WAYNESBURG UNIVERSITY

Date

IMPORTANT: Please use Internet Explorer to complete this form; OR, if using another web browser, save the blank form to your documents FIRST, then complete the form using your saved copy.

Institutional Review Board

HIPAA Waiver of Authorization

1. The quality improvement study entitled _____

necessitates identified members of the capstone project team to access the following elements of protected health information (PHI) for the reasons identified on this form. Alternatives/limitations to the proposed capstone project are also discussed.

2. Identified members of the capstone project team who will have access to PHI (Enter "NONE" in fields where applicable; that is, do not leave any of the next 5 fields blank; identify person by full name in space provided).

Project Leader	
List ALL sub-leaders	
Statistician	
List doctoral/ masters committee members	
List others with access to this PHI	

Note: Others may include key members of the capstone project team that have not been previously named. Examples include, but are not limited to, others who will have access to subjects, either during consenting or during collection of data; others who will have access to identified [raw] data; anyone else who reasonably might have access to any PHI he/she would not reasonably have accessed as part of his/her regular job duties.

3. Elements of protected Health information (PHI) to be accessed (check all that apply):

- ☐ Names
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Email addresses
- ☐ Social Security numbers
- ☐ Medical records numbers
- ☐ Health plan beneficiary numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle ID & serial numbers, license plate numbers
- ☐ Device identifiers & serial numbers
- ☐ Web URL's
- ☐ IP addresses
- ☐ Biometric ID's, including finger and voice prints
- ☐ Full face photographic images & comparable images
- ☐ All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, & their equivalent geocodes, except for the initial 3 digits of a zip code if, according to the current publicly available data from the Census Bureau
- ☐ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
- ☐ Any other unique identifying number, characteristic, or code, except as permitted in section immediately above

PER FEDERAL REGULATIONS: TO BE ELIGIBLE FOR CONSIDERATION OF WAIVER OF AUTHORIZATION, THE USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION CANNOT INVOLVE MORE THAN A MINIMAL RISK TO THE PRIVACY OF INDIVIDUALS. IN ADDITION, THE FOLLOWING CRITERIA MUST BE SATISFIED FOR THE IRB TO APPROVE A WAIVER OF AUTHORIZATION UNDER THE PRIVACY RULE.

4. Describe why this project cannot be completed without accessing PHI or gaining consent of subject to whom PHI belongs (patient).

5. Describe your plan to protect the identifiers from improper use and disclosure.

6. Describe your plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research. Be sure to address both paper and electronic data storage, security, and destruction. If there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, please describe fully.

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7. Project Leader

I hereby assure that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project.

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8. Describe alternatives/limitations to project design if access of PHI is not granted.

9. Complete the following items for each member of the capstone project team who has completed an education event or competency evaluation for the following:

Name	Date of HIPAA completion/update (Must be within past 12 months)	Where HIPAA completed	NIH or CITI training (Provide certificate of completion for each)
			☐ Completed
			☐ Completed
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			☐ Completed
			☐ Completed

10. Signatures

My signature below indicates: 1) that I am submitting this protocol as the project leader and 2) that I have read and had the opportunity to have any questions answered regarding the contents of the Waynesburg University IRB guidelines.

Project leader's name

Date

Project leader's signature -- blue ink only

Title of quality improvement (QI) project

We have reviewed the above information and recommend this project.

Capstone chair's name

Date

Capstone chair's signature -- blue ink only

Dept. Chair/Program Director

Date

Dept. Chair/Program Director's signature -- blue ink only

11. A printed copy of the original signature page (and any additional attachments) must be mailed to Barbara Kirby at 51 W. College St., Waynesburg, PA 15370. You can print this form using the button below. Then, save and send this form as an e-mail attachment to bkirby@waynesburg.edu. **Mail** the original signature page and any attachments. Your IRB application will remain inactive until original copy of signature page and any applicable attachments are received.

Print Form