**NON-EXEMPT PROTOCOL**

 **Allow approximately 3-4 weeks for review of Non-Exempt submissions.**

**Allow approximately 5-6 weeks for Full Board Review.**

**Submit your protocol via SharePoint to the IRB (at www.gonzaga.edu/irb).**

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| **I. ROLES AND RESPONSIBILITIES** |

Roles and responsibilities of relevant study team members should be described, and roles and responsibilities of all collaborators and collaborating institutions should be described. Describe responsibilities by role or title (e.g., “Research Assistant will be responsible for note taking and storage.”)

* The IRB does not need to know the name of every member of your research team - instead, the IRB wants to know who is fulfilling the specific roles for your research.

**ROLE/TITLE:**       **RESPONSIBILITIES**:

**ROLE/TITLE:**       **RESPONSIBILITIES**:

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**ROLE/TITLE:**       **RESPONSIBILITIES**:

**ROLE/TITLE:**       **RESPONSIBILITIES**:

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| **II. STUDY INFORMATION** |

1. **Research Project Title:**
2. **Type of Research:**

 *(Psychological, Educational, Device, Social/Behavioral, Nursing, Economic, Tissue/Blood/ Specimen, Other).*

1. **Phase of Study (if applicable):**
2. **Version / Date (if applicable):**
3. **Research Problem and Brief Literature Review:**

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| **III. STUDY DESIGN** |

Note that as you fill out the sections below, the goal is for another researcher to be able to replicate the research.

 **A. PROCEDURES:**

 *Provide the purpose of the study and list the research objectives (e.g., hypotheses). For each of the research objectives, provide a chronologically ordered, step-by-step description of the corresponding study procedures.*

 \*\***Attach ALL research instruments used in your study.**

 **B. INCLUSION / EXCLUSION CRITERIA:**

 *Justify the exclusion criteria. Explain how subjects will be screened to determine whether they meet the Inclusion criteria and exclusion criteria.*

 **C. SUBJECT RECRUITMENT:**

 *Include a detailed description of the recruitment process and method (who, when, where). Provide recruitment material(s) such as newspaper/email advertisements, telephone interview scripts, radio scripts, etc.*

 *Add any additional information, if needed (e.g., how email addresses will be obtained and how these email addresses will be stored securely then destroyed, how materials will be translated for non-English speakers).*

**D. PARTICIPANTS:**

If applicable, explain how subjects will be randomized or placed into groups:

In the table below, list Number of Subjects (and potential attritions rate), Target Study population, Subject Age Range, and number of those who will serve as “controls” (when applicable).

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| **PARTICIPANT** | **NUMBER** | **AGE RANGE** |
| **\*Normal** |       |       |
| **\*\*Vulnerable (45 CFR 46 subparts B-D)** |       |       |
| **Control *(if applicable)*** |       |       |
| **TOTAL** |       |       |

*\* A “normal” subject would be 18 years of age or older and not in a vulnerable group.*

*\*\* A “vulnerable” subject includes but is not limited to the following groups: children, prisoners, pregnant women, veterans, economically disadvantaged persons, individual with diminished mental capacity, illiterate persons or persons for whom English is a second language, or individuals who are being questioned about a traumatic event (e.g., sexual assault).*

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| **IV. DATA ANALYSIS** |

1. Describe how the data collected in the Procedures will be analyzed
* For studies using multiple measures or tests over time, you can display the data collection schedule in a spreadsheet or tabular format.
* For medical studies, e.g. nursing, indicate if information will be copied or abstracted from medical records. Also indicate how the research is HIPAA compliant.
* For qualitative data, describe the coding system that will be use, with details about any specific procedures that apply (e.g., Qualitative Comparative Analysis).
* For quantitative data, the following format may be helpful. (Repeat for each objective/aim.)

Objective/Aim 1:

Hypothesis 1 (if used):

Statistical Analysis (endpoints, metrics, algorithms, etc.):

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| **CHECKLIST TO BE COMPLETED BY INVESTIGATOR** | **Yes** | **No** |
| 1. Will materials with potential radiation risk be used, e.g., x-rays, radio isotopes?

If yes, please indicate:* Status of annual review by Radiation Safety Officer (RSO). If approved, attach one copy of approval (Attachment F).
* Date the Title of Application was submitted to Radiation Safety Committee (RSC).
 | **[ ]**  | **[ ]**  |
| 1. Will any other hazardous materials come in contact with research subjects? -- If yes, indicate nature of hazard and steps taken to mitigate risk to subjects.
 | **[ ]**  | **[ ]**  |
| 1. Will an investigational new drug (IND) be used?

If yes,* Give name, proposed dosage, how administered, status with FDA, and IND number.
* Enclose one copy of: (1) available toxicity data; (2) reports of animal studies; (3) description of human studies done in other countries; (4) a concise review of the literature prepared by the investigator.
 | **[ ]**  | **[ ]**  |
| 1. Will other drugs be used (including over the counter drugs)?

If yes, give names, dosages, how administered, and side effects:       | **[ ]**  | **[ ]**  |
| 1. Will medical, academic or other records be used?
 | **[ ]**  | **[ ]**  |
| 1. Will audio-visual or tape recordings, or photographs be made?
 | **[ ]**  | **[ ]**  |
| 1. Should this activity be covered by adverse effects insurance?

 If yes, provide name of insurance company and explain why it is needed:       | **[ ]**  | **[ ]**  |

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| **V. INFORMED CONSENT / ASSENT PROCESS** |

**A. Subject Recruitment:**

 1) Who will approach and inform the subject about the study?:

* Attach all recruitment material(s) (newspaper/email advertisements, telephone interview scripts, radio scripts, etc.)

**B. Describe the informed consent / assent process in detail. Include, but do not necessarily restrict yourself to, the following information:**

1. Who will conduct the informed consent process?:
2. If applicable, address how privacy and time for decision-making will be provided and whether or not the potential subject will be allowed to discuss the study with anyone before making a decision.
3. If applicable, describe how the subject’s capacity to consent will be determined and who will make that determination.
4. Is this medical research? [ ]  YES [ ]  NO

If yes, please describe:

*For medical research, such as some nursing studies, address the privacy of medical records information/medical records, Medical Release forms, HIPAA compliance/authorization form.*

**C. ASSENT / CONSENT FORMS: STUDIES WITH MINORS (If applicable)**

If subjects are minors (under 18 years) and they are capable of assent:

1. Describe the provisions for getting their assent as well as the provisions of getting permission of their parent(s) or Legally Authorized Representative (LAR).
2. Attach a copy of the ASSENT FORM or standard briefing statement for children as well as the ADULT INFORMED CONSENT FORM (ICF). Parents, or a legal guardian, must provide a signed Informed Consent form for a minor to be in a study

**d. INFORMED CONSENT / ASSENT DOCUMENT STORAGE**

1. Where will consent/assent forms, research records and data be stored?
2. How long will consent/assent forms, research records and data be stored?
3. How will consent/assent forms, research records and data be destroyed/disposed of?

**E. Concealment and/or Deception**

 *If any concealment or deception (withholding of complete information) is required for the validity of this study, explain why this is*

 *necessary, and describe a debriefing plan and attach a debriefing statement.*

1. Is Concealment necessary? [ ]  YES [ ]  NO

If yes, why?

If yes, is a debriefing statement attached? [ ]  YES [ ]  NO

What is the debriefing plan?

1. Is Deception necessary? [ ]  YES [ ]  NO

If yes, why?

If yes, is a debriefing statement attached? [ ]  YES [ ]  NO

What is the debriefing plan?

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| **VI. SUBJECT & DATA CONFIDENTIALITY / ANONYMITY** |

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| “**CONFIDENTIAL**” is used if the PI has access to identifiable information. * *Confidentiality has to do with keeping data secure once they are collected – e.g., by storing data in a locked file, etc.*
* *Confidentiality for data is* ***required*** *unless subjects give express written permission that their data may be identified.*

“**ANONYMOUS**” is used if the PI has no ability to link data to individual subjects. * *You can “anonymize” subjects or a research setting by giving them pseudonyms.*

**DATA STORAGE:** Per federal guidelines, raw study data must be held for **three years** in a secure place. Paper documents should then be shredded, tapes erased and destroyed, etc. |

1. **ANONYMITY:** Will participation be **ANONYMOUS**?[ ]  YES [ ]  NO
	1. If yes, explain how the investigator will have no way to identify subjects by appearance, name or data:
2. **CONFIDENTIALITY:**  Will participation be **CONFIDENTIAL**?[ ]  YES [ ]  NO
	1. If yes, describe the methods that will be used to ensure the confidentiality of data obtained:
3. **DATA ACCESS:** Who will have access to some, or all, of the data?
	1. What provisions are there for control over access to documents and data?
4. **DATA STORAGE:**
5. How long will data be held? (Be advised that federal guidelines state that research data are to be held for 3 years.
6. How will data be ultimately disposed of?
7. Who will dispose of data?

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| **VII. BENEFITS** |

1. Explain the benefits as stated in the consent form:
* Consider potential psychological, social, material and physical benefits.
* Payment of any kind for participation in the study **IS NOT** a benefit (Instead, go to Section VIII).

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| **VIII. PAYMENT / COMPENSATION**  |

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| **INDUCEMENTS** should never be so great that it might be considered coercion. * It is okay to give study subjects a small token of appreciation (e.g., a Power Bar after they participate in a physical fitness test, refreshments during a focus group interview).
* It is okay to reimburse subjects for expenses they incur as a result of study participation – e.g., parking fees, babysitting, etc.
* If students will get **EXTRA CREDIT** for being in a study, then those students who do not want to be in the study should be given an alternative way of earning the same extra credit.
 |

1. Will subjects receive an inducement (e.g. payment, services without charge, extra course credit?) [ ]  YES [ ]  NO

If yes,

* 1. Describe all inducements and what they are for:
	2. What is the rationale for offering the inducement?
	3. Describe when the subjects will be paid:
	4. Describe the method of payment:
	5. Other information:
1. *Be sure the informed consent communicates these details to potential subjects so participants understand your plan and know about any alternatives or options.*

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| **IX. RISK & INJURY MITIGATION / ADVERSE EVENTS** |

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| * Consider IMMEDIATE as well as DELAYED physical/psycho/social/emotional risks.
* Consider risks that could be incurred by losing privacy.
 |

1. **RISK MITIGATION:**
2. What are the risks (including side effects):
3. What measures will be taken to minimize risks?:
4. Is any follow-up planned as part of risk mitigation procedures?: [ ]  YES [ ]  NO

 If yes, explain:

1. **ADVERSE EVENTS:**
2. What is your plan for handling adverse events or unanticipated problems?:
3. Describe the conditions that would lead you to stop data collection processes or study procedures:
4. Clarify medical care for any research related injury:
5. Identify resources that you would use to assist with handling any adverse events:
6. What are the arrangements for financial responsibility for adverse effects? (*Usually you will want to clarify that these expenses would be incurred by the subject.)*
	1. Has this been clearly stated in your INFORMED CONSENT form? [ ]  YES [ ]  NO
7. Other *(please describe):*

**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.

**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
	+ Recruitment script and/or materials
	+ If deception is involved, provide the debriefing statement
	+ Additional information about the intervention, if an intervention is involved

**Please be sure the information in the attached materials is aligned to the answers in this protocol form.**