IRB Administration Office
Unanticipated Problem (UP) Reviewer Determination /Full Board Checklist

PI's Name	IRB#	Committee Assigned:
IRB UP Reviewer:		

Unanticipated Problem Reviewer's Assessment

☐ Unanticipated Problem **(Complete Section A)**	☐ Non-Compliance **(Complete Section B)**

Section A: Unanticipated Problem

☐ Problem is unanticipated Select all that apply:

1. ☐ Problem is an adverse event related to the research
2. ☐ Indicates that participants or others are at increased risk of harm.
3. ☐ No harm or risk of harm occurred

If 1 & 2 apply, refer to a convened IRB for review and report to regulatory agencies and institutional official.

Comments:

☐ Problem/event was anticipated

1. ☐ No harm or risk of harm occurred
2. ☐ Event is currently identified in the IRB approved consent form
3. ☐ Event is reported for IRB acknowledgement

Comments:

☐ Problem is idiosyncratic

Comments:

☐ Lapse of IRB approval

1. ☐ No harm or risk of harm occurred
2. ☐ Research activities occurred during the lapse in IRB approval Refer to Full Board
3. ☐ Research activities occurred for the safety of the participants Refer to Full Board

Section B: Non-Compliance

Is the event **Non-Compliance?** Non-Compliance is failure to comply with all federal regulations, including Veteran's Administration regulations and guidance, state and local requirements, WSU Policy and determinations of the IRB)

☐ **No** ☐ **Yes** - Explain why the event is Non-Compliance

Justification for Non-Compliance:

If the event is Non-Compliance, is the event **Serious** Non-Compliance? Serious Non Compliance is failure to comply with all federal regulations, including Veteran's Administration regulations and guidance, state, and local requirements, WSU Policy and determinations of the IRB that involve one or more of the following:

- harm to research participants;
- exposing research participants to a significant risk of substantive harm;
- compromising the privacy and confidentiality of research participants;
- damage caused to scientific integrity of the research data that has been collected;
- willful or knowing non-compliance on the part of the investigator; adversely impacting ethical principles.

☐ **No** ☐ **Yes** - Explain why the event is **Serious** Non-Compliance:

Note to reviewer- requires full board review

Justification for Serious Non-Compliance:

If the event is Non-Compliance, is the event **Continuing** Non-Compliance? Continuing Non-Compliance is repeated pattern of non-compliance by an individual investigator or research staff member either on a single protocol or multiple protocols.

☐ **No** ☐ **Yes** - Explain why the event is **Continuing** Non-Compliance

Note to reviewer- requires full board review

Justification for Continuing Non-Compliance:

Section C: Unanticipated Problem Reviewer's Determination

Note: All VA study UP's require a Full Board Review

☐ Requires Full Board Review	☐ Does not require Full Board Review (**continue to section D**)

Unanticipated Problem Reviewer's Full Board Recommendations

Select the required action(s) below:

☐ Suspension of enrollment of new participants
☐ Suspension of research procedures in currently enrolled participants
  ☐ Study involves procedures and/or follow-up necessary for the safety and well-being of the enrolled participants which cannot be suspended
☐ Suspension of the research:
  ☐ Study involves procedures and/or follow-up necessary for the safety and well-being of the enrolled participants which cannot be suspended

---

☐ Termination of the research

☐ Notification of participants when such information may relate to current participants' willingness to continue to take part in the research or there is a risk to the health or safety of the past or current participants
☐ Provide additional information to past participants
☐ Require current participants to be re-consented to protocol with the changes in the informed consent
☐ Request additional information or clarification from the PI, sponsor and/or data safety monitoring committee
☐ Accept report as submitted pending amendment with consent form changes

---

☐ Require additional monitoring by the IRB
  ☐ Monitoring of the consent process
  ☐ Require a change in the continuing review period
  ☐ Request a for-cause audit, if not already done, and/or a follow-up audit
☐ Request further inquiry into other protocols utilizing the experimental drug/device/intervention or procedure in question
☐ Request further inquiry into PI's other active protocols
☐ Determine if a detailed plan for safe withdrawal of participants from the research must be developed to protect the rights and welfare of participants
☐ Use of data should not be permitted
☐ Require changes to corrective action plan
☐ Require IRB education for: ☐ PI ☐ Key Personnel ☐ Other:
☐ Amendment submission required to make required changes to the following documents:
  ☐ Protocol ☐ Consent ☐ Add key personnel
  ☐ Other:

☐ **Require that appropriate federal regulatory agencies, accrediting bodies, sponsors, and institutional officials be notified** of any unanticipated adverse reactions or unanticipated events involving risks to participants or others according to the IRB policies: 13-1, 13-2, 13-5, 15-1 and 15-3.

☐ **VA** ☐ **DoD** ☐ **OHRP** ☐ **FDA** ☐ **DOE**

☐ AAHRPP ☐ Sponsor

☐ Other:

Section D: Unanticipated Problem Reviewer Determinations

(**When event is not referred to Full Board**)

☐ Note the occurrence of the Unanticipated Problem, but take no action (for minor violations)

☐ Require that this plan be submitted to the IRB for review and approval

☐ Additional information needed from PI

☐ Other:

UP Reviewer's Comments:

UP Reviewer's Signature:	**Date:**
UP Reviewer's Name:	

Full Board Determination

IRB meeting date:	IRB#

Unanticipated Problems & Adverse Events:

Check all that apply:

☐ Event is an unanticipated problem involving risk to participants or others:

☐ Event is not expected (in terms of nature, severity, or frequency) given the research procedures described in study related documents

☐ Event suggests that participants, research staff, or others are placed at a greater risk by the research than previously expected.

☐ Event is an adverse event that is related to the research (i.e. definitely, probably, or possibly related)

Non-Compliance Determinations:

Is the event Non-Compliance?

Non-Compliance is failure to comply with all federal regulations, including Veteran's Administration regulations and guidance, state and local requirements, WSU Policy and determinations of the IRB)

☐ **No** ☐ **Yes** - Explain why the event is Non-Compliance

Explain, if different than the UP Reviewer's determination:

If the event is Non-Compliance, is the event Serious Non-Compliance?

- harm to research participants;
- exposing research participants to a significant risk of substantive harm;
- compromising the privacy and confidentiality of research participants;
- damage caused to scientific integrity of the research data that has been collected;
- Willful or knowing non-compliance on the part of the investigator; adversely impacting ethical principles.

☐ **No** ☐ **Yes** - Explain why the event is **Serious** Non-Compliance:

Explain if different than the UP Reviewer's determination:

If the event is Non-Compliance, is the event Continuing Non-Compliance?

Continuing Non-Compliance is repeated pattern of non-compliance by an individual investigator or research staff member either on a single protocol or multiple protocols.

☐ **No** ☐ **Yes** - Explain why the event is **Continuing** Non-Compliance

Explain if different than the UP Reviewer's determination:

Determination of UP Reviewer Recommendations

☐ **Accept reviewer recommendation(s) as presented**	☐ **Reviewer recommendation(s) not accepted**
☐ **Accept reviewer recommendation(s) with modifications**	

IRB Determination Comment(s):

☐ Use of data is not permitted

☐ Require changes to corrective action plan

☐ Require IRB education for: ☐ PI ☐ Key Personnel ☐ Other:

☐ Amendment submission required to make changes to the following documents:

☐ Protocol ☐ Consent ☐ Add key personnel

☐ Other:

IRB Chair's Signature:

Required Reporting for VA Studies: See Q#7 for VA status. These studies have special requirements—see VA Reporting Responsibilities and Procedures Policy 13-5

Required Reporting for DoD, and DoE Studies: These studies have special requirements. See IRB Reporting of Unanticipated Problems, suspensions and terminations, continuing non-compliance Policy 13-2