

dr. A. de Jonge
afdeling midwifery science
BS7, D-444

Medical Ethics Review Committee
VU University Medical Center
chairman: prof. dr. J.A. Rauwerda
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VU medisch centrum

subject our reference
approval VU University Medical Center 2013.409

date
Amsterdam, 17 December 2013



Dear Mrs. de Jonge,

The Medical Ethics Review Committee of the VU University Medical Center (hereafter: METc VUmc) in Amsterdam, recognised in accordance with section 16.2 of the Medical Research Involving Human Subjects Act (WMO, 26th February 1998), has reviewed the research protocol for the following study

“Iris study – The IUGR Risk Selection study”

The METc VUmc hereby gives approval for the proposed research to be performed in the Netherlands at the VU University Medical Center.

The study does not fall within the scope of the Medical Research Involving Human Subjects Act (WMO).

The protocol was discussed at the committee's meeting on 21 november 2013.

Approval is based on the following documents:

- Correspondence between METc VUmc and the researcher d.d. 27 November 2013 and d.d. 4 December 2013
- Cover letter d.d. 1 November 2013
- Privacy regulations VUmc d.d. 1 November 2013
- Research protocol d.d. 30 October 2013
- Written patient information (control group) d.d. 30 October 2013
- Written patient information (experimental group) d.d. 30 October 2013
- Informed Consent d.d. 25 October 2013
- Questionnaire 'Basisgegevens IRIS studie' version 30 October 2013
- Form 'IRIS studie startformulier' version 30 October 2013
- Questionnaire 'IRIS Studie – Vragenlijsten' version 25 October 2013

Members of the committee

prof. dr. J.A. Rauwerda	chairman, surgeon		
dr. K. Hoekman	deputy chairman, medical oncologist		
mw. dr. C. Boer	biomedical scientist	dr. M. Klein	neuropsychologist
mw. dr. M.A. Bremmer	psychiatrist	dr. M.D. Lagerweij	dentist
mw. drs. M.M.E. van Dijk	nurse	mw. P. Roodenberg	lay member
dr. B. Drukarch	pharmacologist	mw. dr. A.F.W. van der Steeg and mw. dr. E.A. te Velde	surgeons
dr. E.G. Haarman	children's pneumonologist	prof. dr. F.J.H. Tilders	pharmacologist
mw. mr. A.J.G.M. Janssen and mr. F.J. Faber	jurists	mw. dr. A.I. Veldkamp and drs. A.J. Wilhelm	hospital pharmacists- clinical pharmacologists
dr. M.J.P.A. Janssens, dr. R. Houtepen and mw. dr. C. Widdershoven	ethicists	dr. ir. P. van de Ven and mw. dr. C.B. Terwee	methodologists
dr. J. Killestein and dr. B.W. van Oosten	neurologists	prof. dr. ir. R. Verdaasdonk and dr. ir. ing. Th.J.C. Faes	clinical physcists

The METc VUmc is registered with the US Office for Human Research Protections (OHRP) as IRB00002991. The FWA number assigned to VU University Medical Center is FWA00017598.

On behalf of the METc VUmc,
sincerely



prof. dr. J.A. Rauwerda, Review Officer

c.c.: drs. G.A.M. Vermeulen, afdelingshoofd midwifery science, p.a. BS7, D-444
c.c.: dr. P. Jellema, afdeling epidemiologie & biostatistiek, BS7 D-518