**EXEMPT PROTOCOL**

*You should allow approximately 2 weeks for the review of Exempt protocols.*

**DATE:**

**NAME:**

**PROTOCOL STUDY TITLE:**

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| **CRITERIA:** Some projects are exempt from *federal regulations for the protection of human research subjects*.  **Exempt determinations will be made in the following situations:**   * The project is not human subjects research, as defined in 45CFR46. * The project is human subjects research, and the ONLY involvement of human research   subjects falls within one or more of the federally established exempt categories in  45CFR46.101(b). |

**DIRECTIONS**: This form is to be submitted to the Gonzaga Institutional Review Board (IRB) before the initiation of a project that may be exempt from regulatory oversight. The information you provide on this form and the materials you submit will be evaluated to determine whether they meet the criteria to be exempt from the Federal Regulations governing human subjects research.

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| **SECTION I: PROJECT OVERVIEW** |
| 1. Location(s) of activities. If more than one site is involved, i.e., the data are provided by one vendor, and supplied to a second party, who then supplies the data to the PI, specify all sites involved, and identify roles of each, etc.  Gonzaga University  Other:  2. Provide a brief description, in lay terms, of the purpose and/or hypotheses of the proposedproject.  3. Please state the eligibility criteria for qualification as a research subject, record, or specimen in your study (examples could be age range, sex, language spoken, etc.). |
| **SECTION II: NOT HUMAN SUBJECTS RESEARCH (E.G., QUALITY IMPROVEMENT)** |
| According to the federal definition, **research** means a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**.  **☐**   This project is research.  **Skip to Section III on Human Subjects Research.**  **☐**  I don’t think this project meets the federal definition of research. **For quality improvement, quality assurance, or program evaluation, do the following:**   1. If you are working with an outside agency, attach a letter or email from that agency stating what the project entails and how the project will help improve agency processes or outcomes. Instead of a letter, you can document that another IRB has determined the project to be Quality Improvement. 2. Also answer the following questions:   **Q1: Is this a quality improvement/quality assurance project, or program evaluation**?  (*These* *types of activities may not meet the definition of research.*  *See the*IRB*web pages*  *for more information.*)  Yes  No    If yes, explain:    **Q2:  What are you hoping to learn from this project?**   **Q3: Will the knowledge you gain be generalizable to other contexts or situations?**  **Q4: Will you be working with academic or medical records?**   Yes  No (*Skip to Q5*)   1. Specify the number of records being secured for purposes of the project. 2. Specify which institution will be responsible for scrubbing data of identifiers. 3. If you work at the institution and will scrub data of identifiers on their behalf, explain how that typically fits within your job duties.   **Q5: Will you interact with individuals to collect data?**  Yes  No (*Skip to Q6*)  A. Which stakeholder groups do you plan to interact with?  B. For each stakeholder group, answer the following questions:  i. How will potential participants be identified and recruited? If surveys are to be  emailed, specify how emails are obtained:  *- Attach recruitment materials, emails, flyers, etc.*    ii. How will participants be fully informed of this this study prior to their participation  (through the use of an informed consent form, study information sheet, letter, etc.)        *- Attach Informed Consent form, etc. Note that the Informed Consent in QI or QA may state that everyone will participate in the activities but that individuals can choose whether to allow their data to be analyzed for the project. For example, in a school setting, all students would be expected to complete all the learning activities, but parental consent would be requested for the data to be analyzed for a graduate project, etc.*  iii. Explain how subject privacy will be protected while data is being collected. For example, if interviewing, where will the interview be conducted?  **Q6: Data storage**  A. Explain how the data will be kept confidential after it has been collected.  B. Explain how long the data will be stored after it has been collected (this should be a  minimum of 3 years; longer if required by the project’s funding source federal  regulations).  **The remainder of the form does not pertain to projects that do not involve human subjects research as defined by 45CFR46. Please submit this form with only Section I and Section II completed.** |

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| **SECTION III: EXEMPT CATEGORIES FOR HUMAN SUBJECTS RESEARCH** | |
| * Please indicate categories into which your research falls with a checkmark in the left column and by answering all questions in that section. * Mark as many as apply. | |
| **CATEGORY 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)]  Will the researchers use their current students or trainees as subjects?  Yes  No Have you received permission from the instructor, department head, or facility where the research will take place?  Yes  No. I will seek permission before initiating the research.  N/A Please explain:   * **After answering these questions, skip to the next category. If your research does not also fall within another exempt category, skip to Section IV and answer the additional questions.** |
| **CATEGORY 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)]  A. Will you or any investigators use your current students or trainees as subjects?  No  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:  B.Will your research involve children in survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities being observed?  No  Yes This study does not meet the criteria for exemption. **Please submit**  **an application for Non-Exempt or Full Board review.**  C.Will you record information in a way that human subjects can be identified,  directly or through identifiers linked to the subjects?  Yes  No  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?  Yes  No  If you answered **Yes to BOTH (2c) and (2d),** the study does not meet the criteria for exemption. **Please submit an application for Non-Exempt or Full Board review.**   * **After answering these questions, skip to the next category. If your research does not also fall within another exempt category, skip to Section IV and answer the additional questions.** |
| **CATEGORY 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:  (A) the human subjects are elected or appointed public officials or candidates for public office; or  (B) 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)]   * **After answering these questions, skip to the next category. If your research does not also fall within another exempt category, skip to Section IV and answer the additional questions.** |
| **CATEGORY 4** | Research involving the collection or study of existing 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)]  Note: To qualify for this exemption, data, documents, records, or specimens must exist at the time the research is proposed and *not prospectively collected*.  Answer the questions below:   1. Include detailed description of the means by which data are secured, source of data, and the methods by which data will be analyzed to achieve project aims. Specify the number of records being secured for purposes of the project. Specify which institution will be responsible for scrubbing data of identifiers. Were data/biological specimens originally collected solely for research purposes?  *[If yes is checked, please attach a copy of the IRB-approved Consent Form and IRB approval letter for the research under which the original data/biological specimens were collected.]*      1. Is the source of the data/biological specimens publicly available and/or commercially purchased?      1. Specify the length of time data will be stored, and when it will be destroyed. Describe the safety measures in place for securing the data, e.g. kept electronically in HIPAA-compliant secured servers, hard copies kept in PI files under lock and key. Identify any and all persons with access to said data.      1. Confirm in an explicit statement that because the data is de-identified, there are no foreseeable risks to individual subjects.      * **The remainder of the form does not pertain to research that is exempt in category 4. If your research does not also fall within another exempt category, please submit this form after completing Section I and the questions in this box.** |
| **CATEGORY 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:  (A) public benefit or service programs;  (B) procedures for obtaining benefits or services under those programs;  (C) possible changes in or alternatives to those programs or procedures; or  (D) possible changes in methods or levels of payment for benefits or services under those programs. [45CFR46.101(b)(5)].  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).  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.  This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.   * **After answering these questions, skip to the next category. If your research does not also fall within another exempt category, skip to Section IV and answer the additional questions.** |
| **CATEGORY 6** | Taste and food quality evaluation and consumer acceptance studies,  (A) if wholesome foods without additives are consumed; or  (B) 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)]   * **After answering these questions, skip to Section IV and answer the additional questions.** |

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| **SECTION IV: ADDITIONAL QUESTIONS** |
| * Pleaseanswer the following questions for each stakeholder group or data collection tool that you will use. For example, some PIs write separate paragraphs under each question to address the different stakeholder groups in each question. |
| 1. List all methods by which information or data about or from subjects will be obtained. Describe the frequency and duration of the procedures. Please SUBMIT all surveys, instruments, interview questions, etc. that will be used for this research.   1. Are you conducting any part of your research in a language other than English?   No Proceed to next question.  Yes   1. How will you identify potential subjects?   A. Provide the process by which potential subjects will be recruited (introduced to the investigator(s) and the research study). Please SUBMIT a copy of all information to be shared with or intended to be seen by potential subjects to inform them of this research and ask for their participation.  B. Note how recruitment or selection will not unfairly target a particular population or will target the population that will benefit from the project/research.   1. Explain how subjects will be fully informed of this research prior to their participation (through the use of a study information sheet, letter, etc. A research Informed Consent Form (ICF) with signature line is not necessarily required). Please SUBMIT a copy. 2. Will you be audio or video recording?   No Proceed to next question.  Yes Complete items A and B below.   1. How do you plan to protect the confidentiality of the audio or video recordings: will they contain subject names or images, where will they be kept, who will have access, will they be destroyed or archived and when? 2. Could the information obtained or recorded about subjects place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, or reputation?   No Proceed to next question.  Yes Please explain:   1. Will subjects be paid for participation in the study (e.g. monetary, meals, free services, gifts, course credit, including extra credit)?   No Proceed to next question.  Yes Complete items a. and b. below.   1. Explain the payment arrangements (e.g. amount and timing of payment and the proposed method of disbursement). NOTE: Payments must accrue and not be contingent upon completion of the study. However, a small payment (bonus) for completion of the study may be acceptable if it is found to not be persuasive for the subjects to remain in the study.        1. Justify the proposed payment arrangements described in section B. (e.g., how this proposed payment arrangement is not considered to be coercive). 2. Will you include any individuals with diminished autonomy (e.g. children, people with limited ability to make decisions) in your research?   No Proceed to next question.  Yes Please explain how they will be protected:   1. Explain how subject privacy will be protected while data is being collected. For example, where will interviews be conducted? 2. Explain how the data will be kept confidential after it has been collected. 3. How will you help to minimize potential risks that individuals may be exposed to while participating in the research? Potentials risks may include psychological, social, legal, physical, etc. |

**SUBMISSION CHECKLIST:**

* COVER SHEET—Faculty or Student version as appropriate (with all signatures/approvals)
* THIS FORM—With detailed answers that are cohesive throughout
* Letter(s) of permission, if applicable
* ALL INSTRUMENTS used in the project:
  + Informed Consent (and/or Assent) documents **OR** an information sheet about the project
  + Recruitment script and/or materials
  + Additional information about the intervention, if an intervention is involved