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
Adverse Events Reporting

Reportable adverse events must be (1) severe, (2) related to your study, and (3) unexpected.

Principal Investigator (PI)

Title of research study or QI project

1. _____ As PI of this study, my initials here indicate that I am reporting unanticipated events that may be related to the above identified protocol. These events, if related to this study/project, may place subjects at greater risk of harm than was previously known.

2. Describe the possible adverse event.

3. Where did this event occur?

4. Was this event previously reported to the IRB? ◯ Yes ◯ No

5. What actions, if any, have you taken in attempt to protect human subjects from subsequent similar events?

6. In light of this potential adverse event, should the consent form be revised?

- ◯ Yes (Attach revised version, with new version identifier).
- ◯ No

7. In light of this potential adverse event, should any part of the study/project plan or methodology be revised?

- ◯ Yes (Attach revisions, with new version identifier).
- ◯ No

8. Should currently enrolled subjects be re-consented?

- ◯ Yes (Attach plan for notification of subjects and re-consenting, with new version identifier)
- ◯ No

Go to next page

9. Signature

Name of PI

Protocol Number

Date

Signature of PI -- blue ink only

10. A printed copy of this original form (and any 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.

Print Form

For IRB Committee use only

1. Does this new information regarding the adverse events necessitate submission of a totally new protocol?

- ◯ Yes
- ◯ No

2. Are the revisions to the plan and consent documents (described by the PI) adequate to protect human subjects?

- ◯ Yes
- ◯ No

3. Are revisions approved by the IRB?

- ◯ Yes
- ◯ No (Please explain why revisions are not approved).

4. Does this new information necessitate more frequent on-going reviews by the IRB?

- ◯ Yes

  If yes, what frequency is requested for review?

- ◯ No