



JOHNS HOPKINS  
M E D I C I N E

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## MEMORANDUM

TO: JHM IRB Chairs & Co-Chairs

FROM: Michael J. Klag, MD, MPH *mjk*

DATE: November 3, 2003

SUBJECT: Event Reporting Policy

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Thank you for all of your help and advice in developing the revised Event Reporting policy. I greatly appreciate the points raised in the chairs' meetings, the revisions provided to the many drafts that have been circulated, and your attention to detail. We have, I think, produced a document that provides clearer guidance to faculty. Attached is a final version that will be posted on the website by November 7, 2003. Please circulate it to the members of your IRB. At the chair meeting scheduled for 11/14/2003, Joanne Pollak would like to review implementation of the policy by the IRBs.

The new policy addresses three important points:

- Observational studies are now defined and the reporting requirement for them is explained.
- Definitions are provided for categories of reportable events, along with reporting time lines.
- For the first time, faculty will have information about protocol deviations and how they should be reported.

This document is not perfect and does not address all of the nuances that arise in discussion of individual protocols and appropriate reporting requirements. The previous policy, however, was outdated and it is very important that we have an up-to-date policy posted on the IRB web. The new policy is a starting point for collection of feedback from the user community. I would like to discuss it again in six months to see how well it is understood by faculty and their research staff, how it is applied by the JHM IRBs, and how well it works for the P&T reviewers.

Thanks again for your help.