

THE REGIONAL SCIENTIFIC ETHICAL COMMITTEE
FOR THE MUNICIPALITIES OF COPENHAGEN AND FREDERIKSBERG

Professor Mads Melbye
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Date: April 5 1995
Ref. no (KF) 01-471/94

Re: project (KF) 01-471/94: "Better health for Mother and Child"

The regional scientific ethical Committee for the municipalities of Copenhagen and Frederiksberg received, on the 28th of December 1994, the scientific application for the above project (dated 21st December 1994) including its appendices.

The project was discussed during the Committee meeting on the 8th of February 1995.

The Committee members noted that the project responsible are aware of the fact that any future use of the project data must be submitted to and approved by the Committee.

The Committee has considered the material received - partly as a demand for approval of the idea of constructing a data bank, and partly as a demand for permission to carry out a pilot study in order to validate and adjust questions etc., as described in your application.

The Committee finds that the mother should be encouraged to discuss participation with the child's father, and also that the mother should receive information about the number of questionnaires, blood samples, etc. she will be asked to take part in/deliver during the project's active phase. Also there should be information about the length of the time span during which she and her child will be active participants. These pieces of information could be incorporated into the consent form if they are not stated in the information leaflet.

The Committee furthermore finds that the child – once he/she turns 18, should be asked to renew the consent, thus accepting that data concerning him/her is used in a specific sub-project.

Finally the Committee would like to be up-dated on the proceedings of the project in approx. 5 years – the number of women/children participating, the quantity of data collected, and the experiences your team of scientists have collected.

The Committee is pleased to see that you have considered the problems and the possible solutions concerning participants who have lost their children, or who aborted.

We ask you please to send us a revised parents' information leaflet.

The Committee asks you please to let the other members of the project management know about our decision in this case. You have the possibility to appeal against the present decision to the Central Scientific Ethical Committee.

Best regards

sign.
J. Fischer Hansen
President

sign.
/ Rikard Vrogaard