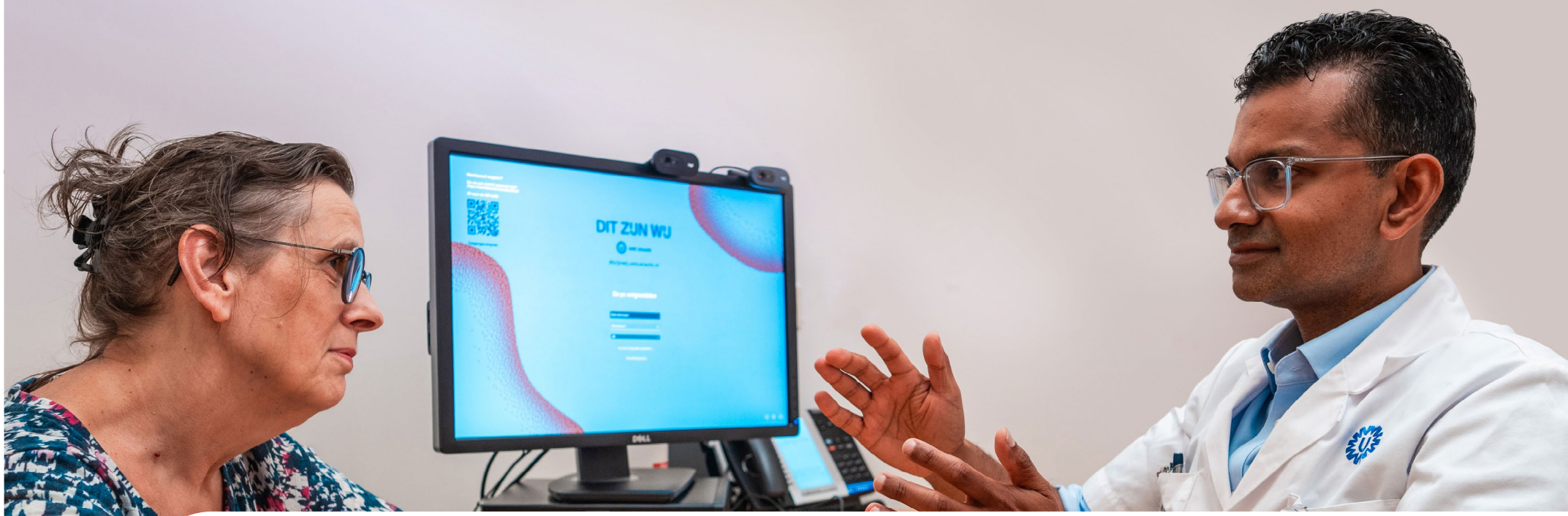

Biobank Research Ethics Committee (TCBio)

Annual Report 2025

UMC Utrecht

tcbio.umcutrecht.nl

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Preface

It is my pleasure to present the 2025 Annual Report of the Biobank Research Ethics Committee (TCBio). This year we saw a clear rise in review activity, including a doubling of new sub-biobank protocols and an increase in release protocol submissions. Despite this growth, the Committee achieved its shortest review times in six years, reflecting the dedication of both Committee members and the supporting staff of the Department of Research Review.

Due to the absence of a national ethical and legal framework governing the establishment and use of biobank collections, the review of multicenter protocols remains challenging. This gap may lead to inconsistencies in the protection of patients participating in the same biobank across different hospitals and does not support researchers conducting multicenter studies. Harmonization of the ethical framework for the collection and use of human tissue in the Netherlands is therefore urgently needed. At the national level, TCBio has contributed to the UMCNL Mutual Recognition project, an important initiative aimed at harmonizing biobank review procedures across the Netherlands. TCBio expects the first submissions under this new agreement in 2026.

We thank the Board of Directors for their continued support of the Committee. This support has contributed to shorter review timelines in recent years and has enabled greater focus on complex protocols and emerging issues.

Prof. dr. Hans van Delden
Chair TCBio in 2025
UMC Utrecht

Summary

TCBio's review activities increased noticeably in 2025. The number of new sub-biobank protocols (n=10) doubled compared to the previous year and the volume of release protocol submissions also rose. Amendments to existing protocols continued their gradual upward trend.

Despite this increase, the Committee achieved its shortest average review time in six years. Reviews of sub-biobank protocols were completed in an average of 33 days, and release protocols in 32 days—both well within the prescribed timelines.

No sub-biobank or release protocol was rejected in 2025. Throughout the year, Committee members and staff continued to invest in professional development by participating in internal training seminars and relevant meetings.

Looking ahead to 2026, TCBio expects to begin working with the national Mutual Recognition procedure. In addition, a start will be made with the alignment of the UMC Utrecht Biobank Regulations and TCBio protocol templates with current institutional and national developments.

TCBio Activities 2025 at a glance

Review volumes

Increase in reviewed dossiers compared to 2024

10
Sub- biobank protocols

82
Release protocols

51
Amended protocols

Average Review Time

Fastest processing time in six years

33 days
Sub-biobanks

32 days
Release protocols

2026 outlook

- Start review according to Mutual recognition procedure
- Start revision TCBio Protocol Templates
- Participation in UMC Utrecht Biobank Regulations update

Other

No rejections
All protocols approved in 2025

Incidental Findings
One reported

Professional Development
Internal trainings
National meetings

1 TCBio

1.1 The Committee's authority and operating procedure

Biobanks, collections of human biological material and associated data, continue to play an essential role in medical-scientific research. At the time of sample collection, the specific research projects in which these materials and data may eventually be used are often not yet fully defined As a result, donors can only be provided with general information about the intended use of their material and data, since researchers typically do not know in advance the specific purposes for which these will be used or by whom. By giving broad consent at the time of donation to the biobank, donors transfer part of their control to the biobank and must be able to trust that their material and data will be managed and used responsibly.

To safeguard donor trust, the following principles are essential:

- protection of the confidentiality of biological material and associated data,
- the type of consent obtained from donors,
- the approach to handling individual findings,
- clarity regarding the ownership of material, and
- transparency concerning potential commercial use.

These principles are established in the UMC Utrecht Biobank Regulations*, adopted by the Board of Directors in 2013. At that time, the Biobank Research Ethics Committee (in Dutch: Toetsingscommissie Biobanken (TCBio), hereafter TCBio) was appointed. TCBio operates independently of the Central Biobank UMC Utrecht, which is responsible for the quality monitoring, registration, and storage of human biological material within sub-biobanks.

The UMC Utrecht Biobank Regulations aim to provide a high-quality, institution-wide infrastructure for medical-scientific research conducted by UMC Utrecht researchers and their partners. To support this objective, TCBio assesses whether the collection and storage of biological material and data within sub-biobanks meet the criteria defined in the Regulations. TCBio also reviews whether the proposed use of material and data in medical-scientific research is responsible and appropriate. This governance model serves the interests of donors, researchers, and society at large by ensuring that scarce material is used for the right purposes and relevant research purposes.

TCBio operates in a manner analogous to an accredited Medical Research Ethics Committee (MREC), with a strong emphasis on the principles underpinning donor trust. The Committee's working procedures are detailed in its rules of procedure (in Dutch: huishoudelijk reglement), which are publicly available here.

In addition to TCBio's review activities, the accredited MREC NedMec has been requested to assess the establishment of sub-biobanks when biological material is collected for as-yet unspecified future purposes in parallel with WMO-regulated medical research. This approach prevents researchers from having to engage with two separate ethics Committees and ensures that the collective donor burden is appropriately considered.

Further information on the background of the UMC Utrecht Central Biobank, as well as the role of TCBio in reviewing sub-biobank protocols and release protocols, is available on the Committee's website**. The website also provides forms, templates, and submission instructions, supporting consistent and efficient review in accordance with the UMC Utrecht Biobank Regulations. The website is accessible in both Dutch and English and can be reached from outside the UMC Utrecht network, ensuring availability for UMC Utrecht researchers and external collaborators.

* UMC Utrecht- BIOBANKREGLEMENT
** Home - Toetsingscommissie Biobanken (umcutrecht.nl)

1.2 TCBio members and meetings

TCBio meetings take place every two weeks on Mondays. Meetings are held alternating online and on location in the UMC Utrecht. In 2025, twenty-four TCBio meetings were held.

Similar to the requirement of an MREC, the following disciplines are required during a TCBio meeting:

- Medical doctor
- Biologist
- Geneticist
- Ethicist
- Methodologist/Statistician
- Lawyer
- Patient advocate specifically for the perspective of the human subject.

In 2025 the TCBio composition remained stable. The UMC Utrecht Board of Directors extended the appointments of Prof. J.J.M. van Delden (ethicist and chair) with one year and of Dr. N.A. Tesselaar (immunologist and deputy chair) with four years. In addition, medical oncologist Dr. J.M.L. Roodhart was appointed as substitute physician member on the 26th of august 2025. A complete list of the Committee members in 2025 is provided in Appendix A.

The Committee is thankful for UMC Utrecht privacy officer Mrs. E. Kruisselbrink who was available for ad hoc advice throughout the year.

Due to the current chairman's approaching end of term, the UMC Utrecht Board of Directors appointed Prof. J.M. Beekman (medical biologist), on the 11th of November 2025, as new chair of TCBio effective from the first of January 2026.

1.3 TCBio secretariat

TCBio is supported by the staff of the Department of Research Review (in Dutch: Afdeling Toetsing Onderzoek) which is part of the UMC Utrecht Directorate Quality of Care & Patient Safety. This department also supports the Medical Research Ethics Committee (MREC, in Dutch: METC) NedMec that is facilitated by the UMC Utrecht, the Princess Maxima Center of Pediatric Oncology and the Foundation Netherlands Cancer Institute – Antoni van Leeuwenhoek Ziekenhuis (in Dutch: Stichting Nederlands Kankerinstituut - Antoni van Leeuwenhoek Ziekenhuis).

Staff members work on location or from home. Most members of staff support either the MREC or the Committee, while others support both Committees. A list of staff members supporting TCBio is provided in Appendix A.

Staff of the Department of Research Review can be contacted daily by e-mail for questions or advice regarding review procedures and requirements. When necessary, researchers are contacted by telephone or offered the option of a video consultation.

2 Review activities in 2025

In compliance with the UMC Utrecht Biobank Regulations, TCBio reviews two types of protocols namely sub biobank protocols (in Dutch: deelbiobankprotocol) and release protocols (in Dutch: uitgifteprotocol) describing the research planned with material and/or data from a specific collection.

2.1 Review of sub-biobanks

As laid down in the UMC Utrecht Biobank Regulations, all new sub-biobank protocols collecting human biological material for yet unspecified research questions are reviewed by TCBio. However, as described in section 1, the MREC NedMec reviews sub-biobanks that are established in conjunction with clinical research subject to the WMO. Therefore, the total number of new UMC Utrecht sub-biobanks in 2025 is reflected by the sum of sub-biobank submissions received for review by either the TCBio or the MREC NedMec.

All sub-biobank protocols received by TCBio were internal requests from UMC Utrecht departments. The total number of sub-biobank reviews in the last six years is depicted in figure 1. For all sub-biobank review procedures completed in 2025, TCBio/ MREC recommended the Board of Directors to approve the sub-biobank. In the last six years there have been no recommendations for sub-biobank rejection.

2025 was a busy year for TCBio with a doubling in biobank recommendations compared to 2024. However, this increase could be part of a pattern of year-to-year variation. The number of sub-biobank recommendations by MREC NedMec remains quite stable at 3-4 dossiers per year for the last six years (Figure 1).

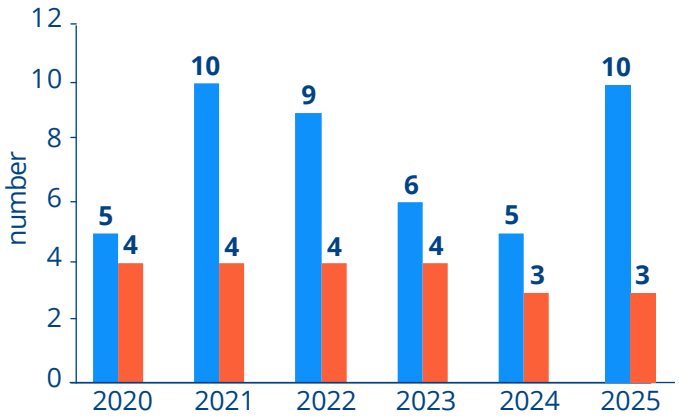

Figure 1: Number of sub-biobanks recommended by the Committee (blue) and MREC (orange) for approval by the Board of Directors in the past years.

2.2 Review of new Release Protocols

The number of assessed release protocols also increased in 2025 compared to 2024 (Figure 2), this is also likely due to a year-to-year variation. No studies were rejected in 2025.

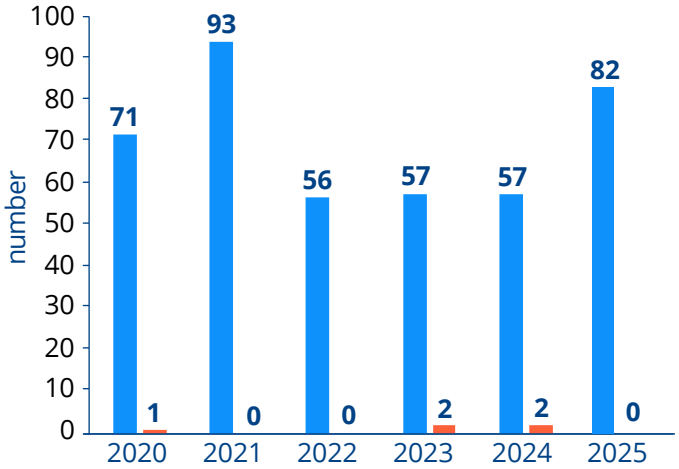

Figure 2: Number of release protocols approved (blue) and rejected (orange) in the last years.

2.3 Review time of new submissions

TCBio set a time limit for assessments of new protocols. For biobank protocols this is set at 56 days and for release protocols at 42 days. In 2025, the average assessment period for both was reduced compared to all previous years (Table 1), despite the increased numbers of both sub-biobank and release protocols.

Year	Sub-biobank	Release protocol
2020	67.6 (n=5)	51.5 (n=72)
2021	66.5 (n=10)	46.5 (n=93)
2022	65.9 (n=9)	37.4 (n=56)
2023	64.5 (n=6)	36.4 (n=59)
2024	60,4 (n=5)	43,5 (n=59)
2025	33,0 (n=10)	32,0 (n=82)

Table 1: Average duration of Committee review (in calendar days) for the recommendations and decisions on sub-biobank and release protocols given in 2025 compared to 2020-2024. The review time limit according to the Committee's rules of procedure are 56 days for sub-biobanks and 42 days for release protocols.

Factors that contributed to shortening the review time include:

- Well-written protocols and response letters that clearly describe all plans without gaps or inconsistencies. Unclarities and inconsistencies often become discussion points during TCBio meetings and frequently lead to follow-up questions or the need to reassess responses in a subsequent TCBio meeting.
- Stable, available and experienced Committee members and office staff, ensuring continuity and efficient handling of submissions.
- Steady stream of submissions, because peaks in workload can result in meetings being filled to more than capacity thereby increasing the likelihood that protocols are deferred to later meetings, adding to the overall review time.

TCBio experienced some submissions with exceptionally long review times. These delays were generally caused by the need to review legal agreements in complex cases e.g. where researchers collaborated with external parties, and the existing agreements did not adequately cover the proposed research.

2.4 Amendments

TCBio has delegated the review of non-substantial amendments to the chair. Only changes that affect the criteria for approval of a biobank or release protocol are reviewed in the TCBio meeting. Amendments for which no review by the complete Committee is required are reported to the TCBio in the subsequent meeting as weekly listings.

The number of amendments to sub-biobank or release protocols appears to gradually increase over the years (Figure 3), adding to the growing workload for both Committee and supporting staff alongside to the rise in new protocol submissions.

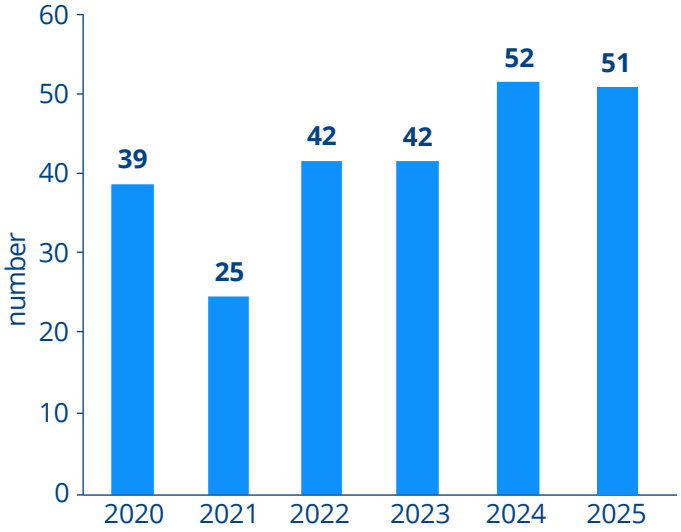

Figure 3: Number of sub-biobank and release protocols amended at least once in the last years.

2.5 Final reports

After release protocol approval researchers are asked to report results within one year of completion of the study. Like previous years, only a few final reports were received in 2025. There has been no active follow-up by TCBio to ascertain study results, as it is considered the responsibility of the researcher to submit the final report.

2.6 Incidental findings

The term “incidental findings” refers to unforeseen individual donor results that raise questions about the obligation to return the results to the donor. In accordance with the Committee’s Standard Operating Procedure Reporting of Findings published on TCBio website here, all reports of incidental findings are subject to review by TCBio. The Committee considers potential implications for the donor and their family members and advises on whether and how a finding should be communicated to the donor.

In 2025 only one report was submitted concerning germline mutations with possible implications for the donor and family members. This low number of reports is consistent with previous years, in which only a few incidental findings were reported. This remains unexpected and concerning.

2.7 Others

As in previous years, no formal appeals against committee decisions or requests for information under the Open Government Act (in Dutch: Wet Open Overheid, WOO) were received in 2025.

3 Developments

3.1 Role in governance of collections within the UMC Utrecht

Although they operate independently, the Committee and the Central Biobank, are part of the same biobank infrastructure of the UMC Utrecht. To further strengthen the infrastructure a quarterly informal coordination meeting is held to exchange information. The meeting is attended by the TCBio chair and secretaries, alongside representatives of the Central Biobank, the Research Office, and researchers.

In 2025 removal of redundancies in sub-biobank and release protocol review were initiated and will continue in 2026.

Developments in legislation and regulations with potential impact on the biobank infrastructure in the coming years were also discussed. This included the Dutch Federation of University Medical Centers (UMCNL) Mutual Recognition project for the review of multicenter biobanks which resulted in the establishment of an implementation workgroup at UMC Utrecht, organized by the Research Office and attended by the Committee secretaries. The first submissions using Mutual Recognition templates are expected in 2026.

3.2 UMCNL Mutual Recognition project

In 2025, TCBio continued to contribute to the UMCNL project on Mutual Recognition of the review of multicenter biobanks. The project aims to harmonize multicenter biobank review procedures across the Netherlands which will eliminate the need for multiple parallel or sequential review procedures. The Committee advised the project team to set a minimal set of standards for review and as a result all participating Committees endorsed the Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks as the framework for their review process.

One of the TCBio official secretaries participated in the Mutual Recognition steering group that, among other things, drafted instruction documents for researchers and committee's to facilitate the implementation of the procedure.

3.3 Training and professional development

To support the TCBio members in their review activities, relevant developments in research ethics and national and international regulations are regularly discussed during TCBio meetings. In addition, approximately once per year an internal training seminar is organized on a topic of of relevance to the Committee's work. This contributes to the continuous training and professionalization of Committee members.

In 2025, TCBio members and staff participated in the following **two internal training seminars**. One about the legal, ethical and scientific view on the right to destruct and discard donated body materials in biobanks and one focusing on the Declaration of Helsinki and developed materials for public activities on biobanking.

Part of the Committee and staff also attended the **annual meeting of MREC NedMec and TCBio**, themed 'Transforming Review Landscape'. The program included two keynote presentations:

- Prof. dr. Hans van Delden on the Declaration of Helsinki.
- Dr. Jan de Vries and Prof. dr. Michel Zwaan on the implications of the evolving review landscape for MREC NedMec.

As part of continued education and professional networking, one or both Committee secretaries actively contributed to discussion about the future organization of the Dutch ethics review landscape and attended the following meetings in 2025:

- **The second national biobank and collections day 2025**, organized by Health-RI bringing together professionals in biobanking to exchange knowledge on the latest developments in the field.
- **The Tenth edition of the Heath-RI Conference**, focused on the European Health Data Space.

3.4 Expectations for 2026

TCBio expects to receive its first submissions under the Mutual Recognition procedure in 2026. The Committee will also participate in the evaluation of this new process.

Furthermore, in response to ongoing local (UMC Utrecht Organizational Transformation) and national developments (Dutch Human Tissue Act and UMCNL Mutual Recognition Project) revisions of the UMC Utrecht Biobank Regulations and TCBio protocol templates will be initiated to ensure alignment.

Appendix A:
TCBio members and office staff in 2025

TCBio members in 2025

Prof. J.J.M. (Hans) van Delden MD PhD	Ethicist, chair
Mr. M. (Martin) Bootsma PhD	Epidemiologist
Mrs. B.C. (Claire) Collins LLM	Lawyer
Mr. J.E. (Jan Erik) Freund	Pathologist
Mr. I. (Imo) Höfer MD PhD	Physician/scientist
Mrs. H.E. (Titia) van Lier LLM MA	On behalf of donors
Mrs. G.V. (Gaby) Minasian LLM	Lawyer
Mr. M. (Marcel) R. Nelen PhD	Geneticist
Mrs. N.A. (Kiki) Tesselaar PhD	Immunologist, deputy chair
Mr. T. (Terry) Vrijenhoek PhD	Geneticist
Mrs. L. (Lotte) van der Wagen MD PhD	Clinical hematologist
Mr. P.M.J. (Paco) Welsing PhD	Epidemiologist

Substitute members in 2025

Mrs. M. (Marieke) Bakker MD	On behalf of donors
Mrs. M. (Marieke) Hollestelle MA	Ethicist
Mrs. J.M.L. (Jeanine) Roodhart MD PhD (from 26-08-2025)	Medical Oncologist

Staff from the Department of Research Review that supported TCBio in 2025

Mr. R.P. (Rutger) Chorus MA	Junior Staff advisor
Mrs. E. (Esther) van Doorn MSc	Senior review procedure coordinator
Mrs. W.A. (Antoinette) Groenewegen PhD	Official Secretary
Mrs. S. (Sigrid) Heinsbroek PhD	Official Secretary
Mrs. A.T. (Arina) Onnink	Secretary
Mrs. S. (Simone) Timmer	Advisor on information and archive
Mrs. K. (Kitty) Valk	Manager Department Research Review a.i.

List of Abbreviations

TCBio	Biobank Research Ethics Committee (in Dutch: Toetsingscommissie Biobanken, TCBio)
MREC	Medical Research Ethics Committee (in Dutch: Medisch-Ethische Toetsingscommissie, METC)
UMC	University Medical Center
UMCNL	Dutch Federation of University Medical Centers (Formerly known als NFU)
WMO	Medical Research Involving Human Subjects Act (in Dutch: Wet Medisch-Wetenschappelijk Onderzoek met Mensen)

Colophon

Data: R. Chorus
Text and graphics: S.E.M. Heinsbroek

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