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| **REVIEWER FORM – EXPEDITED to EXEMPT REVIEW – CW Transfer** | | |
| **PRO #:** | **AME #:** | **CPR #:** |
| **Principal Investigator:** | | **Department:** |

**INSTRUCTIONS**:

Use this form for review of:

* **CW Transfer Projects Moving from Expedited to Exempt Review**

**DO NOT** use this form for review of CW Transfer Projects which qualify for review under *Expedited* categories.

This checklist also contains an [**APPENDIX**](#appendix) containing detailed information regarding the determinations you are making in this checklist. Links in this document link within this document only. No links in this document connect to outside documents/websites. Everything is located here for easy reference.

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| **CONTINUING PROGRESS REPORT** |
| Please complete the following PROJECT STATUS section for all CPRs |
| **PROJECT STATUS** |
| Cumulative enrollment, withdrawals, unanticipated problems, reportable events, and amendments have been reviewed. |
| All [criteria of IRB approval](#Criteria) remain satisfied. |
| Project remains no greater than minimal risk, and benefits outweigh risks. |
| Project does not need verification from sources other than the researchers that no unapproved changes have occurred since previous IRB review. |
| **VULNERABLE POPULATIONS** |
| Complete this section only when vulnerable populations are involved. |
| Subject population includes vulnerable population(s) and project maintains safeguards study to protect the rights and welfare of these subjects.  Check the following if vulnerable populations include:   * Pregnant women, fetuses, neonates. **COMPLETE SEPARATE SUBPART B CHECKLIST.** * Minors. **COMPLETE SEPARATE SUBPART D CHECKLIST**.   NOTE: A separate reviewer with Subpart B or Subpart D expertise may be assigned, in which case the Primary Reviewer should not complete these separate checklists. |
| **CONSENT/ASSENT** |
| Project is closed to enrollment. |
| Project is open to enrollment and consent/assent method remains appropriate. |
| Project is open to enrollment and consent/assent form(s) have been migrated to our newest templates to accommodate 2018 revised Common Rule. |

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| **REVIEWER CHECKLIST – EXEMPT** | | |
| Determination | | |
| This project qualifies as **Exempt** under: | | |
|  | 45 CFR 46.104 (HHS) | 21 CFR 56.104 (FDA) [Approval under Category 6 only] |
| Principles of respect for persons, beneficence, and justice are appropriately addressed. | | |
| The study involves interaction with subjects, and subjects are consented prior to the initiation of research activities (e.g. via an informational letter). | | |
| Exemption Categories. Check all that apply.\* | | |
| \* If any research activity does not qualify under an Exemption category, the project cannot be considered or reviewed as Exempt. | | |
| (1) **Education Evaluation**: 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) **Surveys, Interviews, Focus Groups, Educational tests, Observation**: 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. Check all that apply:*   * 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 * 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 * 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 45 CFR 46.111(a)(7).   + When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.   + For federally funded projects, the NIH Data sharing and Management plan is uploaded | | |
| (3) **Benign Behavioral Interventions**: 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. Check all that apply:*   * 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; * 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 * 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 45 CFR 46.111(a)(7).   + When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. * 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. * 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 Review of Records, Specimens, etc.:** Secondary research uses of identifiable private information or identifiable biospecimens for which consent is not required,*if at least one of the following criteria is met. Check all that apply:*   * The identifiable private information or identifiable biospecimens are publicly available; * 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; * The research involves only information collection and analysis involving the investigator’s use of identifiable health information for the purposes of ‘‘health care operations’’ or ‘‘research’’ or for ‘‘public health activities and purposes’’; or * 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. | | |
| (5) **Federally-Supported research / demonstration projects:** 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.   * 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. | | |
| (6) **Taste and food quality evaluation:** Taste and food quality evaluation and consumer acceptance studies. *Check all that apply:*   * If wholesome foods without additives are consumed, or * 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 requiring broad consent:** Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review. | | |
| (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. Check all that apply:*   * Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained; * Documentation of informed consent or waiver of documentation of consent was obtained; * An IRB conducts a limited IRB review | | |
| NOTE: Because the use of broad consent has not been adopted, the MCW/FH IRB does not utilize Exemption categories 7 and 8. | | |
| **HIPAA** | | |
| The IRB also functions as the privacy board for research projects. While HIPAA determinations will likely mirror consent determinations, they are separate in order to address this dual IRB function. | | |
| Project utilizes MCW ICF templates which contain HIPAA Authorization (Section E).   * Consent/HIPAA recruitment waiver is granted to scan records and identify subjects prior to consent. | | |
| Waiver of HIPAA Authorization granted. | | |
| Subjects include decedents and access to this data is granted. | | |
| Limited Data Set would be utilized, and any necessary data agreements are provided. | | |
| Only de-identified data is utilized. | | |
| HIPAA process has already been determined and no new determinations are needed (e.g. material received from an IRB-approved bank, from another institution, etc.). | | |
| Project does not access or create Personal Health Information. | | |
| Reviewer Comments / Signature | | |
| **Reviewer Comments:** | | |
| IRB Reviewer Name: | | Date: Click here to enter a date. |

**If applicable:**

[**Pregnant Women/Fetuses – Subpart B Checklist**](#SubB)

[**Minors – Subpart D Checklist**](#SubD)

**IRB Member Checklist for Projects involving Pregnant Women and fetuses (subpart B)**

This checklist should be used with submissions for projects which request the inclusion of pregnant women and fetuses. IRB Committee Members should apply the criteria outlined within the *IRB Member SOP: Research with Pregnant Women and Fetuses.*

This project involves the following (check as many as apply):

[Section: Pregnant women or fetuses (45 CFR 46.204](#Pregnant_Women_204)):

[Section: Neonates of Uncertain Viability (45 CFR 46.205 (a) and (b))](#Neonates_205a)

[Section: Nonviable neonates (45 CFR 46.205 (c))](#Neonates_205c)

Reviewers must then complete the corresponding section(s) below, along with [final comments and recommendations.](#Final_Recommendations)

**Section: Pregnant women or fetuses (45 CFR 46.204):**

1. Is this project receiving federal funding for the conduct of the research?

Yes  No

If yes, pregnant women or fetuses may only be involved in the project if the following 10 elements are satisfied.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. Does the application identify where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses?

Yes  No  IRB Chooses to Waive, provide justification:

1. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

Yes  No  IRB Chooses to Waive, provide justification:

1. Any risk is the least possible for achieving the objectives of the research;

Yes  No  IRB Chooses to Waive, provide justification:

1. If the research holds the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with 45 CFR 46.116 and 117

Yes  No  N/A  IRB Chooses to Waive, provide justification:

1. If the research holds the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father is obtained in accord with 45 CFR 46.116 and 117, except that the father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

Yes  No  N/A  IRB Chooses to Waive, provide justification:

1. Each individual providing consent under items 5 or 6 is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

Yes  No  N/A  IRB Chooses to Waive, provide justification:

1. For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of 45 CFR 46 subpart D; *See IRB Member Form: Research Involving Children (subpart D) Checklist*

Yes  No  N/A  IRB Chooses to Waive, provide justification:

1. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

Yes  No  IRB Chooses to Waive, provide justification:

1. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

Yes  No  IRB Chooses to Waive, provide justification:

1. Individuals engaged in the research will have no part in determining the viability of a neonate.

Yes  No  IRB Chooses to Waive, provide justification:

**Section: Neonates of Uncertain Viability (45 CFR 46.205 (a))**

1. Is this project receiving federal funding for the conduct of the research?

Yes  No

If yes, neonates of uncertain viability and non-viable neonates may only be involved in the project if the following 4 elements are satisfied.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates

Yes  No  IRB Chooses to Waive, provide justification:

1. Each individual providing consent under paragraph [45 CFR 46.205(b)(2) or (c)(5)](http://www.dhhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.205) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate

Yes  No  IRB Chooses to Waive, provide justification:

1. Individuals engaged in the research will have no part in determining the viability of a neonate.

Yes  No  IRB Chooses to Waive, provide justification:

1. The requirements of paragraph [45 CFR 46.205(b) or (c)](http://www.dhhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.205) of this section have been met as applicable.

Yes  No  IRB Chooses to Waive, provide justification:

**Section: Neonates of uncertain viability (45 CFR 46.205 (b))**

1. Is this project receiving federal funding for the conduct of the research?

Yes  No

If yes, until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional 2 conditions have been met.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research;

Yes  No  IRB Chooses to Waive, provide justification:

1. The legally effective informed consent of either parent of the neonate or, if neither parent can consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative is obtained in accordance with subpart A of 45 CFR 46, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Yes  No  IRB Chooses to Waive, provide justification:

**Section: Nonviable neonates (45 CFR 46.205 (c))**

1. Is this project receiving federal funding for the conduct of the research?

Yes  No

If yes, nonviable neonates may only be involved in the project if the following 5 elements are satisfied.

If no, the IRB may choose to waive some of the identified elements, with justification.

1. Vital functions of the neonate will not be artificially maintained

Yes  No  IRB Chooses to Waive, provide justification:

1. The research will not terminate the heartbeat or respiration of the neonate

Yes  No  IRB Chooses to Waive, provide justification:

1. There will be no added risk to the neonate resulting from the research.

Yes  No  IRB Chooses to Waive, provide justification:

1. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

Yes  No  IRB Chooses to Waive, provide justification:

1. The legally effective informed consent of both parents of the neonate is obtained in accordance with 45 CFR 46 subpart A except that the waiver and alteration provisions of 45 CFR 46.116(c) and (d) do not apply.

Yes  No  IRB Chooses to Waive, provide justification:

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| **Reviewer Comments** |
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**IRB Member Checklist for Projects involving Minors (subpart D)**

This checklist should be used for submissions for projects which request the inclusion of subjects who are minors. IRB Committee Members should apply the criteria outlined within the *IRB Member SOP: Research involving Children*

1. **Subpart D (children) Determinations (45 CFR 46 or 21 CFR 50)**

Check the allowable category below that best represents the degree of risk and benefit to which the children in this project will be exposed and explain your choice.

**Note: More than one category may be indicated. If multiple categories are indicated, please answer the additional question after each marked category.**

Category 1 (404 or 50.51): The proposed research poses risks no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk).

**Project involves a** **Single Population which falls under this category**

**Project includes more than one population;** **this category applies to the following population:**Click or tap here to enter text.

Category 2 (405 or 50.52): The proposed research poses a greater than minimal risk with the potential for direct benefit to subjects, i.e., the benefit to the subject is at least as favorable as alternative approaches.

**Project involves a** **Single Population which falls under this category**

**Project includes more than one population,** **this category applies to the following population:**Click or tap here to enter text.

Category 3 (406 or 50.53): The proposed research poses a greater than minimal risk with no potential for direct benefit to individuals, but likely to yield vital generalizable knowledge about the subjects’ conditions.

**Project involves a** **Single Population which falls under this category**

**Project includes more than one population,** **this category applies to the following population:**Click or tap here to enter text.

Category 4 (407 50.54): The proposed research does not meet the criteria in the above categories but presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children. **Research which meets this category cannot be approved by the IRB, and must go for review by Secretary of HHS or the Commissioner of Food and Drug to make a determination as outlined per 50.54.**

**Project involves a** **Single Population which falls under this category**

**Project includes more than one population,** **this category applies to the following population:**Click or tap here to enter text.

Explain your choice of category: Click or tap here to enter text.

1. **What permission will be obtained from the parents?**

Permission from only one parent is being requested

Permission will be obtained from both parents where possible.

Note: ***2 parent signatures are required for any project which meets category 3 (406 or 50.53).***

A waiver of parental permission is being requested

Informed Consent/Parental Permission has already been obtained

(i.e., previously IRB approved bank, incoming data from another institution, etc.)

None of the Above – the project qualifies for exempt review. Select the level of contact

Project will not have direct contact with subjects, and an informed consent process or document is not required

Project will have direct contact with subjects, and an informational letter will be provided

1. **Please indicate whether the children in this project are generally capable of providing assent; evaluate age, maturity and psychological state of the children involved. Please be specific:**

All are capable

None are capable; explain: Click or tap here to enter text.

Some are capable; explain: Click or tap here to enter text.

N/A – assent will not be obtained

1. **For subgroups of children capable of assent, how will assent be solicited?** Click or tap here to enter text.
   1. A waiver of assent is being requested
   2. Project is an In Vitro Diagnostic Project which qualifies for Approval without the requirements of Assent and Parental Permission, [per 2006 FDA Guidance](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf).
2. **For subgroups of children capable of assent, how will assent be documented?** Click or tap here to enter text.
   1. A waiver of assent is being requested
   2. Project is an In Vitro Diagnostic Project which qualifies for Approval without the requirements of Assent and Parental Permission, [per 2006 FDA Guidance](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf).
3. **Has the project team developed a plan to consent subjects who reach the age of majority?**  Yes  No  N/A
4. **Describe the proposed plan:** Click or tap here to enter text.

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| **Reviewer Comments** |
| Click or tap here to enter text. |

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| **APPENDIX** |
| NOTE: This Appendix is a work-in-progress. We may continue to add to it, and please let us know if you find it helpful.  We attempt to keep all information here up-to-date but please do not use this in lieu of federal regulation primary sources. |
| **Criteria for IRB 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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(d)(1)), [(4)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(4)), [(5)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(5)), [(6)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(6)), [(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(7)), and [(8)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(d)(2)(i)) and [(ii)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(d)(2)(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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(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:   1. (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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#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.   1. (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:   1. (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.   1. (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:   1. (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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(a)(1)) through [(4)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(a)(4)), [(a)(6)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(a)(6)), and [(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(d)); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with [§46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117); (iii) An IRB conducts a limited IRB review and makes the determination required by [§46.111(a)(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(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.  (Approved by the Office of Management and Budget under Control Number 0990-0260.) |