IRB Exempt Research

Research Activities in which the only involvement of human subjects/participants will be in one or more of the six (6) specific categories that are listed below may qualify for exemption from the full requirement of 45 CFR 46 or 21 CFR 56. It is well to note, however, that at Morgan State University, researchers are not authorized to make the final determination of exempt status themselves.

*The researcher may suggest an Exempt Category on the protocol application; but the final determination is made by the IRB Office ONLY.

*Please remember that exempt is defined as being exempt from further review and approval beyond the IRB Administrator or the IRB Chair. It does not mean that your proposed research project is exempt from being reviewed.

Exempt Categories

| Category 1 | Research conducted in established or commonly accepted educational settings, involving normal education practices, such as:  
| a. research on regular and special education instructional strategies  
| b. research on the effectiveness of, or the comparison, among instructional techniques, curricula, or classroom management methods  
| Note: Use of identifiable data from previous courses is NOT exempt. Such projects are non-exempt. |
| Category 2 | Research involving only the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:  
| a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND  
| b. any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation  
<p>| NOTE: The exemption under Category 2 DOES NOT APPLY to research involving survey or interview procedures or observation of public behavior when individuals under the age of 18 are subjects of the activity except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. |</p>
<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
</table>
| 3        | Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under Category 2, **IF:**  
  a. the human subjects are elevated or appointed public officials or candidates for public office, **OR**  
  b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter |
| 4        | Research involving the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects. |
| 5        | Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:  
  a. public benefit or service programs;  
  b. procedures for obtaining benefits or services under those programs;  
  c. possible changes in or alternatives to those programs or procedures; **OR**  
  d. possible changes in methods or levels of payment for benefits or services under those programs  
  **Note:** To qualify for this category, project must be conducted pursuant to a federal statute. |
| 6        | Taste and food quality evaluation and consumer acceptance studies,  
  a. if wholesome food without additives are consumed; **OR**  
  b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Good Safety and Inspection Service of the U.S. Department of Agriculture |