Implementing the Revised Common Rule
Exemptions with Limited IRB Review

Introduction:

Four of the exempt categories in the revised Common Rule include a provision for limited IRB review. This resource is intended to help organizations understand when limited IRB is required and to aid in planning for implementation. The information in this resource is based upon the revised Common Rule and its preamble, but it is important to remember that Common Rule agencies have the authority to depart from the rule. For example, an agency may choose to restrict use of the exemptions, add additional criteria, or to require review by the convened IRB. Further, the Common Rule does not override state or local laws or regulations, including tribal law, which may include additional requirements or restrictions.

As a reminder, the effective date and the compliance date for these changes currently is January 19, 2018. There is a possibility that either or both dates may change following once the review by the current administration is complete, but whether this will occur is unknown at this time.

Additional information on the revisions to the Common Rule and planning for its implementation are available on HRP's website within the "Common Rule" tab.

When is Limited IRB Review Required?

Under the revised Common Rule, exempt Categories 2, 3, 7, & 8 include a provision for limited IRB review. See **Appendix A** for the full text of these exemptions.

For **exempt categories 2 & 3**, the requirement for limited IRB review is triggered when:

1. T*he 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
2. *Any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation*

For **exempt categories 7 & 8**, limited IRB review is always required. It's also important to remember that exempt categories 7 & 8 are only available for use when broad consent will be (or has been) obtained.

Continuing review is not required for research approved under limited IRB review.

When changes to research are proposed that fall within the scope of the limited IRB review requirement (e.g., storage or maintenance, privacy and confidentiality), the changes must undergo limited IRB review and be approved before implementation (except when necessary to eliminate apparent immediate hazards to subjects).

What does Limited IRB Review Consist Of?

Limited IRB review under **exempt categories 2(iii), 3(i)(c), & 8** requires that the IRB determines that the criteria for IRB approval at §__.111(a)(7) is satisfied.

> §__.111(a)(7): *When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.*
>
> *(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.*

Note the statement that guidance will be issued to assist IRBs in evaluating whether research satisfies this criterion. The preamble to the revised Common Rule provides a framework for the anticipated guidance that organizations may want to consider adopting. Per the preamble, IRB's could consider:

- *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 also requires** that the IRB determines that the proposed secondary research is within the scope of the broad consent.

The requirements for limited IRB review under **category 7** are much more extensive. The IRB must determine that the criteria for IRB approval at §__.111(a)(8) are satisfied, specifically:

1. *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);*
2. *Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §__.117; and*

3. *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.*

The preamble provides insight into the third criteria:

> *The relevant changes do not necessarily involve moving information or biospecimens from one location to another. Rather, the relevant changes include any change for research purposes that introduces or alters risks to the privacy or security of the stored information or biospecimens, including giving access to or transferring information or biospecimens for research purposes to someone who otherwise would not have access.*

The preamble also provides examples that organizations may find helpful:

> *Examples of changed aspects of storage or maintenance for research purposes that would require the IRB to find, before those changes go into effect, whether there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data include the following: if information or biospecimens are moved from one electronic or physical storage location to another due to considerations related to research plans; if information or biospecimens will be stored for longer than they otherwise would have been for the original purpose; if information or biospecimens are placed in a research registry or repository created to serve as a resource for investigators; or investigators are given electronic or physical access to the information or biospecimens.*

Appendix B provides a sample checklist for addressing the **category 7** criteria.

Who may perform limited IRB? And how?

Limited IRB review must be performed by the IRB and can be performed using expedited procedures. Thus, the review may be performed by the IRB Chair or *"one or more experienced reviewers designated by the chairperson from among members of the IRB"*.

As with other expedited reviews, the reviewer may require modifications to or approve the proposed research, but may not disapprove the research. Disapprovals must be by the convened IRB.

Think Abouts:

1. Organizations are not required to adhere to the Common Rule for research that is not covered by the policy (i.e., research that is not conducted or supported by a Federal department or agency that has signed on or taken action to adopt the Common Rule). An organization may choose to adopt different rules for such research. Organizations that are AAHRPP-accredited should be cognizant that AAHRPP currently requires that organizations have and apply equivalent protections for participants in un-regulated research.
2. Organizations that currently allow exempt determinations by non-IRB members, or via the use of a determination tool, will need to modify procedures for the specific exemptions that require limited IRB review. While appointing current exempt designees as IRB members or alternates is an option, organizations will need to be cognizant of the experience requirement for expedited reviewers *("…experienced reviewers designated by the chairperson from among members of the IRB").*

Likewise, if exempt research also requires review of requests for waivers or alterations of HIPAA authorization, organizations will need to ensure that these determinations are conducted by the IRB or a Privacy Board.

3. While not explicitly stated, because IRB members must be kept abreast of research approvals via expedited review, HRP assumes that this requirement would extend to research approved under limited IRB review.
4. Other than exempt category 6, the Common Rule exemptions are not available for FDA-regulated clinical investigations under FDA's current rules.
5. While not required by the revised Common Rule, organizations may want to consider requiring status and closure reports for exempt research so that the organization has an accurate record of active research and basic information available about all research conducted under the auspices of the organization.
6. When considering whether to transition existing studies to comply with the new rule, organizations should be cognizant that some currently exempt studies may not qualify for exemption under the new rule. For example, a study that is currently exempt under category 2 may no longer be exempt if the study includes an educational intervention in addition to educational tests. The potential impacts of changes that may need to be made to research that is already underway should be taken into consideration.

Additional information on the revisions to the Common Rule and planning for its implementation, including important decision-points for organizations, are available on HRP's website within the "Common Rule" tab.

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Appendix A

Revised Common Rule - Exempt Categories

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 .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 .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 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.

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 §__.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 §__.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 §__.117;
   iii. An IRB conducts a limited IRB review and makes the determination required by §__.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.

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Appendix B

Sample Checklist – Exempt Category 7

(This sample checklist is provided as a resource to help organizations prepare for implementation of the revised Common Rule by demonstrating one possible approach to evaluating proposals for exemption under category 7. Sample checklists should always be modified to incorporate any state or local requirements and for consistency with local SOPs. This sample only addresses the requirements of exempt category 7 and does not address any additional requirements that may apply such as COI, HIPAA, etc. Likewise, this sample does not include fields such as PI name, IRB number, reviewer name, date, etc. Tools such as this should always be accompanied by training and other forms of support (links to help, separate guidance documents, etc.) to help reviewers interpret and apply the criteria.)

I. Definitions

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information ("information" hereafter) is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Identifiable biospecimen ("specimen" hereafter) is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Secondary research refers to the re-use for research of information or biospecimens that are or were collected for some other "primary" or "initial" activity (e.g., education, clinical care) distinct from using them in secondary research.

II. Eligibility for Exempt Category 7

Each of the following must be true ('Yes') for the proposal to be eligible for exemption under category 7.

Criteria	Yes	No
The proposal involves the storage or maintenance of identifiable information or specimens for secondary research use	☐	☐
All identifiable information or specimens that will be stored or maintained for secondary research have been or will be obtained for another "primary" purpose	☐	☐
Broad consent will be obtained from <u>all</u> subjects for the storage or maintenance of their identifiable information or specimens for potential secondary research use	☐	☐

The proposal does not include any activities that do not qualify for exemption	☐	☐
The proposal is not for a FDA-regulated clinical investigation (e.g., a post-market approval registry)	☐	☐

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

III. Limited IRB Review – The IRB must determine that each of the following criteria for approval are satisfied.

A. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens will be obtained in accordance with the requirements of 45 CFR 46.116(a)(1)-(4), and (a)(6), and (d)

Each of the following must be true ('Yes') for this requirement to be satisfied unless the criterion has a 'NA' option.

Consent Process	**Yes**	**No**
Before involving a subject in the proposed research, the investigator will obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR)	☐	☐
Informed consent will be sought only under circumstances that provide the prospective 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 that is given to the subject or the LAR is in language understandable to the subject or the legally authorized representative	☐	☐
The prospective subject or the 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	☐	☐
The informed consent does not include any exculpatory language through which the subject or the 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	☐	☐

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

Consent Elements, the proposed broad consent includes each of the following:	**Yes**	**No**	**NA**
A description of any reasonably foreseeable risks or discomforts to the subject	☐	☐	
A description of any benefits to the subject or to others that may reasonably be expected from the research	☐	☐	
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained	☐	☐	
A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and	☐	☐	

the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled			
When appropriate, 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 (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).	☐	☐	☐
A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted	☐	☐	
A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens	☐	☐	
A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite)	☐	☐	
Unless the subject or LAR will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies	☐	☐	☐
Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject	☐	☐	☐
An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm	☐	☐	

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

B. Broad consent will be appropriately documented or a waiver of documentation is appropriate, in accordance with 45 CFR 46.117

Evaluate the consent form and information provided by the investigator to determine whether the criteria for documentation of consent are satisfied ('Yes'). If a waiver of documentation of

consent has been requested, evaluate the request using the checklist in **iii**. If a partial waiver has been requested, complete all applicable tables.

i. Long-form of Consent Documentation

☐ NA, the short form method is being used or a waiver of documentation of consent has been requested.

Criteria	Yes	No
Informed consent will be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's LAR	☐	☐
A written copy will be given to the person signing the informed consent form	☐	☐
The informed consent form meets the requirements of 45 CFR 46.116 (*See III.A)*	☐	☐
The investigator will give the subject or LAR adequate opportunity to read the consent form before it is signed **or** the form will be read to the subject or LAR	☐	☐

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

ii. Short-form of Consent Documentation

☐ NA, the long form method is being used or a waiver of documentation of consent has been requested.

Criteria	Yes	No
A short form written informed consent form stating that the elements required by 45 CFR.116 *(See III.A)* have been presented orally to the subject or the subject's LAR will be used	☐	☐
The written summary of what will be said to the subject or the LAR will be approved by the IRB *(e.g., a long form informed consent form)*	☐	☐
There will be a witness to the oral presentation	☐	☐
The short form will be signed by the subject or the subject's LAR	☐	☐
The witness will sign both the short form and a copy of the written summary	☐	☐
The person obtaining consent will sign a copy of the written summary	☐	☐
A copy of the summary and a copy of the short form will be given to the subject or the subject's LAR	☐	☐

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

iii. Waiver of Documentation of Consent *(Note: Per the preamble to the revised Common Rule, OHRP expects that it will be rarely permissible to waive documentation of broad consent because there will need to be a mechanism to track and identify who has and has not provided broad consent; and because release of records or specimens outside of research usually requires a person's consent or authorization.)*

☐ NA, a waiver of documentation of consent has not been requested

One of the following must be satisfied ('Yes') for a waiver of documentation of consent to be approved. If a partial waiver of documentation of consent has been requested, describe the scope of the waiver in the "Reviewer Comments" section below.

Criteria	Yes	No
The only record linking the subject and the research will be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; OR	☐	☐
The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; OR	☐	☐
The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained	☐	☐

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

C. If a change is made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, adequate provisions must be in place to protect the privacy of subjects and to maintain the confidentiality of data. *(Note: Per the preamble to the revised Common Rule, such changes would not only include moving information or specimens from the original location where they are maintained, but would also include storing information or specimens for longer than they otherwise would have been, granting investigators access to the information or specimens, and any other change that introduces or alters risks to the privacy or security of the information or specimens.)*

☐ NA – no changes are being in made in the way information or specimens are stored or maintained

i. Considering the below, and the information provided by the investigator, have adequate provisions been put into place to protect the privacy of subjects and to maintain the confidentiality of the data?

☐ Yes ☐ No, explain: *Click or tap here to enter text.*

Consider:

- *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.*

IV. Determinations

(Organizations should use this section to document reviewer determinations or recommendations using the terminology and standards for IRB actions described in their SOPs)