

## 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 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
<b>1</b>	<b>104(d)(1)</b>	<b>Research in Established or Commonly Accepted Education Settings that Involves Normal Educational Practices</b>	N/A	<b>Not Likely to Adversely Impact Students’ Opportunity to Learn or Assessment of Educators</b>
<b>2</b>	<b>104(d)(2)</b>	<b>Research only includes Educational Tests, Surveys, Interviews, Public Observation if at least ONE of the following criteria met:</b>	N/A	<b>Data Collection Only; May include visual or auditory recording; May NOT include Intervention</b>
		(i) Recorded information cannot readily identify the subject (directly or indirectly/linked); <b>OR</b>	N/A	<b>Surveys &amp; Interviews: No Children;</b> Educational Tests or Observation of Public Behavior: <b>Can Only include Children When Investigators Do Not Participate in Activities being Observed</b>
		(ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); <b>OR</b>	N/A	<b>Surveys &amp; Interviews: No Children;</b> Educational Tests or Observation of Public Behavior: <b>Can Only include Children When Investigators Do Not Participate in Activities being Observed</b>
		(iii) Information is recorded with identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review	<b>NO Children</b>
<b>3</b>	<b>104(d)(3)(i)</b>	<b>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:</b>	N/A	<b>NO Children;</b> <b>May Not include Medical Interventions;</b> <b>Subject prospectively agrees;</b>
		A. Recorded information cannot readily identify the subject (directly or indirectly/linked): <b>OR</b>	N/A	<b>(ii)BBI must be:</b> <ul style="list-style-type: none"> <li>• <b>Brief in Duration</b></li> <li>• <b>Painless/Harmless</b></li> <li>• <b>Not Physically Invasive</b></li> <li>• <b>Not Likely to Have a Significant Adverse Lasting Impact on Subjects</b></li> <li>• <b>Unlikely that Subjects Will Find Interventions Offensive or Embarrassing</b></li> </ul> <b>(iii)No deception unless participant prospectively agrees</b>
		B. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); <b>OR</b>	N/A	
		C. Information is recorded with identifiers & IRB conducts Limited Review	Privacy and Confidentiality Review	

4	104(d)(4)	<b>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:</b>		<b>No Primary Collection from subjects for the research; Allows Both <u>Retrospective and Prospective Secondary Use</u></b>
		(i) Biospecimens or Information is Publically Available; <b>OR</b>	N/A	Must be publicly 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; <b>OR</b>	N/A	
		(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"; <b>OR</b>	N/A	HIPAA still applies; HIPAA protections include authorization or waiver of authorization;
	(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)	<b>Research and demonstration projects supported by a Federal Agency/Dept. AND Designed to study, public benefit or service programs.</b>	N/A	<b>Must be posted on a federal web site</b>
6	104(d)(6)	<b>Taste and Food Quality</b>	N/A	
7	104(d)(7)	<b>Storage or Maintenance of Identifiable Private Information or Identifiable Biospecimens for Secondary Research For Which Broad Consent Is Required</b>	-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	<b>All requirements for Broad Consent Met;</b>  <b>MUST TRACK REFUSALS –as the IRB may not waive consent for use of identifiable material for any individual who refuses</b>  <b>NOTE: Due to logistical limitations, UTC IRB will not be issuing exemptions under categories 7 and 8.</b>
8	104(d)(8)	<b>Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent was Required</b>	-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 <b>No plan to return research results;</b> <b>MUST TRACK REFUSALS as the IRB may not waive consent for use of identifiable material for any individual who refuses</b>