AURORA RSPP GUIDANCE DOCUMENT: SUBJECT NONCOMPLIANCE VS. REPORTABLE NONCOMPLIANCE

This guidance serves to provide the RSPP’s position with regard to the distinction between reportable noncompliance and subject noncompliance (not reportable as noncompliance per Aurora RSPP SOP 601).

Per SOP 601, subject noncompliance is not a reportable noncompliance event. But what constitutes subject noncompliance?

It is the Aurora RSPP’s position that subject noncompliance occurs when an event is controlled by the subject or their situation. Little can be done on the part of the research team to rectify the event or prevent it from occurring. The following are some examples of subject noncompliance, proposed by the Aurora RSPP, that may not need to be reported per SOP 601:

- the subject is a “no-show” at a scheduled study appointment;
- the subject calls the research team the morning of a study visit, and states that he/she cannot make the visit because they have car trouble or there is a snow storm that prevents him/her from getting to the appointment;
- the subject is hospitalized and cannot make their scheduled appointment;
- the subject chooses not to complete a research test/procedure [e.g. doesn’t update their study diary, or refuses to return it at the end of the interventional period; the subject does not schedule a protocol-required eye exam; he/she refuses to have blood drawn or do another 6 minute walk test, etc.];
- the subject does not take their investigational agent as instructed by the study team.

The sponsor/IRB is expecting the approved research protocol to be followed. Therefore if there is an opportunity for the research team to take action following notification by the subject to negate any possible noncompliance – for example, rescheduling an appointment within the study defined window so that the subject visit is not “out of window” – this should be done.

However, we know that conflicts/issues can occur in research which may make deviations of the approved protocol a necessity/reality. The Aurora IRB has provided a mechanism – the protocol exception – to obtain advanced approval of an individual subject change which would prevent a reportable instance of noncompliance. The sponsor’s approval of the protocol exception must occur prior to requesting the protocol exception of the Aurora IRB.

We acknowledge that some sponsors do not allow for individual subject protocol deviations from the approved protocol. In those cases, any deviation from the approved protocol would need to be processed by the study team as outlined in RSPP SOP 601.

In summary, if the IRB approved sponsor’s protocol cannot be followed, the study team’s options are to:

1) request of the sponsor/Aurora IRB for a protocol exception for the individual patient event before the event occurs (under SOP 403), OR
2) submit the event as reportable research noncompliance under SOP 601.

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**REMEMBER**

- Not all IRBs allow for Protocol Exceptions. If your study is ceded to an IRB other than the Aurora IRB, please seek out their specific policy on study noncompliance. The Aurora RSPP process for protocol exceptions may only be used when the Aurora IRB is the IRB of record for your study.

- Subject noncompliance is not reportable under Aurora RSPP SOP 601. However, instances of subject noncompliance must be considered for reporting as an Unanticipated Problem under RSPP SOP 410.
  - Per RSPP SOP 410, **ONLY** if the investigator determines that the subject noncompliance more likely than not meets the criteria of a local UP/UIRSE should the event be reported using Aurora RSPP Form 410 (Unanticipated Problem Reporting form).