pennsylvania
DEPARTMENT OF HEALTH

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

Policy: The following types of research projects involving human subjects require the review of the Department of Health's Institutional Review Board (IRB): (1) grants for which a Department of Health program is applying; (2) grants awarded by the Department of Health to grantees; (3) research conducted by the Department of Health; (4) entities using Department of Health biological specimens and/or data; or (5) research to be conducted at a DOH licensed/approved nursing home or long-term care facility. A human subject is a living person about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual or (2) personally identifiable information. Completed form should be submitted to the PADOH IRB Administrator at ra-dhirb@pa.gov.

Project Name:

Principal Investigator Information (Please Attach Proof of Training)

Name:	Name and address of institution:	Phone:
Title:		Fax:
		Email address:

Co-investigators (Please attach proof of training for each investigator.)

Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
Name:	Email:	Phone:
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Name:	Email:	Phone:

Reason for Submission to DOH IRB

There are several characteristics of research that require a researcher to submit an application to the DOH IRB. These characteristics are listed in the policy at the top of the application. Please select which of the following characteristics applies to this project:

☐ Research involving grants for which Department of Health programs are applying

☐ Research involving grants awarded by the Department of Health to grantees

☐ Research conducted by the Department of Health

☐ Research involving the use of Department of Health biological specimens and/or data

☐ Research to be conducted at a DOH licensed/approved nursing home or long-term care facility

Anticipated Level of Review (Check one.)

☐ A. Project requires full IRB review.

☐ B. Project requires expedited IRB review for the reasons indicated below.

☐ **C.** Project is exempt from IRB for the reasons indicated below. **Following this point, complete only project detail and signature sections.**

☐ D. IRB review has been conducted by another IRB. Attach copy of approval or exemption and continue to fill out application in accordance with the type of review you are requesting.

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Name of other IRB_____

Type of review: ☐ Full review ☐ Expedited review ☐ Exempt from review

Date of IRB action:_____

Request for Exemption from Review
(Check any of the following that apply.)

☐ A. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods

☐ B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (1) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (2) any disclosure of the human subjects' responses outside the research that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation

☐ C. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph B above, if: (1) the human subjects are elected or appointed public officials or candidates for public office; or (2) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter

☐ D. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects

☐ E. Research and demonstration projects which are conducted by or subject to the approval of the Department of Health, and which are designed to study, evaluate 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. Taste and food quality evaluation and consumer acceptance studies, (1) if wholesome foods without additives are consumed or (2) if 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
(Check any of the following that apply.)

☐ A. Clinical studies of drugs and medical devices when an investigational new drug application is not required

☐ B. 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. 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
- ☐ 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. Prospective collection of biological specimens for research purposes by noninvasive means

☐ E. Research involving 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)

☐ F. Collection of data from voice, video, digital or image recordings made for research purposes

☐ G. 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

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

- ☐ The research is permanently closed to the enrollment of new subjects.
- ☐ All subjects have completed all research related interventions.
- ☐ The research remains active only for long-term follow-up of subjects.
- ☐ No subjects have been enrolled and no additional risks have been identified.
- ☐ The remaining research activities are limited to data analysis.

Project Detail

Describe the project purpose. (Provide a brief explanation in layman's terms.)

Are you requesting to obtain any data from the department? Please provide a detailed description of any data you are seeking from the Department of Health and what the data will be used for. Specify if the Department of Health data will be linked to any other data. Attach data sharing agreements if applicable

Describe the research methods. (Provide a brief explanation in layman's terms.) Attach copies of any printed materials, scripts and surveys that will be used.)

Anticipated time period for conducting the research

From_____ To_____

Anticipated source of funding:	Anticipated level of funding:

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Information About Subjects

Approximately how many subjects do you anticipate enrolling in this study? If it becomes necessary to enroll more subjects in this study, a change of protocol request form must be submitted.

Please provide a description of the subjects you will be enrolling in the study. (Example characteristics include age range, gender, geographical region, etc.)

Will you be studying or including any of the following in your subject pool? Check all that apply:

☐ Abortion materials

☐ Tissues

☐ In vitro fertilization

Will subjects in your study belong to any of the following vulnerable populations? Check all that apply.

☐ Pregnant women

☐ Neonates

☐ Fetuses

☐ Prisoners

☐ Children

☐ Mentally disabled individuals

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

Explain how the research necessitates or justifies the inclusion of subjects with the characteristics you have 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 do you foresee any reasons an enrolled subject would be removed from the study?

Subject Recruitment

How do you plan on identifying potential subjects in order to recruit them into your study? In other words, what methods will you use to find people who fit the characteristics of subjects you described in the Information About Subjects section?

How will you recruit subjects? Please specify the methods and the medium through which these methods will be disseminated. Also, provide a copy of any recruitment materials including oral scripts, posters, advertisements for any medium, letters and any other material you will be using to recruit subjects.

If applicable, describe where in regard to a specific location, region or organization the 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 yes, please list any type of personally identifiable data you plan to collect and how you plan to collect it.

Will your data be stored via:

☐ Electronic records

☐ Hard copies

☐ Both

Describe how the data will be stored in a secure way. Include a description of any encryption methods that may be used.

Who will have access to the data collected in this 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. Please explain why informed consent is not necessary for your study.

What process will you use to obtain consent (examples include informed consent, assent, parental permission, etc.)? Attach any forms or copies of any verbal scripts that will be used in the consent process.

Anticipated Benefits and Risks

How will the research potentially benefit the population of potential subjects for this study?

How will the research potentially benefit society as a whole?

What potential risks could affect participants in this study? Please include any possible risks you have considered even if they are unlikely.

How do you plan to minimize the risk subjects could incur from participation in this 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	Title
Signature	Date

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Phone	Fax

Department of Health Institutional Review Board Approval

Project is exempt from Department of Health IRB review: ☐ Yes ☐ No

If yes, determination is based on this this exemption criteria: ☐ A ☐ B ☐ C ☐ D ☐ E ☐ F

Project underwent expedited review: ☐ Yes ☐ No

If yes, determination is based on this expedited review criteria: ☐ A ☐ B ☐ C ☐ D ☐ E ☐ F ☐ G ☐ H

Project underwent full review: ☐ Yes ☐ No

Approval:

☐ Approved ☐ Approved with conditions ☐ Disapproved

Name of signatory	Title of signatory
Signature	Date

Application Checklist

Mandatory documents:

☐ IRB application

☐ Research protocol

☐ Copies of certification of appropriate research training

Other documents that are required if applicable to this project:

☐ Any questionnaires and/or surveys that will be used

☐ Any printed materials the subjects will be shown

☐ Script of what will be said to subjects during the experiment

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

☐ Copies of all recruitment materials

☐ Consent document(s)

☐ Approval form from another IRB

☐ Data sharing agreements

☐ Any other supporting material you believe will better help the IRB understand your research

DOH Office Use Only:

☐ Reviewed Outcome:_____Date: _____