CAMPBELL UNIVERSITY	**IRB SOP:** Reportable Events		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-158	IRB Chair, IRB Office Campbell University	10/08/2019

1 PURPOSE

1.1 This procedure establishes the process to manage information reported to the IRB to ensure that information that represents Reportable Events including, Adverse Events, Unanticipated Problems Involving Risks to Subjects or Others, Non-Compliance, and/or suspensions or terminations of the research by the sponsor, investigator, or institution are managed to protect the rights and welfare of subjects.

1.2 The process begins when the IRB receives a reportable event submitted by the investigator or new information provided by someone else, other than the investigator.

1.3 The process ends when the reportable event is determined not to represent a problem that requires management, is managed administratively, or referred to the convened IRB for review.

2 PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 The institution will notify the applicable, if required, federal agencies such as the Office of Human Research Protections (OHRP), the Food and Drug Administration (FDA), or other applicable federal agencies within 30 business days of any IRB determinations that constitute Serious and/or Continuing Non-Compliance, Unanticipated Problems involving Risks to Subjects or Others (UPIRSO), Suspension or Termination of that research as outlined in SOP - External Reporting Process.

3.1.1 For Department of Defense (USDOD) research, the report is sent to the DOD human research protection officer.

3.2 The institution will promptly notify the USDOD if the IRB of record changes.

4 RESPONSIBILITIES

4.1 The IRB Office staff members carry out this procedure.

5 PROCEDURE

5.1 Review the information reported, and request more information as needed from the investigator or person submitting the RE.

5.1.1 Is this an Adverse Event?

5.1.2 Is this an Unanticipated Problem Involving Risks to Subjects or Others?

5.1.3 Is this an Allegation of Non-Compliance?

5.1.4 Is this a Finding of Non-Compliance?

5.1.5 Is this an Unanticipated Problem Involving Risks to Subjects or Others?

5.1.6 Is this a Suspension or termination of the research by the sponsor, investigator, or institution?

5.2 If you are unable to answer a question, consult the IRB Chair or Research Integrity Officer.

5.3 If the answer is “no” to all questions in section 5.1; consult with the IRB Chair to determine whether it should be placed on the agenda of a convened IRB meeting or undergo Non-Committee Review.

5.3.1 If the answer is “no” to all questions and no additional review is required, skip ahead to section 5.7.

5.4 If the answer is “yes” to one or more questions, then follow the corresponding sections below.

5.4.1 Allegations of Non-Compliance: Determine whether each Allegation of Non-Compliance has any basis in fact.

5.4.1.1 If yes, follow the procedures under Findings of Non-Compliance.

5.4.1.2 If no, follow any other corresponding sections.

5.4.2 Findings of Non-Compliance: Determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance.

5.4.2.1 If no, follow the procedures under Non-Serious/Non-Continuing Non-Compliance.

5.4.2.2 If yes, follow the procedures under Serious or Continuing Non-Compliance.

5.4.3 Non-Serious/Non-Continuing Non-Compliance

5.4.3.1 Require the individual or group responsible for the Non-Compliance to develop and implement a suitable corrective action plan.

5.4.3.2 If the individual or group responsible for the Non-Compliance is unable or unwilling to develop and implement a suitable corrective action plan, consider the Non-Compliance to be Continuing Non-Compliance and follow the procedures for Serious or Continuing Non-Compliance.

5.4.4 Serious Non-Compliance; Continuing Non-Compliance; Suspension or termination of the research by the sponsor, investigator, or institution; or Unanticipated Problem Involving Risks to Subjects or Others

5.4.4.1 Place on the agenda for the next available convened IRB meeting as an item of Serious Non-Compliance; Continuing Non-Compliance; Suspension or termination of the research by the sponsor, investigator, or institution or Unanticipated Problem Involving Risks to Subjects or Others.

5.4.5 Suspension or termination

5.4.5.1 If in your opinion the rights and welfare of subjects might be adversely affected before the convened IRB can review the information, contact the IRB chair to consider a Suspension of IRB Approval following the *IRB SOP: Suspension or Termination Issued Outside of Convened IRB*.

5.4.5.2 If the IRB votes for a Suspension or Termination of IRB Approval follow *IRB SOP: Suspension or Termination of IRB Approval by Convened Panel*.

5.5 If the notification involves a subject becoming a Prisoner in a study not approved by the IRB to involve Prisoners:

5.5.1 Confirm that the subject is currently a Prisoner.

5.5.1.1 If the subject is currently not a Prisoner no other action is required.

5.5.2 Consider whether stopping all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject until the subject is no longer a Prisoner would present risks to the subject.

5.5.2.1 If the subject's involvement in the research cannot be stopped for health or safety reasons, do one of the following:

5.5.2.1.1 Keep the subject enrolled in the study and review the research for involvement of Prisoners. If the research is subject to DHHS oversight, notify OHRP.

5.5.2.1.2 Remove the subject from the study and provide the study intervention as clinical care.

5.5.2.2 If the subject's involvement in the research can be stopped, inform the investigator that all research interactions and interventions with, and obtaining identifiable private information about, the now-incarcerated subject must be stopped immediately until the subject is no longer a Prisoner,

5.5.3 For US Department of Defense (USDOD) research, promptly report all determinations to the US Department of Defense (USDOD).

5.5.4 The US Department of Defense (USDOD) must concur with the IRB before the subject can continue to participate while a prisoner.

5.6 Take any additional actions required to resolve any concerns or complaints associated with the information.

5.7 If the information does not involve a Serious Non-Compliance; Continuing Non-Compliance; Suspension or termination of the research by the sponsor, investigator, or institution or Unanticipated Problem Involving Risks to Subjects or Others (UPIRSO), complete review and prepare and send letter per *IRB SOP: Post-Review Activities*.

6 MATERIALS

6.1 FORM: Reportable Event Submission Form

6.2 IRB SOP: Suspension or Termination Issued Outside of Convened IRB Meeting

6.3 IRB SOP: Suspension or Termination of IRB Approval by Convened IRB Meeting

6.4 IRB SOP: Post-Review Activities

6.5 IRB SOP: External Reporting Process

7 REFERENCES

7.1 45 CFR §46.108(3)(iii), 45 CFR §46.108(4)(i), (ii)

7.2 21 CFR §56.108(b)

7.3 32 CFR §219.103(b)(5), 32 CFR §219.113