Adverse Event Form

Instructions: Federal regulation requires that any Adverse Events or Unanticipated Problems associated with participation in a research study be reported to the IRB.

The U.S. Department of Health & Human Services defines an Adverse Event as follows: Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

The Office for Human Research Protections, a branch of the Department of Health and Human Services, considers *unanticipated problems*, in general, to include any incident, experience, or outcome that meets **all** of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Section I: Study Information

Study Title	
IRB Protocol #	
Name of Primary Investigator (PI)	
PI Email	

Section II: Adverse Event Description:

Date of Event:

Location of Event:

Please describe the nature of the adverse event or unanticipated problem in detail:

How many individuals have participated in this study to date?

How many more participants are needed?

Have similar adverse events occurred in this study? If yes, please describe.

How likely was the adverse event caused by the procedures of this study?

☐ Not related
☐ Unlikely
☐ Possibly
☐ Probably
☐ Definitely

How was the adverse incident handled, and the situation resolved?

Describe how you intend to protect future participants from experiencing the same harm:

As a result of this event, indicate the modifications you will make to resolve the current issue and to prevent similar events from occurring in the future (select all that apply):

☐ Modification to protocol/study procedures
☐ Modification to level of risk
☐ Modification to informed consent form
☐ Provide additional information to participants
☐ Re-consent current participants
☐ Research will voluntarily be placed on hold
☐ Re-training of research staff to prevent future events
☐ No action is planned
☐ Other planned action (describe):

Additional Comments:

Section III: Certification

I hereby certify that the adverse event information is accurate to the best of my knowledge.

PI Name	
PI Signature	
Date	

Completed IRB Forms and supporting documentation should be submitted to (OIRE@nwfsc.edu) in one communication.