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DEPARTMENT OF HEALTH

CONTINUING REVIEW OF APPROVED RESEARCH

TO THE

PENNSYLVANIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD

For

Review 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; or (4) entities using Department of Health biological specimens and/or data; (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.

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

Project Detail

Attach a copy of the project protocol. Have any modifications been made to the protocol since the last review? If so, please describe the changes.

Attach a copy of the method(s) of obtaining consent. Have any modifications been made to the consent process since the last review? If so, please describe the changes.

Describe recent literature related to the research.

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Subject Information

How many subjects have been accrued since the last review?

Describe all adverse events and all unanticipated problems involving risks to the subjects.

List any subject withdrawals.

Project Progress

Describe the research findings thus far. Attach relevant multi-center trial reports if applicable.

List any complaints about the research since the last review.

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
Phone	Fax

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Application Checklist

Mandatory Documents:

☐ IRB Continuing Review Application

☐ Research protocol

Other Documents that are required if applicable to this project:

☐ Consent document(s)

☐ Multi-center trial reports

☐ Any print materials or scripts that have been modified since the last review

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

DOH Office Use Only:

☐ Reviewed Outcome: _____ Date: _____