

Research Determination Worksheet

Version 2/20/2014

GEISINGER HEALTH SYSTEM

Human Research Protection Program (HRPP)

100 North Academy Avenue
Danville, PA 17822-3069
570-271-8663

For HRPP Use Only

- Does not meet definition of "research".
- Does not meet the definition of "human subjects"
- Requires submission of an IRB application for review

Signature HRPP Reviewer _____ Date _____

Email a PDF of this completed form to the IRB at bkent@geisinger.edu for IRB review and determination.

The IRB will review your completed worksheet to determine if your proposed activity is human subject research and regulated by Health and Human Services (HHS) and/or Food and Drug Administration (FDA). Once a determination is made, you will receive an IRB Determination Letter with the outcome.

PLEASE DO NOT USE THIS FORM if drugs, devices or biologics are involved. You must submit a new study application to the IRB within iRIS. Contact the IRB at 570-271-8663 for assistance.

Project Title:

Principal Investigator (Name):

MD DO PhD EdD Pharm D DNP Other (Specify):

Job Title:	Phone:	Fax:
Address:	Internal M.C.:	Pager:
	E-mail:	

Sub-or Co-Investigator (Name):

MD DO PhD EdD Pharm D DNP Other (Specify):

Job Title:	Phone:	Fax:
Address:	Internal M.C.:	Pager:
	E-mail:	

Contact Person (Name):

MD DO PhD EdD Pharm D DNP Other (Specify):

Job Title:	Phone:	Fax:
Address:	Internal M.C.:	Pager:
	E-mail:	

Briefly describe your project below. This should include the purpose, description of the subjects, data and/or specimens to be studied.

Please answer the following questions:

Yes <input type="checkbox"/> No <input type="checkbox"/>	A. Is the activity a systematic investigation, including research development, testing and evaluation?
Yes <input type="checkbox"/> No <input type="checkbox"/>	B. Is the activity intentionally designed to develop OR contribute to generalizable knowledge?
Yes <input type="checkbox"/> No <input type="checkbox"/>	C. Is the data the investigator planning to obtain, whether directly from individuals or from their records, about living individuals?

If you answered **NO to ANY** of the questions (A, B, or C) above, this form is completed. Sign the last page and submit.
If you answered **YES to ALL** of the questions (A, B, or C) above, please complete the questions on the next page.

1. The investigator plans to obtain data through one or more of the following (Check all that apply):

- Physical procedures performed on individuals
- Manipulation of individuals
- Manipulation of individuals' environments
- Communication with individuals
- Interpersonal contact with individuals

2. Are any of the following true? (Please check all that apply):

- The information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place.
- The individual has provided the information for specific purposes and can reasonably expect that the information will not be made public. This could include, for example, medical records or school records.
- The identity of the individual is **or** may readily be ascertained by the investigator from the information received.
- The identity of the individual is **or** may readily be associated with the information received.

3. Will the PI and/or study team receive any of the following elements (PHI)? (Check all that apply):

- Names
 - Geographic subdivisions smaller than a state (e.g., street address, city, county, zip code, geocodes)
 - Dates (except 'year' alone) directly related to an individual (e.g., date of birth, admission, discharge, test, etc.) or elements of date (including 'year' for persons ≥ 90 years old)
 - Telephone numbers
 - Fax numbers
 - E-mail addresses
 - Social security numbers
 - Medical record numbers
 - Health plan beneficiary numbers
 - Account numbers
 - Certificate/license numbers
 - Vehicle identifiers and serial numbers, including license plate numbers
 - Device identifiers and serial numbers
 - Web addresses – universal resource locators (“URLs”)
 - Internet protocol (“IP”) address numbers
 - Biometric identifiers, including fingerprints and voice prints
 - Full face photographic images and any comparable images
 - Other unique identifying number, characteristic, or code
- Describe:

PI Signature

Date