

IRB QA/QI (EXEMPT) RESEARCH QUESTIONNAIRE

DIRECTIONS: This form is to be neatly typed and uploaded into IRBNet along with a copy of your protocol to the IRB for an exemption determination. This form should only be used when the investigator is contemplating the initiation of a research project which, in the investigator's judgment, is exempt from IRB review. The IRB will then determine whether the activity is covered by the regulations. **Please fill out completely.** *Type only in the gray boxes. To mark a box as checked, double-click the box, select "checked", and click "OK".*

Please submit this completed form together with the following:

- A copy of the protocol or a detailed description of the research;
- Copies of all data collection tools including surveys; and
- Copies of any interview or focus group questions that will be used.

Research activities are exempt from regulations for the protection of human research subjects when they are considered minimal risk (the probability or magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (as defined by 45 CFR 46.102(i)) and the ONLY involvement of human subjects falls within one or more of the exempt categories listed below.

The exempt categories outlined below do not apply to research involving prisoners or research involving a test article regulated by the FDA, unless the research meets the criteria for exemption described in 45 CFR 46.101(b)(6) and 21 CFR 56.104(d).

NOTE: Research involving Protected Health Information (PHI) is NOT eligible for approval under Exempt Category 4.

QA/QI Activities that do not meet the definition of human research will be reviewed and granted a letter of QA/QI review and acknowledgement from the IRB. If there is interest in disseminating or publishing the results of the QA/QI activity, this correspondence can be submitted to a peer-reviewed journal or other publication as evidence of IRB review

The exempt categories outlined below are based solely on methods of research, and do not take the level of risk into consideration. Although most exempt research requires no further oversight to be conducted ethically, some exempt research raises ethical concerns or requires measures to protect participants. As such, the IRB will not consider any research exempt that does not fulfill ethical principles reflected in the Belmont Report.

Research that otherwise would be exempt by federal regulations that raises ethical concerns or requires measures to protect subjects may be denied and/or moved to a higher level of review (i.e. expedited or full IRB review).

I. HHS Determination: Human Research

Please check one of the 3 boxes below which best describes your project.

1. A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
2. Quality improvement or quality assurance activity where the results may be generalizable outside of the institution and publication or dissemination of results may be contemplated.

IRB QA/QI (EXEMPT) RESEARCH QUESTIONNAIRE

3. **NOT** a systematic investigation designed to contribute or develop to generalizable knowledge (e.g., medical case reports of 3 or fewer patients, quality improvement or quality assurance activities developed for a specific clinical area or patient population with no intent to publish or disseminate the results outside of the institution).

II. FDA Determination: Human Research (Clinical Investigation)

Does the research involve use of any of the following FDA regulated products?

1. Drug or Biologic
2. Medical Device
3. Dietary Supplement where the supplement is used for diagnosing, mitigating, treating or curing a specific disease or class of diseases

In this case, the dietary supplement is subject to FDA drug regulations.

None of the above

III. Institutional Operations

Is the goal of this project to advance clinical quality or operational goals for a department/unit?

- Yes
 No

SECTION I: EXEMPT CATEGORY

Check the appropriate category(ies) that applies to your research project and answer any related questions:

<input type="checkbox"/>	<p>1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. [45CFR46.101(b)(1)]</p> <p>Will the researchers use their current students or trainees as subjects?</p> <p><input type="checkbox"/> Yes. <input type="checkbox"/> No. Have you received permission from the instructor, department head, or facility where the research will take place? <input type="checkbox"/> Yes. <input type="checkbox"/> No. I will seek permission before initiating the research. <input type="checkbox"/> N/A. Please explain:</p>
<input type="checkbox"/>	<p>2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.[45CFR46.101(b)(2)]</p> <p>a. Will you or any investigators use your current students or trainees as subjects?</p> <p><input type="checkbox"/> No. <input type="checkbox"/> Yes. Please explain what additional measures will be taken to ensure that participants do not feel pressured or coerced during recruitment for or participation in the research:</p> <p>b. Will your research involve children in survey procedures, interview procedures, or observation of</p>

IRB QA/QI (EXEMPT) RESEARCH QUESTIONNAIRE

	<p>public behavior when the investigator(s) participate in the activities being observed?</p> <p><input type="checkbox"/> No.</p> <p><input type="checkbox"/> Yes. This study does not meet the criteria for exemption. Please submit an application for Expedited or full Board review.</p> <p>c. Will you record information in a way that human subjects can be identified, directly or through identifiers linked to the subjects?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>d. Could any disclosure of the subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If you answered Yes to BOTH (2c) and (2d), the study does not meet the criteria for exemption. Please submit an application for Expedited or full Board review.</p>
<input type="checkbox"/>	<p>3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 above, if either:</p> <p style="padding-left: 40px;">(i) the human subjects are elected or appointed public officials or candidates for public office; or</p> <p style="padding-left: 40px;">(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. [45CFR46.101(b)(3)]</p>
<input type="checkbox"/>	<p>4. Research involving the collection or study of <u>existing</u> 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. [45CFR46.101(b)(4)]</p> <p>To qualify for this exemption, data, documents, records, or specimens must exist at the time the research is proposed and not prospectively collected.</p> <p>a. When was the original data collected or created? *(i.e. the dates <u>must</u> be in the past; if you will use any data that was collected in the current year, please list the month as well)</p> <p style="padding-left: 40px;">From to</p> <p>b. What is the source of the data?</p> <p style="padding-left: 40px;"><input type="checkbox"/> Student Records <input type="checkbox"/> One of the investigators collected it in the past</p> <p style="padding-left: 40px;"><input type="checkbox"/> Publicly available database <input type="checkbox"/> Other:</p> <p style="padding-left: 40px;"><input type="checkbox"/> Medical or Patient Records - Please note if you are VIEWING medical records you must not record 16 specified identifiers that are listed in the regulations, including: name, street address, telephone and fax numbers, e-mail address, social security number, certificate/license number, vehicle identifiers and serial numbers, URLs and IP addresses, and full face photos and other comparable images.</p> <p>c. Will you be using a data collection form?</p> <p style="padding-left: 40px;"><input type="checkbox"/> Yes. I will submit the form with this application.</p> <p style="padding-left: 40px;"><input type="checkbox"/> No. Here is my list of data points (e.g. test scores, sex, race, age) :</p>
<input type="checkbox"/>	<p>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:</p> <p style="padding-left: 40px;">(i) public benefit or service programs;</p> <p style="padding-left: 40px;">(ii) procedures for obtaining benefits or services under those programs;</p>

IRB QA/QI (EXEMPT) RESEARCH QUESTIONNAIRE

	<p>(iii) possible changes in or alternatives to those programs or procedures; or</p> <p>(iv) possible changes in methods or levels of payment for benefits or services under those programs. [45CFR46.101(b)(5)].</p> <p>The program under study must deliver a public benefit (for example, financial or medical benefits as provided under the Social Security Act) or service (for example, social, supportive, or nutrition services as provided under the Older Americans Act).</p> <p>The research or demonstration project must be conducted pursuant to specific federal statutory authority, must have no statutory requirement that an IRB review the project, and must not involve significant physical invasions or intrusions upon the privacy of the subjects.</p> <p>This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.</p>
<input type="checkbox"/>	<p>6. Taste and food quality evaluation and consumer acceptance studies,</p> <p>(i) if wholesome foods without additives are consumed; or</p> <p>(ii) 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 Food Safety and Inspection Service of the U.S. Department of Agriculture. [45CFR46.101(b)(6) and 21 CFR 56.104(d)]</p>