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 HHS regulations at 45 CFR 46. 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 such as annual review requirements and IRB notification of study closure. There is an institutional requirement to use an information sheet(s), as needed, to support the ethical principle of “Respect for Persons”. See Appendix 1 Exemption Categories, for descriptions and examples.

   NOTE: Exemption categories do not apply to the following research activities:
   • FDA regulated research for Categories 1 – 5
   • Research involving prisoners as a targeted or known population
   • 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. The submitting Investigator must meet the qualifications and requirements of Principal Investigator (PI) as defined in OHSP Policy 901 Investigator Responsibilities.
      • Note that a Department or School may require that a full time faculty member be listed as PI.
   b. When submitting an application for initial review, Investigators must include all applicable materials for submission listed in Policy 502 Types of RSRB Submissions.
      • The Non-Biomedical or Secondary Analysis of Specimens/Records Protocol Template and Information Sheets may be utilized as applicable to ensure sufficient information is provided for the RSRB to make a review determination and that institutional standards are met.
   c. 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 or study team 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.

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, regulatory, and additional RSRB requirements, including but not limited to the following:
         • 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 (i.e., appropriate encryption measures are in place according to the UR Information Technology Policies);
         • Selection of subjects is equitable;
         • If there is subject interaction, 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 or study team at any point during the review process prior to a final review determination, should more information or clarification be requested by the RSRB.
      iii. Once a review determination is made, the application does not need further review by the RSRB, as long as no changes are made.
   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. These materials will be reviewed 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 will need to be completed for further RSRB review under the appropriate review level (i.e., expedited or convened board review).

4. Exempt Review Determination and Notifications
   a. Once an exempt determination is made by the RSRB Staff, the study is sent to the designated RSRB reviewer to record the final review determination within the electronic submission system. Review determinations are made by RSRB staff (Senior Specialist or RSRB Director).
      - **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 research event reporting requirements. Compliance with institutional policies pertaining to security, privacy and the Health Insurance Portability and Accountability Act (HIPAA) may also be required based on the activities being conducted.

   b. Investigators are notified of an exempt review determination according to OHSP Policy 403 Notification of RSRB Determinations.

   c. Upon confirmation of an exempt determination, Investigators are required to follow the responsibilities outlined in the OHSP Summary of Responsibilities for Investigators Conducting Exempt Research.
Appendix 1: Exemption Categories

The RSRB will consider the following human subject research activities exempt (Categories 1-6 of exemption are allowed by the University of Rochester as identified in 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).

Note: These categories do not apply to prisoners and categories 1 – 5 do not apply to FDA regulated research.

<table>
<thead>
<tr>
<th>Exemption Category and Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Educational Research Conducted in Educational Settings</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>“Commonly accepted educational settings” include (but are not limited to) K-12 schools and college/university classrooms. They may also include after-school programs, preschools, vocational schools, alternative education programs, residency programs, and other sites where educational activities regularly occur.</td>
</tr>
<tr>
<td>“Normal educational practices” are activities that could occur regardless of whether the research is conducted. Examples include established teaching methods (not considered to be experimental) or curriculum, and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher.</td>
</tr>
<tr>
<td>Examples of research that is exempt under Category 1:</td>
</tr>
<tr>
<td>• A study evaluating the effectiveness of a commonly accepted science curriculum. For the study, researchers will observe classroom instruction and collect quizzes and class evaluations that are part of the curriculum and classroom practice.</td>
</tr>
<tr>
<td>• A study comparing two curricula that are currently being implemented (or one that is current but recently replaced an older version). Researchers will observe classrooms as well as interview instructors about their experiences implementing the instructional materials and collect class evaluations.</td>
</tr>
<tr>
<td>• A study involving interviews of 3rd Grade teachers regarding their experiences and techniques with implementing new math standards. Researchers will obtain lesson plans and ask the teachers to provide reflective journals for one week.</td>
</tr>
<tr>
<td>• A study comparing driver’s education curricula offered by area driving schools. The researcher will observe and compare group driving test scores at the end of the courses.</td>
</tr>
<tr>
<td>• A study using surveys will ask residents in the orthopedic rotation to provide their feedback on a recently approved surgical skill curriculum.</td>
</tr>
</tbody>
</table>

(continued next page)
### Exemption Category and Examples

#### 2. Surveys/Interviews/Educational Tests/Observation of Public Behavior

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’ response 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.

**EXCEPTION:** This exemption does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

#### Anonymous:
- Required if your survey or questionnaire involves questions of sensitive nature.
- No identifiers can be connected to the data, either directly or through a coding system.
- Video/audio recordings, images and photographs are considered to be identifiable; therefore, any data collection that involves these activities would not be considered anonymous.
- Multiple pieces of information, none of which are identifiable on their own, may uniquely identify a person when brought together; in this case, the data would be identifiable and would not be considered anonymous.

#### Identifiable (risk of disclosure):
- Allows for data to be collected with identifying information (e.g., the researcher has a key linking respondents' names to coded identifiers), but the information is so innocuous that, in the event of disclosure outside of the research, there would be no detrimental consequences to the subject.

#### Public behavior:
- Refers to behavior taking place in a publicly accessible location in which the subject does not have an expectation of privacy (e.g., a public plaza or park, a street, a building lobby, a government building, some websites and social media sites (where the user’s account is set to public)). If subjects have a reasonable expectation of privacy (e.g., medical exam room, private office) at the location where the researcher is conducting the observation, the project may not be considered exempt.

#### Tasks:
Federal guidance about exempt status indicates that “tasks” exclude research from Category 2 exempt status (although research involving tasks might qualify for Category 7 expedited review). Many studies involving interviews, surveys, or focus groups ask subjects to engage in some type of activity in connection with the question or discussion. RSRB uses the term “task” to describe activities that preclude interviews, surveys, and focus groups from Category 2 exempt status.

RSRB considers the following activities to **always** be a “task”:
- Asking subjects to physically manipulate an object
- Asking subjects to play a game
- Asking subjects to complete a specific physical action

Examples that would **not** involve tasks:
- Asking participants in a focus group to read something for the purpose of stimulating the group’s discussion is not a task.
**Exemption Category and Examples**

- Writing activities in a survey, interview, or focus group context are not tasks if the purpose of the writing is to communicate information about the subject as a person, rather than to describe how individuals solve specific, well-defined tangible problems or accomplish specific well-defined tangible goals.

Activities such as reading, writing, looking at visual stimuli, listening to auditory stimuli, music lyrics, or imagining something may be tasks, or may instead simply be part of questions being asked. Making this determination is a judgment based on:

- The specific details of the activity, such as whether the subjects received specific instructions that require active engagement with the material and accomplishment of a specific, objective, endpoint.
- The intent or purpose of the activity. Activities intended to elicit information about the subjects (for example, their reaction to something or thoughts about something) would generally not be considered tasks. Activities intended to elicit subjects’ strategy, method, or ability for performing a specific goal-directed activity would usually be considered a task, if the purpose of the research is focused on that issue.
- The intent or purpose, and specific context/format, of the interview, survey, or focus group. When the intent is to determine how an activity changes subjects or their performance, it is generally a task (or intervention), and therefore does not qualify for Category 2 exempt status. An example of non-exempt research: research whose purpose is to determine whether subjects’ thoughts, emotions, behaviors, or cognitive performance can be manipulated or changed by activities.
- The nature of the questions or discussion points.
- What a reasonable person would conclude.

**Examples of research that is exempt under Category 2:**

- A study in which an anonymous survey about workplace satisfaction is given to employees at local businesses.
- An observational study of children playing in a public park; the researcher takes notes of what occurs, recording sex, race, and length of activity of children, but does not interact with subjects.
- A study in which college seniors (age 18 and older) are interviewed about their plans after graduation. The researcher will record their date of birth and give the participant an algorithm to create a unique code (e.g., the last 4 digits of your cell phone number + the first four letters of your mother’s maiden name). This could be identifiable, but the answers to questions asked would present no risks to subjects if divulged outside the research.
- A study in which anonymous surveys are collected from patients about their recent visit for treatment on depression.
- A study involving an anonymous survey of college seniors regarding recreational drug use.

**Examples of research that is NOT exempt under Category 2:**

- A study involving audio-recorded interviews where the researcher is examining how being diagnosed with fibromyalgia affects parenting. No names or other identifying information will be collected. The study is not considered anonymous because the interviews will be audio-recorded, and medical information is generally deemed sensitive information.
- Research involving interviews with the underage children about their TV habits. Research involving the survey of minors does not qualify for Category 2 exemption.
- An observational study where a researcher pretends to fall and records helping behavior in children in a public park. Observational research involving children does not qualify for Category 2 exemption in cases where the researcher will interact with participants.
### Exemption Category and Examples

#### 3. Surveys/Interviews/Observation of Public Behavior

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.

**Example of research that is exempt under Category 3:**
- Interview with government officials

#### 4. Secondary Use of Existing Data

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens,

i) if these sources are publicly available, or

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.

**Examples of research that is exempt under Category 4:**
- “Existing data” means that the information or materials must already exist at the time the research is proposed (i.e., no on-going collection).
- Investigator (i.e., study team)

**A copy of the data or specimen collection sheet(s) must be submitted.**

#### 5. Evaluation of Public Benefit or Service Program

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:

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);

ii) project must be conducted pursuant to specific federal statutory authority;

iii) there must be no statutory requirement that the project be reviewed by an IRB;

iv) the project must not involve significant physical invasions or intrusions upon the privacy of participants.

**Examples of research that is exempt under Category 5:**
- Department or Agency heads = Health and Human Services
- Research is designed or authorized by federal agencies (e.g., Medicare, Social Security) or departments
- Food stamps, AFDC, welfare reform
6. **Taste and Food Quality Evaluation**
   Taste and food quality evaluation or consumer acceptance studies:
   i) if wholesome foods without additives are consumed, or
   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.

*Example of research that is exempt under Category 6:*

- Taste comparison of two marketed nutritional drinks.