Complete this form and submit to the link provided on the [IRB website](https://www3.uwsp.edu/acadaff/orsp/Pages/What-is-IRB.aspx) within 72 hours of the event.

**Date:**

**Principal Investigator:**

**Study Title:**

**Protocol Number:**

**Event Summary**

Please provide details regarding the event, problem, or injury that occurred. When appropriate, please include the dated of the event or discovery, whether the event is resolved, and whether the participant remains on the study. Please indicated if the event was described in the approved consent document.

**Unanticipated Problem**

Nature of event (check all that apply):

Was unexpected

Was related or possibly related to participation in the study

May place subjects or others at greater risk of harm than previously recognized

If all boxes are checked, please describe how subject safety for continuing research activities is being ensured, and describe actions already taken to ensure safety of currently enrolled subjects. Indicate if a modification to your approved protocol and/or consent document is requested.

**Protocol Application and Informed Consent Documentation**

Does the protocol require changes as a result of the event?  Yes  No

If yes, a protocol modification form must be submitted to the IRB and approved before changes commence.

Does the informed consent documentation require changes as a result of the event?  Yes  No

If yes, do currently enrolled subjects require notification and/or re-consent as a result of the event?

Yes  No

If yes, detail when and how notification and/or re-consent will occur:

By checking this box and signing below, I attest that the above information is accurate to the best of my knowledge. J

Signature of PI:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB USE ONLY BELOW THIS LINE

After review of this event I recommend:

This event does not represent and unanticipated problem involving risks to participants or others

No further action required at this time

Referral to IRB for review of proposed modifications to previously approved research

Referral to IRB for review of possible unanticipated problem involving risks to participants or others

Summary

Signature of Reviewer:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Reviewed:      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_