent with the ethical principles in the Belmont Report

6. ☐ Taste and Food

6.1. ☐ The research involves taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or 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

6.2. ☐ The research does NOT involve <Prisoners> as subjects

6.3. ☐ The research is NOT <Classified Research> conducted or supported by DOE

6.4. ☐ The research is consistent with the ethical principles in the Belmont Report

Footnotes

1. 45 CFR 46.101(b)(1)-(6) (Pre-2018 Requirements); 45 CFR 46.104(d)(1)-(8) (Pre-2018 Requirements); DOD: 32 CFR 219
2. In this worksheet,"research" means < Research as Defined by HHS> involving <Human Subjects as Defined by HHS> and "subject" means <Human Subject as Defined by HHS>
3. 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.
4. Educational tests may be cognitive, diagnostic, aptitude, or achievement.
5. Such 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.
6. 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.
7. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website 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.
8. Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.
9. "Existing" means existing at the time the research is proposed.