

**Rochester Regional Health System Clinical Investigation Committee
Supplement to Application for Review
Exemption Categories**

Please check the box you are proposing your project meets.

The following categories are identified in **45 CFR 46.101 (b)**

You will receive a letter from the CIC giving final determination and approval of your project. Research may not begin until you receive final approval by the Committee

Category	
<p>1. Educational Research Conducted in Educational Settings Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:</p> <ul style="list-style-type: none"> i) research on regular and special education instructional strategies, <u>or</u> ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. 	
<p>2. Surveys/Interviews/Standardized 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 if:</p> <ul style="list-style-type: none"> i) information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; <u>or</u> ii) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation. <p>• This section is not applicable to survey or interview procedures involving children. Observation of public behavior in children may be exempt <u>only</u> when investigator(s) does not participate in the activities being observed.</p>	
<p>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 officials.</p>	
<p>4. Secondary Use of Pre-existing Data Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens,</p> <ul style="list-style-type: none"> i) if these sources are publicly available, <u>or</u> ii) 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. 	
<p>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. The following criteria must be satisfied to qualify for exemption:</p> <ul style="list-style-type: none"> 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. 	

Signature of Investigator
10/08

Date