HARRIS-STOWE STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD APPLICATION
for Exempt, Expedited and Full Board Studies

OFFICE USE ONLY

DATE RECEIVED _____/_____/_____	REVIEW TYPE (CHECK ONE) ☐ EXEMPT ☐ EXPEDITED ☐ FULL REVIEW	
RECEIVED BY LAST NAME	RECEIVED BY FIRST NAME	
☐ ACCEPTED ☐ REJECTED	VICE PRESIDENT'S SIGNATURE	DATE _____/_____/_____
ADDITIONAL ADMINISTRATIVE SIGNATURE		DATE _____/_____/_____
IRB COMMITTEE DATE RECEIVED _____/_____/_____		
☐ ACCEPTED ☐ REJECTED	SIGNATURE	
☐ ACCEPTED ☐ REJECTED	SIGNATURE	
☐ ACCEPTED ☐ REJECTED	SIGNATURE	
☐ ACCEPTED ☐ REJECTED	SIGNATURE	
☐ ACCEPTED ☐ REJECTED	SIGNATURE	

PROJECT INFORMATION

PROJECT TITLE
APPLICATION TYPE ☐ INITIAL APPLICATION ☐ RESUBMISSION

PLEASE NOTE THAT HANDWRITTEN AND OR INCOMPLETE FORMS WILL NOT BE ACCEPTED.

PART I - INVESTIGATOR AND KEY RESEARCH PERSONNEL

Principal Investigator

LAST NAME	FIRST NAME	TITLE ☐ DR. ☐ MR. ☐ MS.	
INVESTIGATOR STATUS ☐ FACULTY ☐ GRADUATE STUDENT ☐ STAFF	DAYTIME TELEPHONE ( )		
E-MAIL ADDRESS			
COLLEGE/DEPARTMENT			
CAMPUS ADDRESS	CITY	STATE	ZIP CODE
MAILING ADDRESS	CITY	STATE	ZIP CODE

Principal Investigator *Continued*

State the research activities which this person will be involved in and whether formal training has been received (i.e., acquiring consent, recruiting, data monitoring, administering questionnaires, etc.):

What is the anticipated amount of time this individual will spend on this project?

Faculty Sponsor (If Applicable)

LAST NAME	FIRST NAME	TITLE ☐ DR. ☐ MR. ☐ MS.	
INVESTIGATOR STATUS ☐ FACULTY ☐ GRADUATE STUDENT ☐ STAFF ☐ OTHER		DAYTIME TELEPHONE ( )	
E-MAIL ADDRESS			
COLLEGE/DEPARTMENT			
CAMPUS ADDRESS	CITY	STATE	ZIP CODE
MAILING ADDRESS	CITY	STATE	ZIP CODE

State the research activities which this person will be involved in and whether formal training has been received (i.e., acquiring consent, recruiting, data monitoring, administering questionnaires, etc.):

What is the anticipated amount of time this individual will spend on this project?

Co-Investigator (If Applicable)

LAST NAME	FIRST NAME	TITLE ☐ DR. ☐ MR. ☐ MS.	
INVESTIGATOR STATUS ☐ FACULTY ☐ GRADUATE STUDENT ☐ UNDERGRADUATE STUDENT ☐ STAFF ☐ OTHER		DAYTIME TELEPHONE ( )	
E-MAIL ADDRESS			
COLLEGE/DEPARTMENT			
CAMPUS ADDRESS	CITY	STATE	ZIP CODE
MAILING ADDRESS	CITY	STATE	ZIP CODE

Co-Investigator (If Applicable) ***Continued***

State the research activities which this person will be involved in and whether formal training has been received (i.e., acquiring consent, recruiting, data monitoring, administering questionnaires, etc.):

What is the anticipated amount of time this individual will spend on this project?

PART II - FUNDING INFORMATION

Check all of the appropriate boxes for funding sources for this research. Include pending funding source(s).

☐ INTRAMURAL ☐ GRANT/RESEARCH ☐ COLLEGE/UNIVERSITY ☐ DEPARTMENT ☐ OTHER

P.I. OF GRANT/CONTRACT LAST NAME	P.I. OF GRANT/CONTRACT FIRST NAME
SPONSOR LAST NAME	SPONSOR FIRST NAME
GRANT/CONTRACT NUMBER (IF APPLICABLE)	
GRANT/CONTRACT TITLE	

You must submit all necessary documentation regarding research and grant proposals.

PART III - RESEARCH BACKGROUND

START DATE _____/_____/_____	END DATE _____/_____/_____	
Will the research result in any of the following? (Check all that apply.) ☐ THESIS ☐ DISSERTATION ☐ PUBLISHED RESEARCH		
MAXIMUM NUMBER OF PARTICIPANTS	PARTICIPANT MINIMUM AGE	PARTICIPANT MAXIMUM AGE
GENDER ☐ MALES ☐ FEMALES	LOCATION OF RESEARCH RECRUITMENT	
CRITERIA FOR PARTICIPANT SELECTION		
CRITERIA FOR NONSELECTION OR EXCLUSION (IF NONE, ENTER "NONE.")		

Methods of Enrollment

Indicate method(s) for finding potential participants. (Check all that apply and attach copies of recruitment materials.)

☐ CLASSROOM RECRUITMENT	NO. OF PARTICIPANTS EXPECTED FROM THIS METHOD:
☐ ADVERTISEMENT	NO. OF PARTICIPANTS EXPECTED FROM THIS METHOD:
☐ WEB LISTING/E-MAIL	NO. OF PARTICIPANTS EXPECTED FROM THIS METHOD:
☐ OTHER (PLEASE DESCRIBE.)	NO. OF PARTICIPANTS EXPECTED FROM THIS METHOD:

Methods of Enrollment *Continued*

How will potential participants be approached? (Check all that apply.)

☐ DIRECT CONTACT ☐ LETTER ☐ PHONE CALLS ☐ OTHER_____

Will medical clearance or a medical screening be necessary for subjects to participate because of the administration of food or physical exercise conditioning? ☐ YES ☐ NO

If yes, explain below how clearance will be obtained. If a screening instrument will be used, please attach a copy to the application.

SPECIAL POPULATIONS (i.e., POTENTIAL RISK CATEGORIES)

☐ CHILDREN (UNDER 18 YEARS OF AGE) ☐ PREGNANT WOMEN ☐ PSYCHOLOGICALLY IMPAIRED

☐ COGNITIVELY IMPAIRED ☐ INCARCERATED INDIVIDUALS (ADULT OR JUVENILE) ☐ ELDERLY (65 & OLDER)

☐ STUDENTS ENROLLED IN A CLASS IN WHICH THE INSTRUCTOR IS THE INVESTIGATOR

Is the use of existing data archival record? ☐ YES ☐ NO

Is the use of existing data publicly available? ("Publicly available" means that the information is accessible to anyone without any fees or authorizations.) ☐ YES ☐ NO

Describe how you will gain access to data and any confidentiality processes used to protect participant identity.

Project Abstract: Provide a brief summary, 100 words or less, of the project abstract. Include the purpose/ hypothesis, experimental design, proposed procedure and importance of knowledge reasonably expected to result from the research. If the research involves more than minimal risk, describe the research plan for monitoring the data collected to ensure the safety of participants.

Level of Review

Are you requesting Exempt Status? (Please refer to IRB document on description of Exempt Status.) ☐ YES ☐ NO
Are you requesting Expedited Status? ☐ YES ☐ NO

PART IV - PRIVACY AND CONFIDENTIALITY PROCEDURES

Will audio data be recorded? ☐ YES ☐ NO	Will video data be recorded? ☐ YES ☐ NO
Will photographs be taken? ☐ YES ☐ NO	
Please describe methods for preserving confidentiality. How will data be recorded and scored — with or without identifiers? If identifiers are used, describe the type (names, job titles, number code, etc.). How will reports be written — in aggregate terms or will individual responses be described? Will subjects be identified in reports? Describe disposition of materials at the end of the study. Describe any future use of materials.	

PART V - INFORMED CONSENT INFORMATION

Informed Consent: Please attach, as an appendix, an informed consent document to this application. If subject participation is not anonymous, you must attach a consent form to this application. (Please attach your participation and permission forms for parents/legal guardians or consent forms for adult participation.)
Who will be consenting to participate in the research? ☐ PARTICIPANT (MUST BE 18 OR OLDER) ☐ PARENT(S) OF CHILDREN (BELOW 18 YEARS) ☐ GUARDIAN ☐ LEGALLY AUTHORIZED REPRESENTATIVE
Is the primary language of the consent process English? ☐ YES ☐ NO
If No: 1. State other language(s) and indicate who will provide verbal and written translation services: LANGUAGE(S) LAST NAME FIRST NAME 2. Submit appropriately translated consent document(s) following IRB ESL mandates, prior to consenting non-English speaking participants.

Waiver of Consent Process

In requesting a waiver of consent, explain below how this research involves no more than minimal risk to the subject. Loss of confidentiality is, under most circumstances, more than minimal risk. However, contact by primary care givers or others who by the nature of their involvement with the subject already have access to the data, will be considered no further loss of confidentiality and, therefore, may be less of a risk to subject confidentiality. Risk may also vary with the type of information being collected.
Is a waiver of the consent process requested? ☐ YES ☐ NO
If yes, explain the reason for the waiver:

Waiver of Signed Written Consent

Participants will not be required to sign a consent document when a waiver of signed written consent is reviewed and approved by the IRB. If the IRB waives the requirement of documentation of informed consent, the IRB may require the investigator to provide a written statement of the research to the participant. The IRB shall review and approve the written statement prior to the investigator providing the statement to the participant. The consent form reviewed and approved by the IRB may also serve as the written statement.
Is a waiver of signed written consent requested? ☐ YES ☐ NO
If yes:

1. Explain the reason for the waiver:	

2. Select either Category 1 or Category 2 below:	
☐	Category 1: The only record linking the participant and the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he or she wants documentation linking him or her with the research and his or her wishes will govern. The research is not subject to FDA regulations. Explain:
☐	Category 2: The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. Explain:

PART VI - RISKS AND BENEFITS

1. Does the research involve any of the following possible risks or harms to subjects? Check all that apply:

☐ Use of deception*

(*If deception is used, please describe below. Also describe the debriefing process and include the debriefing script. In addition, the principal investigator should offer the participant the opportunity to withdraw his or her data after learning that deception was used in the study. Please include this information in the debriefing script submitted to the IRB.

☐ Use of confidential records (e.g., educational or medical records)

☐ Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stressors, etc.

☐ Any probing for personal or sensitive information in surveys or interviews

☐ Presentation of materials that subjects might consider sensitive, offensive, threatening or degrading

☐ Invasion of privacy of subject or family

☐ Social or economic risk

☐ Risk associated with exercise or physical exertion

☐ Legal risk

☐ Employment/occupational risk

☐ Other risks

Explain other risks:

Will any record of the subject's participation in this study be made available to his or her supervisor, teacher or employer? ☐ YES ☐ NO

If yes, explain:

2. Describe the nature and degree of all risk and or harm associated with participation in the study, including those checked in the previous section. If none, state "None."

3. Explain what steps will be taken to minimize risk and or harm and to protect participant welfare. If the research will include special populations, please identify each group and answer this question for each group. Outline steps to be taken to address confidentiality for all participants.

4. Describe the anticipated benefits of this research for the individual participants in each subject group. If none, state “None.”
5. Describe the anticipated benefits of this research for society and explain how the benefits outweigh the risks.

PART VII - COMPENSATION INFORMATION

Will any compensation be offered to the participants for their participation? ☐ YES ☐ NO
(Please Note: Course credit cannot be a contingent factor for participation in the research. Participants may also reserve the right to withdraw from the research at any time without penalty.)
If yes, describe these inducements below and include a statement in the informed consent document explaining how compensation will be handled in the event the participant withdraws from the study.

PRINCIPAL INVESTIGATOR/FACULTY SPONSOR ASSURANCE

I certify that the information provided in this application is complete and correct.

I understand that as Principal Investigator, I have the responsibility for the conduct of the study, the ethical performance of the project and protection of the rights and welfare of human participants.

I agree to comply and assure that all affiliated personnel comply with all HSSU policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human participants in research.

I assure that this study is performed by qualified personnel adhering to the HSSU IRB approved protocol.

I assure that no modification to the approved protocol and consent materials will be made without first submitting it for review and approval by the HSSU IRB as an amendment to the approved protocol.

I agree to obtain legally effective informed consent from the research participants as applicable to this research and as prescribed in the approved protocol.

I will promptly report unanticipated problems to the HSSU IRB by using the appropriate form.

I will adhere to all requirements for continuing review.

I will advise the HSSU IRB of any change of address or contact information as long as this protocol remains active.

I assure that I have obtained all necessary approvals from entities other than the HSSU IRB that are necessary to conduct this research.

By my signature on this research application, I certify that I am knowledgeable about the regulations and policies governing research with human subjects and have sufficient training and experience to conduct this particular study in accordance with the research protocol.

Principal Investigator

PRINT LAST NAME	PRINT FIRST NAME
SIGNATURE	DATE _____/_____/_____

Faculty Sponsor

PRINT LAST NAME	PRINT FIRST NAME
SIGNATURE	DATE _____/_____/_____

Co-Investigator

PRINT LAST NAME	PRINT FIRST NAME
SIGNATURE	DATE _____/_____/_____

For More Information and Application Submission, contact:

Dr. Dwyane Smith
HSSU IRB Committee Chairman
3026 Laclede Avenue, Room 106; St. Louis, MO 63103
Phone: (314) 340-3612 Fax: (314) 340-3398
SmithD@hssu.edu