

Exempt Review: Research Category Guidance

[NOTE: Adapted from the University of Kentucky IRB]

Category	45 CFR §46 Citation	Exempt 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, or Public Observation if at least ONE of the following criteria is 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)	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 Administered/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)	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 Administered/Observed
		(iii) Information is recorded with identifiers or code linked to identifiers & IRB conducts Limited Review	Limited Review: see 45 CFR §46.111(a)(7)	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 is met:	N/A	NO Children ; May Not include Medical Interventions; BBI must be:
		A. Recorded information cannot readily identify the subject (directly or indirectly/linked)	N/A	<ul style="list-style-type: none"> Brief in Duration Painless/Harmless Not Physically Invasive Not Likely to Have a Significant Adverse Lasting Impact on Subjects
		B. Any disclosure of responses outside of the protocol would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, education, reputation)	N/A	<ul style="list-style-type: none"> Unlikely that Subjects Will Find Interventions Offensive or Embarrassing
		C. Information is recorded with identifiers & IRB conducts Limited Review	Limited Review: see 45 CFR §46.111(a)(7)	No deception unless participant is informed in the prospective agreement that he/she will be unaware of or misled regarding the true nature or purpose of the study

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4	104(d)(4)	Secondary Research for Which Consent is Not Required: Use of Identifiable Information or Identifiable Biospecimens that have been or will be collected for some other 'primary' or 'initial' activity, if ONE of following criteria is met:		No Primary Collection from subjects for the research; allows Both <u>Retrospective and Prospective Secondary Use</u> .
		(i) Biospecimens or Information is Publicly Available	N/A	Must be publicly available (e.g., commercially available specimen or open access data). May also qualify as not human research (NHR). However, IRB review generally required for thesis, dissertation, or academic programs.
		(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	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"	N/A	HIPAA regulations still apply; HIPAA protections include authorization or waiver of authorization; Does not include Biospecimens (only PHI); Only covers "investigator's use"; 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	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 <u>Federal Agency/Dept.</u> AND designed to study...improve...public benefit or service programs.	N/A	Must be posted on a federal website.
6	104(d)(6)	Taste and Food Quality	N/A	Wholesome food without additives; ingredient level and use found to be safe.
7*	104(d)(7) NSU NOT USING	Storage or Maintenance of Identifiable Private Information or Identifiable Biospecimens for Secondary Research for which Broad Consent Is Required.	Limited Review: see 45 CFR §46.111(a)(7)	(Details not included here)
8*	104(d)(8) NSU NOT USING	Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for which Broad Consent was Required.	Limited Review: see 45 CFR §46.111(a)(7)	(Details not included here)