

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

dr. K. Hoekman

mw. dr. C. Boer
mw. dr. M.A. Bremmer
mw. drs. M.M.E. van Dijk
dr. B. Drukarch

dr. E.G. Haarman
mw. mr. A.J.G.M. Janssen and
mr. F.J. Faber
dr. M.J.P.A. Janssens,
dr. R. Houtepen and
mw. dr. C. Widdershoven
dr. J. Killestein and
dr. B.W. van Oosten

chairman, surgeon

deputy chairman, medical oncologist

biomedical scientist
psychiatrist
nurse
pharmacologist

children's pneumonologist
jurists

ethicists

neurologists

dr. M. Klein
dr. M.D. Lagerweij
mw. P. Roodenberg
mw. dr. A.F.W. van der Steeg and
mw. dr. E.A. te Velde
prof. dr. F.J.H. Tilders
mw. dr. A.I. Veldkamp and
drs. A.J. Wilhelm
dr. ir. P. van de Ven and
mw. dr. C.B. Terwee

prof. dr. ir. R. Verdaasdonk and
dr. ir. ing. Th.J.C. Faes

neuropsychologist
dentist
lay member
surgeons

pharmacologist
hospital pharmacists-
clinical pharmacologists
methodologists

clinical physicits

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