

CHANGE OF PROTOCOL APPLICATION

TO THE

PENNSYLVANIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD

For

Approval of Protocol Change 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

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

Reason for Protocol Change

Describe the reason the original protocol needs to be changed.

Protocol Changes

Describe the changes that need to be made to the protocol. Attach a copy of the revised protocol

Will this change to the protocol effect the benefits or risks to the subjects in any way? If so, please describe how.

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 |

DOH Office Use Only:

Reviewed Outcome: _____ Date: _____