



Research standard violations

Case study 1

Source: Committee on Publication Ethics, [Case 04/38](#)

Consent and ethics approval questioned after acceptance

In a paper detailing a physiological study of healthy human volunteers the authors stated that ethics committee approval had been granted and that the participants had given informed consent. After peer review the paper was revised and accepted.

During the production phase the journal received an email from a researcher who was reviewing another paper from the same authors for a different journal. The reviewer had been sent the draft of the "paper in press" to provide additional information for the submission being reviewed. The reviewer was concerned that both studies were unethical on the grounds that the preparation being administered to the volunteers was insufficiently pure and had not been previously tested thoroughly in animals.

The editors asked for clarification and also sought a translation of the consent form. The authors provided further verification from the ethics committee, and argued that the animal testing was not a legal or ethical requirement at the time of their study. The reviewer and authors still disagree. The consent form seems to lack information on potential side effects, but the authors' previous preliminary research had not revealed any adverse reactions.

Discussion

- This warrants further investigation.
- It may be helpful to find more referees in this area and subject the paper to further peer review.
- The Editors' Code of Conduct emphasises that even with ethical approval, a study may not be ethical.

Action

- Write to the editor of the other journal outlining the concerns.

Outcome

Unknown to COPE.