

# Series 601 Reportable Events | Institutional Review Board

## Reportable Events from Series 601 of the Standard Operating Procedures

### I. Reportable Events

A reportable event is an occurrence or omission in the context of a human subjects research study which warrants communication with the Institutional Review Board due to one or more of the following:

- The event's unanticipated or harmful nature, or
- Because the event provides additional information about the risks or benefits of the project that were previously unaccounted for in the IRB's review of the protocol; or
- The event renders a reviewed and approved part of the protocol obsolete or inaccurate.

The types of reportable events are defined and discussed in this SOP, including timeframes for reporting to the IRB based on the appropriate categorization of the event.

### II. Deviations

Deviations are the most common type of Reportable Event. A Deviation is a notable variance from the procedures, processes, and/or activities associated with an approved or exempted protocol which does not indicate the existence of previously unknown or unapproved risks or benefits to participants. (An easy way to think about whether something is a Deviation is to consider whether it would have been approved as an amendment if it had been submitted before its occurrence.) Examples of common deviations include:

- Allowing CITI-trained research staff to serve as investigators on the study prior to IRB approval of the staffing change.
- Recruiting participants outside of the +15% threshold of the approved numbers of participants.
- Failing to submit a Status Report for an annual continuation review in time for the continuation review to be completed, but within one week of the protocol's expiration (for an un-funded research project).

When a Deviation is identified by a member of the IRB, the IRB member should request a Report Form from the Principal Investigator of the affected study. When a member of the research staff discovers a Deviation, they should submit a Report Form to the IRB.

### III. Reporting and Processing Deviations

Deviations must be submitted within 30 calendar days of their occurrence.

Deviation Reports are first processed by the HRP Coordinator who receives the Form. It is reviewed for accuracy, and sent to the HRP Director, IRB Chair, IRB Vice Chair, or to the Institutional Official (in that order of availability). If the report represents variances that are more than a Deviation (those categories are defined below), the report will be forwarded on to the IRB Chair or Vice Chair for a determination regarding next steps. In general, when the Deviation Report Form reports a Deviation, the Report Form is simply made available to the IRB for notice & comment at the next scheduled meeting, due to their low-risk nature. Once the IRB has had an opportunity for notice and comment, the Deviation Report Form is filed to the appropriate protocol file. If any follow up is needed, the HRP Office will reach out to the study team. When a Deviation represents an ongoing change, the study team should also file an amendment to the protocol to

secure approval of those ongoing changes. The Deviation Report only accounts for the time from when the Deviation first occurred to the time of the report to the IRB.

#### IV. Unanticipated Adverse Events & Unanticipated Problems

Occasionally, an Unanticipated Adverse Event (UAE) or Unanticipated Problem (UP) occurs during the conduct of research. Unanticipated Adverse Events are identifiable by the following three criteria, all of which must be met:

1. The event was unanticipated, meaning that the nature, severity, or frequency of the event is not consistent with the determinations and approvals in place at the time that the IRB approved it;
2. The event was adverse, meaning that the event was an untoward or unfavorable occurrence for one of your participants, including abnormal signs, symptoms, or outcomes.
3. The event is related or possibly related to participation in the study.

Unanticipated Adverse Events need to be reported to the IRB as soon as is feasible, and no later than five business days after the study team becomes aware of its occurrence. Upon submission to the IRB, the HRP staff should immediately route the report to the IRB Chair or, if unavailable, the Vice Chair. The first question the IRB Chair must address is whether the UAE constitutes a "serious" UAE. An Unanticipated Adverse Event is serious if it results in any of the following:

- Death;
- Placement of participants at immediate risk of death;
- Hospitalization or prolonged medical care;
- A persistent or significant disability/incapacity;
- A congenital anomaly or birth defect; or
- May jeopardize the participant's health and require further intervention to prevent one of the other outcomes listed here, including potential dependency on drugs (prescription or otherwise) or the potential for drug abuse.

Serious UAEs require the Convened IRB to gather to reconsider the protocol's risks. The IRB should convene as soon as possible for a Serious Unanticipated Adverse Event's consideration.

If the IRB Chair determines that the UAE is not serious, they must next determine whether the UAE suggests that the risks of participation are greater than were previously known. Generally, the IRB Chair will consult with another IRB member or colleague with relevant scientific expertise in order to make that determination. It is not unusual for a study to be paused while the IRB Chair consults with the appropriate personnel to render this determination. If so, a review of the protocol shall be re-initiated with a scientific reviewer whose scientific expertise aligns with the subject matter of the protocol to ascertain updated information about risks, benefits, alternative procedures, and informed consent.

Finally, the IRB Chair may implement interim measures regarding the study, in order to minimize the occurrence of future Unanticipated Adverse Events. The study team should propose, in the Unanticipated Adverse Event/Problem Report Form, what measure or future corrective action should be taken, if any. The UAE/UAP, along with all of the steps implemented by the IRB Chair and consultants, will be reported to the Convened IRB for further consideration at its next available meeting.

#### V. Noncompliance

**Noncompliance** is a failure (whether intentional or unintentional) to comply with applicable federal, state, or local laws or regulations; requirements or determinations of the IRB; or university policy regarding research involving human subjects. Noncompliance can be an action or an omission.

Any type of reportable event could constitute Noncompliance, but in most cases, the reportable event is disposed of via the processes outlined above. If the reportable event cannot be processed via the Deviation or Unanticipated Adverse Event processes, it will be processed as Noncompliance.

There are two avenues for processing Noncompliance, and the process undertaken depends on whether the Noncompliance is considered to be serious or continuing.

**Serious Noncompliance** is any noncompliance which, in the judgment of the IRB, places human subjects at elevated or unreasonable risk; decreases potential benefits to participants; jeopardizes the safety, welfare, or rights of research participants or others; compromises a research participant's ability to render informed consent; or compromises integrity of the human research protection program.

**Continuing Noncompliance** is any action or omission which, in the judgment of the IRB Chair or Convened IRB, demonstrates a pattern of noncompliance over time and/or across research projects. Such a pattern suggests that the likelihood of noncompliance will continue without intervention.

If the Noncompliance is minor (i.e. not serious or continuing), it is processed by the IRB Chair or the Institutional Official. An abbreviated investigation will take place, findings will be reported to the IRB Chair or IO, and that person will design a Corrective Action Plan.

If the Noncompliance is Serious or Continuing, an investigation will take place, and findings are submitted to the Convened IRB for consideration. The Convened IRB will render a final determination regarding the Serious or Continuing nature of the Noncompliance, and also designate a Corrective Action Plan. Serious or Continuing Noncompliance requires notification of the Noncompliance to institutional leaders, sponsors, and other parties as deemed relevant by the Convened IRB.

## VI. Suspension or Termination of Previously-Approved Research

The IRB Chair is authorized to suspend (defined as temporarily discontinuing) previously-approved human subjects research in order to minimize risks to participants or others while a Reportable Event is processed. The IRB is authorized to terminate (defined as permanently discontinuing) research in order to protect the rights and welfare of research participants and others. Suspension determinations shall be ratified by the membership of the IRB at the earliest possible opportunity.

Suspensions may be lifted if the resolution of the Reportable Event demonstrates that the research is safe and appropriate and, in light of any new information, all of the criteria for approval are still in place.

## VII. Reporting Prisoner-Participants

A "prisoner-participant" as used in this section refers to a participant who was not incarcerated when originally enrolled in the study, but became incarcerated during the term of their enrollment in the study. When this occurs, the PI should submit a Reportable Events form to the IRB within ten business days, indicating that a participant has become a prisoner-participant.

If the prisoner-participant is incarcerated temporarily (fewer than 30 days and prior to the end of the study), and the incarceration has no effect on the study, the investigator should plan to keep the prisoner-participant enrolled in the study, and the Convened IRB should support that determination if the risk analysis does not indicate otherwise. If the prisoner-participant's temporary incarceration does have an effect on the study, the Convened IRB must meet as soon as is practicable to determine whether the participant should remain in the study. At the next available meeting, during the Deviation Review portion of the agenda, the Convened IRB should render a determination regarding whether:

- The reported prisoner-participant is actually a prisoner under the DHHS regulations and guidance; and
- The prisoner-participant's enrollment should be terminated; or
- Whether the protocol should be reviewed under Subpart C and a Prisoner's Checklist completed.

The prisoner-participant's participation should not be terminated if the risks associated with termination indicate that remaining in the study is in the prisoner-participant's best interests. If the participant does need to be removed from the study, investigators should explore ways to keep the participant on the intervention, if possible, using non-research

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means of doing so. If termination should not take place due to health or safety reasons, the protocol must be reviewed under Subpart C, and determinations on the Prisoner's Checklist rendered by the Convened IRB, and with the Prisoner's Advocate present.

If the Convened IRB determines that the participant should remain in the study but not all requirements of Subpart C can be met, the HRP Director shall inform the Office for Human Research Protections of the decision and the justification for the decision, in writing, no more than ten business days following the meeting of the Convened IRB.