**Appendix A – Changes to Exempt Categories with Revised Common Rule**

| Areas | DHHS Current Common Rule (through 1/20/19) | DHHS New Common Rule (provisions effective Jan 21, 2019) | Comments on Changes in the New Rule |
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| **LIMITATIONS ON EXEMPTIONS** | …the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. [footnote in §__.101] | Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:<br>(1) **Subpart B [pregnant women, fetuses, neonates]**. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.<br>(2) **Subpart C [prisoners].** 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.<br>(3) **Subpart D [children]**. The exemptions (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.<br>Exemption (2)(i) and (ii) may only 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.<br>Exemption (2) (iii) may not be applied to research subject to subpart D<br>Exemption (3) may not be applied to research subject to subpart D | |

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| **EXEMPT RESEARCH** | 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods. [§__.101(b)(1)]<br><br>2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation. [§__.101(b)(2)] | 1. **Restrictions added:** 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. [§__.104(d)(1)]<br><br>**2. Expanded:** 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:**<br><br>(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;<br><br>(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;<br><br>(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 | **Exemption #1**<br><br>▪ **Key change – the research must have no adverse impact on students' learning or assessment of educators**<br><br>▪ **Some research that qualifies for exempt 1 today may not qualify under the revised rule**<br><br>**Exemption #2**<br><br>▪ **Data collection only – no interventions!**<br><br>▪ **Data collection can include audio and video recording**<br><br>▪ **Some research that qualifies for this exemption will undergo limited IRB review to evaluate the adequacy of provisions to protect participants' privacy and confidentiality**<br><br>▪ **Paragraph (i) and (ii) of this section only may apply to research subject to subpart D (research with minors) involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed.**<br><br>▪ **Paragraph (iii) of this section may not be applied to research subject to subpart D (research with involving minors)** |

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| | 3. **(ELIMINATED)** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under category # 2 (above), if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. [§__.101(b)(3)] | identifiers linked to the subject, **and an IRB conducts a limited IRB review** to make the determination required by §__.111(a)(7). [§__.104(d)(2)]<br><br>3. **NEW:**<br>(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 audio visual recording **if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:**<br>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;<br>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;<br>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 subject, and an IRB conducts a limited IRB | **Exemption #3**<br>▪ **Permits benign behavioral interventions combined with data collected through verbal or written responses or audiovisual recording**<br>▪ **Adults only**<br>▪ **Prospective agreement**<br>▪ **Deception only permitted if authorized**<br>▪ **Some research that qualifies for this exemption will undergo limited IRB review to evaluate the adequacy of provisions to protect participants' privacy and confidentiality** |

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| | | review to make the determination required by §__.111(a)(7).<br>(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 subjects play an online game, having them solve puzzles under various noise conditions, or have them decide how to allocate a nominal amount of received cash between themselves and someone else.<br>(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the following is met: The subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that they are unaware of or misled regarding the nature or purposes of the research. [§__.104(d)(3)] | |
| | 4. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that the | **4. Expanded, with changes (ESSENTIALLY NEW):** 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:** | **Exemption #4**<br>▪ **Secondary research only**<br>▪ **Data/specimens can be both retrospective and prospective**<br>▪ **To qualify under 4.iii, PHI cannot be shared outside of a covered entity (e.g., with a** |

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| | subjects cannot be identified directly or through identifiers linked to the subjects. [§__.101(b)(4)] | (i) The identifiable private information or identifiable biospecimens are publicly available;<br>(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 subject, the investigator does not contact the subjects, and the investigator will not re-identify subjects;<br>(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 [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or "public health activities and purposes" as described under 45 CFR 164.512(b); or<br>(iv) The research is conducted by, or on behalf of, a Federal dept 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 the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy | **collaborator or statistician that is not part of a covered entity). This will be especially challenging within hybrid entities where some components are covered (e.g., university clinics) and others are not (e.g., faculty departments).** |

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| | 5. Research and demonstration projects which are conducted by or subject to the approval of [Federal] dept or agency heads and which are designed to study, evaluate or otherwise examine: (i) public benefit or service programs, (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures or (iv) possible changes in methods or levels of payment for benefits or services under those programs. [§__.101(b)(5)] | 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. [§__.104(d)(4)]<br><br>5. **Expanded with changes:** Research and demonstration projects that are conducted or supported by a Federal dept or agency, or otherwise subject to the approval of dept 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 section 1115 and 1115A of the Social Security Act, as amended.<br><br>Each Federal dept 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 dept or agency head may determine, a list of the research and demonstration projects that the Federal dept or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to | **Exemption #5**<br><br>▪ **Scope broadened to include research supported by a federal department or agency (instead of only conducted by such)**<br><br>▪ **Scope broadened to include research designed to improve, not just evaluate, public benefit or service programs**<br><br>▪ **Exemption only permitted if the research is listed on a federal website (or other similar mechanism)** |

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| | 6. Taste and food quality evaluation and consumer acceptance studies, if: (i) 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 FDA or approved by the EPA or the Food Safety and Inspection Service of the USDA. [§__.101(b)(6)] | commencing the research involving human subjects. [§__.104(d)(5)]<br><br>6. **UNCHANGED!** (Taste and food quality evaluation and consumer acceptance studies) [§__.104(d)(6)]<br><br>7. **NEW, OPTIONAL:** 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). [§__.104(d)(7)]<br><br>8. **NEW, OPTIONAL:** 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:<br>(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); | **Exemption #'s 7, 8 are not adopted at this institution.** |

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| | | (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §__.117;<br>(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<br>(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. [§__.104(d)(8)] | |