**Expedited Review Form**

**Principal Investigator (PI) Information:**

|  |  |
| --- | --- |
| Name of PI: | School/Department: |
| Email Address: | Phone Number: |
| PI Status:  Faculty  Adjunct Faculty  Graduate Student  Undergraduate Student  Staff  Other (Specify:      ) | |
| Protection of Human Subjects Training:  Date of Completion:  Additional Training, Date of Completion:  Please include a copy of completion certificate with this application. Completion Date must be within past three years. Please note that anyone that will be interacting with human subjects in addition to the PI should have completed training. | |

**For Sponsored Projects (required when the PI is a student):**

|  |  |
| --- | --- |
| Supervising Faculty: | School/Department: |
| Email Address: | Phone Number: |

**Project Information:**

|  |
| --- |
| Project Title: |
| Type of Project:  Individual Research Project  Class Project  Thesis/Dissertation  Other: |

**Does this research involve minors?**  Yes  No

**Does this research involve other vulnerable populations (i.e., prisoners, individuals with impaired decision-making abilities)?**  Yes  No

**Do the procedures pose more than minimal risks to participants?**  Yes  No

**Please review the nine [9] categories of research that are eligible for an expedited review process and check all that apply to your research.**

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

1. 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.)
2. 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. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1. from healthy, nonpregnant 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
2. 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. Prospective collection of biological specimens for research purposes by noninvasive means.  
Examples: (a) hair and nail clippings in a nondisfiguring 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. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. 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. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch 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. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. 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. Continuing review of research previously approved by the convened IRB as follows:

1. 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
2. where no subjects have been enrolled and no additional risks have been identified; or
3. where the remaining research activities are limited to data analysis.

9. 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..

**Summary**: Please provide a brief summary of the objectives and significance of this research.

**Participants:** Please describe your participants. Include an estimated total number of participants, a description of the population they will be recruited from, and a description of how they will be recruited. Please submit all recruitment materials with this application.

**Does your study involve transferring identifiable information and/or biospecimens to and/or from a European Country (e.g., an online survey open to participants in Europe)**

Yes  No

**Are you requesting a waiver or alteration of informed consent?**  Yes  No

**If yes, please justify why informed consent should be waived/altered:**

**If no, how will you be documenting informed consent?**

**If you are working with minors, will you be obtaining assent?**  Yes  No  N/A

**If yes, please describe your assent process?**

**If no, please justify why you are not obtaining assent.**

Will you be obtaining broad consent?  Yes  No

Please submit all consent/assent documents with this application.

**Will participants be compensated for participation?**  Yes  No

**If yes, how?**

**Methodology:** Please provide a complete description of how the research will be conducted, including what participants will be told and what they will be doing. Please submit all questionnaires, surveys, or other measures with this application.

**Confidentiality:** Please provide a brief but complete description of how confidentiality will be maintained before, during, and after data collection

**Risk Management and Adverse Events:** Please provide plans for assessing and managing risk to participants throughout the study and for reporting adverse events.

**Assurances:**

I, the investigator (and if applicable, the faculty sponsor), certify that to the best of my knowledge the research described above qualifies for expedited review under 45 CFR§46.110). I agree that any changes to the project will be submitted to the Institutional Review Board before they are implemented, and that any adverse events will be reported in a timely manner. I also recognize that the Institutional Review Board is only responsible for ensuring the safety and integrity of human participants. I recognize that I am responsible for ensuring this research complies with the mission statement of the University.

The PI’s signature (and that of the faculty sponsor, if applicable) is required before this application can be processed (electronic signatures are acceptable). Send this application and all supporting documents to [irb@caldwell.edu](mailto:irb@caldwell.edu). Please note that this document and any others requiring IRB stamps must be in doc/docx format so that the electronic stamp may be applied. Any other formats will be returned.

**Principal Investigator** **Date**

**Faculty Sponsor Date**

|  |
| --- |
| **This Section is for IRB Use Only**  Approved  Not Eligible for Expedited Review, Recommend Full Review  Notes:  Reviewed by:  Stamp: |