SOP 11.04 – Suspension or Termination of Approved Research

1. Objective

This SOP describes the basic conditions and processes surrounding decisions made by the UNLV Institutional Review Board (IRB) to suspend or terminate approved research.

2. General Description

Under 45 CFR 46.113 (FDA 21 CFR 56.113) the IRB has the authority to suspend or terminate previously-approved research that has exhibited serious harm to subjects, and/or is not being conducted in accordance with IRB requirements, and/or is suspected /confirmed to be in noncompliance with applicable rules, procedures, and/or policies.

3. Roles & Responsibilities

Execution of SOP: Principal Investigators (PI)/Study Personnel (SP), IRB Chair, IRB, Office of Research Integrity – Human Subjects (ORI-HS) Staff.

The fully convened IRB, or IRB Chair acting on behalf of the IRB has the responsibility for reviewing problems (see SOP 11.01), or possible issues of noncompliance associated with approved research (see SOP 11.02).

The PI is responsible for reporting problems (see SOP 11.01), or possible issues of noncompliance (see SOP 11.02) approved research to the IRB. The PI is responsible for reporting to the IRB self-directed suspension or early termination of their research. Also, the PI has the responsibility to report to the IRB if an outside entity with the proper authority suspends or directs an early termination of the study (see SOP 11.01).

Definitions

Study Suspension - a temporary halt to IRB approval that includes a stop to the enrollment of new subjects, activities involving previously enrolled subjects, and other research activities.

Study Termination – a permanent end to IRB approval prior to study expiration that includes a permanent halt in the enrollment of new subjects, approved activities involving previously enrolled subjects, and other research activities.

4. Procedures

Suspension or Termination directed by the Principal Investigator or an outside entity must be reported to the ORI-HS in a timely or immediate manner as directed by SOP 11.01. UNLV IRB directed suspension or termination is discussed below.

In some instances, study suspension or early termination may have an adverse effect on currently enrolled or past subjects. Every effort will be made to reduce risk of harm to subjects or others resulting from suspension or termination. This may include corrective action directed to the Principal Investigator by the convened IRB that requires study-related activity during suspension, or after termination.

Suspension

The IRB Chair on behalf of the IRB, or IRB may suspend the approval of previously approved research if in their assessment: 1) study suspension will reduce or remove the likelihood of serious harm to subjects or others (See SOP 11.01), 2) the study is not being conducted in accordance with IRB requirements, or 3) there is suspected or confirmed noncompliance with applicable rules, procedures, and/or policies (See SOP 11.02). There must be sufficient evidence or just cause before a decision to suspend a study is made. The IRB Chair acting on behalf of the IRB may request more information, but should refrain from requesting corrective action. This will be documented in the study file and a formal notification will be sent to the Principal Investigator.

If a study is suspended, the associated incident(s) will be placed on the next Full Board agenda for further discussion. The convened IRB may direct a request for additional information, request corrective action such as, but not limited to, study modification, remove study suspension, terminate study approval. All determinations made by the convened IRB will be documented in the IRB meeting minutes (See SOP 12.02). A formal notification will be sent to the Principal Investigator, and a copy will be included with the study file.

Removal of Suspension

When a study is suspended, the convened IRB, may remove study suspension and reinstate IRB approval. The IRB must have sufficient and documented cause that concerns and issues raised during the initial suspension have been rectified. All determinations made by the convened IRB will be clearly documented in the IRB meeting minutes (See SOP 12.02). A formal notification from the IRB office will be made to the Principal Investigator, and a copy will be included with the study file.

Termination

The fully convened IRB may terminate the IRB approval of research if in their assessment study termination is the most favorable response to help prevent or reduce the likelihood of serious harm to subjects (See SOP 11.01), or if the study is confirmed to be in serious and/or continuing noncompliance with applicable rules, procedures, and/or policies (See SOP 11.02). There must be sufficient evidence or just cause before a decision to terminate a study is made. The determination to terminate study approval will be clearly documented in the convened IRB meeting minutes (See SOP 12.02). A formal notification will be sent to the Principal Investigator, and a copy will be included with study file.

Formal Notification

Formal notification of study suspension or termination issued to the Principal Investigator from the IRB office may include the following:

- An explanation of the extent of the suspension/termination in terms of enrollment, recruitment, interventions, interactions, and data analysis;
- The reason(s) for the suspension/termination, and a possible request for the investigator to respond to the convened IRB in writing;
- As appropriate, a request for an investigator-initiated corrective action plan intended to protect the rights and welfare of current subjects or others;
- A description of any IRB proposed corrective actions, or notice that none have been proposed at this time;
- Notice that the investigator may make an appeal;
- Additional language as may be directed by SOP 11.01, or 11.02.

Investigator Appeal
A Principal Investigator may appeal a decision to suspend or terminate their study. Provisions for making an appeal will be provided in the formal notice of suspension/termination from the IRB office. Appeals will be considered by the convened IRB. All efforts will be made by the IRB to assess a PI's appeal in a timely manner.

Considerations for Additional Reporting of Suspension or Termination
Where outside entities, regulatory agencies, and/or appropriate organizational officials are involved with the research, then additional reporting of study suspension, termination, or other actions taken during incident resolution may be required or desired and should seek to be made within 30 business days from the date of the notice. For UNLV researchers, it is highly recommended that you consult with the IRB office prior to making a report to outside entities.

Additional internal (within UNLV) reporting may also be desired or required. Additional reporting to other UNLV departments will be at the discretion of the ORI Executive Director.

In some instances, a formal notification to currently enrolled or past subjects may be warranted and will be considered on a case-by-case basis.

All decisions for internal or external reporting will be discussed with the convened IRB prior to reporting absent extenuating or unique circumstances.

5. References

21 CFR 56.113
45 CFR 46.113
UNLV Policy on Research Involving Human Subjects 2013
UNLV Rules and Procedures for Conducting Human Subjects Research, 4.1