Centramed Deskundig in medische aansprakelijkheid

MEDICAL RESEARCH (HUMAN SUBJECTS) ACT CERTIFICATE

Policy number 624.529.204

ON BEHALF OF THE COMMITTEE FOR MEDICAL RESEARCH,
AND WHOMEVER IT MAY CONCERN

Stichting VUmc, hereinafter to be referred to as the 'institute', has taken out an insurance with the insurer mentioned under D of this certificate — the signatory thereof — to cover the human subjects of clinical trials commencing in the period from 1 January 2022 to 1 January 2023. The insurance meets the requirements of the Dutch Medical Research (Human Subjects) Act (Wet medisch-wetenschappelijk onderzoek met mensen) and the Compulsory Insurance for Medical Research (Human Subjects) Decree 2015 (Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen 2015).

A. Sums Insured

A1	€ 650,000	as maximum per claim per subject, with a maximum of
A2	€ 5,000,000	per clinical trial project, on the understanding that should the institute conduct or have conducted more than one clinical trial project, the total sum insured is limited to
A3	€ 7,500,000	per insurance year for injuries that manifest themselves as a result of these clinical trials.

B. Exclusions regarding the human subjects of the clinical trial

The insurance does not cover claims for injuries:

B1 that manifest themselves in the subject's descendant as a result of an adverse effect of the clinical trial on the subject and/or his/her descendant, unless the trial/research concerns:
- a) a clinical trial that focuses on pregnancy and is conducted with a subject who is pregnant at the time the trial starts, as referred to in Article 7, first paragraph, of the WMO, or
- b) scientific research as referred to in paragraph 4 or 5 of the Embryo Act (Embryowet).

B2 that are inevitable or practically inevitable, given the nature of the clinical trial;

B3 resulting from the subject's own failure to follow the instructions, or to follow them completely, insofar as the subject is able to do so.

C. The Centramed Clinical Trial Insurance Policy Conditions 2021 (version May 2021) prevail and are available upon request.

D. Onderlinge Waarborgmaatschappij Centramed B.A.

Zoetermeer, January 2022



drs. L. van Dijk RC
Chairman of the Board

bezoekadres Maria Montessorilaan 9, 2719 DB Zoetermeer
postadres Postbus 7374, 2701 AJ Zoetermeer
t 070 301 70 70
e info@centramed.nl
kvk 00000000
iban NL00 XXXX 0000 0000 00