



MOUNT SINAI
SCHOOL OF
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Mount Sinai Medical Center Program for the Protection of Human Subjects E-Newsletter

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[Adverse Event Reporting POLICY AND FORMS CHANGE](#)

The PPHS has significantly revised its adverse event reporting policy and forms, and the changes go into effect immediately. The implications of the new policy are:

- 1) The number of adverse events that investigators must report to the IRB will be significantly reduced;
- 2) Data Safety Monitoring Plans will take a more central role in determining the scope and nature of adverse events to be captured and analyzed;
- 3) Clinical research sponsors will need to be notified by investigators that information related to external events that do not have an impact on the assessment of risk or result in changes to the research (i.e. protocol or consent) will no longer be accepted by the IRB;
- 4) IRB submission requirements for annual reports of adverse events have been modified to better assist in the annually assessment of risks to the human subjects.

The new policy can be found at http://www.mssm.edu/pphs/docs/IRB10_PolicyAE.doc and hard copies will be available in the PPHS office.

Internal vs External Events

The most impactful change is a new distinction between internal events and external events. Most external events will no longer be reported to the IRB unless they have an impact on the study itself, while internal events will still need to be reported if they meet certain criteria (please see policy for specifics). Therefore, the adverse event reporting form has been modified and is now called the Internal Adverse Event/Unanticipated Problem Report form (located at http://www.mssm.edu/irb/docs/IRB10_internal_AEUP_form.doc; Form #10).

Relatedness

Another change is an expanded clarification on the topic of “relatedness” (the relationship of adverse events to the research study). This is important since, except in the case of deaths occurring during a study, an adverse event will only need to be reported to the IRB now if it is related (at least “possibly related”) to the research study. See the policy at: http://www.mssm.edu/pphs/docs/IRB10_PolicyAE.doc for further details.

Unanticipated Problems

A new distinction made in the policy is the difference between “adverse events”, which are generally defined as untoward medical events, and “unanticipated problems”. Guidance is now provided that indicates what kinds of unanticipated problems must also be reported to the PPHS. An example of an unanticipated problem is the loss of sensitive identifiable research data; it is not an untoward medical event, but it is an unanticipated situation that has the potential for increasing the risk of harm to subjects (in this case, to subject privacy and data confidentiality). Unanticipated problems can be reported on the Internal Adverse Event/Unanticipated Problem Report form #10 (located at http://www.mssm.edu/irb/docs/IRB10_internal_AEUP_form.doc). Please see the policy for further details.

Deaths on Protocol

There is a new form specifically designed for reporting deaths. Deaths that occur as internal research study events, regardless of expectedness or relatedness to the protocol, must be reported within 24 hours of the investigators being notified of the event. Unless the previously IRB approved data safety monitoring plan specifically makes provision for the non-reporting of such deaths. The form is called the Death on a Protocol Report Form, located on our website at: http://www.mssm.edu/pphs/docs/IRB101_ROD_report.doc (Form #10.1).

Reporting Timeframe

The timeframe for reporting of adverse events and unanticipated problems has been modified. Internal events that are serious, unexpected, and related (or possibly related) must be reported as soon as possible, but no later than 5 working days / 7 calendar days after the investigator is notified of the event. Internal events that are non-serious, unexpected, and related (or possibly related) must be reported as soon as possible, but no later than 20 working days / 30 calendar days after the investigator is notified of the event. Deaths must be reported within 24 hours after the investigator is notified of the event. Please see the policy for details, at our website location: http://www.mssm.edu/pphs/docs/IRB10_PolicyAE.doc.

Annual Adverse Event Reporting

Due to the modified reporting requirements, the *Annual* Adverse Event Report Form has also been revised. That form (IRB Form #5) can be found in its standard location on our website at http://www.mssm.edu/pphs/docs/IRB5Annual_AE_report.doc. The requirements for what information needs to be submitted at the time of a continuation are referred to in the policy.

Making the Transition

The new reporting requirements are in effect immediately. Industry sponsors who require submission of adverse events for which Mount Sinai's PPHS no longer requires submission should be provided with a copy of the official policy.

If you have further questions after reviewing the policy and forms, please contact the PPHS office.