

## Tanggung jawab hukum tenaga medis dalam menerapkan tindakan medis tanpa uji klinik = Legal responsibilities of medical personnel in implementing medical treatment without clinical trial

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### Abstrak

#### <b>ABSTRACT</b><br>

Dalam ilmu kedokteran, demi tercapai keselamatan pasien maka tindakan medis harus sesuai dengan evidence based medicine (EBM) berdasarkan uji klinik. Namun, kerap kali tenaga medis menerapkan tindakan medis tanpa uji klinik. Penelitian ini bertujuan untuk membahas mengenai pengaturan dan penerapan uji klinik terhadap tindakan medis, serta pertanggungjawaban hukum tenaga medis yang melakukan tindakan medis tanpa uji klinik ditinjau dari hukum kesehatan Indonesia. Penelitian ini menggunakan metode penelitian yuridis-normatif, dimana menitikberatkan pada studi kepustakaan sebagai data utamanya serta wawancara dan studi dokumen yang berfungsi untuk melengkapi serta menunjang data kepustakaan. Hasil penelitian ini bersifat deskriptif analitis. Dalam hukum positif Indonesia, belum ada pengaturan mengenai penerapan uji klinik terhadap tindakan medis secara khusus. Adapun pedoman penerapan uji klinik terhadap tindakan medis ialah International Conference on Harmonization-Good Clinical Practice (ICH-GCP) yang tidak memiliki kekuatan hukum. Tenaga medis yang melakukan tindakan medis tanpa uji klinik, maka ia telah melakukan pelanggaran disiplin karena tidak bertindak sesuai standar profesi kedokteran, pengetahuan, pengalaman, dan kualifikasinya. Sehingga, diperlukan pengaturan secara khusus mengenai uji klinik terhadap tindakan medis serta diperlukan perubahan atas sifat Majelis Kehormatan Disiplin Kedokteran Indonesia yang sebelumnya bersifat pasif menjadi aktif agar dapat mengusut penerapan tindakan medis tanpa uji klinik sebagai pelanggaran disiplin, meskipun tidak ada pengaduan sebelumnya.

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#### <b>ABSTRACT</b><br>

In medical science, in order to achieve patient safety, medical treatment must be in accordance with evidence based medicine (EBM) based on clinical trials. However, often medical personnel apply medical treatment without clinical trials. This study aims to discuss the regulation and application of clinical trials on medical treatment, as well as the legal responsibility of medical personnel who carry out medical treatment without clinical trials in terms of Indonesian health law. This study uses a juridical-normative research method, which focuses on the study of literature as the main data as well as interviews and document studies that serve to supplement and support library data. The results of this study are descriptive analytical. In Indonesian positive law, there are no regulations regarding the application of clinical trials to medical treatment specifically. The guidelines for the implementation of clinical trials on medical measures are the International Conference on Harmonization-Good Clinical Practice (ICH-GCP) which has no legal force. Medical personnel who carry out medical actions without clinical trials, they have committed disciplinary violations because they do not act according to medical professional standards, knowledge, experience, and qualifications. Thus, special regulation are needed regarding clinical trials of medical treatments and changes the trait of the Indonesian Medical Disciplinary Board (MKDKI) are needed from passive to active,

in order to be able to investigate the application of medical treatment without clinical trials as disciplinary violations, even though there were no previous complaints.