**WSU IRB Exempt Determination Checklist**

If the ONLY involvement of human subjects will be in one or more of the following categories AND all the answers in one or more categories is “True” (except where noted), the research can be determined exempt from IRB review by the IRB Office or an IRB Reviewer.

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| **Checklist Statement** | **True**  **√** | **Not True**  **√** |
| **Category 1: For Educational Settings:** |  |  |
| The research will only be conducted in established or commonly-accepted educational settings including but not limited to schools and colleges. (May include other sites where educational activities regularly occur.) |  |  |
| 2\* The research will involve only normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. |  |  |
| 3\* The research will not involve individuals as participants who are known to be prisoners. |  |  |
| 4\* The research is not subject to FDA regulations. |  |  |
| **Category 2: For Educational Tests, Surveys, Interviews, Public Behavior Observations** |  |  |
| 5\* The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. |  |  |
| 6\* **Address statement 6 only if the research will involve children (defined as <18 years old) as participants. If children will NOT participate, indicate N/A and continue with statement 7.**  Children are involved and the procedures will be limited to observation of public behavior where the investigator will NOT participate in the activities being observed. |  |  |
| 7\* The information obtained from educational tests, survey procedures, interview procedures or observation of public behavior will be recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects.  **‘True’ to either statement 7 or 8 will qualify for exemption if statements 9 and 10 are true.** |  |  |
| 8\* Any disclosure of the human subjects' responses outside the research could NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. |  |  |
| **Checklist Statement** | **True**  **√** | **Not True**  **√** |
| 9\* The research will not involve individuals as participants who are known to be prisoners. |  |  |
| 10\* The research is not subject to FDA regulations. |  |  |
| **Category 3: Public Officials - Educational Tests, Surveys, Interviews, Public Behavior Observation** |  |  |
| 11\* The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND the human subjects are elected or appointed public officials or candidates for public office. (Applies to senior officials such as mayor or school superintendent rather than a police officer or teacher.)  **‘True’ to either statement 11 or 12 will qualify for exemption if statements 13 and 14 are true.** |  |  |
| 12\* The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. |  |  |
| 13\* The research will not involve individuals as participants who are known to be prisoners. |  |  |
| 14\* The research is not subject to FDA regulations. |  |  |
| **Category 4: Existing Data, Documents and Specimens** |  |  |
| The research will involve only the collection or study of ***existing*** data, documents, records, pathological specimens, or diagnostic specimens. (“Existing” means existing before the research is proposed to the IRB to determine whether the research is exempt. All materials to be reviewed currently exist at the time of this exemption request.) |  |  |
| The sources of the existing data, documents, records or specimens are publicly available **OR** the information will be recorded by the investigator in such a manner that participants cannot be readily identified either directly or through identifiers (such as a code) linked to them. |  |  |
| The research will not involve individuals as participants who are known to be prisoners. |  |  |
| The research is not subject to FDA regulations. |  |  |

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| **Checklist Statement** | **True**  **√** | **Not True**  **√** |
| **Category 5: Federal Public Benefit or Service Programs** |  |  |
| The project is a research or demonstration project conducted by or subject to the approval of a (federal) Department or Agency head and which is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those public benefit or service programs. |  |  |
| The research will not involve individuals as participants who are known to be prisoners. |  |  |
| The research is not subject to FDA regulations. |  |  |
| 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). |  |  |
| The research or demonstration project will be conducted pursuant to specific federal statutory authority. |  |  |
| There is no statutory requirement that the project be reviewed by an IRB. |  |  |
| The project does not involve significant physical invasions or intrusions upon the privacy of participants. |  |  |
| The exemption has authorization or concurrence by the funding agency. |  |  |
| **Category 6: Taste and Food Quality and Consumer Acceptance Studies** |  |  |
| The research involves only a taste and food quality evaluation or a food consumer acceptance study in which (i) wholesome foods without additives will be consumed **OR** (ii) food will be consumed that contains a food ingredient, agricultural chemical or environmental contaminant that is at or below the level found to be safe by the Food and Drug Administration or is approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. |  |  |
| The research will not involve individuals as participants who are known to be prisoners. |  |  |
| HIPAA: If the research involves protected health information (PHI), the investigator provided adequate justification to waive authorization or is obtaining written authorization. Note that if study investigator accesses PHI but doesn’t record identifiers, the research still involves PHI. |  |  |