**Gonzaga University Institutional Review Board (IRB)**

# Exempt Research Human Research Checklist

# and Abbreviated protocol

Date:

Protocol Study Title:

Anticipated End Date:

Sponsor/Advisor:

Principal Investigator (PI) Name & Title:

PI Phone, Institution, Address, Email:

Additional Study Staff Info:

**DIRECTIONS**: This form is to be submitted to the GU IRB only when the Principal Investigator (PI) is considering the initiation of a research project which is exempt from regulatory oversight.

**CRITERIA:** Research activities are exempt from *federal 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 research subjects falls within one or more of the exempt categories listed below.

## Section I: Exempt Category

|  |  |  |
| --- | --- | --- |
| **Check the appropriate category(ies) that applies to your research project and answer any related questions:** | | |
|  | 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: |
|  | 1. 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  Expedited 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 Expedited or full Board review. |
|  | 1. 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:   **(i)** the human subjects are elected or appointed public officials or candidates for public office; or  **(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)] |
|  | 1. 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)]   **To qualify for this exemption, data, documents, records, or specimens must exist at the time the research is proposed and *not prospectively collected*.** |
|  | 1. 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:   **(i)** public benefit or service programs;  **(ii)** procedures for obtaining benefits or services under those programs;  **(iii)** possible changes in or alternatives to those programs or procedures; or  **(iv)** 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. |
|  | 1. Taste and food quality evaluation and consumer acceptance studies,   **(i)** if wholesome foods without additives are consumed; or  **(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)] |

## Section II: Performance Site

**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.**

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Other:

## Section III: Research Description

1. **Provide a brief description, in lay terms, of the purpose and/or hypotheses of the proposed project.**

1. **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.).**

**Complete the questions below ONLY if you selected Category 4 in Section I above.**

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.**

**Complete the questions below ONLY if you selected Categories 1, 2, 3, 5, or 6 in Section I above.**

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. **a. Provide the process by which potential subjects will be identified and 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. Explain how it will be ensured that 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.**

1. **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?**

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. 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).**

1. **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, if interviewing, where will that be conducted?**

1. **Explain how the data will be kept confidential after it has been collected.**

1. **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.**