

Editors-in-Chief Statement Regarding IRB Approval of Clinical Trials by Joachim Boldt

February 4, 2010

To our readers:

Landesärztekammer Rheinland-Pfalz ("LÄK-RLP"), the State Medical Association of Rheinland-Pfalz, Germany, today announced the first results of a review of the papers published by Prof. 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.

Based on today's announcement, LÄK-RLP has reviewed 74 scientific articles describing clinical trials subject to the requirements of the German Medicinal Act. This includes the article by Professor Boldt recently retracted by *Anaesthesia & Analgesia* and an article submitted by Professor Boldt to *Anaesthesia* but not published. By law 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.

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

LÄK-RLP 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.

We, the undersigned Editors-in-Chief, on behalf of our Editorial Boards, affiliated societies, and publishers, affirm the commitment stated in our respective Guide for Authors to the ethical conduct of research. Human research without IRB approval is unethical. If LÄK-RLP identifies clinical studies in our respective journals that were conducted without IRB approval, those articles will be retracted.

Retraction for lack of IRB approval does not address whether the published research was compromised by data fabrication, manipulation, or misrepresentation. A separate investigating committee at Klinikum Ludwigshafen is assessing the integrity of Professor Boldt's published research. We will retract any article for which the data are found to be fraudulent.

We extend our appreciation to LÄK-RLP for their review of the status of IRB approval for Professor Boldt's research and to the investigating committee at Klinikum Ludwigshafen for their ongoing review of his research findings.

On behalf of our respective journals,

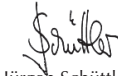


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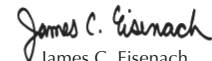
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