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

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## **Parents- not allowed to consider experimental gene therapy for children with therapy resistant cancer?**

*Example from a clinical research study application to a Regional committee for medical research ethics in Norway: Parents- not allowed to consider experimental gene therapy for children with therapy resistant cancer?*

This clinical example of a gene therapy trial was presented both for a Regional Committee for Medical Ethics in Norway (REC), where I was the deputy chair at the time, as well as for the The Norwegian Medicines Agency (Statens Legemiddelverk), a national regulatory authority for supervising drug trials. The Norwegian Medicines Agency is also responsible for evaluating gene therapy trials. The title of the research study was: " Phase I-II study of vaccination treatment with RNA transfected dendritic cells in high risk neuroblastoma". The study would include children, being the only age group affected by this rare and highly malignant disease.

The principal investigator planned to obtain informed consent from parents of children with these malignant neuronal derived tumors, where primary therapy had failed and no further standard treatment was available. Study information for the affected children was also provided, adapted to diverse levels of understanding.

After correction of patient and parent information, the study protocol and informed written consent was approved by REC. However, the study was initially not approved by the Norwegian Medicines Agency, referring to the Declaration of Helsinki and concern for experimental research on children.

The presentation will include a short popularized summary of the gene therapy principles proposed in the clinical study. The further fate of the study will be presented, including whether the parents were given the opportunity to decide whether they would consider the participation of their child in such an experimental gene therapy study.