Exempt Category Guidance

Addendum I

Category	Considerations	Consent

1.	• **Key change**-no adverse impact on students' learning or assessment of educators
	• Some research that qualifies for exempt 1 today may not qualify under the revised rule
	• Examples:
	  ○ Research conducted by department or program chairs who also hold responsibility for evaluation of faculty
	  ○ Research involving the assignment of students to either a proven educational technique and a novel educational technique
		• For studies in which participants will complete study activities solely for research purposes, such as an evaluation of clinical skills for residents, study teams must obtain consent from participants prior to conducting the study activities.
		• For studies in which participants will complete activities as part of an educational experience and not solely for research purpose4s, the study team must obtain consent prior to obtaining data for research, such as grades or other results on the participants.
		• Members of the study team who may have a status relationship with the prospective participants of a category 1 study should not conduct the consent process.
		• If student records will be used in the category 1 exemption study, the Family Education Rights and Privacy Act (FERPA) may apply.

2.	• Data collection only – no interventions!
	• Data collection can include audio and video recording
	• Three standalone criteria to qualify (no interdependency)
	  ○ Data is recorded such that subject identifies cannot be readily ascertained; or
	  ○ Disclosure of data not likely to be harmful; or
	  ○ Identities can be ascertained but the IRB reviews (expedited) the provisions to protect privacy and confidentiality
	• Restricted: Category 2(a) and (b) for children
	• Not Permitted: Category 2(c) for children
	• Some research that today undergoes expedited or even possibly convened board review may qualify for exemption.
	• But, some of these studies will have to undergo a limited IRB review
	• Not allowed under this exemption category
	  ○ Interventions
	  ○ Collection of Biospecimens
		• Survey studies may supply abbreviated consent information to participants such as in an email, an information sheet, or in an introductory section at the beginning to the survey.
		• Interview studies benefit from a more detailed information sheet. If the interview is to be audio- or video-recorded, this must be included in the consent information. An oral consent script may be used instead of or in addition to the information sheet.
		• Focus group studies may use an oral consent script and/or a consent information sheet. If the focus group is to be audio- or video-recorded, this must be included in the consent information. Also, researchers should remind focus group participants that what is discussed in the focus group should be kept confidential.
		• If the study collects identifiable health information and members of the study team are employed by the Community Healthcare System, HIPAA Privacy rule requirements need to be met.
		• Observations of public behavior generally do not require a consent process, as long as the behavior is truly public. Observations of clinical practices and workflow are not considered public behavior and cannot be considered to be exempt under category 2.

	○ Linking to additional personally-identifiable data Research with children, except for research involving educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior if the investigator does not participate in the activities being observed	
3.	• Permits **benign behavioral interventions** combined with data collected through verbal or written responses or audiovisual recording • ADULTS only – *NO CHILDREN* • Prospective agreement • **Deception** only permitted if authorized – defined as withholding the purpose of the research • Three standalone criterial to qualify (no interdependency) ○ Data is recorded such that subject identifies cannot be readily ascertained; or ○ Disclosure of data not likely to be harmful; or ○ Identities can be ascertained but the IRB reviews (expedited) the provisions to protect privacy and confidentiality • More behavior research will qualify for exemption • But, some of these studies will have to undergo a **limited IRB review – Rational** collecting identifiable information so IRB conducts a Limited Review to assure privacy and confidentiality of information • Not allowed under this exemption category: ○ Research with children ○ Deception unless prior agreement obtained ○ Physiological data collection methods (e.g., EEG, Wearable devices, blood pressure monitors) ○ Linking to additional personally-identifiable data	• Studies involving benign behavioral interventions benefit from a more detailed information sheet. In order for a study to qualify for exemption under this category, potential participants must be made aware of the research procedures, unless the intervention involves public observation where subjects are not aware that they are participating in research (such as videotaping pedestrian behavior when a walk/don't walk sign is being manipulated for study purposes). • If the research involves audio- or video-recordings, this must be included in the consent information. An oral consent script may be used instead of or in addition to the information sheet.
4.	• Applies to **secondary research only where consent is not required** • **Identifiable Data/Specimens** can be both retrospective and prospective • Four Standalone qualifications (no interdependency) ○ Data/Specimens are publicly available	**Limitations on Exemptions** • Research involving pregnant women, fetuses, and/or neonates may be exempt *if the conditions of the exemption are met* • Research involving prisoners may not be exempt when the research *only incidentally includes prisoners*

	○ Data is recorded such that subject identities **cannot** be readily ascertained **AND** the investigator **does not contact** or **re-identify** the subjects; OR ○ Data includes only identifiable health information protected under HIPAA; OR ○ The research is conducted by or on behalf of a Federal department using government data obtained for nonresearch reasons AND, if identifiable adheres to specified privacy standards. • Some research that currently requires expedited or convened board review will now qualify for exemption • While coded information may qualify, guidance is needed to understand the implications of the accompanying requirement that investigators will not re-identify subjects • Similarly, while research involving PHI may qualify, guidance is needed to understand what data sharing, if any, would be permitted outside of covered entities (e.g., external statistician)	• Some research involving children may be exempt but there are specific restrictions that IRBs, researchers , and others charged with making exempt determinations must be cognizant of ○ The exemptions at paragraphs (d)(1), (4), (5), (6), (7) and (8) may be applied to research subject to subpart D if the conditions of the exemption are met ○ Paragraphs (d)(2)(i) and (ii) may apply to research subject to subpart D involving education tests or the observation of public behavior when the *Investigator does not participate in the activities being observed.* Paragraph (d)(2)(iii) may not be applied to research subject to Subpart D 45 CFR § 46.104
5.	• Scope broadened to include research supported by a federal department (instead of only conducted by such) • Scope broadened to include research designed to improve, not just evaluate, public benefit or service programs • Exemption only permitted if the research is listed on a federal website (or other similar mechanism)	
6.	No Change	
7.	• **Category 7 will not be available since the CHS CIRB has chosen not to adopt Broad Consent** • **Broad consent is an option not a requirement** • New exemption to enable storage or maintenance of identifiable data/specimens for secondary research ○ Broad consent must be obtained(no waiver of consent is allowed by waivers of documentation of consent are unlikely but passible) ○ Limited IRB review is required for all research under this exemption	
8.	• **Category 8 will not be available since the CHS CIRB has chosen not to adopt Broad Consent**	

	• **Broad consent is an option not a requirement** • New exemption for secondary research only when broad consent has been obtained • Limited IRB review is required for all research under this exemption, and includes; • Privacy and confidentiality • Secondary research is within the scope of the broad consent	