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

Exempt Application - Quality Improvement (QI) Project

IMPORTANT: ALL RESPONSES MUST FIT WITHIN EACH TEXT BOX

1. Title of QI project

2. Project Leader

Dept./University

Home Address

E-mail

Phone Number

☐ I certify that I have completed NIH or CITI training or read the Waynesburg University IRB guidelines. Provide copy of certificate of completion of training.

3. Does this QI project involve withholding , not offering, or withdrawing any treatments that are accepted as "effective" or "helpful" for the subjects' conditions?

☐ Yes (STOP...COMPLETE FULL BOARD IRB APPLICATION)

☐ No

4. Does this QI project involve the use of any item (drug or device) that is NOT currently approved by the FDA for this use (new drug/device or off-label use of established drug/device)?

☐ Yes (STOP...COMPLETE FULL BOARD IRB APPLICATION).

☐ No

5. Which of the following is the primary purpose for undertaking this QI project?

☐ Capstone project

☐ Class project

☐ Discovery of new information to be generalized to multiple facilities (reconsider if research protocol application is more appropriate for this project)

☐ Publication or presentation of outcomes of this project

☐ Other

6. Does this QI project include an intervention?

☐ No

☐ Yes **Please describe in detail, including how determination will be made of who will/will not receive the intervention. (Reconsider if a research protocol application is more appropriate for this project).**

7. In what facility will this QI project take place? (Include as an attachment the approval of QI project from host facility or letter of commitment from administrative representative of the facility that indicates intent of facility to participate in and host this project).

7a. Are you an employee of the above facility?

- ◯ No (Skip to question 8)
- ◯ Yes

7b. Do you have a supervisory, evaluative, and/or hiring role over any participant or subject?

- ◯ No
- ◯ Yes (Describe below)

8. Projected start date

Note: No project may begin before approval by Waynesburg University's IRB.

9. Projected end date of project

10. List Goals of QI project

11. List specific outcomes will this QI project evaluate?

12. What SPECIFIC improvements do you anticipate in the local environment? Check ONLY those that apply.

☐ List improvements to patient-centered care.

☐ List improvements to the communication, collaboration, or teamwork.

☐ List improvements to evidence-based practices.

☐ List improvements to safety.

☐ List improvements to informatics.

☐ List improvements to health care economics.

☐ List improvements to staff or patient satisfaction.

13. Will any protected health information be accessed or collected by ANY member of this QI team? Please refer to the HIPAA Waiver form.

- ◯ No (Skip to number 15)
- ◯ Yes (Select from the list below 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

14. Describe HOW the above identified protected health information will be accessed, obtained, collected, and stored. Attach the data collection form you intend to use.

15. Provide a detailed summary of your proposed project, including consenting process and all other procedural elements.

16. Are there any costs to the subjects for participating in this QI project (including emotional, physical, inconvenience, or monetary costs)?.

- No
- Yes (Describe costs to subjects below).

17. Will you provide any incentives to subjects who participates in the QI project?

- No
- Yes (Describe incentives).

18. Why do you think this project is quality improvement and not research?

19. Signatures

My signature below indicates: 1) that I am submitting this applicationas 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 QI project

I have reviewed the above information and recommend this project.

☐ I certify that ALL members of the Capstone Committee, including myself, have completed NIH or CITI training. Please provide copies of certificates of completion.

List Capstone Committee

Capstone chair's name

Date

Capstone chair's signature -- blue ink only

Program Director/Chair

Date

Program Director/Chair signature -- blue ink only

Dean of GAPS

Date

Deans of GAPS signature -- blue ink only

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20. 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