

## Exemption Categories

- 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 activities involving a broader subject population that only incidentally includes prisoners
- Subpart D: Children are allowed in categories 1, 2, 3, & 4 & 5 & 6 & 7 & 8 & 9 & 10 & 11 & 12 & 13 & 14 & 15 & 16 & 17 & 18 & 19 & 20 & 21 & 22 & 23 & 24 & 25

Category	New Citation	Exemption Category Description	Limited IRB Review	Conditions/Allowances/Limitations
1	104(d)(1)	Research in Established Schools or Community Accepted Educational Settings that Involves Normal Educational Practices	N/A	Not Open to Researcher's Students Appropriate Assessment of Educational Practices No Disruption
2	104(d)(2)	Research Involving Educational Tests, Surveys, Interviews, Public Observation if at least ONE of the following criteria met: (i) Recorded information cannot readily identify the subject (directly or indirectly/linked); OR (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 (iii) Information is recorded with identifiers or code linked to identifiers & IRB conducts Limited Review	N/A	Data Collection Only May include institutional records May NOT include: • Intrusive interactions  Surveys & Interviews: No Children • Educational tests or observation of public behavior can only include children when investigators do not participate in activities being observed  Surveys & Interviews: No Children • Educational tests or observation of public behavior can only include children when investigators do not participate in activities being observed
3	104(d)(3)	Research Involving Brief Behavioral Interventions (but through verbal, written responses, including data entry or audiovisual recording) from adult subject who prospectively agrees and ONE of following met: A. Recorded information cannot readily identify the subject (directly or indirectly/linked): OR 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 C. Information is recorded with identifiers & IRB conducts Limited Review	N/A	No Children May NOT include medical interventions Subject prospectively agrees:  • Brief Duration • Painless & harmless • Not Physically Invasive • Not Likely to Have a Significant Adverse Lasting Effect on Subject • Interventions Intensive or Embarrassing (IRB exception unless participant prospectively agrees)

Category	New Condition	Exemption Category	Destination	Limited IRB Review	Conditions/Any/All/None/No Limitations
					Collection from subjects for the research; Allows Both Retrospective and Prospective Secondary Use
					Must be duplicately available
4				N/A	PI does not contact: Will not re-identify
				N/A	HHS still applies; IRB protections include authorization or waiver of authorization; Does not include Biospecimens (only PHI); Federal guidance needed on how to apply this criterion?
				N/A	If research generates identifiable private information, it is subject to specified federal privacy laws (see iv for list)
5				N/A	Research on a Federal Web Site
6				N/A	
7					-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
					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					-Privacy and confidentiality -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