Johnson County Community College
Research Participant Protection Program
Application for Expedited Research Involving Human Subjects

A. GENERAL INFORMATION

1. Principal Investigator(s):
2. JCCC Department/Program:
3. JCCC Campus Address:
4. JCCC Phone Extension:
5. JCCC E-mail Address:
6. JCCC Faculty Supervisor (if student project):
7. Title of Project:
8. Type of Project:

   Faculty/Staff Research ☐

   Student Research ☐

   Class Project (Please specify class)_____

   Other (Please explain)_____
9. Expected Project Start Date:
10. Expected Project Completion Date:
11. Is this a funded project? ☐ Yes ☐ No

    If yes, please specify:

    Funding Source:

    Duration of Funding:

Are there any potential financial conflicts of interest which need to be declared? In other words, are you, any other project personnel, or family members of you or project personnel in the position to gain financially from the results of the research? ☐ Yes ☐ No

If yes, please explain:

12. Has this project been submitted and/or reviewed by another Human Subjects Protection Program (HSPP) or Institutional Review Board (IRB)? ☐ Yes ☐ No

    If yes, please specify:

Name of HSPP or IRB and its decision:

Please include a copy of approval letter if applicable

13. Will this project take place at JCCC or on JCCC property? ☐ Yes ☐ No

14. Will your subjects include JCCC students, faculty or staff? ☐ Yes ☐ No

Please be aware that if your project includes the collection of personal information, you may be subject to the Family Educational Rights and Privacy Act (FERPA) and/or the Health Insurance Portability and Accountability Act (HIPAA) guidelines as well. Failure to comply may result in the revocation of your right and ability to conduct research at JCCC and/or with JCCC students, faculty and/or staff, as well as make you liable for local, state and/or federal civil and criminal penalties.

B. RESEARCH CLASSIFICATION

Please indicate by checking the appropriate box(es) the reasons you believe your proposed research is expedited. If your research is not within one of the categories listed below, you will need to complete the appropriate application for either Exempt or Full Review.

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

    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.)

    b. ☐ 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:

    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. ☐ Prospective collection of biological specimens for research purposes by noninvasive means.
   a. ☐ Hair and nail clippings in a non-disfiguring manner;
   b. ☐ Deciduous teeth at the 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 removal 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; or
   k. ☐ Other (explain below):
   _____ .

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.)
   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; or
   f. ☐ Other (explain below):
   _____

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 protections of human subjects [45 CFR 46.101(b)(2) and (b)(3)]. This listing refers only to research that is not exempt.)

C. RESEARCH PROJECT

Please address the statements and questions below as completely and thoroughly as possible.

Project Abstract
Please provide a brief summary of the proposed project using language that is understandable by those not in your field/discipline. Your abstract should not exceed 350 words.

Research Question
Please state your research question or hypothesis in plain language, using non-technical terms, if possible.

Specific Aims
What are the specific aims (goals) of the proposed research?

Study Design
What study design will be used in this study (i.e., randomized, double-blind, two-arm, etc.)?

Study Site
Where will the proposed research take place? Please explain the rationale for choosing this site, if formal permission is needed to use this site, and if that permission has been received, and any additional pertinent information about the study site.

Participant Recruitment and Selection
Please explain how research participants will be recruited and selected. For example, will participants be recruited via newspaper ads, fliers, word of mouth, etc.? If using written or visual materials, please include a copy with this application.

Special and Vulnerable Populations

If special and/or vulnerable populations are a part of this proposed study, what safeguards will be employed to protect their rights. Special populations include the socio-economic disadvantaged, religious minorities, those with certain health conditions (e.g., cancer patients), etc. Vulnerable populations include minors, pregnant women, those with cognitive disabilities, individuals in correctional facilities, etc.

Risk and Benefit Information

Please explain the potential risks and benefits that the proposed research presents to participants, as well to the general population.

Informed Consent Information

Please explain how you will obtain informed consent from the research participants, as well as the type of consent (i.e., written, tape-recorded, video-recorded, etc.) you will be using. (NOTE: Even if you are not using written consent, you still need to follow the format on the JCCC RPPP Consent Form unless written permission has been received from the JCCC RPPP stating otherwise.)

Privacy and Confidentiality

What measures will be employed to protect research participant confidentiality? How will the data collected in the proposed research study be protected? Where will the data be stored? Who will have access to the data? How long will the data be kept? How will the data be destroyed? (NOTE: If you are collecting sensitive data such as information on illegal activities, sexual activities, genetic data, etc., you will need to obtain and complete a Certificate of Confidentiality from the JCCC RPPP.)

Research Personnel
Please provide the names, titles, roles and affiliations of all investigators, research assistants or grant personnel who will be involved with the proposed research.

D. CERTIFICATIONS

As the Principal Investigator:

1. I agree that this application reflects the proposed research in an accurate and truthful manner.
2. I agree to report any problems with the research to the JCCC RPPP immediately.
3. I agree to report any changes in the research protocol to the JCCC RPPP immediately.
4. I comprehend and agree to follow all JCCC RPPP guidelines and protocols.
5. I am familiar with and agree to follow the ethical guidelines and standards for research and the treatment of human subjects associated with my particular discipline.
6. I agree not to begin the proposed research until action is taken on this application and I am notified of this action by the JCCC RPPP.

Signature_____ Date_____

As Department Chair, Program Facilitator, Assistant Dean and/or an Official Representative of the Principal Investigator's Department, Division or Program, I approve the submission of this application and certify that the Principal Investigator (or Faculty Supervisor in the case of a student application) is capable and qualified to conduct and/or supervise this research.

Signature_____ Date_____

SUBMIT

E. JCCC RPPP *ONLY*

Expedited ☐ Yes ☐ No

Signature_____

Date _____

Recommendations/Comments_____

_____

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