Informed Consent bagi Manusia yang Menjadi Subjek Eksperimen Medis (Studi Informed Consent di IMERI FK UI) = Informed Consent for Humans Becoming Medical Experiment Subject (Informed Consent Study at IMERI FK UI)

Firyal Arva Orvala, author

Abstrak

Skripsi ini mengkaji pengaturan informed consent di Indonesia terhadap manusia yang menjadi subjek eksperimen medis, perlindungan hukum atas risiko dan dampak yang ditimbulkan pada manusia sebagai subjek eksperimen medis, dan aturan pelaksanaan eksperimen medis pada Indonesian Medical Education and Research Institute (IMERI) Fakultas Kedokteran Universitas Indonesia. Menggunakan metode yuridis-normatif, dengan tipe penelitian deskriptif, data penelitian dikumpulkan melalui data sekunder yang terdiri dari bahan hukum, dan data primer melalui wawancara mendalam dengan IMERI FK UI. Simpulan penelitian ini adalah: pengaturan informed consent di Indonesia terhadap manusia yang menjadi subjek eksperimen medis terdapat pada Undang-Undang Nomor 36 Tahun 2009 tentang Kesehatan, Peraturan Pemerijntah Nomor 39 Tahun 1995 tentang Penelitian dan Pengembangan Kesehatan, Keputusan Menteri Kesehatan Nomor 1333/Menkes/SK/X/2002 tentang Persetujuan Penelitian Kesehatan terhadap Manusia, dan Peraturan Menteri Kesehatan No 657 tahun 2009 tentang Pengiriman dan Penggunaan Spesimen Klinik, Materi Biologik dan Muatan Informasi. Bentuk perlindungan hukum atas risiko dan dampak yang ditimbulkan pada manusia yang menjadi subjek eksperimen medis adalah bentuk perlindungan hukum perdata, pidana, dan administrasi. Adapun aturan pelaksanaan eksperimen pada IMERI FK UI merujuk pada konvensi internasional, peraturan perundang-undangan nasional, etika penelitian kesehatan, prosedur good clinical practice, serta Joint Commission International, dan Human Research Subject Program. Penelitian ini menyarankan, gagasan general informed consent dapat ditindaklanjuti oleh para pihak terkait

.....This thesis examines the regulation of informed consent in Indonesia for humans who are subject to medical experiments, legal protection of risks and impacts caused to humans as subjects of medical experiments, and the rules of conducting medical experiments at the Indonesian Medical Education and Research Institute (IMERI) Faculty of Medicine, University of Indonesia (FK UI). Using juridical-normative methods, with descriptive research type, research data was collected through secondary data consisting of legal material, and primary data through in-depth interviews with IMERI FK UI. The conclusions of this study are: the regulation of informed consent in Indonesia for humans who are subjected to medical experiments is contained in Law Number 36 of 2009 concerning Health, Government Regulation Number 39 of 1995 concerning Health Research and Development, Minister of Health Decree Number 1333 / Menkes / SK / X / 2002 concerning the Approval of Health Research on Humans, and Minister of Health Regulation No. 657 of 2009 concerning the Delivery and Use of Clinical Specimens, Biological Materials and Information Contents. The form of legal protection for risks and impacts caused by humans who are the subject of medical experiments is a form of legal protection for civil, criminal and administrative matters. The rules of conducting experiments on the IMERI FK UI refer to international conventions, national legislation, health research ethics, good clinical practice procedures, as well as the International Joint Commission, and the Human Research Subject Program. This research suggests, the idea of general

informed consent can be followed up by related parties