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Title of research protocol: Treatment of Anastomotic Leakage after colon cancer resection: the TENTACLE – Colon study.

File number: 2024-17491.

Dear Jobbe Lemmens,

You have requested the medical ethical review committee East-Netherlands (in Dutch: METC Oost-Nederland) to issue a statement regarding whether the abovementioned research falls under the Medical Research Involving Human Subjects Act (WMO) and, therefore, needs to be reviewed by an accredited medical ethics review committee.

The research participants will not be subjected to WMO-required procedures, nor will they be required to perform WMO-required behaviors.

Based on this, the METC Oost-Nederland declares that the abovementioned research does not fall under the WMO. Therefore, a positive judgement from the METC Oost-Nederland or another accredited medical ethics review committee is not required for the execution of your research.

The abovementioned research has also been submitted to the CMO Radboudumc (local review committee for non-WMO research). The CMO Radboudumc reviews non-WMO research in the following cases:

- The research involves a non-negligible chance of generating new findings about the (future) health condition of the participants (or their blood relatives).
- The research is socially controversial: it concerns a field of research on which there are different philosophical or moral opinions within society regarding its admissibility.

Your research does not fall under either of these two review grounds. Therefore, CMO Radboudumc judges that no assessment by the CMO Radboudumc is required for the execution of your research.

I trust this message has been of service to you. I wish you success in the execution of your research.

Kind regards,

Dr. Jaap Deinum
Vice-Chairman METC Oost-Nederland
Chairman CMO Radboudumc

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Received documents:

- Letter of application, 22 august 2024
- Research protocol TENTACLE - Colon version 2.3, 22 august 2024
- Case report file, 22 august 2024