**Regis IRB Application for Exemption**

***Please include a cover letter before this page listing all included materials!***

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| **I. Study Title:**  (If funded, the study title must match the sponsored title.) |  | | | | **Today’s Date:** | |
| **II. Principal Investigator Information** | | | | | | |
| A. Name of Principal Investigator | |  | | | | B. Are You? (Please check) |
|  | |  | | | | Faculty |
| C. Mailing Address: | |  | | | | Staff |
|  | |  | | | | Undergraduate Student |
| D. Department: | |  | | | | Graduate Student |
|  | |  | | | | Postdoctoral fellow |
| E. Email address: | |  | | | | Other: |
| F. Primary Phone Number: | |  | G. Alternate Phone: |  | |  |
| H. Faculty Advisor’s Name: | |  | I. Faculty Advisor’s Phone: |  | |  |
| J. Faculty Advisor’s E-mail: | |  | | | | |
| **III. Funding** | | | | | | |
| A. **None**  Do you plan to apply for funding in the future?  Yes  No If yes, please explain:  B.  **University Funded:** List source:  C.  **External, non-federal**\*: List source and grant number:  D.  **Federal\***: List agency, department, and sponsor’s award number:  \*Wait until you have been notified that your project will be funded before seeking IRB approval unless otherwise instructed by the funding source. If federal funding is involved, submit documentation of funding status with a complete copy of the funding proposal with this form.  E. Is Regis College the primary awardee for the grant?  Yes  No If no, please list primary awardee:  F. Are there subcontracts?  Yes  No If yes please list sub-contractors: | | | | | | |

## Part IV: Review Exemption Checklist

*Check all that apply. If you can check* ***all*** *items, proceed to Part V. If not, your research does not qualify for exemption and you will need to complete the application for expedited/full review instead.*

The research does not involve prisoners, fetuses, the seriously ill, or mentally or cognitively compromised adults.

The research does not involve participants under the age of 18 OR only involves observation of participants under the age of 18 in which there is *no interaction between the researcher and participants [45CFR 46.401(b) or educational research* [45CRF 46.101(b)(1)]

The procedures of this research are generally free of foreseeable riskto participants. *[i.e. research involves only procedures, and data is collected and maintained in a manner such that the study is unlikely to cause physical, psychological, social, financial or legal harm to participants]*

The research does not involve the use of FDA-regulated drugs, biologics or devices.

## Part V: Exemption Category Checklist

*Check any that apply. If you can check* ***at least one*** *item* ***AND*** *all activities you intend to conduct fall into one of the below categories, your research may qualify for exemption.*

[45CRF 46.101(b)(**1**)] The research will be conducted in *established or commonly accepted educational settings* (e.g., school or university classrooms, educational centers, etc.) involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research goals are pedagogical, focused on improving student understanding, educational performance, ability to function productively in the classroom, and so forth.

[45CRF 46.101(b)(**2**)] The research will involve the use of educational tests (cognitive, diagnostic, aptitude or achievement tests); survey procedures; interview procedures; or observation of *public* *behavior.* In order for a study to fall into this exemption category, *at least one* of the following must be true:

*Information will be recorded* ***anonymously*** (i.e., so that participants cannot be identified, directly or through identifiers linked to individuals)

The information collected could not reasonably place participants at risk of civil or criminal liability nor be damaging to participants’ financial standing, employability or reputation if disclosed.

[45CRF 46.101(b)(**3**)] The research will involve the use of cognitive, diagnostic, aptitude or achievement tests; survey procedures; interview procedures; or observation of public behavior *that is not exempt under (b)(2) above* **AND** *all participants are elected or appointed public officials or candidates for public office; or federal statutes require that without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter.*

The research will involve non-participant observation of a regularly occurring event. According to Qualitative Research Methods: A Data Collector’s Field Guide developed by Family Health International, it is not necessary to obtain formal informed consent for participant observation if the *activity normally occurs and the researcher is not requiring any changes to the event.* “However, when talking to people informally about the research and the researcher’s  role in it, it is important to emphasize that participants are not required to talk to the researcher and that there will be no repercussions if they do not.”  Mack, N., Woodsong, C., Macqueen, K. Guest, G., Namey, E. (2005). Qualitative Research Methods: A Data Collector’s Field Guide. Family Health International retrieved from https://www.fhi360.org/sites/default/files/media/documents/Qualitative%20Research%20Methods%20- %20A%20Data%20Collector's%20Field%20Guide.pdf

[45CRF 46.101(b)(**4**)] The research will involve the collection or study of *existing data, documents, records, pathological specimens, or diagnostic specimens*. These sources are either publicly available or recorded by the investigator anonymously (i.e. subjects cannot be identified). All data, documents, or records must already exist prior to IRB review; the proposed research must be strictly retrospective.

[45 CRF 46.101(b)(**5**)] The research (including demonstration projects) will be conducted by or subject to the approval of federal department or agency heads, and is designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs (e.g., social security, welfare, etc.); (ii) Procedures for obtaining benefits or services under those programs or procedures; (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.

[45 CRF 46.101(b)(**6**)] The research involves *taste or food quality evaluations* or *consumer acceptance studies* and the tested products are wholesome foods without additives or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the US Department of Agriculture.

Exempt research activities that will not induce distress beyond that of daily life may include (but are not limited to) non-physically invasive interventions or performance of tasks such as reading/writing/drawing tasks, physical activities such as walking, sitting, or manipulating an object, computer tasks and/or Internet searches, talking and/or listening to words, then making selections, or “think-aloud” exercises, viewing media, role-playing, completing a specific physical or mental action (“imagining”), passive monitoring of space (environment) with sensors, playing a game, height/weight measurements. *This exemption category does NOT apply to federally-funded research.*

## Part VI: Study Specific Information - Required

*Please type or copy-and-paste answers to the following questions in the text boxes provided.*

***Note: The IRB cannot accept proposals in which the answers to these questions are marked in a separate project summary or grant proposal document. Copy-and-paste or type the relevant information into the fields below.***

1. **What is the purpose of the proposed study? Please include a short paragraph with the rationale for the study.**

1. **Describe the pool of participants that will be involved in the proposed research, including participants’ expected age range.**

1. **Describe how subjects will be recruited and selected.** *Include copies of all recruitment scripts, flyers, e-mail notices, etc. you will be using with your proposal (in Word - .doc or .docx -format).* If the research will be carried out in an institutional setting (i.e., at a school, social service agency, hospital, etc.), *include an email or letter from an appropriate administrator at that institution, indicating that he/she gives permission for the research to be done in that setting and what that institution is expected to do or provide.*

1. **Briefly describe all research procedures that will apply to participants.** Approximately how much time is each participant expected to devote to the research? Will all of the data be collected at one time or is data collection spread out over time?

1. **If you are collecting data directly from participants, list or describe any research instruments that will be used ‑‑** that is, anything that a participant must complete (surveys, tests or measures, demographic forms, etc.) and attach copies of each to your submission.

1. **Describe how you will preserve participant anonymity and/or confidentiality of data.**

1. **If subjects will receive payment or compensation (i.e., gift card, entry into lottery, etc.) for their time and effort,** describe in detail the amount or value of this compensation, when and how it will be delivered, and how the researcher will prorate compensation for subjects who withdraw early. If you plan on using a raffle or lottery, indicate the chances of winning.

1. **Describe any relationships between the researcher(s) and subjects, such as: teacher-student, friend-friend, employer-employee, etc.** If such a relationship exists, what procedures will you use to ensure that participants are free to decline participation without penalty and that no undue influence to participate exists?

1. **Briefly describe the consent procedure to be used, if applicable**. At a minimum, a consent procedure should includethat the activity involves research, participation is voluntary, a description of the procedures, and investigator contact information.

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| **SIGNATURES** | | |
| **SIGNATURE OF PRINCIPAL INVESTIGATOR** | | |
| The undersigned accept(s) responsibility for the study, including adherence to the ethical guidelines set forth in the Belmont Report, Declaration of Helsinki, the Nuremberg Code, the ethical principles of your discipline, the Common Rule and Regis College policies regarding protections of the rights and welfare of human participants participating in this study. In the case of student protocols, the faculty supervisor and the student share responsibility for adherence to policies. | | |
|  |  |  |
| Print Name of Principal Investigator | Signature of Principal Investigator | Date |
| **SIGNATURE OF FACULTY RESEARCH SUPERVISOR --- REQUIRED FOR STUDENT RESEARCH** | | |
| By signing this form above, the faculty research supervisor attests that s/he has read the attached protocol submitted for IRB review, and agrees to provide appropriate education and supervision of the student investigator and share the above Principal Investigator responsibilities. | | |
|  |  |  |
| Print Name of Faculty Research Supervisor | Signature of Faculty Research Supervisor | Date |
| **SIGNATURE OF DEPARTMENT CHAIR OR DEAN --- REQUIRED FOR FACULTY RESEARCH** | | |
| Your signature below affirms that you have been informed about the research project | | |
| Name, Dean | e-signature |  |
| Print Name of Department Chair or Dean | Signature of Department Chair or Dean | Date |

[include certificates here for P.I., Co-investigators, advisors: must be completed within past 3 years]