Exemption Categories under Revised Regulations

Category	Regulatory Language	Other Considerations
1	**Research 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.**	**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 at least ONE of the following criteria met:**	**Includes data collection through interactions or observation, not interventions. May include visual or auditory recording.**
	(i) 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	**Surveys and Interviews: No Children** **Educational Tests or Observation of Public Behavior: Can only include children when investigators do not participate in activities being observed**
	(ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation	
	(iii) Information is recorded by the investigator in such a manner that the identity can be readily ascertained with identifiers or code linked to identifiers & IRB conducts Limited Review (review to ensure that data security is adequate relative to the risk)	**No Children**
3	**Research involving benign behavioral interventions (BBI) 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:**	**No Children;** **No Medical Interventions;** **(ii) BBI must be:** • **Brief in Duration** • **Painless/Harmless** • **Not Physically Invasive** • **Not Likely to Have a Significant Adverse Lasting Impact on Subjects** • **Unlikely that Subjects Will Find Interventions Offensive or Embarrassing** **(iii)No deception unless participant prospectively agrees to participate in research in which the subject is told that he or she will be unaware of or misled regarding the nature or purposes of the research** Examples: having subjects play on online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of cash between themselves and someone else
	A. 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 responses outside of the research would NOT reasonably place subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation	
	C. Information is recorded by the investigator in such a manner that the identity can be readily ascertained with identifiers or code linked to identifiers & IRB conducts Limited Review (review to ensure that data security is adequate relative to the risk)	

Category	Exemption Category Description	Conditions/Allowances/Limitations
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:**	**No primary collection from subjects for the research; Allows both retrospective and prospective secondary use of data**
	(i) Identifiable private information or identifiable biospecimens are publicly available	**Information is identifiable in the primary source and does not need to be deidentified by investigator** **Examples: study of voter records, Facebook posts, etc.**
	(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subject cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact subjects and will not re-identify the subjects	**Information is identifiable in the primary source and must be deidentified by investigator when recording data** **Examples: student coursework, medical records, parole records, etc.**
	(iii) Collection and analysis involving investigators use of identifiable private health information (PHI) when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"	**HIPAA regulations still apply; use of PHI still requires HIPAA authorization or waiver of authorization; does not include biospecimens (only PHI); does not indicate that sharing is permitted under this exemption.**
	(iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities	**Rarely used at ISU**
5	**Research and demonstration projects conducted or supported by a Federal Agency/Dept. AND designed to study, evaluate, improve or examine public benefit or service programs.**	**Rarely used at ISU** **Must be posted on list of research and demonstration projects on a Federal Web site**
6	**Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed or if the food consumed contains a food ingredient at or below the level and for a use found to be safe…**	**No change from pre-2018 rule**
Consistent with most institutions, Illinois State University has chosen not to implement Exemption Categories 7 and 8 at this time until further guidance from OHRP is promulgated on appropriate use of Broad Consent.		
7	**Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which Broad Consent is required**	**Broad consent was appropriately given** **PI must track all refusals; IRB may not waive consent for future use of identifiable material for any individual who refuses**
8	**Secondary research involving use of identifiable private information or identifiable biospecimens for which Broad Consent was required**	**Broad consent was appropriately given** **PI must track all refusals; IRB may not waive consent for use of identifiable material for any individual who refuses** **Limited IRB review required** **Results must not be returned to subjects**