

Radboud university medical centre
Regional medical ethical committee of
Arnhem-Nijmegen

628

Radboudumc
Department of surgery
Mw. M. Verstegen, MD

PO Box 9101, 6500 HB, Nijmegen
Radboudumc internal adress: r628
Geert Grooteplein 10
T (+31 24) 361 31 54

commissiemensgebondenonderzoek@radboudumc.nl
KvK 41055629/4

Our reference
PvW/CMO 153

Date
February 5th 2019

**Title: TENTACLE study: Treatment of Anastomotic Leakage after Esophagectomy
Filenummer CMO : 2018-4585**

Dear Mrs. Verstegen,

On behalf of the research ethics committee of the Radboud University Nijmegen Medical Centre I hereby let you know that the abovementioned study doesn't fall within the remit of the Medical Research Involving Human Subjects Act (WMO).

The study has been reviewed by the ethics committee on the basis of the Dutch Code of conduct for health research, the Dutch Code of conduct for responsible use, the Dutch Personal Data Protection Act and the Medical Treatment Agreement Act

The ethics committee has passed a positive judgment on the study.

The documents mentioned in appendix 1 have been reviewed.

Best regards,



Prof. dr. P.N.R. Dekhuijzen, Chairman

Appendix 1

- Application letter of M. Verstegen, received d.d. July 12th 2018
- Correspondance letter of M. Verstegen, received d.d. August 14th 2018 (including appendix)
- Correspondance letter of M. Verstegen, received d.d. January 2nd 2019
- TENTACLE study research protocol version d.d. January 9th 2019