Reporting Unanticipated Problems to Quorum IRB

Step 1:
Unanticipated Problem Defined

Any event that meets all three criteria:

UNEXPECTED
The nature, severity, or frequency of the event is not described in protocol-related to documents (e.g. protocol, consent, Investigator's Bochure).

RELATED OR POSSIBLY RELATED TO PARTICIPATION IN THE RESEARCH
There is a reasonable possibility that participation in the research caused the event.

GREATER RISK OF HARM
Places research participants or others at greater risk of harm than previously known or recognized.

Participants or others experience or could have experienced physical, psychological, economic, or social harm as a result of the event.

Step 2:
Reporting Explained

All unanticipated problems must be reported to Quorum Review in the following manner:

PROMPTLY
Report all unanticipated problems no later than 10 business days of becoming aware of the event.

UTILIZING THE PROPER FORM
Report all unanticipated problems utilizing Quorum's Unanticipated Problem Report Form:

www.QuorumReview.com/sites/safety-reporting/form

Do Report:

- Serious adverse events probably related to the study product (such as unexpected worsening of the underlying disease condition; anaphylactic reaction resulting from improper dosing of study drug; neutropenic fever resulting from study drug administration)
- Major protocol deviations (such as significant dosing error; study procedures initiated before informed consent; failure to perform required laboratory test)
- Miscellaneous events, including adverse audit findings from a sponsor or agency; unfavorable publication in literature; unresolved participant complaints; breach of confidentiality (including loss of a laptop with study data); problem involving control of study product (e.g., lost shipment of study drug); research personnel misconduct
- SUSAR reports; IND Safety Letters; or CIOMS reports that report serious unexpected adverse events probably related to the study product

Do NOT Report:

- Serious illness or injury unrelated to the study product (such as a car accident)
- Minor adverse events (such as a minor headache)
- Expected adverse events (such as an expected worsening of the underlying disease condition)
- Minor protocol deviations (such as an insignificant delay in performing study procedure; minor window violation; failure to initial every page of a consent form; participant failure to return study diaries)

Additional Examples
For more examples, please see the Office of Human Research Protections (OHRP) Guidance titled: *Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events*
www.hhs.gov/ohrp/policy/advevntguid.html

Contact us at ClientSupport@QuorumReview.com for more information.

qid.174.3.16

More Information Available

For more information on reporting unanticipated problems check out the following:

Understanding Reporting Obligations to the IRB

http://youtu.be/fCZX6TLXI84

Quorum Website: Safety Reporting

QuorumReview.com/sites/safety-reporting

Quorum's Researcher Handbook (ch. 6)

Current Quorum Review OnQ Portal users may access this comrehensive document through their account. Non-Portal users may receive a copy of the Hanbook by calling (206) 448-4082.

Quorum's Help Desk

Quorum has experienced staff available, 8am to 8pm EST, to answer questions about unanticipated problems and reporting.

Call (206) 448-4082

Contact us at ClientSupport@quorumreview.com for more information.

qid.174.3.16