Exemption Categories

- Subpart B: Studies involving pregnant women, fetuses, and neonates are eligible for exempt status under all 8 categories
- Subpart C: Exemptions do not apply to research involving prisoners except "for research aimed at involving a broader subject population that only incidentally includes prisoners"
- Subpart D: Children are allowed in categories 1, 4, 5, 6, 7, & 8. There are limitations or exclusions in categories 2 & 3.

Category	New Citation	Exemption Category Description	Conditions/Allowances/Limitations
1	**104(d)(1)**	**Research conducted in established or commonly accepted educational settings, involving 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.**	
2	**104(d)(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 <u>at least one</u> of the following criteria are met:**	Data collection only; May NOT include intervention; May not include children; Educational tests or observation of public behavior can only include children when investigators do not participate in activities being observed.
		(i) information obtained is recorded in such a manner that 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 could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation	
		(iii) 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).	May not include children

3	**104(d)(3)(i)**	**Research involving Benign Behavioral Interventions (BBI) through verbal written responses, (including data entry or audiovisual recording) from adult subjects who prospectively agrees and <u>ONE</u> of the following are met:**	May not include children; May not include medical interventions; subject must prospectively agree; Privacy and confidentiality must be reviewed **(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**
		(A) Recorded information cannot readily identify the subject 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, civil liability or be damaging to the subjects' financial, employability, educational advancement, or reputation;	
		(C) 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).	
4	**104(d)(4)**	**Secondary research for which consent is not required: use of identifiable information or identifiable biospecimen that have been or will be collected for some other activity other than for reserach, if <u>ONE</u> of the following criteria are met:**	No primary collection from subjects for the research; Allows both retrospective and prospective secondary use
		(i) Biospecimen or information is publically available;	Must be publically available
		(ii) Information 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 use of identifiable health information that is regulated by HIPAA;	HIPAA still applies; HIPAA protection include authorization or waiver of authorization; Privacy and confidentiality must be reviewed
		(iv) Research information collected by or on behalf of federal government generated or collected information obtained for non-research activities.	If researcher generates identifiable private information it is subject to specified federal privacy laws.

5	**104(d)(5)**	**Research and demonstration projects supported by a federal agency/department AND designed to study or improve public benefit or service programs.**	Must be posted on federal web site.
6	**104(d)(6)**	**Taste and food quality evaluation and consumer acceptance studies. (6)(i) if wholesome foods without additives are consumed OR (6)(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	**104(d)(7)**	**Storage or maintenance of identifiable private information or identifiable biospecimen for secondary research for which broad consent is required.**	**NOTE: At this time, UL does not permit the use of broad consent.**
8	**104(d)(8)**	**Secondary research involving use of identifiable private information or identifiable biospecimen for which broad consent was required.**	**NOTE: At this time, UL does not permit the use of broad consent.**

*Table created by University of Kentucky Office of Research Integrity