
VIII Annual Symposium on Biomedicine, Ethics and Society: "Rethinking Informed Consent: The limits of autonomy"

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Valid informed consent possible in phase II cancer clinical trials?

One of the ethical pillars of human subject research is informed consent. According to all regulations with respect to human subject research, subjects need to give consent before participating in medical experimental research. The doctrine of informed consent comes from the medical-ethical principle of respect for autonomy. In this paper I will address the meaning of respect for autonomy for medical experimental research with cancer patients, the conditions that have to be fulfilled in order to speak about "valid" consent, and whether valid consent of patients who are offered Phase II cancer clinical trials is possible and feasible. The significance of the risk benefit assessment by IRB members of phase II cancer clinical trials for informed consent by patients, is discussed by presenting own empirical data of 53 IRB members of six academic hospitals and specialized cancer centers in the Netherlands. Also, own empirical data are presented on whether IRB members know how patients come to decide whether to give their consent.

The conclusion is that there are reasons to question the validity of the consent by cancer patients who are offered phase II cancer clinical trials. Not only is it questionable whether patients – considering their illness and the other dependencies they are in (family pressure, physicians etc.) – are able to decide autonomously and in freedom what they want. It also remains questionable whether making an autonomous decision about trial participation is what patients really want or whether they prefer to make the autonomous decision to leave the decision to others (e.g. their physician).