RSPP/IRB – Noncompliance Reporting During COVID-19 Pandemic

Revised June 3, 2020

While restrictions on the conduct of human subjects research at Advocate Aurora Health have been lifted (as of June 2, 2020), the changes in noncompliance reporting will remain in effect until June 30, 2020, at which time reporting per SOP 5 will again resume.

During the COVID-19 pandemic, and while AAH restrictions are in place for the conduct of human subject research at AAH, the AAH RSPP has taken the following measures to reduce the number of noncompliance events that must be reported to the AAH RSPP no later than 10 days of discovery. In order to eliminate the need for reporting of noncompliance events it is recommended that the study investigator and/or sponsor temporarily revise the research protocol to modify study activities that cannot/will not occur. Otherwise any action that does not follow the IRB approved protocol is an incidence of noncompliance.

During this interim period, an incidence of protocol noncompliance does not need to be reported within 10 day of discovery to the RSPP unless it:

- Negatively impacts the risks to subjects,
- Has a negative effect on study integrity
- Or is an instance of continuing noncompliance that is not related to institutional measures taken to minimize risks to subjects during the COVID-19 pandemic.

Example – DO immediately submit to the RSPP incidents such as:

- One or more participants withdrawn from IP without tapering
- Missed study treatment/dosage(s)
- Safety visits/procedures will not be conducted because facility is closed or institutional mandates do not allow for the test/procedures/labs to be done.

Example – No need to immediately submit to the RSPP incidents such as:

- Patient visits out of window due to self-quarantine.

NOTE noncompliance events that do not require immediate reporting during the pandemic must still be reported to the AAH RSPP – but may be done so as a group. Unreported protocol noncompliance should be tracked and reported on a monthly basis within 10 days of the end of the month until the AAH human subject research restrictions related to the COVID-19 pandemic have been lifted.

The noncompliance reporting log should be study specific and should include the following information for each reported event: date of occurrence, subject ID number, brief statement of the type of noncompliant event, an explanation as to why the noncompliance did not increase the risk of harm to the subject OR have a negative impact on the research study. The RSPP will review the log and acknowledge its receipt. This acknowledgement
will be returned to the submitter. **Once the AAH HSR restrictions are lifted, normal noncompliance reporting per RSPP SOP #5 will resume.**

As always, incidents of noncompliance initiated by the subject do not need to be reported to the RSPP.

In summary, it is expected that the PI will review all incidents of noncompliance and determine/report within 10 working days of discovery those incidents which negatively impact the research subjects, negatively impact the integrity of the research study or are instances of Continuing Noncompliance. Those incidences of noncompliance that do not meet these interim reporting criteria may be reported monthly by study in a group format/log. This requirement is in effect for studies overseen by the Aurora/Advocate IRB as well as those ceded to an external IRB.