

Dialogue 6

Informed Consent or Informed Contract?

Hans-Martin Sass, PhD

Georgetown University

Noon, Friday, April 17, 2009

Sylvester Comprehensive Cancer Center, Room 1301

—————→ NO lunch will be provided – Bring your own lunch. ←————
(No RSVPs required)

Progress in medical and genomic knowledge, the growth of transnational multi-center studies and the globalization of drug trials call for a review of existing regulatory frameworks in clinical research. New models for developing and approving individualized drug therapies need to be tested and new forms of partnership between physicians and patients, probands, investigators, sponsors, and oversight and regulatory bodies have to be tested for liability-sharing and benefit-sharing. One might be considered to replace the soft-paternalistic model Informed Consent with a more adequate model of Informed Contract. A look at Pre-Nuremberg Code 1900 Prussian and 1931 German Guidelines might help to illuminate our models of regulation, liability and risk-and-benefit communication.

Hans-Martin Sass, PhD, is a Founder and Member of the Center for Medical Ethics, Ruhr University, Bochum, Germany, since 1986; he is also a Senior Research Scholar at the Kennedy Institute of Ethics at Georgetown University, Washington DC and holds academic positions in China, where he teaches regularly.

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