



PUBLIC RESPONSIBILITY IN
MEDICINE AND RESEARCH

On behalf of PRIMR and ARENA we thank you for the opportunity to share thoughts, concerns and suggestions regarding the handling of adverse events in human research.

The goals are obvious:

Individual research participants reasonably expect that research is monitored for safety and that they will be informed of all relevant details and risks during the course of the research.

Investigators must clearly understand and fulfill their responsibility for evaluating as well as reporting adverse events.

IRBs must feel comfortable that they are in timely receipt of information that may alter risk assessment or require re-contacting participants to ascertain their willingness to continue in the research. The information must be reliable, relevant, useful and presented in a comprehensive and comprehensible format.

But – meeting these goals is difficult. Current regulations are riddled with inconsistent language and inconsistent requirements that foster confusion and can lead to under as well as over-reporting. The system needs improvement – hence this hearing. David Borasky has presented responses to the specific questions posted. I would like to add a few brief comments that embellish these responses.

First the need for harmonization:

Today the focus is FDA regulated research – but the topic of adverse event reporting does not respect that boundary. Study participants expect the same level of protection regardless of regulatory assignment to the FDA or the Common Rule. IRBs should not have to tier the level of protection as a function of specific regulatory construct. Please keep in mind that IRBs can best protect subjects if allowed to implement uniform definitions and rules for all research. Please harmonize – not only between the different centers at FDA – but between the relevant federal agencies as well.

Second - make certain the solution fits today's heterogeneous research paradigm. While the challenges of multi-center research with numerous sites, numerous investigators and numerous IRBs scream for attention, remember, single-site investigator-initiated protocols still exist. Adverse events will occur in all research models – any solution must respect and be applicable to the entire spectrum.

Finally – make proposed solutions achievable – please consider the logistics and the necessary resources. For example, if more Data Monitoring Committees will be required – consider the fact that even now, investigators have difficulty identifying people willing to serve on DSMBs or even to serve in lesser oversight roles. If more independent monitoring is required - how will these people be found? Be paid? Be vetted as free of conflict of interest?

On behalf of PRIMR and ARENA – we thank you for the opportunity to discuss this with you today – and we welcome the opportunity to work with you in the development of new guidance, policies or regulations.

Respectfully Submitted,

A handwritten signature in black ink that reads "P. Pearl O'Leary".

Chair, Board of Directors
Public Responsibility in Medicine and Research

