

<b>Geisinger HRPP</b>	<b>Exemption Eligibility</b> <b>Determining if Human Subject Research is Exempt from Regulations</b>	
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The research involves prisoners as participants	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<b>Exemption <input type="checkbox"/></b> <b>prohibited</b> (if <b>any</b> are "yes")
For categories 1 through 5: The research is subject to FDA regulation	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
Research conducted in established or commonly accepted educational settings involving normal educational practices	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<b>Category 1 <input type="checkbox"/></b>  OK if both "yes"
The research is on: <input type="checkbox"/> regular and special education instructional strategies, Or <input type="checkbox"/> the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
The research involves the use of one or more of the following <input type="checkbox"/> Educational tests (cognitive, diagnostic, aptitude, achievement) <input type="checkbox"/> Survey procedures <input type="checkbox"/> Interview procedure <input type="checkbox"/> Observation of public behavior of adults	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<b>Category 2 <input type="checkbox"/></b>  OK if both "yes"
<input type="checkbox"/> Information obtained is recorded in such a manner that participants CANNOT be identified, directly or through identifiers linked to the participants Or <input type="checkbox"/> Any disclosure of the participants' responses outside the research could NOT reasonably place them at risk of criminal or civil liability*, or be damaging to their financial standing, employability, reputation	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
The research involves the use of either or both of the following <input type="checkbox"/> Educational tests (cognitive, diagnostic, aptitude, achievement) <input type="checkbox"/> Observation of public behavior of children where the investigator(s) will NOT participate in the activities being observed	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<b>Category 2 <input type="checkbox"/></b>  OK if both "yes"
<input type="checkbox"/> Information obtained is recorded in such a manner that participants CANNOT be identified, directly or through identifiers linked to the participants Or <input type="checkbox"/> Any disclosure of the participants' responses outside the research could NOT reasonably place them at risk of criminal or civil liability*, or be damaging to their financial standing, employability, or reputation	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
The research is NOT exempt under Category 2 above	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<b>Category 3 <input type="checkbox"/></b>  OK if all "yes"
The research involves the use of one or more of the following <input type="checkbox"/> Educational tests (cognitive, diagnostic, aptitude, achievement) <input type="checkbox"/> Survey procedures <input type="checkbox"/> Interview procedures <input type="checkbox"/> Observation of public behavior	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
<input type="checkbox"/> The participants are elected or appointed public officials or candidates for public office Or <input type="checkbox"/> Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens (Material has been collected BEFORE the start of the project)	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<b>Category 4 <input type="checkbox"/></b>  OK if both "yes"
<input type="checkbox"/> These sources are publicly available Or <input type="checkbox"/> Information is recorded by the investigator in such a manner that both statements apply: <input type="checkbox"/> Participants cannot be directly identified AND <input type="checkbox"/> Participants cannot be identified through identifiers linked to them	No <input type="checkbox"/>	Yes <input type="checkbox"/>	

<b>Geisinger HRPP</b>	<b>Exemption Eligibility</b> Determining if Human Subject Research is Exempt from Regulations		
<b>Protocol Director:</b>		<b>Protocol ID:</b>	
<b>Category 5</b>			
The project is a research or demonstration project	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<b>Category 5 <input type="checkbox"/></b> OK if all "yes"
The project is conducted by or subject to the approval of Department or Agency heads	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
The project is designed to study, evaluate, or otherwise examine one or more of the following: <input type="checkbox"/> Public benefit or service programs; <input type="checkbox"/> Procedures for obtaining benefits or services under those programs; <input type="checkbox"/> Possible changes in or alternatives to those programs or procedures; <input type="checkbox"/> Possible changes in methods or levels of payment for benefits or services under those programs	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act)	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
The project is conducted pursuant to specific federal statutory authority	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
The project has authorization or concurrence by the funding agency.	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
The project does NOT involve significant physical invasions or intrusions upon the privacy of participants	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
<b>Category 6</b>			
The research involves a taste and food quality evaluation and consumer acceptance studies	No <input type="checkbox"/>	Yes <input type="checkbox"/>	<b>Category 6 <input type="checkbox"/></b> OK if all "yes"
The research involves one of the following: <input type="checkbox"/> Wholesome foods without additives will be consumed <input type="checkbox"/> A food will be consumed that contains a food ingredient when the food ingredient is at or below the level to be safe OR the food ingredient is for a use found to be safe	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
A food will be consumed that contains an agricultural chemical or environmental contaminant and one of the following is true: <input type="checkbox"/> The agricultural chemical or environmental contaminant is at or below the level found to be safe by the Food and Drug Administration <input type="checkbox"/> The agricultural chemical or environmental contaminant is at or below the level approved by the Environmental Protection Agency <input type="checkbox"/> The agricultural chemical or environmental contaminant is at or below the level approved by the Food Safety and Inspection Service of the U.S. Department of Agriculture	No <input type="checkbox"/>	Yes <input type="checkbox"/>	
<b>Other Determinations – Complete this section</b>			
The project does NOT involve significant physical invasions or intrusions upon the privacy of participants	No      Yes		
The project meets the organizations ethical standards governing the conduct of research (e.g., acceptable risk-benefit relationship, equitable selection, informed consent, protections of privacy, maintenance of confidentiality, and protections for vulnerable populations)	No      Yes		