**EXEMPT RESEARCH PROTOCOL**

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

**DATE:**

**NAME:**

**PROTOCOL STUDY TITLE:**

*Note: The same title should appear on all documents related to the research unless participants will be debriefed about omission or deception.*

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| Some projects are exempt from *federal regulations for the protection of human research subjects*.  **CRITERIA:**  **Exempt determinations** will be made when the project is minimal risk, and the ONLY involvement of human research subjects falls within one or more of the federally established exempt categories in 45CFR46.101(b).  **According to the federal definition, “***minimal risk* means that the probability and 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.”  Note that IRB submissions are not needed for projects that ONLY involve publicly-available data, data in public records, or datasets with no identifying information.  For more information, see the IRB website, specifically the FAQ on data that has been stripped of identifying information. |

**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 IRB oversight and that participants are treated in accordance with the principles of the Belmont Report.

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| **SECTION I: PROJECT OVERVIEW** |
| 1. Specify all sites involved.  Gonzaga -- Within your department or division (If this is the only site, skip to Section II.)  Gonzaga – Outside of your department or division. Please specify:  Outside of Gonzaga - Please specify:  If your project is conducted outside of your department or division at Gonzaga, you may need a letter of support or permission. See FAQ #12 on the IRB website for more information. |

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| **SECTION II: 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)]  A. Will the researchers use their current students or trainees as subjects?  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:  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:  B. Please explain how you have ensured that the research does not adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction.   * **After answering these questions, skip to the next category. If your research does not also fall within another exempt category, skip to Section III 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 research.**  C.Will you record information in a way that human subjects can be identified,  directly or through identifiers linked to the subjects?  Yes  No  *Note: Audio/video recordings and images of people are identifying information.*  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 C and D above,** the study does not meet the criteria for exemption. **Please submit an application for Non-Exempt research.**   * **After answering these questions, skip to the next category. If your research does not also fall within another exempt category, skip to Section III and answer the additional questions.** |
| **CATEGORY 3**  **(new in 2019)** | Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audio/visual recording.  *Notes:*   * *“benign behavioral interventions” include benign manipulations of individuals or their environment, provided that the interventions or manipulations are “brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing”* * *Examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.* * *This exemption category also includes survey and interview research where the researcher provides a stimulus in order to prompt a response from the subject.* * *Examples of activities that would not qualify for this exemption include personally intrusive questions, mental health questionnaires, disturbing images, or being presented with scenarios likely to trigger a strong negative emotion (e.g., distress).*   A. Will subjects prospectively agree to the information collection in an informed consent process?  Yes Explain the informed consent process in Section III.  No This study does not meet the criteria for exemption. Please submit  an application for Non-Exempt research.  B. Will you record information in a way that human subjects can be identified,  directly or through identifiers linked to the subjects?  Yes  No  *Note: Audio/video recordings and images of people are identifying information.*  C. 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 B and C above,** the study does not meet the criteria for exemption. **Please submit an application for Non-Exempt research.**  D. Does the research involve deceiving the subjects regarding the nature or purposes of the research?  No (Proceed to next question)  Yes Explain how subjects are *informed of, and agree to, any deception*  *prior to participation.* Be sure to address anything the participants will  be unaware of or misled regarding the nature or purposes of the  research:   * **After answering these questions, skip to the next category. If your research does not also fall within another exempt category, skip to Section III and answer the additional questions.** |
| **CATEGORY 4**  **(Revised in 2019)** | Secondary research involving identifiable information or identifiable biospecimens for which consent is not required because the investigator will have no contact with the subjects:*.*  *Notes:*   * *The data does not have to be pre-existing. Prospective data may be used, if that data is not collected for research purposes, such as routine medical and academic records.* * *Use of medical record data may still be subject to the Health Information Portability and Accountability Act (HIPAA), even if determined exempt under these criteria.* * *Use of academic record data may still be subject to the Family Educational Rights and Privacy Act (FERPA), even if determined exempt under these criteria.*   A. Are data/biological specimens pre-existing?  No Skip to part C  Yes Continue to part B below.  B. Were data/biological specimens originally collected solely for research purposes?  No  Yes **This study cannot be considered exempt under Category 4**  C. Which of the following will be included in your research? (Select all that apply and provide details about your selections below.)  Identifiable private information or identifiable biospecimens that are or will be publicly-available;  Information, which may include information about biospecimens,that are or will be recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linkedto the subjects, the investigator does not contactthe subjects, and the investigator will not re-identifysubjects;  The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of ‘‘health care operations’’ or ‘‘research’’ as those terms are defined at 45 CFR 164.501 or for ‘‘public health activities and purposes’’ as described under 45 CFR 164.512(b);  The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.  For each group selected above, please explain the nature and source of the data/samples:  Also explain whether or not the secondary analysis will include identifying information.  If none of the options in question C pertains to your research**,** **this study cannot be considered exempt under Category 4**.  D. Will either of the following will be included in your research?  FDA regulation  Yes  No  Targeted recruitment of prisoners  Yes  No  **If you answered “yes” to either option in part D, your research cannot be considered exempt under Category 4**   * **After answering these questions, skip to the next category. If your research does not also fall within another exempt category, skip to Section III and answer the additional questions.** |
| **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 III 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 III and answer the additional questions.** |

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| **SECTION III: ADDITIONAL QUESTIONS** |
| **1. Will you manipulate or interact with individuals to collect data (i.e., prospective collection of data/specimens)?**  Yes  No    A. Which stakeholder groups do you plan to interact with? Specify any pertinent eligibility criteria for each stakeholder group (e.g., years worked, etc.)  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 will be obtained, stored securely, and then disposed of:     * *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 Information Sheet or Informed Consent form, if applicable.*   iii. Explain the procedures that will be used to collect data from research participants.   * *Attach all surveys, instruments, interview questions, etc.*   iv. Explain how subject privacy will be protected while data is being collected. For example, if interviewing, where will the interview be conducted?  **2. Will you access and analyze existing *data/specimens* (e.g., archived academic, medical or personnel records)?**  Yes  No (*Skip to Question 3.)*  If yes, answer parts A through F below for each stakeholder group:  *Also note that the responsible PI on the cover sheet is tasked with ensuring that privacy regulations (e.g., HIPAA, FERPA) are followed in this study.*   1. Will a Data Use Agreement be executed to conduct this study? If yes, explain the process you are in to establish the Data Use Agreement and be sure all the answers below match the agreement. 2. State the eligibility criteria for the records that will be included for each stakeholder group (e.g., age range, gender, language spoken, etc.). 3. Specify the number of records being secured for purposes of the project: 4. List the variables to be extracted from the records and included in the data sets: 5. Will the *data/ specimens be coded* such that a link exists that could allow the source of the data/ specimens to be re-identified (i.e., key available to decipher the code)?   N/A The provider of the data/ specimens will remove the code before sending the data/specimens to the researcher. (***Skip to question 3)***  Yes, provide details that describe how the data are coded, by whom, and how the key is to be stored (if applicable).  *Include any applicable documentation of agreements (e.g., if the holder of the key and the investigator have documented that the release of the key would be prohibited until the individuals are deceased, this document could be attached)*  No, the data/specimens will be identifiable. (Answer part F below.)   1. Describe the safety measures in place for securing identifiable 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.   **3. 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 archived and if so, how; might they be used for secondary uses, and when will they be destroyed?   *Be sure the informed consent document provides the same information to the participants and allows them to explicitly agree to the process of recording and also to any additional use of the video or audio files.*   1. 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 This study does not meet the criteria for exempt research. *Please submit an application for Non-Exempt research.*  **4. 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 part A above. (e.g., how this proposed payment arrangement is not considered to be coercive).   **5. Will you include individuals in the following groups in your research?** (Select all that apply. For each selection, explain preventative measures that you will take to prevent exploitation and/or coercion):  Individuals with diminished autonomy (e.g. children, people with limited ability to make decisions)  Subordinates to the investigators (e.g., employees or students whose boss or teacher are conducting a study in their own setting)  Speakers of a foreign language (e.g., individuals who could not complete the research tasks in English)  Other vulnerable subjects. Please specify:  For each group selected above, please explain how they will be protected:  None of the above  **6. Will personally identifiable information be collected in your research?** (i.e., emails or data linked to an identifier like a patient number or a physical address)  No Proceed to next question.  Yes Complete parts A and B below*.*  A. Explain how identifiable information will be kept confidential after it has been collecte    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).    **7. How will data be analyzed?**  Explain the methods by which data will be analyzed to achieve project aims.  *Be sure the information in the protocol provides details that show how these analyses can be carried out. For example, if you state that you are going to conduct a dependent t test, be sure the reviewer can see how you will link the pre and post test information for each subject.*  **8. Are there any features of your participants, the setting, or your research that introduce potential risks that haven’t been addressed yet on this form?** Potentials risks may include psychological, social, legal, physical, etc.  No Proceed to the Submision Checklist  Yes Complete items A and B below.  A. Explain how will you help to minimize potential risks that individuals may be exposed to while participating in the project.  B. Explain how you have determined that the risk in this study is no more than the participants would encounter in a typical day. |

**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

**SUBMISSION INSTRUCTIONS:**

You can submit your protocol by going to [www.gonzaga.edu/irb](http://www.gonzaga.edu/irb) and clicking on the Submission Process tab. Go to “Submit Your Study Materials.” This link takes you to the IRB SharePoint site where you fill out the required information and attach all your study materials.