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Research Policy Update

Final Rule: Exempt Research

In 1991, the Federal Policy for the Protection of Human Subjects, also known as the **Common Rule**, was published. The Common Rule is a regulation that guides research protections for studies with human subjects funded by certain federal agencies. U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) have separate but complimentary regulations for ethical research with human subjects.

On January 21, 2019, recent revisions to the Common Rule (known as the Final Rule) went into effect for studies and IRBs under HHS regulations. The U.S. Food and Drug Administration will be updating their Protections for Human Subjects to match with HHS regulations in the future. A comprehensive list of federal departments and agencies signed on to follow the Common Rule can be found at http://bit.ly/2Fqbvhr.

The NCAI Policy Research Center created this series of Research Policy Updates on the Final Rule. These updates provide a brief overview of only some recent changes to the Common Rule. Please visit the HHS Office for Human Research Protections website or read the regulation: http://bit.ly/2CqTH1I

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Exempt Research – *What is exempt research? Who can determine?*

Exempt research is research that, due to its low level of risk, is not required to go through the full Institutional Review Board (IRB process).[1] However, some categories of exempt research do need to go through a limited IRB review. The 2019 Common Rule updates revised, removed, and added to the list of exempt research categories. There are currently eight categories for exempt research.

The U.S. Department of Health and Human Services (HHS) **does not specify who at an institution determines exempt research**. Researchers are not prohibited by HHS from determining if his/her own research is exempt from IRB review. However, due to potential conflicts of interest, the Office for Human Research Protections (OHRP) recommends against researchers determining the exempt status of his/her own study. Instead, OHRP recommends that institutions define a specific individual or individuals to determine if research studies qualify as exempt.[2] In addition, some of the new exempt categories require limited review by the IRB chair to ensure privacy safeguards are adequate.

IRBs and/or researchers must **first determine if the proposed activity is research,** which is defined as a "systemic investigation designed to develop or contribute to generalizable knowledge."[3] OHRP has a number of decision charts to help make these determinations.[4] If the activity is determined to be research and it involves human subjects, then there needs to be a determination if it is "exempt" from IRB review, or whether it must go through an expedited or full IRB review. The following sections review the eight separate categories for exempt research. Each category will be identified as new, replaced, or revised category based on the recent updates to the Common Rule. A summary of the changes is included below.

Updates to Exempt Research Categories – Final Rule		
Category 1	REVISED	Educational Settings – new conditions
Category 2	REVISED	Public Behavior – clarifications, must meet one of three criteria which could include limited IRB review
Category 3	REPLACED	Benign Behavioral Interventions – defined conditions, must meet one of three criteria with possible limited IRB review required
Category 4	REVISED	Secondary Research with No Required Consent – now includes biospecimens, must meet one of four criteria, new HIPAA requirements, federal data requirements
Category 5	REVISED	Research and Demonstration Projects – added research supported by federal agency, not just conducted by federal agency
Category 6	UNCHANGED	Taste and Food Quality
Category 7	NEW	Storage & Maintenance of Secondary Data under Broad Consent – requires limited IRB review
Category 8	NEW	Secondary Research with Required Broad Consent – requires limited IRB review

Exempt Category 1 – *Educational Settings*

Exempt category one (1), research "**conducted in established or commonly accepted educational settings,**"[5] was revised in the 2019 Common Rule updates:[6] The 2019 changes to this exemption added the requirement that the research cannot negatively impact students' ability to learn required course content or the normal assessment of teachers.[7] Research can only include testing on normal teaching strategies, assessments, curriculum, and classroom management.[8]

Exempt Category 2 – *Public Behavior*

Exempt category two (2), "**Research that only includes interactions involving educational test, survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)**"[9] was revised in the 2019 Common Rule updates[10] with changes related to visual and auditory recordings, identifiable or sensitive information, and limited IRB review.[11] The changes made to this category made the requirements clear that research qualifying for this exemption only includes certain interactions or observations, and any research with an intervention or an alteration of the environment does not quality under this category.[12] Visual and auditory recordings were added as a research method in this category.

To qualify under this category, research must meet at **least one** of the following requirements:

i. Information collected must be recorded in such a way that **individuals are not identifiable**.[13] Research falling under this requirement cannot survey or interview children. Children can only be included in research if the researcher does not participate in the activities being observed.[14]

ii. Disclosure of individuals' identities or responses outside the research space **does not place the research subjects at a risk for harm**, including criminal or civil liability, or financial, employment, educational, or reputational disadvantage or damage.[15] Again, children can only be included in research if the researcher does not participate in the activities being observed.[16]

iii. If identifiable information is collected with the potential for harm, **limited IRB review** is required to determine that research contains appropriate protections for research subjects' privacy, maintains confidentiality, and the information is gathered and recorded in a way in which individuals are not identifiable.[17] [18] [19] Children cannot be included under an exemption in this category.[20]

Exempt Category 3 – *Benign Behavioral Interventions*

Exempt category three (3), "**Research that involves [both] benign behavioral interventions and the collection of information from adults through verbal answers, written answers, and/or audiovisual recordings. The participant must agree to the intervention and collection of information,"**[21] is a new exempt category in the 2019 Common Rule updates that previously required expedited IRB review.[22]

Benign behavioral interventions in this category should be "brief in duration, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the subjects and…. [there also should be] no reason to think the subjects will find the interventions offensive or embarrassing."[23] [24] No research involving children, adults with limited decision making abilities, or any medical interventions are allowed under any section of this exemption.[25] The use of deception is not allowed unless the research subjects agree to be misled or unaware of the purpose of the research.[26]

Exempt research under this category needs to fit into **at least one** of the three requirements below:

i. Information must gathered from the intervention in such a way that the study participants cannot be easily identified or linked to his/her responses.[27]

ii. If study participants can be linked to his/ her own answers, the release of the participants' responses will not reasonably put participants at risk for criminal or civil liberty violations, nor damage the participants' financial, educational, employment, or reputational standing.[28]

iii. If information is available that can easily link a participant to his/ her answers and disclosure is a potential for harm to the participant, a limited IRB review must be conducted for privacy and confidentiality protections.[29]

Exempt Category 4 – *Secondary Research with No Required Consent*

Exempt category four (4), "**Secondary research for which consent is not required: secondary research uses of identifiable private information or identifiable biospecimens"** [30] was revised in the 2019 Common Rule updates to include biospecimens, data under HIPPA authority, federally conducted research, and federally generated data."[31] No primary data collection can occur under this exemption. Data and biospecimens from pregnant women, children, prisoners, and adults with impaired judgement are not allowed under this exemption.[32]

Research is exempt and does not require informed consent if **at least one** of the following four requirements are met:

i. Publicly available data, including identifiable private information or identifiable biospecimens, is being used.[33]

ii. Information is recorded in a way in which study participants cannot be readily identified, and the researchers do not have contact with participants and will not re-identify them.[34]

iii. The research uses health information regulated by HIPPA and is specifically for "health care operations" and "public health activities or purposes."[35] HIPPA regulations still apply and HIPPA authorizations and waivers are still required and must be obtained.[36]

iv. The research is done by, or on behalf of, a federal agency and uses federally collected data that was collected initially for non-research activities. If the research uses identifiable data, the research project may fall under the scope of the E-Government Act of 2002 or the Paperwork Reduction Act of 1995.[37]

Exempt Category 5 – *Research and Demonstration Projects*

Exempt category five (5), **"Research and demonstration projects that are conducted or supported by a Federal department or agency, or [are] otherwise subject to the approval of department or agency heads…, and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs,"**[38] was revised in the 2019 Common Rule updates to include research supported by a Federal agency in addition to research conducted by a Federal agency.[39]

If research falls under this category, researchers must define the public benefit and service program that is being researched. Exempt research must be listed on a publicly available Federal website operated by or maintained for the department or agency conducting or supporting the research. "The research or demonstration project must be published on this list prior to [the beginning of the] research involving human subjects."[40]

Exempt Category 6 – *Taste and Food Quality*

Exempt category six (6), ***"Taste and food quality evaluation and consumer acceptance studies,"***[41] is the only category that was unchanged in the 2019 Common Rule updates.[42]

Research in this category must already have satisfied requirements and regulations for food safety and consumption by the U.S. Food Safety and Inspection Service in the U.S. Department of Agriculture and/or the U.S. Environmental Protection Agency.[43] This category relates only to testing already defined safe foods for taste and quality. Including children and pregnant women in research under this exemption is allowed.[44]

Exempt Category 7 – *Storage and Maintenance of Secondary Data under Broad Consent*

Exempt category seven (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,"***[45] is one of two new categories from the 2019 Common Rule updates.[46]

This new category only applies to the **storage and maintenance** of identifiable biospecimens or private information gathered under broad consent and prior to any secondary data analysis, not the act of using the data for research. Storage and maintenance for data under this category will need to undergo a limited IRB review to establish that procedures and policies are in place to protect the privacy and confidentiality of the data.[47]

The limited IRB review will need to confirm that all requirements for broad consent were met and the consent was received for the data storage and secondary use. IRBs may not waive consent in this exemption for any individual who refused consent.[48]

Exempt Category 8 – *Secondary Research with Required Broad Consent*

Exempt category eight (8), ***"Secondary research for which broad consent is required. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use,"***[49] is the second new exempt category from the 2019 Common Rule updates.[50]

While the seventh category for exempt research relates only to the storage and maintenance of data, the eighth category specifically relates to the USE of the stored identifiable private data or identifiable biospecimens.[51] A limited IRB review is required prior to secondary analysis for this exemption. The review will ensure that proper privacy and confidentiality procedures are in place, proper broad consent was received, no plans to return research results to participants exist, and the proposed research falls under the scope of the initial broad consent. IRBs may not waive any refused consent under this exemption.[52] To learn more on secondary research and broad consent, read the NCAI Policy Research Center *Research Policy Update – Final Rule Part 3, Informed and Broad Consent* brief.

Considering Changes to Exempt Research

The U.S. Department of Health and Human Services has the overall authority to define when research qualifies as exempt. To prevent inaccurate decisions and conflicts of interest, OHRP recommends researchers do NOT determine if his/her own research is exempt and to also have institutionally identified individuals and policies on how to determine projects' exempt status.[53]

When considering making changes to exempt research projects, OHRP recommends first contacting the individual who initially granted the exempt status. Each institution will need to make their own policies on how to make changes to exempt research. Making these policies can help ensure research projects maintain the correct exempt or non-exempt status.[54]

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Questions: NCAI Policy Research Center – email: research@ncai.org; website: http://www.ncai.org/prc

Endnotes

[1] [45 CFR 46.104(a), Subpart A]

[2] "Exempt Research Determination FAQs." Office for Human Research Protections, U.S. Department of Health and Human Services. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/index.html.

[3] [45 CFR 46.102(l), Subpart A]

[4] OHRP. Human Subject Regulations Decision Charts. Accessed on June 18, 2019 at: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c1.

[5] [45 CFR 46.104(d)(1), Subpart A]

[6] Hicks, Lorna. "Final Rule Material: Changes to Exempt Determination Process." 2017. https://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf.

[7] "Exempt Research Under the Revised Common Rule." KUMC Guidance Document for Exempt Research 2018 Common Rule Changes. January 2019. http://www.kumc.edu/Documents/hrpp/Topical Guidance/Guidance Document for Exempt Research Jan 21, 2019.pdf.
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[11] "What's New with the Final Rule?" Committee on the Use of Human Subjects, Harvard University. https://cuhs.harvard.edu/what's-new-final-rule.
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[13] [45 CFR 46.104(d)(2)(i), Subpart A]
[14] Selwitz, Ada Sue, and Belinda Smith. "New Rule Exemption Categories Handout." PRIM&R Focus on the Revised Common Rule. December 8, 2018. https://www.primr.org/commonrule/resources-tools/.
[15] [45 CFR 46.104(d)(2)(ii), Subpart A]
[16] Selwitz, Ada Sue, and Belinda Smith. "New Rule Exemption Categories Handout." PRIM&R Focus on the Revised Common Rule. December 8, 2018. https://www.primr.org/commonrule/resources-tools/.
[17] [45 CFR 46.104(d)(2)(iii), Subpart A]
[18] [45 CFR 46.111(a)(7), Subpart A]
[19] Hicks, Lorna. "Final Rule Material: Changes to Exempt Determination Process." 2017. https://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf.
[20] Selwitz, Ada Sue, and Belinda Smith. "New Rule Exemption Categories Handout." PRIM&R Focus on the Revised Common Rule. December 8, 2018. https://www.primr.org/commonrule/resources-tools/.
[21] [45 CFR 46.104(d)(3)(i), Subpart A]
[22] "What's New with the Final Rule?" Committee on the Use of Human Subjects, Harvard University. https://cuhs.harvard.edu/what's-new-final-rule.
[23] [45 CFR 46.104(3)(ii), Subpart A]
[24] University of Pittsburgh University Marketing Communications Webteam. "Benign Behavioral Intervention." Benign Behavioral Intervention: Exemption Criteria 45 CFR 46.104(d)(3). http://www.irb.pitt.edu/BenignBehavioralIntervention.
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[31] "What's New with the Final Rule?" Committee on the Use of Human Subjects, Harvard University. https://cuhs.harvard.edu/what's-new-final-rule.
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[33] [45 CFR 46.104(d)(4)(i), Subpart A]

[34] [45 CFR 46.104(d)(4)(ii), Subpart A]
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[39] Hicks, Lorna. "Final Rule Material: Changes to Exempt Determination Process." 2017. https://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf.
[40] [45 CFR 46.104(d)(5)(i), Subpart A]
[41] [45 CFR 46.104(d)(6), Subpart A]
[42] Hicks, Lorna. "Final Rule Material: Changes to Exempt Determination Process." 2017. https://about.citiprogram.org/wp-content/uploads/2018/07/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf.
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[44] "Exempt Research Under the Revised Common Rule." KUMC Guidance Document for Exempt Research 2018 Common Rule Changes. January 2019. http://www.kumc.edu/Documents/hrpp/Topical Guidance/Guidance Document for Exempt Research Jan 21, 2019.pdf.
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