Population Screening Act: The second round of The Maastricht Study

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Executive summary

Health Council of the Netherlands

Maastricht UMC+ has applied for a permit to carry out follow-up measurements among participants of The Maastricht Study. The Maastricht Study is an observational population-based cohort study that focuses on type 2 diabetes mellitus, cardiovascular diseases and other chronic conditions. Enrollment started in 2010. Participants underwent measurements and filled out questionnaires. The aim of the follow-up round is to collect data on changes in health status and disease progression among the participants.

At the request of the State Secretary for Health, Welfare and Sport (VWS), the Population Screening Committee of the Health Council of the Netherlands has examined whether the permit application complies with the requirements of the Population Screening Act.

The Committee concludes that the proposed research is scientifically valid and that the benefit-risk ratio is favourable. The Committee advises the State Secretary for Health, Welfare and Sport to grant the permit for a period of four years, subject to the following conditions:

- The information letter will contain information on the risks of the PTSD (post-traumatic stress disorder) measurement.
- A text must be added to the information letter and the consent form stating that the participant is free to refuse measurements.
- The consent and withdrawal form will specify the sources from which (special) personal data will be collected. In addition, an overview will be given of the categories of (special) personal data that will collected from these sources.
- A text must be added to the information letter and the consent and withdrawal form stating that if a participant withdraws his or her consent, the participant has the right to have his or her biobank samples (e.g. blood, urine) to be destroyed. If the samples have already been used to generate some data, these data may still be used for the study.
- A DNA analysis plan will be written by the researchers and reviewed by the clinical medical ethics decision-making team (KMEB) prior to the start of the study. Also for future DNA analyses, a DNA analysis plan will be reviewed by the KMEB prior to the start of the analyses.

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