Revised 29 July 2019

**COVER PAGE FOR IRB SUBMISSION**

# Purdue University, Institutional Review Board

Type of Submission:  Human subjects determination worksheet [*complete both sides of this form*]

New exemption determination [*complete both sides of this form*]

New application narrative [*complete both sides of this form*]

Check here if you believe your protocol will require full board review:

*Complete* ***#1, 2, 11 &******12*** *below* ***AND*** *PI signature at bottom of page 2*

Amendments to approved protocol / **IRB Protocol #:**

Renewal of approved protocol / **IRB Protocol #:**

Revisions requested by IRB / **IRB Protocol #:**

Study Closure / **IRB Protocol #:**

1. Project Title:

2. Principal Investigator:

(Name, Title, Department, E-mail, Phone; ***Must sign at the bottom of page 2***)

3. Co-Investigators, Key Personnel and/or Consultants (Name, Title, Department, E-mail, Phone, for each):

4. Has the PI and all Co-Investigators, Key Personnel and Consultants completed CITI training?

Yes (Proceed to 5)

No (STOP here: [CITI training](http://www.citiprogram.org) must be completed by all prior to submission of this application)

5. This project will be conducted at the following location(s):

Purdue, West Lafayette Campus  Purdue, Regional Campus (Specify):

Other (Specify, including city and state):

6. Check the box(es) below if your project involves any of the following (check all that apply):

Vulnerable populations (Children, pregnant women, or prisoners/incarcerated individuals)

Elderly persons

Economically/educationally disadvantaged persons

Mentally/emotionally/developmentally disabled persons

Minority groups and/or non-English speakers

University students (Purdue PSY Department subject pool? Yes  No  )

7. Indicate the anticipated maximum number of subjects to be enrolled or number of records or specimens

to be included under this protocol as justified by the hypothesis and study procedures: \_\_\_\_\_\_\_\_\_\_\_\_

(Suggestion: if unsure, err on the side of a higher sample size)

8. Will this project involve the use of an investigational new drug (IND), investigational medical device or

an FDA-approved drug/device for an unapproved use:  YES  NO

9. Check the box(es) below if your project involves any of the following (check all that apply):

Intervention(s) that include medical or psychological treatment

Use of voice, video, digital, or image recordings

Subject compensation: Please indicate the maximum payment amount to a subject: US $

VO2 max exercise test

Magnetic Resonance Imaging (MRI) (Location: Purdue Campus  Other )

Radioactivity/ Radioisotopes (Radiation Safety Committee approved? Yes  No  )

Request for Waiver of informed consent

Request for Waiver of documentation (signed) of informed consent

Use of blood: Total amount of blood: \_\_\_\_\_\_\_\_\_\_\_\_(volume) over \_\_\_\_\_\_\_\_\_\_\_\_ days.

Use of human tissue, cell lines, or other human bodily fluids

Use of Protected Health Information (PHI) obtained from healthcare practitioners or institutions

Use of academic records obtained from an educational institution

10. Suggest the appropriate IRB to review your research given your study (final decision determined by IRB):

Biomedical (*research involving human diseases, epidemiology, drugs, devices)*

Social/Behavioral (*research involving education, social and behavioral science)*

11. How will this study be funded?

Unfunded  Purdue University  External sponsor (provide name):

12. The Principal Investigator on this application is responsible for ensuring that all persons responsible for the design, conduct, or reporting on this research protocol have disclosed any research-related Significant Financial Interests (SFIs), see [here](https://webapps.ecn.purdue.edu/VPR/PDD/ptDefinitions#sfi). All Investigators with SFIs, are required to fill out a Research Related Significant Financial Interest Disclosure at: <https://webapps.ecn.purdue.edu/VPR/PDD>

Do you or any investigator on this study have a Significant Financial Interest related to this study?

YES  UNSURE (Contact [fcoi@purdue.edu](mailto:fcoi@purdue.edu))  NO

By signing below, I give my assurance that information supplied to IRB relevant to this project is complete and accurate. All materials submitted for review within this submission, unless otherwise indicated, are the original work of myself or those working in collaboration with me. I agree to accept responsibility for the scientific conduct of this project and agree to uphold the policies and procedures of the Purdue IRB and approved protocol(s). I understand my obligations as Principal Investigator. I agree to oversee the project to comply with all federal, state, and local laws regarding the protection of human participants in research.

Signature of Principal Investigator Date Signed