Researchers:
- Use this tool to guide determination for Exempt Research categories

Lead Researcher / Investigator Name:

**Category 1: Education**  
(the following criteria must be met)

<table>
<thead>
<tr>
<th></th>
<th>Research is conducted in established or commonly accepted educational settings and 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</th>
</tr>
</thead>
</table>

1. 45 CFR 46.104  
2. Research, Human Subject  
3. Research is not FDA-regulated  
4. Research does NOT involve prisoners as subjects except for research aimed at involving a broader population that only incidentally includes prisoners  
5. Research is NOT classified research conducted or supported by DOE  
6. Research is consistent with the ethical principles of the Belmont Report  
7. The Department of Justice (DOJ) and the Food and Drug Administration (FDA) have not yet adopted the revised Common Rule.  
8. The Federal Policy for the Protection of Human Subjects will not affect any state/local laws or regulations, including tribal law passed by the official governing body of an American Indian or Alaska Native tribe  
9. Minimal Risk threshold: explanation of minimal risk + appendix  
10. Final Rule preamble explanation
### Category 2: Interactions

One or more of the following criteria must be met:

- The research only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording).

One of the following criteria must be met:

- 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.

- 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.

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

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11 Final Rule preamble explanation

12 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 section 1115 and 1115A of the Social Security Act, as amended.

13 Subpart D applicable only when involving educational tests or the observation of public behavior when the investigator(s) do NOT participate in the activities being observed.

14 If identifiers are maintained and disclosure would reasonably place subjects at risk, IRB conducts a limited IRB review.

15 Subpart D is not applicable.
### Category 3

**Behavioral Interventions** *(one or more of the following criteria must be met)*

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>The research involves 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.</td>
</tr>
<tr>
<td>☐</td>
<td>The research does not involve deceiving the subjects regarding the nature or purpose of the research.</td>
</tr>
<tr>
<td>☐</td>
<td>The subject will be informed that he/she will be unaware of or misled regarding the nature or purpose of the research and will authorize the deception through a prospective agreement to participate.</td>
</tr>
<tr>
<td>☐</td>
<td>The 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.</td>
</tr>
<tr>
<td>☐</td>
<td>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.</td>
</tr>
<tr>
<td>☐</td>
<td>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.</td>
</tr>
<tr>
<td>☐</td>
<td>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.</td>
</tr>
</tbody>
</table>

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16 **Subpart D is not applicable**

17 **Final Rule preamble explanation**

18 **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.**

19 **SACHRP Guidance: Attachment B – Guidance and Educational Tool for Benign Behavior Interventions**

20 If identifiers are maintained and disclosure would reasonably place subjects at risk, **IRB conducts a limited IRB review.** (Continuing review is not required for research approved under limited IRB review.)
<table>
<thead>
<tr>
<th>Category 4 21: Secondary Research Without Consent 22 (one or more of the following criterias must be met)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ The research involves the use of identifiable private information or identifiable biospecimens</td>
</tr>
<tr>
<td>One of the following must be met:</td>
</tr>
<tr>
<td>☐ The identifiable private information or identifiable biospecimens are publicly available 23</td>
</tr>
<tr>
<td>☐ 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 24</td>
</tr>
<tr>
<td>☐ 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) 25</td>
</tr>
<tr>
<td>☐ 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 26</td>
</tr>
</tbody>
</table>

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21 SACHRP Guidance: Attachment B - Common Rule HIPAA Exemption Guidance
22 Final Rule preamble explanation
23 Final Rule preamble explanation
24 Final Rule preamble explanation
25 Final Rule preamble explanation
26 Final Rule preamble explanation
**Category 5: Federal Demonstration Projects**  
(One or more of the following criteria must be met)

- 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), 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.

- 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).

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

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

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

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27 Final Rule preamble explanation

28 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 section 1115 and 1115A of the Social Security Act, as amended.

29 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.
<table>
<thead>
<tr>
<th>Category 6: Taste and Food ³⁰ (the following criteria must be met)</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
</tr>
</tbody>
</table>

³⁰ Final Rule preamble explanation
### Category 7: Collection of Data for Secondary Research with Broad Consent 31, 32, 33 (one or more of the following criteria must be met)

- 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

One of the following must be met:

- No change is being made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained
- There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

- The investigator will obtain the legally effective informed consent of the subject or LAR

- 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

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

- 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

- 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

The consent will include the required elements:
- Risks
- Benefits
- Confidentiality
- Investigator contact
- Independent contact
- Injury contact
- Voluntary
- Refusal
- Withdrawal
- Types of research
- What might be used
- Duration
- Details of research
- Return of Results 34

If applicable, the consent will include:

- 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 35

One of the following criteria must be met:

- Consent will be documented in writing
- Written documentation of consent is waived

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31 SACHRP Guidance: Attachment C - Broad Consent
32 Final Rule preamble explanation
33 IRB conducts a limited IRB review. [Continuing review is not required for research approved under limited IRB review.]
34 SACHRP Guidance: Attachment F – Sharing Study Data and Results - Return of Incidental Findings
35 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.
<table>
<thead>
<tr>
<th>Category 8: Use of Data for Secondary Research with Broad Consent 36, 37, 38 (one or more of the following criterias must be met)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with the 2018 Exempt Category #7 criteria</td>
</tr>
<tr>
<td>□ One of the following criteria must be met:</td>
</tr>
<tr>
<td>□ □ Consent was documented in writing</td>
</tr>
<tr>
<td>□ □ Written documentation of consent was waived</td>
</tr>
<tr>
<td>□ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data</td>
</tr>
<tr>
<td>□ The research to be conducted is within the scope of the broad consent</td>
</tr>
<tr>
<td>□ The investigator does not include returning individual research results to subjects as part of the study plan 39</td>
</tr>
</tbody>
</table>

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36 SACHRP Guidance: Attachment C - Broad Consent
37 Final Rule preamble explanation
38 IRB conducts a limited IRB review. [Continuing review is not required for research approved under limited IRB review.]
39 This provision does not prevent an investigator from abiding by any legal requirements to return individual research results. [SACHRP Guidance: Attachment F – Sharing Study Data and Results - Return of Incidental Findings]
Figure 1

[Diagram: Research with data and biospecimens under the revised Common Rule]

Source: [http://healthaffairs.org/blog/2017/02/06/a-new-day-for-oversight-of-human-subjects-research/](http://healthaffairs.org/blog/2017/02/06/a-new-day-for-oversight-of-human-subjects-research/)
## Limited IRB Review

### Categories 2(iii), 3(i)(c), and 8: must meet the following criteria [45 CFR 46.111(a)(7)]

<table>
<thead>
<tr>
<th>§__.111(a)(7): When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) The Secretary of HHS will, after consultation with the Office of Management and Budget’s privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.</td>
</tr>
</tbody>
</table>

#### Considerations:

- The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;
- The use of the information;
- The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;
- The likely retention period or life of the information;
- The security controls that are in place to protect the confidentiality and integrity of the information; and
- The potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

### The limited IRB review under category 8 requires that the IRB determines that the proposed secondary research is **within the scope of the broad consent**.

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### Category 7: must meet the following criteria [45 CFR 46.111(a)(8)]

<table>
<thead>
<tr>
<th>All the following elements are required:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §__.116(a)(1)-(4), (a)(6), and (d);</td>
</tr>
<tr>
<td>Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §__.117; and</td>
</tr>
<tr>
<td>If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. 40, 41</td>
</tr>
</tbody>
</table>

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40 Final Rule preamble explanation
41 Final Rule preamble explanation