APPLICATION
TO THE
PENNSYLVANIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD
FOR
Approval of Research Project under the Federal Policy for the Protection of Human Subjects

General Policy: A human subject is defined as a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. 45 CFR § 46.102(e)(1).

The following types of research studies involving human subjects require the review of the Pennsylvania Department of Health Institutional Review Board (PA DOH IRB):

(1) Studies involving grants for which a Department of Health program is applying

(2) Studies involving grants awarded by the Department of Health to grantees

(3) Studies conducted by the Department of Health

(4) Studies using Department of Health biological specimens and/or data

(5) Studies conducted at a Department of Health licensed/approved nursing home or long-term care facility

Completed Applications: This application form and all supporting documents must be submitted to the PA DOH IRB Administrator at RA-DHIRB@pa.gov. Please note that the PA DOH IRB will not review an application unless it is accompanied by the following documents:

(1) Complete research protocol

(2) Copies of certification of appropriate research training (CITI Training when appropriate)

(3) Consent forms (if applicable)

(4) Completed waiver of authorization form (if applicable)

(5) Copies of any prior IRB determinations (if applicable)

Study Name

Principal Investigator Information (Please attach proof of training)		
Name:	Name and address of institution:	Email address:
Title:		Phone:
		Fax:

Co-investigator Information (Please attach proof of training for each co-investigator)		
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:

Study Characteristics
(Please check any of the following that apply)

☐ Study involves grants for which Department of Health programs are applying.

☐ Study involves grants awarded by the Department of Health to grantees.

☐ Study is being conducted by the Department of Health.

☐ Study involves the use of Department of Health biological specimens and/or data.

☐ Study will be conducted at a Department of Health licensed/approved nursing home or long-term care facility.

☐ Principal Investigator (PI) anticipates, or has received, state funding for this study.

☐ PI anticipates, or has received, a combination of state and federal funding for this study.

☐ Study involves vulnerable populations, including but not limited to pregnant women, human fetuses, neonates, children, individuals with impaired decision-making capacity, prisoners, and economically or educationally disadvantaged persons.

Anticipated Level of Review
(Please check one)

☐ A. Study requires full review.

☐ B. Study requires expedited review.
Please ensure that the reason for this level of review is selected in the appropriate section below.

☐ C. Study is exempt from review.
Please ensure that the reason for this exemption is selected in the appropriate section below, after which only the study description and signature sections need to be completed.

Prior IRB Approval/Exemption

If this study has already been reviewed by another IRB, please complete this section and continue to fill out the rest of the application in accordance with the type of review being requested. Remember to attach a copy of the prior approval or documentation of exemption to this application.

Name of IRB that performed prior review:

_____

Type of review performed by this IRB:

☐ Full review ☐ Expedited review ☐ Exempt from review

Date of IRB action: _____

FWA Number: _____

Request for Exemption from Review
(Please check any of the following that apply)

☐ A. Study will be conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

☐ B. Study is limited to interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, and at least one of the following criteria is met:

(1) the information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

(2) any disclosure of the human subjects' responses outside the research that would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement.

☐ C. Study is limited to benign behavioral interventions (defined as brief in duration, harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the subjects) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry), or audiovisual recording if the subject prospectively agrees to the intervention and information collection, and at least one of the following criteria is met:

(1) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

(2) any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

*Please note that if this study involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ D. Study is limited to secondary research uses of identifiable private information or identifiable biospecimens, and at least one of the following criteria is met:

(1) the identifiable private information or identifiable biospecimens are publicly available;

(2) information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(3) this study involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(4) this study is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

☐ E. Study is conducted by, or subject to the approval of, the Department of Health and is designed to research, evaluate, improve or otherwise examine: (1) public benefit or service programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures; or (4) possible changes in methods or levels of payment for benefits or services under those programs.

☐ F. Study is limited to taste and food quality evaluation and consumer acceptance studies during which: (1) wholesome foods without additives are consumed; or (2) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Request for Expedited Review
(Please check any of the following that apply)

☐ A. Study is limited to clinical research of drugs and medical devices for which an investigational new drug application is not required.

☐ B. Study is limited to research on medical devices for which an investigational device exemption application is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ C. Study is limited to the collection of blood samples by finger stick, heel stick, ear stick or venipuncture from:

☐ Healthy, nonpregnant adults who weigh at least 110 pounds, for which 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

☐ Other adults and children for which 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.

☐ D. Study is limited to the 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.

*Please note that 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.

☐ E. Study is limited to the prospective collection of biological specimens for research purposes by noninvasive means.

☐ F. Study is limited to 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).

☐ G. Study is limited to the collection of data from voice, video, digital or image recordings made for research purposes.

☐ H. Study is limited to 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.

☐ I. Study is limited to interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

☐ J. Study is limited to benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry), or audiovisual recording if the subject prospectively agrees to the intervention and information collection, and the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects.

Study Description

Describe the purpose of the study in a brief statement.

If the PI is requesting any data from the Department of Health, please provide a detailed description of the data, the intended use of the data, and specify whether this data will be linked to any other data. Remember to attach any applicable data sharing agreements to this application.

Describe the research methodology of the study in a brief statement. Remember to attach copies of any printed materials, scripts, or surveys that will be used to this application.

Anticipated time frame of the study:

From: _____

To: _____

Funding

Anticipated source of funding:

_____

Ex. Federal (NIH, CDC etc.), State (Department of Health, C.U.R.E., etc.), or Combination (list all sources of funding)

Grant funding year:

_____

Ex. SFY 2022 or FY 2022

Anticipated level of funding:

_____

Ex. % of each funding source (State 40% Federal 60%)

Deputate, Bureau, Office, Division etc. distributing funds:

_____

Ex. Long Term Care Facility

Information About Subjects

Approximately how many subjects is the study anticipated to enroll? If it becomes necessary to enroll more subjects in this study, a change of protocol request form must be submitted.

_____ subjects

Provide a description of the subjects the study will be enrolling. (For example: age range, gender, geographical region, etc.)

Will the study be researching or including any of the following? Check all that apply:

☐ Abortion materials

☐ Tissues

☐ In vitro fertilization

Will the study be enrolling any of the following vulnerable populations as subjects? Check all that apply:

☐ Pregnant women

☐ Neonates

☐ Fetuses

☐ Prisoners

☐ Children

☐ Individuals with impaired decision-making capacity

☐ Economically or educationally disadvantaged persons

☐ General population, which may Include any of the above vulnerable populations

Explain how the study necessitates or justifies the inclusion of subjects with the characteristics described in the three questions above.

Are there any characteristics that will be used to exclude potential subjects from participating in the study and/or does the PI foresee any reasons an enrolled subject would be removed from the study?

Subject Recruitment
What methods will the study employ to identify potential subjects that fit the characteristics described in the preceding section?
How will the study recruit subjects? Please specify the methods and the medium through which these methods will be disseminated. Remember to provide a copy of any recruitment materials including oral scripts, posters, advertisements for any medium, letters and any other material being used to recruit subjects.
If applicable, describe the specific location, region or organization that recruitment will take place.
Will an incentive be offered for participation? If so, please describe it here.
Data Privacy
Will any personally identifiable information be collected? If so, please list any type of personally identifiable data the study plans to collect and how the study plans to collect it.
Does the study necessitate the collection of protected vital events data from the Department of Health's Division of Vital Records? ☐ Yes ☐ No
How will the data be stored? Check all that apply:

☐ Electronic records ☐ Hard copies
Describe how the data will be stored in a secure way. Please include a description of any encryption methods that may be used.
Who will have access to the data collected in the study?
Will the data collected in the study and/or borrowed from the Department of Health be linked to any other data? If so, please specify how it will be linked and if there are any precautions that will ensure the data is still deidentified.
How long will the data be stored? _____
If applicable, describe how the data will be disposed of.

Informed Consent
Will informed consent be collected? ☐ Yes ☐ No If no, please explain why informed consent is not necessary for the study:
What process will the study use to obtain consent? (For example: informed consent, assent, parental permission, etc.). Remember to attach any forms or copies of verbal scripts that will be used.
Anticipated Benefits and Risks
How will the study potentially benefit the population of potential subjects?
How will the study potentially benefit society as a whole?
What potential risks could affect participants in the study? Please include any possible risks, no matter how unlikely.
How does the PI plan to minimize the risk that subjects could incur from participation in the study?

Signature	
The official signing below certifies that the information provided above and in any related attachments is correct and that, as required, future reviews will be requested and certification will be provided.	
Name of official:	Phone:
Title:	Fax:
Signature:	Date:

Application Checklist

Mandatory documents:

☐ PA DOH IRB application

☐ Research protocol

☐ Copies of certification of appropriate research training (CITI Training when appropriate)

Other documents (required if applicable):

☐ Any questionnaires and/or surveys that will be used

☐ Any printed materials the subjects may see, hear, or read

☐ Script that subjects may hear, see, or read during the research process

☐ Any forms that will be used in the data collection process

☐ Copies of all recruitment materials

☐ Consent document(s)

☐ Approval form from another FWA compliant IRB

☐ Data sharing agreements

☐ Any other supporting material the PI believes will help the PA DOH IRB understand the study

To be completed by PA DOH IRB personnel		
Study is exempt from Department of Health IRB review:	☐ Yes	☐ No
If yes, determination is based on this exemption criteria:	☐ A ☐ B ☐ C ☐ D ☐ E ☐ F	
Study underwent expedited review:	☐ Yes	☐ No
If yes, determination is based on this expedited review criteria:	☐ A ☐ B ☐ C ☐ D ☐ E ☐ F ☐ G ☐ H ☐ I ☐ J	
Study underwent full review:	☐ Yes	☐ No
Institutional Review Board Result: ☐ Approved ☐ Approved with conditions ☐ Disapproved		
_____ Signature	_____ Date	