GUIDELINE FOR EXEMPT STATUS DETERMINATION

The Office for Human Subject Protection (OHSP) Policy 501 describes the levels of RSRB review for proposed research activities, including certain types of research, which are exempt from the 45 CFR 46 regulations. This guideline describes the regulatory categories and institutional standards for Investigators proposing research activities to the Research Subject Review Board (RSRB) to determine whether an exemption is applicable. The RSRB reserves the right to deny exemption requests whenever there is a concern for the welfare of human subjects.

1. Pre-Submission Regulatory Considerations

The RSRB will consider human subjects research Categories 1-6 of exemption as identified in the regulations 45 CFR 46.101(b), 45 CFR 46.201(b), 45 CFR 46.301(a), 45 CFR 46.401(b), and 21 CFR 56.104. An exempt status determination means the research is “exempt” from federal regulations, including annual review requirements, IRB notification of study closure, and the need for informed consent; however, there is an institutional requirement to use information letters, as needed, to support the ethical principle of “Respect for Persons.” The application does not need further review by the RSRB for that activity, as long as no changes are made. See Appendix 1 Exemption Categories, for descriptions and examples.

NOTE: Exemption categories do not apply to the following research activities:

- Research involving prisoners as a targeted or known population
- FDA regulated research for Categories 1 – 5
- Category 2 – Survey or interview procedures involving children
- Category 2 – Observation of public behavior involving children (unless the Investigator/research team does not participate in the activities being observed)

2. Investigator Submission Requirements

a. When submitting applications for initial review, Investigators must include all applicable materials for submission listed in Policy 502 Types of RSRB Submissions.

   - The applicable Protocol Template and Information Sheets may be utilized to ensure institutional standards are met.

b. Upon receipt of an application by the RSRB Specialist, a pre-review of the submission will be completed (e.g., to verify whether the submission materials are completed, required education is completed, etc.). The Specialist makes an initial determination as to whether the activities involve human subject research (see OHSP Guideline for Determining Human Subject Research) and is eligible for exempt review (i.e., meets regulatory qualifications). The Specialist may request more information from the Investigator during this pre-review process for clarification or completeness of the application. Once the application is considered complete, the Specialist will proceed with
review under the exempt review process or may re-assign the application for consideration of expedited or convened board review, if appropriate (see OHSP Guideline for Expedited Review of Research).

3. Exempt Review Procedures
   a. Initial Review
      i. The RSRB Specialist will review the submission to ensure the research meets the institution’s ethical standards, and regulatory and additional RSRB requirements, including but not limited to the items listed below:
         • The research holds out no more than minimal risk to subjects.
         • There are adequate provisions to maintain subject privacy;
         • If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of data on the recording device (i.e., appropriate encryption measures are in place according to the UR Information Technology Policies);
         • Selection of subjects is equitable;
         • If there are interactions with subjects, there is an adequate process to disclose the following information, at a minimum: activity involves research, description of the procedures, participation is voluntary, and the name and contact information for the Investigator or study team and the RSRB.
           o This process is typically achieved through an information letter or verbal script.
           o There may be certain research activities meeting an exempt status where written informed consent should be obtained and documented (e.g., obtaining written permission from parents for research involving educational strategies for their children, or used as appropriate to the culture in which the research is being conducted).
           o When applying for exemption category #3, the following information is required to be disclosed, at a minimum: activity involves research, description of the procedures and the name and contact information for the Investigator or study team and the RSRB. This decision was made based upon the population under study; in that an elected official would understand that there is no requirement to complete the survey.
      ii. The application may be sent back to the Investigator at any point during the review process, prior to final review determination, should more information or clarification be requested by the RSRB.

   b. Changes (Amendments) to Research Previously Determined as Exempt
      i. The RSRB Specialist receives all information submitted for changes to the research, including the Amendment Form and revised study materials, and will review these materials to ensure the research activities continue to meet the criteria for exemption.
      ii. If the research no longer meets the criteria for exemption based on the submitted changes, the Specialist will request that the Investigator withdraw the amendment
and a New Application form will need to be completed for further RSRB review under the appropriate review level (e.g., expedited or convened board review).

4. Exempt Review Determination and Notifications
   a. Once an exempt determination is made by the Specialist, the study is sent to the designated Senior Specialist (or RSRB Director) to record the final review determination within the electronic submission system.

   • Note: Research granted exempt status by the RSRB may be “exempt” from federal regulations; however, it does not mean that the research is exempt from RSRB oversight and institutional policies, such as, reportable events and compliance with the Health Insurance Portability and Accountability Act (HIPAA).

   b. Investigators are notified of exempt review determination according to OHSP Policy 403 Notification of RSRB Determinations.
## Appendix 1: Exemption Categories

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<th>Exemption Category</th>
<th>Examples/Comments</th>
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- This category may be applied to research involving children. |
| Research conducted in established or commonly accepted educational settings, involving 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  
• Research does not involve prisoners as subjects  
• Research is not FDA-regulated |
| **2. Surveys/Interviews/Standardized Educational Tests/Observation of Public Behavior** | - Anonymous testing, surveys or interviews of adults  
- Non-anonymous testing, surveys or interviews of adults if the information is not of a sensitive nature  
- Observation of naturally occurring public behavior with no manipulation by the investigator |
| Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless:  
i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and  
ii) 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.  
Note: This section is not applicable to survey or interview procedures involving children. Observation of public behavior in children may be exempt only when the investigator(s)/research team do not participate in the activities being observed.  
• Research does not involve prisoners as subjects  
• Research is not FDA-regulated |
| **3. Surveys/Interviews/Observation of Public Behavior** | - Interview with government officials  
Include copies of research materials as in Category 2 above. |
| Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior if the subjects are elected or appointed public officials or candidates for public office.  
• Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.  
• Research does not involve prisoners as subjects  
• Research is not FDA-regulated |

*(categories 4, 5 and 6 continued next page)*
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<th>Exemption Category</th>
<th>Examples/Comments</th>
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<tr>
<td><strong>4. Secondary Use of Existing Data</strong></td>
<td>• “Existing data” means that the information or materials must already exist at the time the research is proposed (i.e., no on-going collection).</td>
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<td>Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens,</td>
<td>• Investigator (i.e., study team)</td>
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<td>i) if these sources are publicly available, or</td>
<td>A copy of the data or specimen collection sheet(s) must be submitted.</td>
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<td>ii) if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly, or indirectly through identifiers linked to the subjects.</td>
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<tr>
<td>• Research does not involve prisoners as subjects</td>
<td></td>
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<tr>
<td>• Research is not FDA-regulated</td>
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<td><strong>5. Evaluation of Public Benefit or Service Program</strong></td>
<td>• Department or Agency heads = Health and Human Services</td>
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<td>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 public benefit or service programs (i.e., procedures for obtaining benefits or services under such programs, possible changes or alternatives to the programs, or possible changes in methods or levels of payment for benefits or services under the programs). The following criteria must be satisfied to qualify for exemption:</td>
<td>• Research is designed or authorized by federal agencies (e.g., Medicare, Social Security) or departments</td>
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<td>i) The program must deliver 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);</td>
<td>• Food stamps, AFDC, welfare reform</td>
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<td>ii) project must be conducted pursuant to specific federal statutory authority;</td>
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<td>iii) there must be no statutory requirement that the project be reviewed by an IRB;</td>
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<td>iv) the project must not involve significant physical invasions or intrusions upon the privacy of participants.</td>
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<td>• Research does not involve prisoners as subjects</td>
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<td>• Research is not FDA-regulated</td>
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<td><strong>6. Taste and Food Quality Evaluation</strong></td>
<td>• Taste comparison of two marketed nutritional drinks.</td>
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<td>Taste and food quality evaluation or consumer acceptance studies:</td>
<td>Include any appropriate documentation</td>
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<td>i) if wholesome foods without additives are consumed, or</td>
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<td>ii) if 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.</td>
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