University of Kentucky Office of Research Integrity Exemption Categories Tool

- Subpart B: Studies Involving Pregnant Women, Fetuses & Neonates are Eligible for Exempt 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 B: Children are allowed in categories 1,4,5,6,7, & 8; Limitations & Exclusion of Children in Category 2 & 3

Category	New Citation	Exemption Category Description	Limited IRB Review	Conditions/Allowances/Limitations
1	**104(d)(1)**	**Research in Established or Commonly Accepted Education Settings that Involves Normal Educational Practices**	N/A	**Not Likely to Adversely Impact Students' Opportunity to Learn or Assessment of Educators Providing Instruction**
2	**104(d)(2)**	**Research only includes interactions involving Educational Tests, Surveys, Interviews, Public Observation if at least ONE of the following criteria met:**	N/A	**Data Collection Only;** **May include visual or auditory recording;** **May NOT include Intervention;** **Only includes Interactions**
		(i) Recorded information cannot readily identify the subject (directly or indirectly/linked); **OR**	N/A	**Surveys & 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 (criminal, civil liability, financial, employability, educational advancement, reputation); **OR**	N/A	**Surveys & Interviews: No Children;** Educational Tests or Observation of Public Behavior: Can Only include Children When Investigators Do Not Participate in Activities being Observed
		(iii) Information is recorded with identifiers or code linked to identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review	NO Children
3	**104(d)(3)(i)**	**Research involving Benign Behavioral Interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subject who prospectively agrees and ONE of following met:**	N/A	**NO Children;** **May Not include Medical Interventions;** **Subject prospectively agrees;** **(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 indirectly/linked): **OR**	N/A	
		B. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); **OR**	N/A	
		C. Information is recorded with identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review	

Category	New Citation	Exemption Category Description	Limited IRB Review	Conditions/Allowances/Limitations
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 'primary' or 'initial' activity, if ONE of following criteria met:**		**No Primary Collection from subjects for the research;** **Allows Both <u>Retrospective and Prospective Secondary Use</u>**
		(i) Biospecimens or Information is Publically Available; **OR**	N/A	Must be publically available
		(ii) Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects; **OR**	N/A	PI does not contact: Will not re-identify
		(iii) Collection and Analysis involving Investigators Use of Identifiable Health Information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"; **OR**	N/A	HIPAA still applies; HIPAA protections include authorization or waiver of authorization; Does not include Biospeciments (only PHI); Federal guidance needed on how to apply this criterion
		(iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities	N/A	If research generates identifiable private information it is subject to specified federal privacy laws (see iv for list)
5	**104(d)(5)**	**Research and demonstration projects supported by a Federal Agency/Dept. AND Designed to study…improve… public benefit or service programs.**	N/A	**Must be posted on a Federal Web Site**
6	**104(d)(6)**	**Taste and Food Quality**	N/A	
7	**104(d)(7)**	**Storage or Maintenance of Identifiable Private Information or Identifiable Biospecimens for Secondary Research For Which Broad Consent Is Required**	-Broad consent is obtained --Documented or documentation waived - If there is a change made for research purposes in the way material stored or maintained, Privacy and confidentiality review	**All requirements for Broad Consent Met;** **MUST TRACK REFUSALS –as the IRB may not waive consent for use of identifiable material for any individual who refuses**
8	**104(d)(8)**	**Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent was Required**	-Privacy and confidentiality review & -research is within the scope of the broad consent & -PI does not plan to return research results	Privacy and Confidentiality protections adequate; Broad consent was obtained**;** Documented or documentation waived **No plan to return research results;** **MUST TRACK REFUSALS as the IRB may not waive consent for use of identifiable material for any individual who refuses**