REGIS UNIVERSITY
REGIS.EDU

Expedited/Full-Board Application Form

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: Administrative Information (5 Questions)

1.1 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 Start Date of Study	Click or tap to enter a date.
Projected End Date of Study	Click or tap to enter a date.

1.2 Co-PI's, faculty advisors, and members of the research team (if applicable)

Co-PI Name	Co-PI Email
Faculty advisor name or other co-investigators	Click or tap 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.

1.3 Funding

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

☒ Yes ☐ No

1.4 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?

☐ Yes ☐ No ****If yes, please contact IRB@Regis.edu for further instructions. You may not need to complete the remainder of the form. ****

Part 2: Self-Assessment

The following are the research categories eligible for expedited or full-board review/approval (OHRP Categories of Research & 63 FR 60364-60367).

Please **check the box** next to the research category under which you are requesting expedited review.

1. I am conducting a clinical study of a drug/medical device under condition (a) or (b).
   ☐ (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   a. ☐ Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. I am collecting blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. ☐ (a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. ☐ from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. ☐ I am conducting prospective collection of biological specimens for research purposes by noninvasive means.

   Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by

buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. ☐ I am collecting data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. **Note:** Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

5. ☐ My research involves materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. ☐ I am collecting data from voice, video, digital, or image recordings made for research purposes.

7. ☐ I am conducting research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. ☐ This is a continuing review of research previously approved by the convened IRB as follows:
   a. ☐where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b. ☐where no subjects have been enrolled and no additional risks have been identified; or
   c. ☐where the remaining research activities are limited to data analysis.

9. ☐This is a continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Part 3: Study Design, Methods, and Procedures (7 Questions)

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

3.2 Justification for an expedited study
Provide a short statement to indicate why this is an expedited study.

3.3 Contributions to field
Briefly describe how the project will advance knowledge in this field, and/or improve understanding of the topic being studied.

3.4 Data collection method
Select **all** methods of data collection that will be used in this study. Then, describe how implemented in the space provided.

☐ In-person interviews
☐ Focus group
☐ Telephone survey
☐ Paper or Internet survey (including online and email)
☐ Other communication/electronic devices (e.g., cell phones, texting devices, etc.)
☐ Social Networking sites
☐ Observation
☐ Experimental measures
☐ Clinical measures
☐ Audio/Video recording
☐ Cognitive or behavioral measures, including daily diaries
☐ Anthropometric measures (e.g., height, weight, etc.)
☐ Self-health monitoring (e.g., pedometers)
☐ Transcription software
☐ Other (Please describe below)

3.5 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 from each participant.

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

3.7 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
☐ International location (Consult International Compilation of Human Research Standards for specific regulations.

Part 4: Participants (9 Questions)

4.1 Number
Indicate the number of participants you plan to enroll.

4.2 Age
Specify the age range of the participants.

4.3 Participant Description

Select which types of participants will be included in your study. Then, describe in the additional space provided.

☐ Regis students
☐ Adult volunteers (over 18 years of age)
☐ Vulnerable population group
    ☐ Pregnant women
    ☐ Economically disadvantaged
    ☐ Cognitively disadvantaged
    ☐ Prisoner/incarcerated individual
    ☐ Children under 18
☐ Other (please specify)

4.4 Participant Description Inclusion Criteria

Describe the participant criteria for inclusion in the study.

4.5 Participant Description Exclusion Criteria

Describe the participant criteria for exclusion from the study.

4.6 Participant Termination

Describe the circumstances in which the participant's participation will be terminated by the investigator.

4.7. Participant Recruitment Tools

Select **all** 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)

4.8 Participant Recruitment Description
Briefly describe recruitment method in the space below.

4.9 Participant Compensation
Will participants be compensated for participation?
☐ Yes ☐ No
If yes, please describe how participants will be compensated. Include information about: how participant anonymity will be preserved, how compensation will be given to participants, and when compensation will be provided.

Part 5: Risks and Benefits (3 Questions)

5.1 Risks
Address any physical, emotional, psychological, financial, academic, employability, and/or reputation risks. This may include immediate or future risks.

5.2 Risk Minimization
Describe any efforts to minimize risks to participants.

5.3 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 stored?
Select **all** that apply. Then, describe the location by indicating which personnel have access to the data, the storage location, and other relevant information.

☐ Locked office
☐ Locked filing cabinet
☐ 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
☐ Audio and/or video recordings will be transcribed and then modified
☐ Audio, photos, and/or video recordings will be modified to eliminate the possibility that study participants can be identified
☐ Access rights are terminated when authorized study personnel leave the study
☐ Other (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 form 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 should review and approve 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.