



Editorial Statement
Investigation of Clinical Trials by Joachim Boldt

February 22, 2011

To our readers:

Landesärztekammer Rheinland-Pfalz (LÄK-RLP), the State Medical Association of Rheinland-Pfalz, Germany, has announced the first results of a review of the papers published by Professor Joachim Boldt. The ethics committee of LÄK-RLP serves as the Institutional Review Board (IRB) for clinical research at Klinikum Ludwigshafen, where Professor Boldt's recent research was conducted.

According to its announcement, LÄK-RLP has reviewed 74 published articles and 1 PhD dissertation describing clinical trials subject to the requirements of the German Medicinal Act. By law in Germany these studies required IRB approval. Although the articles typically stated that IRB approval had been obtained, LÄK-RLP could not find evidence of approval for 68 of these articles, nor for the PhD dissertation.

LÄK-RLP also identified 30 published articles that describe research that did not fall under the jurisdiction of the German Medicinal Act. If the human research does not fall under the German Medicinal Products Act, physicians must conform to the Code of Deontology, which includes a requirement for IRB review of all human research. Some articles describing epidemiological studies with non-identifiable data did not require ethical review. For six articles LÄK-RLP was able to document ethical approval. For the remaining articles LÄK-RLP has not been able to document IRB review.

LÄK-RLP has stated that it has again contacted and asked the authors of published articles for which LÄK-RLP cannot document IRB approval to provide evidence of such approval. LÄK-RLP is presently awaiting documentation of IRB approval from the first/corresponding author of every questioned article before making a final determination. LÄK-RLP will notify the respective journals of articles describing clinical research for which there is no evidence of IRB approval.

On behalf of *Critical Care Medicine*, we affirm the commitment stated in our Guide for Authors to the ethical conduct of research. Human research without IRB approval is unethical. The LÄK-RLP investigation is ongoing, and we await the announcement of its final results. If LÄK-RLP conclusively identifies any clinical studies published in our journal that were conducted without IRB approval, those articles will be retracted.

We extend our appreciation to LÄK-RLP for their review of the status of IRB approval for Professor Boldt's research..

This notice will appear on our web site.

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