# CHAPTER 8 Investigator Reporting

**Responsibilities**

After a research project is approved, there are many situations requiring communication with IREC during the conduct of the research. These communications result from events that unfold (and may or may not be expected) as the research is taking place. Investigators are required to submit reports or communication on: adverse events, unanticipated problems, changes, study continuing reviews, expiration of approval period, study completion, and terminations/suspensions. This chapter provides an introduction to each of these sections.

**REPORTABLE EVENTS: ADVERSE EVENTS AND UNANTICIPATED PROBLEMS**

After an Adverse Event or an Unanticipated Problem occurs, the principal investigator is required to submit a reportable event form as soon as possible to IREC. The principal investigator's report should contain enough information for IREC to determine whether the event increases the level of risk to participants, requires a research design change or necessitates modification to the informed consent form.

***Definitions***

**Adverse Events** are defined as 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.

**Serious Adverse Events** (**SAEs**) are those that: are fatal or life threatening, result in significant or persistent disability, require or prolong hospitalization, result in a congenital anomaly/birth defect, or in the opinion of the investigators, represent other significant hazards or potentially serious harm to research subjects or others.

**Unanticipated** or **Unexpected** refers to adverse events or other problems in the research, the specificity or severity of which is not consistent with the information already provided to the IREC, including the investigator's brochure, research protocol or consent form.

**Unanticipated Problems Involving Risks to Subjects or Others** (**UPX**) includes any incident, experience, or outcome that is unexpected, related or possibly related, and 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.

**CHANGES TO PREVIOUSLY APPROVED RESEARCH**

Any proposed change to a previously IREC approved research project must be submitted to and approved by IREC before the change is implemented, except when necessary to eliminate apparent immediate hazards to the subjects. Amendment submissions will be reviewed by the IREC Chair amd may require

review by the expedited review procedure or require review by the fully convened IREC depending on the assessment of associated risk. Typically, minor changes are reviewed and approved by the NU IREC Chair. Minor changes do not alter the risk/benefit ratio in previously approved research (e.g. correction of typos, adding PIs to the project, etc.).

All NU investigators proposing modifications to a previously approved human subject research project must submit an amendment application. The amendment application serves as a "form" that lists/details the proposed changes to the study. In addition to the amendment application, investigators must make the changes to the originally submitted new study application. In reviewing amendments, IREC analyzes whether the changes pose additional risks to subjects or represents a significant change in study procedures and may impose additional contingencies before approving the amendment.

**CONTINUING REVIEW**

In accordance with NU regulations, all non-exempt research protocols undergo continuing review at intervals appropriate to the degree of risk, but not greater than once per year. The frequency and extent of continuing review for each study is based upon the nature of the study, the degree of risk involved, the novelty of the research procedures, and the vulnerability of the study's subject population. After a careful consideration of each of these factors, each protocol is assigned an approval period, after which the study must be re-reviewed by IREC.

Each investigator must abide by the approval period imposed by IREC at the time of the most recent IREC approval. Each IREC approval notice designates a period of time during which activities involving human research subjects may be *undertaken*. No research project may continue to recruit, enroll, or treat subjects or analyze data after the IREC approval expiration date (except where doing so would cause harm to the subjects).

It is the investigator's responsibility to ensure that approval for an active protocol remains current.

**EXPIRATION OF APPROVAL PERIOD**

In the event that a protocol expires and the withdrawal of research interventions may place study subjects at risk, the investigator may request that IREC grant permission to allow the continuation of activities. If subject safety would be compromised by study closure, investigators can request that the IREC allow continuation of study activities for currently enrolled subjects. If research-related interventions have been continued with subjects on an expired protocol, IREC must be immediately informed of the circumstances that necessitated this action.

Requests justifying continuation of currently enrolled subjects will be forwarded to the IREC Chair for consideration. If the IREC Chair grants permission to allow the continuation of research interventions with previously enrolled subjects for reasons related to subject safety, the IREC will send written notification to

the investigator. Other research activities (such as recruitment, enrollment, data analysis, etc.) may only be resumed after the investigator receives continuing approval for the research.

**STUDY COMPLETION**

A research project is closed when subject accrual, subject follow-up and data analysis are completed at NU. Once a study is closed, no further research activity, including data analysis, may occur.

**TERMINATION/SUSPENSION OF A STUDY**

Termination is when IREC permanently withdraws approval of ALL research activities for a particular study. Terminated research is no longer required to undergo continuing review. The convened IREC, IREC Chair, and IREC Vice Chair (in the absence of the Chair) are authorized to suspend or terminate research. If there is an urgent situation requiring suspension or termination of a study, the IREC Chair or Vice Chair may make this determination. If the IREC Chair or Vice Chair terminates or suspends a study on his/her own, IREC is notified by the Chair at the next IREC meeting.

Suspension is when the IREC temporarily or permanently withdraws approval of some or all research activities. Suspended research is still under the jurisdiction of IREC.