WAYNESBURG UNIVERSITY

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.

Date

Protocol Number

Institutional Review Board
Amendment and Renewal Request & Monitoring Report Form

☐ Amendment Request ☐ Renewal Request ☐ Monitoring Report (as request by IRB)

1. **Have there been any research-related problems, complications, or mishaps affecting the research subjects since the last IRB review? Unanticipated adverse events must be reported via Adverse Event form.**

◯ Yes (Describe below any changes in the research risk to the human subjects) ◯ No

2. **Has the nature of the contact with human subjects changed since the last review? If yes, does this increase the research risk to the subjects?**

◯ Yes (Explain below the change and increased risk in detail). ◯ No

3. **Has the study method or sampling plan (data collection methods or instruments; size, sex, or age of the target population) been altered ?**

◯ Yes (Explain alterations in detail below) ◯ No

4. Has the environment for subject contact been changed or altered?

◯ **No**

◯ **Yes** (Explain alterations in detail below. 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).

5. Have the investigators or persons having contact with the subjects or subject data changed?

◯ Yes (Explain in detail below. List those who are NO LONGER investigators. For those who are NEW investigators, complete last page of this form.)

◯ No

6. Have all subjects in the study signed the consent form?

◯ Yes

◯ No (Explain in detail below)

7. Have there been problems associated with obtaining informed consent?

◯ Yes (Explain in detail below)

◯ No

8. Is a copy of each signed consent form on file, stored in a secure manner, and available for review by appropriate authorities?

◯ Yes ◯ No (Explain in detail below)

9. Has work with human subjects been completed? If yes, enter date completed in box below.

◯ Yes Date completed ◯ No (Explain in detail below)

10. Do you want the IRB to close this file? If yes, complete Closure Report.

◯ Yes (Complete closure form) ◯ No (Describe reason for requesting continuation below)

11. Signature

I certify that the above statements and attachments (if needed) concerning this research are true.

Investigator's Name

Date

Investigator's signature (sign in blue ink only)

Department Chair's Name

Date

Department Chair's signature (sign in blue ink only)

Protocol Number

12. A printed copy of the original signature page (and any additional lists of sub-investigators that do not fit on this form) must be mailed to Barbara Kirby at 51 W. College St., Waynesburg, PA 15370. If no additional sub-investigators to list on the next page, you can print this form using the button below. (If you have additional names to add, there is another print button at the end of the next page). Then, save and send this form as an e-mail attachment to bkirby@waynesburg.edu. REMEMBER to **mail** the original signature page and any attachments.

Print Form

Scroll to next page if you need to list additional sub-investigators.

13. Extra page to list additional sub-investigators:

Name

Dept./University

Address

E-mail Phone

Name

Dept./University

Address

E-mail Phone

Name

Dept./University

Address

E-mail Phone

Name

Dept./University

Address

E-mail Phone

Name

Dept./University

Address

E-mail Phone

☐ I certify that the additions to key personnel have completed CITI or NIH training.

Date

Principal investigator's signature -- blue ink only

Title of study

Protocol No.

Print Form

Renewal Form