

招聘講演

南アフリカにおける臨床研究の倫理と規制*¹

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Ethics and regulations of clinical research in South Africa

Translated by Chieko Kurihara

National Institute of Radiological Sciences, National Institute
for Quantum and Radiological Science and Technology**Abstract**

This is the record of lecture of Professor Ames Dhai, at the seminar titled “Japanese new law on clinical research and human research ethics in South Africa: Development and ethical partnership toward global health”, organized by “Clinical Research Risk Management Study Group”, co-organized by “Clinical Evaluation (Rinsho Hyoka Kankokai Inc.)”, supported by “Japan Pharmaceutical Industry Legal Affairs Association (JPILA)” and “Japanese Association of Pharmaceutical Medicine (JAPhMed)”. The seminar was held on September 29, 2016, at Venue: Mitsui Sumitomo Insurance, Tokyo, Japan.

She introduced her contribution to set up the Centre with the name of Steve Biko, a prominent human rights activist, who was killed at 31 years of age, in the apartheid regime, as he struggled for “black consciousness” and establishment of equality and freedom of black people.

After the abolishment of apartheid in 1994, South African Constitution was established. It defines the “Bill of Rights” which clarifies that everyone has the right to bodily and psychological integrity, including the right not to be subjected to medical or scientific experiments without their informed consent. This is based on the United Nation’s International Covenant on Civil and Political Rights as agreed in 1966.

She also introduced South Africa’s regulatory framework of research ethics to protect human and animal research subjects, including ICH-compatible GCP regulations for clinical trials. Her lecture provided much of insights and wisdom for the Japanese to learn true meaning of ethics, human rights and research regulations in the international context.

Key words

bioethics, human rights, South Africa, apartheid, clinical trial

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*¹ 本稿は、「日本における臨床研究法と南アフリカにおける臨床研究規制・研究倫理—グローバル・ヘルスに向けた研究開発と倫理的なパートナーシップ—」と題するセミナーでのAmes Dhai教授の講演「南アフリカにおける臨床研究の倫理と規制」の記録の和訳である。セミナーは、臨床研究リスク管理研究会主催、臨床評価刊行会共催、医薬品企業法務研究会及び日本製薬医学会の後援により、2016年9月29日(木)、三井住友海上駿河台ビル(東京)において、開催された。原文は以下。Dhai A. Ethics and regulations of clinical research in South Africa. *Rinsho Hyoka (Clin Eval)*. 2017 ; 45 (3) : W15-35. Available from : http://cont.o.oo7.jp/45_3/w15-w35.pdf