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Summary of Changes – Revised Common Rule

Changes are effective January 21, 2019 unless otherwise noted

Section	Summary of Change	Impact	Organizational Notes
To what does this policy apply .101(f) **Cooperative research** .114(b)(2)(i) **General requirements for informed consent** .116(i) and .116 (j)	All references that cite state or local law now include "tribal law passed by the official governing body of an American Indian or Alaska Native tribe."	Documents such as standard operating procedures (SOPs) may need to be updated if they directly cite the current regulatory language.	
Membership .107(a) **Criteria for IRB approval of research** .111(a)(3) and .111(b)	Revised description of "vulnerable" • Removed "pregnant women". • Replaced "handicapped or mentally disabled persons" with "individuals with impaired decision-making capacity", • Added "economically or educationally disadvantaged persons".	Documents such as SOPs, submission forms, and reviewer worksheets may need to be updated. Consider updating IRB member records and roster to capture expertise for modified vulnerable populations.	
To what does this policy apply? .101(a)	Change to support the use of external IRBs and facilitate single IRB use, IRBs that are not part of a FWA-holding organization ('Independent IRBs') are subject to compliance enforcement • Added: Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy. • Removed: Footnote "Institutions with HHS-approved assurances	Review reliance agreements to determine if updates may be needed (reporting responsibilities, etc.). Independent IRBs may need to update their	

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	on file will abide by provisions of Title 45 CFR part 46 subparts A-D." • FWAs will now only apply to federally conducted or supported research and non-federal research will not be part of the assurance or subject to federal oversight.	SOPs, compliance statements, and other documents.	
Definitions for purposes of this policy .102	New definitions • Clinical trial (b), Identifiable biospecimens (e), Public health authority (k), and Written, or in writing (m). Revised definitions • Human subject (e) now references biospecimens and adds obtaining, storing, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens as trigger events. • Intervention (e) now references biospecimens. • Legally authorized representative (i) adds specific authorization to use institutional policy when there is no applicable law addressing this issue. • Research (l) has been expanded to list activities that are specifically deemed not to be research (e.g., oral history, journalism, public health surveillance, criminal justice or criminal investigative activities, and activities in support of intelligence, homeland security, defense, or other national security missions).	Documents such as SOPs, submission forms, and reviewer worksheets may need to be updated.	
Assuring compliance with this policy—research conducted or supported by any Federal department or agency .103	When IRB oversight is conducted by an IRB that is not operated by the institution • New subsection (e) requires that the institution and the organization operating the IRB document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of the final rule (e.g., in a	Documents such as SOPs and reliance agreement templates may need to be updated.	

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	written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol). The list of requirements for written procedures was moved from .103 to .108 to be consistent with FDA regulations 21 CFR 56.108.		
Exempt research .104[i]	Section .104, has been assigned as "Exempt Research" Revisions to exemptions • New restrictions have been added to the old exemptions – only the taste and food quality study exemption remains the same. • New subsection (b) describes the use of and restrictions on exemptions for research subject to Subparts B, C, & D including an allowance for the exemptions to apply to research aimed at involving a broader subject population that only incidentally includes prisoners. • The following exemptions require a "limited IRB review": (d)(2)(iii), (d)(3)(i)(C), (d)(7), (d)(8) New exemptions • Research involving benign behavioral interventions in conjunction with the collection of information from adults (d)(3). • Secondary research uses of identifiable private information or identifiable biospecimens (d)(4). • Storage or maintenance for secondary research use of private information or identifiable biospecimens (d)(7). • Research involving the use of private information or identifiable biospecimens that have been stored or maintained for research use (d)(8).	Documents such as SOPs, submission forms, reviewer worksheets, and template letters may need to be updated. IRB electronic systems may require modification.	

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IRB functions and operations .108	The list of requirements for written procedures was modified and moved from .103 to .108 to be consistent with FDA regulations 21 CFR 56.108. • The requirement for meeting space and sufficient staff to support the IRB in old section 46.103(b)(2) is now found at .108(a)(1). • The IRB roster detail requirements formerly in old section 46.103(b)(3) is now found at .108(a)(2). • Requirements for written procedures described in the old section 46.103(b)(4) and 46.103(b)(5) have been included at .108(a)(3) and (4). • Revised (a)(3)(iii) to include "Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB" (except when necessary to eliminate apparent immediate hazards to the subject).	Citations in documents such as SOPs may need to be updated. Documents such as SOPs, guidelines, and letters that describe reporting obligations and modifications to research may need to be updated.	
IRB review of research .109	Revision to describe the new "limited IRB Review" • An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under §46.104 for which limited IRB review is a condition of exemption (under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)). New subsection (f)(1) eliminates continuing review in the following circumstances (unless an IRB determines otherwise) • Research eligible for expedited review in accordance with §46.110; • Research reviewed by the IRB in accordance with the limited IRB	Documents such as SOPs, submission forms, and reviewer worksheets may need to be updated. Procedures that may currently be tied to continuing review (e.g., training verification, conflicts review) may need to be modified. IRB electronic systems	

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	review described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8); • Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.	may require modification. Consider whether organization would benefit from an annual report in lieu of IRB continuing review.	
Expedited review procedures .110	Revised to permit "limited IRB review" to be conducted through expedited review. • Research for which limited IRB review is a condition of exemption under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8). Revised to create a default position that the published categories of research that may be reviewed by expedited review are minimal risk, unless the reviewer determines otherwise for a study.	Documents such as SOPs, submission forms, and reviewer worksheets may need to be updated. IRB electronic systems may require modification.	
Criteria for IRB approval of research .111	A new subsection (8) has been added to essentially eliminate consideration of the "111 criteria" when conducting "limited IRB review" and describing the criteria the IRB must consider instead. • (8) For purposes of conducting the limited IRB review required by §46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations: (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §46.116(a)(1)-(4), (a)(6), and (d); (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §46.117; and (iii) If there is a change made for research purposes in the way the identifiable private information or	Documents such as SOPs, submission forms, and reviewer worksheets may need to be updated. IRB electronic systems may require modification.	

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	identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.		
Cooperative research .114	*The compliance date for this part of the regulations (§46.114(b)) is January 2020.* Revised to add a requirement (b) for institutions located in the United States that are engaged in cooperative research to rely upon approval by a single IRB for that portion of the research that is conducted in the U.S. • The reviewing IRB will be specified by the federal department or agency supporting or conducting the research; the "lead institution" may propose the reviewing IRB, but final federal approval will be required. • Specifies circumstances when requirement for single IRB does not apply (reasons of law or as determined by the federal department or agency conducting or supporting the research)	Documents such as SOPs, guidelines, and forms and templates utilized for reliance may need to be updated.	
IRB records .115	Revised to describe additional documentation requirements • Documentation of the rationale for conducting continuing review of research that otherwise would not require continuing review (3). • Documentation of the rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk (8). • Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of the final rule (9).	Documents such as SOPs, reviewer checklists, and forms and templates utilized for reliance may need to be updated.	
General requirements for informed consent .116	Section .116 is one of more extensively modified sections, primarily due to added regulations for the use of biospecimens in research. • New subsection .116(a) has been added to describe the general requirements for informed consent, and stipulate that broad	Documents such as SOPs, guidelines, submission forms, reviewer worksheets,	

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	consent may be obtained in lieu of informed consent only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. • The list of conditions previously embedded in a paragraph has been separated and the conditions numbered as .116(a) (1-3) and (6). • Subsection .116(b) now contains the basic elements of consent and .116(c) the additional elements. *General* .116(a) - Summary of new requirements • .116(a)(4) states that subjects must be provided with the information that a "reasonable person" would want to have in order to make an informed decision and subjects must be provided an opportunity to discuss that information. • .116(a)(5)(i) states that the informed consent process must begin with a concise and focused presentation of the "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subsection also requires that this part of the informed consent be "organized and presented in a way that facilitates comprehension." • .116(a)(5)(ii) states that informed consent as a whole must present information in sufficient detail and organized in such a way that does not "merely provide lists of isolated facts, but rather facilitates the prospective subject's … understanding of the reasons why one might or might not want to participate." *Basic elements of informed consent* .116(b) - Summary of new requirements • .116(b)(9) requires one of two statements when the research involves the collection of identifiable private information or	and consent templates may need to be developed or updated. Systems to track refusals for future research may need to be developed. Procedures to support compliance with the requirement to post clinical trial consent forms may need to be developed.	

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	identifiable biospecimens: ○ Identifiers might be removed and the de-identified information or biospecimens used for future research or distributed to another investigator without additional informed consent from the subject; or, ○ The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed. *Additional elements of informed consent* .116(c) – Summary of new requirements (when appropriate) • .116(c)(7) requires a statement that 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. • .116(c)(8) requires a statement about whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. • .116(c)(9) requires a statement about whether the research project will or might include whole genome sequencing. *Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens* .116(d) – New This subsection addresses the use of broad consent, and specified elements, as a permitted alternative to the use of the standard elements for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. • .116(d)(1) specifies the basic elements from .116(b) and (c) that must still be included (risks, benefits, confidentiality, voluntary, commercial profit, and whole genome sequencing). • .116(d)(2) requires a general description of the types of research		

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	that may be conducted. • .116(d)(3) requires a description of the identifiable information or identifiable biospecimens that might be used in future research; whether sharing might occur; and, the types of institutions or researchers that might conduct research. • .116(d)(4) requires a description of the length of time that the identifiable information or identifiable biospecimens may be stored, maintained and used. • .116(d)(5) unless subjects will be provided details about specific studies, this element requires a statement that subjects will not be informed of the purposes or details of any specific research studies that might be subsequently conducted, and, that they might have chosen not to consent to some studies. • .116(d)(6) unless it is known that clinically relevant research results will under all circumstances be disclosed to subjects, this element requires a statement that research results may not be disclosed to subjects. • .116(d)(7) requires contact information to be provided for questions about rights, questions about storage and use, and in the event of a research-related harm. *Waiver or alteration of consent in research involving public benefit and service programs conducted by/subject to the approval of state or local officials* .116(e) – New • Specifies that if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use for this individual. • Specifies that IRB's may not omit or alter any of the requirements of consent (.116(a)). If a broad consent procedure is used, an IRB may not omit or alter any of the required		

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	elements at .116(d), i.e., alteration is not permitted. *General waiver or alteration of consent* .116(f) – Summary of new requirements • .116(f)(1) cautions that if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use for this individual. • 116(f)(2) addresses alterations of informed consent. Two new conditions/restrictions are included. An IRB may not omit or alter any of the .116(a) general requirements for informed consent. If a broad consent procedure is used, an IRB may not omit or alter any of the required elements at .116(d), i.e., alteration is not permitted. • .116(f)(3) includes the four existing waiver conditions with the following addition: for research that involves using identifiable private information or identifiable biospecimens, it is a requirement that the research could not practicably be carried out without using such information or biospecimens in an identifiable format. *Screening, recruiting, or determining eligibility* .116(g) – New • Effectively eliminates need for an IRB to grant screening or recruitment waivers by stating that an IRB may approve research in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without first obtaining informed consent, if either of the following conditions are met: ○ the information will be obtained through oral or written		

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	communication with the prospective subject, or ○ by accessing records or stored biospecimens. *Posting of clinical trial consent form* .116(h) – New • Addresses requirements for posting clinical trial consent forms on a publicly available federal website that will be established as a repository for consent forms. According to subsection .116(h)(3), one consent form for each clinical trial must be posted on the federal website after the trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. A federal department or agency may permit or require redactions.		
Documentation of informed consent .117	Revisions to documentation requirements • .117(a) now specifically allows electronic signatures for consent documentation and specifies that a written copy must be given to the person signing the consent form. • .117(b)(1) specifically allows consent forms to be read to the subject. • .117(b)(2) requires that, when using the short form to document consent, the informed consent must begin with a concise and focused presentation of the key information to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subsection requires that this part of the informed consent must be organized and presented in a way that facilitates comprehension. • .117(c) still addresses waivers for the requirement to obtain a signed consent form and maintains the two pre-existing exceptions. Importantly a third category is added that allows waiver of documentation of consent if the subjects are members of a distinct cultural group or community in which	Documents such as SOPs, guidelines, submission forms, reviewer worksheets, and consent templates may need to be developed or updated.	

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	signing forms is not the norm. This added category is restricted to minimal risk research and requires an appropriate alternative method for recording that informed consent was obtained.		

The below table highlights additional impacts of the rulemaking that are described in the preamble or elsewhere but not captured above.

Additional Impacts	Summary	Impact
Common Rule Agencies	• A list of departments and agencies that have adopted the revised Common Rule can be found at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html • Department of Labor is a new signatory and is codifying the final rules into its own agency regulations. • Department of Justice (DOJ), a current signatory, is not listed as a signatory on the new final rule.	Documents such as SOPs, submission forms, and reviewer checklists may need to be updated. Monitor DOJ rules, specific SOPs may be needed for organizations engaged in DOJ research.
Newborn Blood Spots	• Once the Rule becomes effective, it eliminates the requirement that blood spots be considered research with human subjects. IRBs may waive informed consent for federal research involving newborn blood spots.	Documents such as SOPs, submission forms, and reviewer checklists may need to be updated.
Existing Master IRB Reliance Agreements	• Existing IRB reliance agreements under which new research proposals may be reviewed after the compliance date of the new rule (January 21, 2019) will need to comply with the documentation requirements of the new rule. 103(e)	Review and update existing reliance agreements, procedures as needed.
Grant applications	• The final rule eliminates the current requirement at .103(f) for IRB review of grant applications as part of the Certification process.	Documents such as SOPs, submission forms, and reviewer checklists may need to be updated.
Federalwide Assurances (FWA) and IRB Registrations	• The Rule eliminates the current FWA procedural option to voluntarily extend a FWA to nonfederal research. Institutions may still have internal policies that voluntarily extend the regulations to all research conducted by the institution (i.e., apply consistent policies and procedures to all research), but this extension will no longer be part of the assurance process and, importantly, such research will not be subject to federal oversight. *10/22/18 update: In response to feedback about the potential impact on research conducted in certain states, OHRP has recently commented that it may delay the removal of the voluntary extensions on the FWA.*	Update FWA and IRB Registration(s).

Additional Impacts	Summary	Impact

	• The final rule eliminates the following requirements:
	  • Statement of ethical principles by which an institution will abide
	  • Submission of an up-to-date list of IRB members and their qualifications
	  • Designation of one or more IRBs on FWA	

Ongoing research 101(l)	• If an institution takes no action, studies initiated before January 21, 2019 will continue to be subject to the pre-2018 Common Rule. However, if an institution takes action to transition a study or studies to the revised rule during the delay period (July 19, 2018 through January 20, 2019), those studies will then be required to comply with the revised Common Rule as of January 21, 2019. • Institutions may make the voluntary determination for studies what were initiated before January 21, 2019 to comply with the revised Common Rule on a per-study basis or for a group of studies. Also, note that the IRB must document the institutional decision to comply with the new rule (which necessitates re-review of the study to ensure that the study does in fact comply with the new rule). [Refer to 45 CFR 46.101(l)]	Consider review of ongoing research for compliance with updated rule (for example, at continuing review) or establishing procedures for ongoing research to ensure compliance with pre-2018 requirements.
Federal Reexamination of "identifiable"	• The definitions of "identifiable private information" and "identifiable biospecimens" will be reexamined within one year and at least every four years thereafter. • Assessment of analytic technologies or techniques that should be considered as generating "identifiable private information" or "identifiable biospecimens" within one year and at least every four years thereafter. Publication of a list of such technologies or techniques in the Federal Register and on a publicly accessible website.	Monitor for changes and update materials accordingly.
Federal Reevaluation of expedited categories	• The revised rule mandates that the list of categories of research eligible for expedited review is reevaluated at least every 8 years.	Monitor for changes and update materials accordingly.

[i] §**46.104 Exempt research.**

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

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

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

(2) Subpart C. The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) Subpart D. The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(c) [Reserved.]

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

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of

received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal 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. (ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed, or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117; (iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results. (Approved by the Office of Management and Budget under Control Number 0990-0260)