REGIS UNIVERSITY
REGIS.EDU

Request for IRB Exemption

Tip: Prior to submission, go to the IRB page on Regis.edu for IRBNet training guides, sample documents, and other information helpful to your research project.

Part 1: Is this the correct form? (5 Questions)

1.1 Risk Assessment
Will the proposed research include activities that are more than minimal risk or involve discomfort beyond what is normally experienced in daily life?
☐ No
☐ Yes – If you selected "Yes", stop completing this form as this research does not qualify as exempt.

1.2 Vulnerable Populations
Will the proposed research collect information about individuals considered by Regis to be part of a vulnerable population (children under 18 years of age, prisoners, individuals with impaired decision-making ability, pregnant women, or economically disadvantaged)?
☐ No
☐ Yes – If you selected "Yes", stop completing this form as this research does not qualify as exempt.

1.3 Deception
Does the research involve deception or purposefully withholding study information from participants?
☐ No
☐ Yes – If you selected "Yes", stop completing this form as this research does not qualify as exempt.

1.4 Protected Information
Will Protected Health Information or student education records be collected?
☐ No
☐ Yes – If you selected "Yes", stop completing this form as this research does not qualify as exempt.

1.5 Review by Additional IRB's
Has another IRB approved or do you anticipate a need to send your project to another IRB in addition to Regis University's IRB?
☐ No
☐ Yes ****If yes, please contact IRB@Regis.edu for further instructions. You may not need to complete the remainder of the form. ****

Part 2: Administrative Information (3 Questions)

2.1 Principal Investigator (PI) Contact Information

Project Title	Enter Title
Principal Investigator Name	Enter Name
Principal Investigator Phone	Enter Phone
Principal Investigator Email	Enter PI Email
Select PI Status	☐ Student ☐ Faculty ☐ Other
Select PI Area	☐ Anderson ☐ Dayton Library ☐ Regis College ☐ RHCHP ☐ Other
Projected Study Start Date	Click or tap to enter a date.
Projected Study End Date	Click or tap to enter a date.

2.2 Co-PI's and members of the research team (if applicable)

Co-PI Name	Co-PI Email
Faculty advisor name or other co-investigators	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.
Click here to enter text.	Click here to enter text.

2.3 Funding

Is this research being funded by an external funding agency outside Regis?

☒ Yes ☐ No

Part 3: Self-Assessment (1 Question)

3.1 Selection of exemption category

I understand that exempt studies will not involve members of vulnerable populations; data collection related to Federal Departments, their employees, nor eligible beneficiaries; nor international studies. I request that my study be exempt from the Regis University IRB human subjects protection board review process based on one of the following exempt study categories from 45CFR46.101.b.

Please check the appropriate box.

☐ (1) **Research involving normal educational practices** that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction such as:

(1) Most research on regular and special education instructional strategies; or

(2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management.

☐ (2) **Research that only includes interaction involving the use of educational tests** (cognitive, diagnostic, aptitude, achievement**), survey procedures, interview procedures or observation of public behavior** (including visual or auditory recording) if at least one of the following is met:

(1) Information obtained is recorded by the investigator in such a manner that the identity of human subjects can**not** be readily ascertained, directly or through identifiers linked to the subjects; or

(2) Any disclosure of the human subjects' responses outside of the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, **and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).** Children may only be included in research under this exemption when involving educational tests or observation of public behavior if the investigator(s) do not participate in the activities being observed and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly, or through identifiers linked to the subjects

☐ (3) **Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collected and at least one of the following is met**;

(1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects;

(2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(3) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained, directly or through identifiers linked to the subjects, **and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).** For the purpose of this provision, benign behavioral interventions 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 (e.g., playing an online game, solving puzzles, etc.)If the research involves deception, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research and the subject is informed that they will be unaware of or they will be misled regarding the nature or purposes of the research.

☐ (4) **Secondary research for which consent is not required:** Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria are met:

(1) The identifiable private information or identifiable biospecimens are publically available; or

(2) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or

(3) 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 160 and 164, Subparts A and E (HIPAA), for the purposes of "health care operations" or "research" as those terms are defined under HIPAA or for "public health activities and purposes" under HIPAA; or
(4) The research is conducted by, or on behalf of a Federal department or agency using government-generated or government-collected information obtained for non-research activities.

☐ (5) **Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine**:

(1) Public benefit or service programs; this exemption is for federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining "public benefit or service programs:"
   a. The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act);
   b. The research or demonstration project must be conducted pursuant to specific Federal statutory authority;
   c. There must be no statutory requirements that the project be reviewed by an IRB; and
   d. The project must not involve significant physical invasions or intrusions upon the privacy of participants.

(2) Procedures for obtaining benefits or services under those programs;
(3) Possible changes in or alternatives to those programs or procedures; or
(4) Possible changes in methods or levels of payment for benefits or services under those programs.
(5) This exemption is for projects conducted by or subject to approval of Federal agencies and requires authorization or concurrence by the funding agency.

☐ (6) **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.

☐ (7) **Storage or maintenance for secondary research for which broad consent is required:** Storage or maintenance of identifiable private information or identifiable biospecimens for post secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).

☐ (8) **Secondary research for which broad consent is required**: Research involving the use of identifiable private health information or identifiable biospecimens for secondary research use, if the following criteria are met:

(1) Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116 (a)(1)-(4), (a)(6), and (d);

(2) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117;

(3) An IRB conducts a limited review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in (d)(8)(i); and

(4) The investigator does not include returning individual research results to subjects as part of the study plan.

Part 4: Study Design, Methods, and Procedures (7 Questions)

4.1 Project overview

Provide a lay summary of the study. Include the study purpose and the research questions.

4.2 Justification for an exempt study

Provide a short statement to indicate why this is an exempt study.

4.3 Contributions to field

Briefly describe how the project will advance knowledge in the field, and/or improve our understanding of the issue being studied.

4.4 Data collection method

Select **all** methods of data collection that will be used in this study. Then, describe how these methods will be implemented in the space below.

☐ Telephone survey
☐ Paper or Internet survey (including online and email)
☐ Cognitive or behavioral measures
☐ Observation
☐ Self-health monitoring (e.g., pedometers)
☐ Transcription software
☐ Other (Please describe below)

4.5 Methodology/Protocol

Describe the tasks that participants will be asked to perform for each phase of the study. Provide an estimate of the time commitment required from each participant.

4.6 Citations/Reference List
Please include a reference list/bibliography for sources cited.

4.7 Study location
Where will the research activities take place? [You may be required to obtain a site approval letter or permissions to conduct your research. A sample template is available on the CSRE web page.] **Select ALL** appropriate boxes and describe in the space provided below.

☐ Regis University campus
☐ Non--Regis location
☐ Other organization/institution
☐ Other off-campus location

Part 5: Participants (9 Questions)

5.1 Number
Indicate the number of participants planned for the project.

5.2 Age
Specify the age range of the participants.

5.3 Participant Description
Select which types of participants will be included in your study. Then, describe in the space provided below.

☐ Regis students
☐ Adult volunteers (over 18 years of age)
☐ Other (please specify)

5.4. Participant Recruitment Tools

Select the tools you intend to use for recruiting participants.

☐ Flyers
☐ Email
☐ Online advertisements
☐ Internet social media or online networking
☐ TV, radio, print ads
☐ Regis participant pool
☐ Face-to-face/word of mouth
☐ Presentations at meetings
☐ Other (please specify)

5.5 Participant Recruitment Method

Briefly describe how you will recruit participants.

5.6 Participant Compensation

Will participants be compensated for participation?

☐ Yes ☐ No

If yes, please describe how participants will be compensated including information about how participant anonymity will be preserved, how compensation will be given to participants, and when compensation will be provided.

5.7 Risks

Address any physical, emotional, psychological, financial, academic, employability, and/or reputation risks. This may include immediate or future risks. Risk should be no greater than what would be achieved in normal life for Exempt studies.

5.8 Risk Minimization

Describe any efforts to minimize risks to participants.

5.9 Benefits

Detail any benefits which the participants may receive.

Part 6: Privacy and Confidentiality (4 Questions)

6.1 Access to Personal Identifiers

Will any member of the research team collect any of the personal identifiers listed below? Select **all** that apply.

☐ No member of the research team will have access to any personal identifiers
☐ Name
☐ Date of birth
☐ Mail or email address
☐ Phone or FAX number
☐ Social Security number
☐ Student identification number
☐ Medical records
☐ License, certificate, or vehicle ID
☐ IP address
☐ Biometric identifiers (e.g., fingerprint, DNA, face recognition, etc.)
☐ Photos/images/audio recording
☐ Signatures, handwriting samples
☐ Other unique identifier

6.2 Data Storage Location

How will the research data and/or specimens be protected against inappropriate use or disclosure? Select **all** that apply. Then, describe the location by indicating which personnel have access to the data and the storage location and other relevant information.

☐ Locked office
☐ Restricted access to authorized study personnel
☐ Secure computer/laptop
☐ Individual ID plus password protection
☐ Encryption of digital data
☐ Destruction of source data immediately after data collection
☐ Access rights are terminated when authorized study personnel leave the study
☐ Other (please describe below)

6.3 Data Storage Length

Identify how long research records will be retained. (The Office of Human Research Protections requires records to be retained for three years following the conclusion of the study. If Protected Health Information is collected, records must be retained for six years.)

6.4 Data Protection

Select **all** choices below which indicate how the data will be protected against inappropriate use or disclosure. Then, describe in the space provided below.

☐ Individual ID plus password protection
☐ Encryption of digital data
☐ Destruction of source data immediately after data collection
☐ Audio and/or video recordings will be transcribed and then modified for anonymity
☐ Audio, photos, and/or video recordings will be modified for anonymity
☐ Permissions will be obtained for specific use of photos, audio, and/or video recordings (e.g., educational, presentations, publications)
☐ Access rights are terminated when authorized study personnel leave the study
☐ Other (describe below)

Part 7: Conflict of Interest (2 Questions)

7.1 Financial Conflict of Interest Disclosure

Do any of the investigators, their spouses/significant other, or dependents have any personal financial interest or commitment with any company or entity that sponsors or supports this research?

☐ Yes ☐ No

If yes, provide a brief description of the conflict of interest.

7.2 Relationships with Participants

Do any of the investigators have a personal or professional relationship with the participants?

☐ Yes ☐ No

If yes, provide a brief description of the relationship and potential impact on the research.

Part 8: Adverse Event Reporting (1 question)

8.1 Adverse Events

I am aware of the requirement to **report serious adverse events (e.g., physical or psychological injury) to IRB@Regis.edu within 24 hours of occurrence** should anything happen during your project. **Adverse**

events, which are less serious in nature, must be reported within 72 hours of occurrence. **An Adverse Event form must also be submitted to IRBNet.** If research is taking place on a Regis campus, a Campus Safety Incident Report must be filed with Campus Safety (safety@regis.edu) If you have questions, contact IRB@Regis.edu.
By checking the box below, investigator is attesting to awareness of this requirement.
☐ Yes

Appendix: Submission Checklist

☐ CITI completion report is included in submission (The CITI completion report will display which courses were taken and when those courses were taken)

☐ Regis CITI requirements have been met (CITI requirements chart is also available in iRBNet by clicking the "Forms and Templates" button or on www.one.regis.edu)

☐ Application form has been proofed for spelling, grammar, readability, and track changes are removed

☐ New Protocol Reviewer Form has been consulted to see how IRB reviewers evaluate protocols

☐ Copies of all data instruments, materials, questionnaires, consent forms, recruitment materials, and other items that are going to be distributed to participants are attached and listed as separate documents

☐ Consent/Information form (if applicable) is written at no higher than an 8th grade reading level as evaluated by the Flesch-Kincaid reading test

☐ Students: Make sure to share the project with your faculty research advisor

☐ Faculty Advisor: Faculty advisor has read and approved all student application materials including, but not limited to recruitment materials, application, survey questions, and consent forms.

Reminder: A Project Closure Form should be submitted in IRBNet upon the completion of your study. IRBNet will generate a reminder email in accordance with your projected study expiration date.