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Nordic Committee on  
Bioethics

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## Informed consent - in whose interest?

Mini Symposium in connection with VIII Annual Symposium on  
Biomedicine, Ethics and Society: *"Rethinking Informed Consent: The limits  
of autonomy"*

13.6.2006, Sandham, Sweden

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### **Informed consent: implementation controversies**

The presentation focuses on the results of anonymous survey on informed consent conducted in 2001 in Lithuania. A test case of placebo controlled double blind (PCDB) clinical trial has been chosen to check if patients participating in the trial understand its study design and main goals. The survey has revealed a rather strong discrepancy between what we might call practice and "theory" of informed consent in clinical trials. For example, it appeared that the fact that some of the participants of the PCDB trial receive a new drug while others receive the substance without any pharmaceutical activity (placebo) was understood by only one third of research participants.

The following issues seem to be important for the further discussion. First, are the problems revealed by the survey also important to Nordic and Western European countries or do they rather reflect a particular socio-cultural background of European transition society that has rather recently started to implement international research ethics guidelines? Second, how should the implementation of informed consent be interpreted in a broader context of normative issues (e.g., risk/benefit ratio, conflict of interests, etc.) and how are these issues integrated in the ethical review of biomedical research?