Biobank Research Ethics Committee (TCBio)

Annual Report 2023

UMC Utrecht

tcbio.umcutrecht.nl

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Preface

This annual report describes the results of the reviews by the Biobank Research Ethics Committee (BREC, in Dutch: TCBio) in 2023. As part of the UMC Utrecht's biobank governance structure, the reviews of sub-biobank protocols to collect and store patient's tissue and release protocols using their tissues contributes to protect the rights and interests of these patients. In addition, the biobank catalogue constitutes an integral part of the governance structure. By providing an overview of the available materials, the catalogue contributes to efficient use of the collected material for purposes for which patients donated their materials. The Committee, the Central Biobank and the Biobank Catalogue can be viewed as part of the biobank ecosystem. The different parts in this biobank ecosystem are interdependent and could strengthen each other. Further development of this ecosystem, in which researchers as well as patients take part, should be initiated with this ecosystem in mind.

With the support of the Board of Directors, the meeting frequency and Committee support was increased during 2021. For the second consecutive year, this has resulted in faster review of release protocols. In addition, it allowed more focus on complex protocols and issues. We therefore thank the Board of Directors for their continued support of the Committee.

Due to the lack of a national ethical and legal framework for the initiation and the use of biobank collections, review of multicenter protocols for both biobank set up and release protocols is hampered. This may result in differences in protection of rights of patients taking part in the same biobank in different hospitals and does not facilitate researchers collaborating in multicenter research. Therefore, harmonization of the ethical framework for the collection and use of human tissues in the Netherlands is urgently needed. In the NFU project Mutual Recognition the first steps are taken towards this goal. In 2023, the Committee has played its role in this project and will continue to do so in 2024.

Prof. J.J.M. van Delden (MD PhD, chair)

Summary

The reporting year 2023 was in many ways comparable to the year 2022. The key facts are summarized below.

Review of new sub-biobank submissions comprise a relatively small part of the Committee's review procedures. In 2023, there was a small decrease in the number of sub-biobank submissions (from 7 submissions in 2022 to 5 in 2023) and biobank recommendations to the Board of Directors (from 9 recommendations in 2022 to 6 in 2023). Thus the slow decrease of the previous years continued as expected. This decrease is in line with efficient use of resources as collection of human biological material and associated data in itself is not the aim of the biobank system.

Release protocol reviews comprise the majority of the Committee's review procedures. In 2023, while the number of release protocol submissions decreased (from 68 in 2022 to 54 in 2023), the number of decisions taken on release protocols submissions remained at about the same level (56 in 2022 and 59 in 2023).

The average review time for sub-biobank submissions was 64.5 days (n=6). On average this duration is just above the time limit set by the Committee's Rules of Procedure (56 days). Longer review times may be due to complex submissions that contain biobank design elements for which the review criteria are not yet clear. A more complex design frequently leads to more rounds of questions and a prolonged review time. In addition, multicenter biobanks frequently take longer to review due to a lack of national legislation. In order to improve the latter, in 2023 the Committee participated in the first pilot of the project 'Mutual Recognition' that has been initiated by the NFU (in Dutch: Nederlandse Federatie van Universitair Medische Centra).

Release protocol reviews were on average completed within 36.4 days (n=59). This is again well within the time limit set by the Committee 's Rules of Procedure (42 days). The increased meeting frequency and increase of supporting staff as of April 2021 are the most likely factors that have contributed to keeping the review time within the time limit.

1 Competent authority BREC

Biobanks, comprising collections of human biological material and associated data, are increasingly important in medical-scientific research. Typically, the research question for which the human biological material and associated data will be used, is only globally known at the time donors provide their material to the biobank. Also, researchers generally do not know for which specific purpose the material and data will be used and by whom. This allows only general information to be provided to the donor. By giving broad consent at the time of donation to the biobank, donors transfer part of their control rights over the material and data to the biobank. To continue donor support for biobanks now and in the future, donors must be able to rely on their material and data being handled in a responsible manner in the biobank and during the medical-scientific research.

The following principles are important for donor trust:
- protection of confidentiality of the human biological material and associated data,
- type of donor consent,
- handling of findings,
- ownership of the material, and
- transparency on commercial use.

For the UMC Utrecht, these principles are detailed in the UMC Utrecht Biobank Regulations.

As a result of the UMC Utrecht Biobank Regulations* adopted by the Board of Directors in 2013, the Biobank Research Ethics Committee (BREC, in Dutch: Toetsingscommissie Biobanken – TCBio, hereafter: the Committee) was appointed by the UMC Utrecht Board of Directors. The Committee operates independently from the Central Biobank UMC Utrecht. The latter is responsible for the monitoring of the quality, the registration and the storage of the human biological material as sub-biobanks.

With the Biobank Regulations the UMC Utrecht aims to build a high-quality infrastructure for medical-scientific research for all UMC Utrecht researchers and their partners. To reach this goal, the Committee reviews whether the human biological material and associated data are collected and stored as sub-biobanks in the Central Biobank UMC Utrecht in accordance with the criteria laid down in the UMC Utrecht Biobank Regulations. Similarly, the Committee reviews whether the human biological material and associated data will be used in a responsible way in medical-scientific research. This governance model does not solely serve the interests of the donor but also those of the researcher and society as a whole ensuring that (scarce) material will be used for the right purposes. Donors must be able to rely on their material and data being used for relevant medical-scientific research only.

In addition to reviews by the Committee, the MREC NedMec has been requested by the Committee to perform the review of the establishment of the sub-biobank in parallel with the WMO review when human biological material is collected for yet unspecified purposes from participants during clinical research that is subject to the Medical Research Involving Human subjects Act (WMO). This prevents that researchers have to deal with two separate ethics committees for parallel or sequential review procedures.

* For details on the UMC Utrecht Biobank Regulations, refer to Biobanks UMC Utrecht - Toetsingscommissie Biobanken.

2 Committee members

The UMC Utrecht divisions propose new Committee members to replace members that leave. In 2023, the Committee was happy to welcome geneticist dr. M. R. Nelen as a new member. In addition, instead of membership, UMC Utrecht privacy officer Mrs. E. Kruisselbrink is available for ad hoc advice at the request of the Committee.

The chair, prof. dr. J.J.M. van Delden, was replaced by the deputy chair, dr. K. Tesselaar, during his leave of absence from May to August 2023.

A complete list of the Committee members in 2023 is provided in Attachment 1.

3 Committee secretariat

The Committee is supported by the staff of the Department of Research Review (in Dutch: Afdeling Toetsing Onderzoek). The Department is part of the UMC Utrecht Directorate Quality of Care & Patient Safety.

The Department's staff 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.

In 2023, there were no changes in the members of staff who support the Committee. A list of the staff member who support the Committee is provided in Attachment 1.

4 Committee’s operating procedure

The Committee operates analogous to an accredited MREC. The Committee’s operating procedures have been laid down in the rules of procedure (in Dutch: huishoudelijk reglement). For the most recent version refer to the Committee’s website here. Committee meetings take place every two weeks on Mondays. Meetings are held alternating online and on location in the UMC Utrecht. In 2023 twenty-three committee meetings were held.

Committee members download the meeting documents from a password protected digital platform. The chair checks at the start of each Committee meeting that all required experts are present. Members present who have a conflict of interest with any of the files leave the meeting for the duration of the discussion of that specific file. These issues are noted in the minutes of the meeting. For each file, the relevant review criteria are discussed in a point-by-point fashion. For each review criterion, committee members offer their advice when relevant. Members do not put their advice in writing ahead of the meeting. In general, decisions are reached unanimously.

5 Results of 2023 and aims for 2024

5.1 Results of 2023

In addition to the review of biobank and release proposals, each year the Committee aims to improve the governance of the collection and use of human biological material in the UMC Utrecht.

In 2023 the following were achieved :

A) A template patient information leaflet to obtain specific consent for direct use of the fresh residual material was finalized and published on the Committee's website. This template was developed to use in the simplified procedure drawn up in 2022. Provided specific criteria are met, this procedure allows researchers to directly use fresh residual material from routine care in a single study without the need to first set up a formal sub-biobank. The procedure and the template information letter can be found on the Committee's website here.

B) The NFU (in Dutch: Nederlandse Federatie van Universitair Medische Centra) has started a project in which the first steps are taken to harmonize review of multicenter biobanks within The Netherlands. Due to a lack of a national legal framework, criteria and procedures for setting up a biobank involving multiple medical centers vary across the country. Similarly, every medical center has its own review procedures and criteria for use of the human biological material collected in the biobanks. The aim of the NFU project Mutual Recognition(Dutch: Wederzijdse Erkenning) to is to identify the issues on which the centers are in agreement and on which they differ. In this way, the centers may be able to accept each other's approval. As a result multiple parallel or sequential procedures may become no longer necessary.

In the autumn of 2023, the Committee participated in pilot phase 1 of the Mutual Recognition project by reviewing a fake biobankprotocol and returning the Committee's findings. As part of the NFU project, templates for e.g. the biobankprotocol are being developed.

In 2023, the Committee aimed to update the template sub-biobank protocol. Given the development of NFU templates, the Committee wishes to align its updated version with the national NFU template where possible. The new template would therefore be suitable for both mono and multicenter biobanks. As the NFU project is still ongoing, the new Committee's template sub-biobank protocol will need to be developed accordingly.

C) As the NFU template biobank protocol became available in late 2023, efforts to update the Committee's template biobank protocol with regards to privacy aspects, e-consent and patient participation could not be completed.

D) The year 2023 marked the 10th anniversary of the Committee. To celebrate this occasion, a small meeting with presentations by invited speakers on the past, the present and the future of (the review of) biobanks was held for Committee members in November. This meeting is therefore also regarded as training for Committee members. The names of the speakers and the titles of their presentations are listed in section 10.1.

5.2 Aims for 2024

The following will continue in 2024:

A) Provide input in subsequent phases of the NFU project Mutual Recognition of the review of multicenter biobanks.

B) Further development of the template biobank protocol in parallel with the NFU template biobank protocol. The updated version should provide an improved lay-out, and include clear questions on privacy aspects. In addition to the NFU template, questions on e-consent and patient participation will be included.

In addition, the following will be initiated:

C) Although they operate independently, the Committee and the Central Biobank, are part of the same biobank infra-structure of the UMC Utrecht. To further strengthen the infrastructure, in 2024 actions will be initiated to improve the cohesion between the different parts.

6 Review of sub-biobanks and release protocols

To comply with the UMC Utrecht Biobank Regulations, two types of protocols may be submitted: sub biobank protocols (in Dutch: deelbiobankprotocol) and release protocols (in Dutch: uitgifteprotocol).

6.1 Sub-biobank submissions

6.1.1 Number of new sub-biobanks submitted

As laid down in the UMC Utrecht Biobank Regulations, all new sub-biobank protocols collecting human biological material for as yet unspecified research questions are reviewed by the Committee. However, as described in section 1, the MREC NedMec reviews sub-biobanks that are established when human biological material for storage for later, not yet specified use is also collected from subjects taking part in clinical research subjected to WMO review by the MREC.

Given the above, the total number of new UMC Utrecht sub-biobanks submissions in 2023 is therefore reflected by the sum of sub-biobank submissions received for review by either the Committee or the MREC NedMec.

The total number of sub-biobank submissions decreased slightly in 2023 compared to 2022 (Figure 1). This decrease in new sub-biobanks is not unexpected as for most patient populations sub-biobank have probably been set up. The decrease also indicates efficient use of available resources as increasing the number of new collections is not an aim in itself. Five out of nine sub-biobanks were received by the Committee while the remaining four sub-biobank protocols were submitted by UMC Utrecht departments to the MERC NedMec in parallel with clinical research that was subject to the WMO (see section 1).

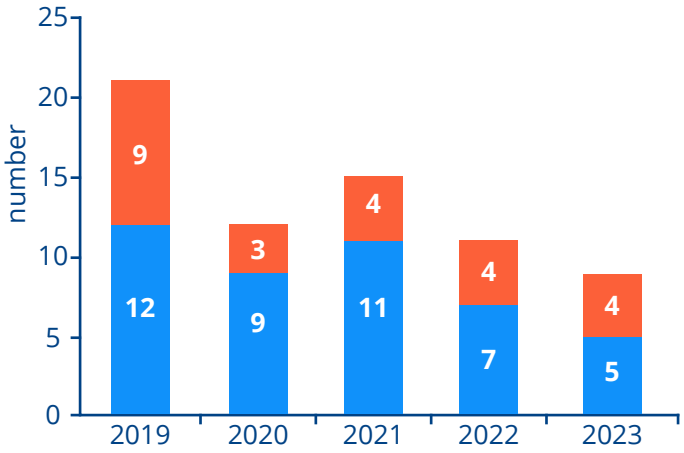

Figure 1: Number of sub-biobank protocols submitted to the Committee (blue) and the MREC (orange) in 2023 compared to 2019-2022.

6.1.2 Number of recommendations to the Board of Directors issued on sub-biobanks

For all nine sub-biobank review procedures completed in 2023, the Committee/MREC recommended the Board of Directors to approve the sub-biobank (Figure 2). There were no recommendations for rejection. Compared to 2022, the total number of recommendations for approval decreased slightly in 2023 (Figure 2).

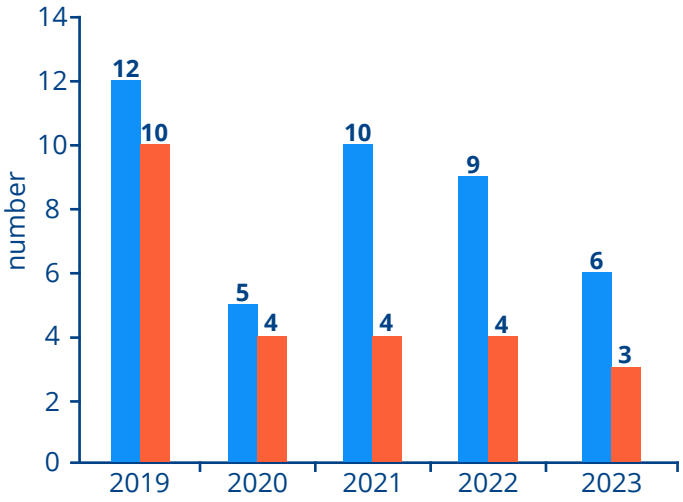

Figure 2: Number of sub-biobanks recommended by the Committee (blue) and MREC (orange) for approval by the Board of Directors in 2023 compared to 2019-2022.

Note: Review procedures may extend into the next calendar year. Therefore, the sum of both committees' recommendations (for either approval or rejection) within a calendar year may differ from the total number of submissions in that year shown in Figure 1.

6.1.3 Sub-biobanks submitted by UMC Utrecht Divisions

Of the five sub-biobank protocols submitted by UMC Utrecht divisions to the Committee (Figure 1), two protocols were submitted by the division Images & Oncology, two by the division of Internal Medicine & Dermatology and one by the division Women & Babies. No new sub-biobank protocols were submitted by the remaining UMC Utrecht divisions.

In addition, the MREC received three sub-biobank protocols for review in parallel with a WMO review (Figure 1), which were submitted by the UMC Utrecht divisions Brain, Surgical Specialties and Heart & Lung. The fourth sub-biobank protocol was reviewed by the MERC at the request of an external organization not associated with the UMC Utrecht. Also in this situation, the protocol was reviewed according to the UMC Utrecht Biobank Regulations.

6.2 Release protocols

6.2.1 Number of new release protocols submitted

The total number of new release protocol submissions in 2023 decreased compared to 2022 (Figure 3). Of the total number of submissions (54), the majority of release protocol submissions (42) still originated from UMC Utrecht divisions. This number was comparable to the number of submissions in 2022 (44). A breakdown of the release protocol submissions by UMC Utrecht division in 2023 is given in section 6.3.2.

In previous years, a substantial number of release protocol submissions originated from the Foundation HUB Organoids Technology. Founded by Hubrecht Institute, UMC Utrecht and Royal Academy of Arts and Sciences (KNAW), the Foundation aims to refine organoid development and foster organoid adoption globally . The Foundation manages the organoid sub-biobanks in cooperation with the UMC Utrecht Central Biobank. As for all UMC Utrecht sub-biobanks, release requests from the Foundation's sub-biobanks are reviewed by the Committee. The Foundation facilitates release protocol submissions from the Foundation's sub-biobanks. These submissions therefore also include a small number of release protocols for studies by UMC Utrecht researchers although the vast majority of release protocols concern requests not directly related to UMC Utrecht research.

Due to organizational factors, the number of release protocols submitted by the Foundation was reduced by 50 percent from 24 in 2022 to 12 in 2023. This reduction largely explains the overall decrease in the number of release protocol submissions in 2023.

In addition to requests for release from UMC Utrecht sub-biobanks, as an exception to the rule, the Committee is sometimes prepared to review release protocols from biobanks not linked to the UMC Utrecht or any other institution with a biobank ethical review committee. In these cases, and in the absence of applicable national legislation, the Committee still applies the UMC Utrecht Biobank Regulation to review the release protocol even though these external requests do not formally fall within the scope of the UMC Utrecht Biobank Regulation. In 2023 no request from such external parties were received.

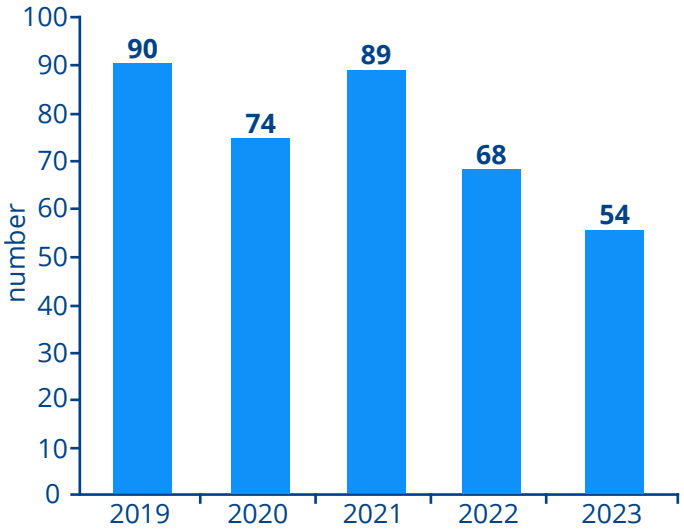

Figure 3: **Number of new release protocols submitted in 2023 compared to 2019-2022.**

6.2.2 Number of decisions regarding release protocols

In contrast to the decreased number of release protocol submissions, the number of decisions in 2023 was comparable to 2022 (Figure 4). This difference may be due to a number of factors. For example, no decision can be reached if the researcher does not respond to Committee's questions. Procedures are terminated if no response is received within one month and the researcher does not respond to reminders for a response.

Link to the Foundation's website: Foundation Hubrecht Organoid Biobank

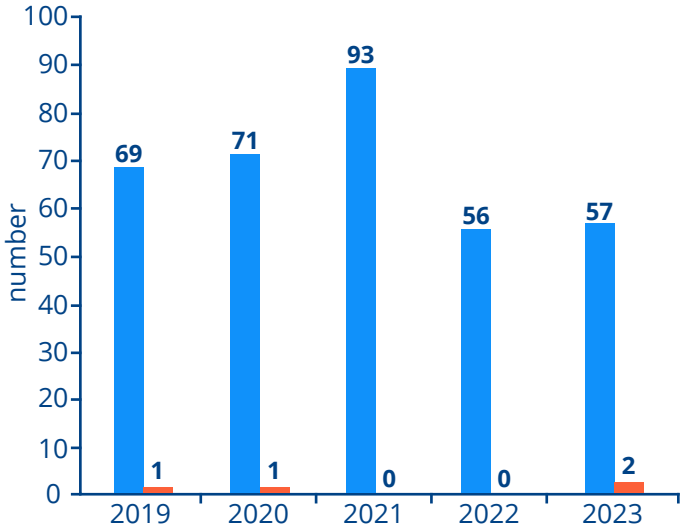

Figure 4: Number of release protocols approved (blue) and rejected (orange) in 2023 compared to 2019 2022.

Note: Review procedures may extend into the next calendar year. Therefore, the sum of the approvals and rejections within a calendar year may differ from the total number of submissions in that year shown in Figure 3.

6.2.3 Release protocols submitted by UMC Utrecht Divisions

The number of release protocol submissions per UMC Utrecht division varied in 2023 from 0 and 11 (Figure 5). Similar to the year 2022, the highest number of release protocols were submitted by the division Laboratories, Pharmacy and Biomedical Genetics although this number was more than 50% reduced compared to the peak year 2021.

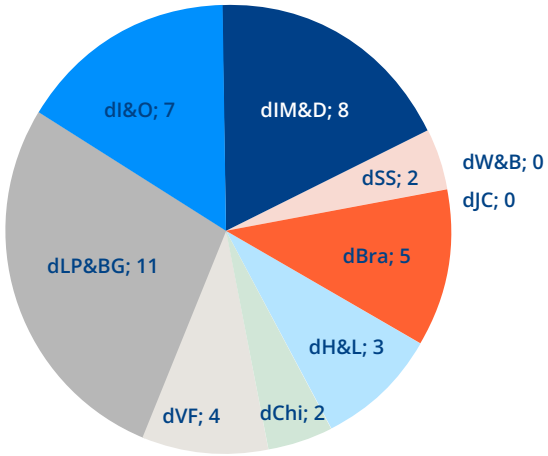

Figure 5: Number of release protocols submitted in 2023 per UMC Utrecht division.

6.3 Review time

The average total time the committee needed for protocol reviews in 2023 is shown in Table 1. Compared to 2022, the average number of days for release protocols remained within the committee's time limit of 42 days. However, the average number of days for sub-biobanks remained above the committee's time limit (set at 56 days).

Year	Sub-biobank	Release protocol
2019	54,9 (n=12)	48,3 (n=70)
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)

Table 1: Average duration of committee review (in calendar days) for the recommendations and decisions on release protocols given in 2023 compared to 2019-2022. 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 may contribute to longer review of sub-biobank submission could include:

- The relatively small number of files reviewed such that outliers disproportionally impact the average review time. Of note, 3 out of the 6 files were reviewed within the time limit of 56 days (number of days needed by the committee: 43, 44, and 53 days).
- Biobank design elements for which no specific criteria are available in the UMC Utrecht Biobank Policy and as such add to the complexity of the biobank and thereby its review (e.g., inclusion of vulnerable donors, such as children or incapacitated participants).
- Submissions of multicenter biobanks. Due to the lack of national regulations and therefore national review criteria for biobanks, templates and procedures differ between hospitals. This may lead to additional questions and prolong the review time, as the committee is only competent to review according to the UMC Utrecht Biobank Policy. Furthermore, multicenter biobanks require legal agreements between participating centers, which frequently lead to further delays.

6.4 Amendments

The committee 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 Committee meeting. Amendments for which no review by the Committee is required are reported to the Committee in the subsequent meeting as weekly listings.

By contrast to the reduction in the number of new release protocols submitted in 2023, the number of amendments to sub-biobank or release protocols remained at the level as in 2022 (Figure 6).

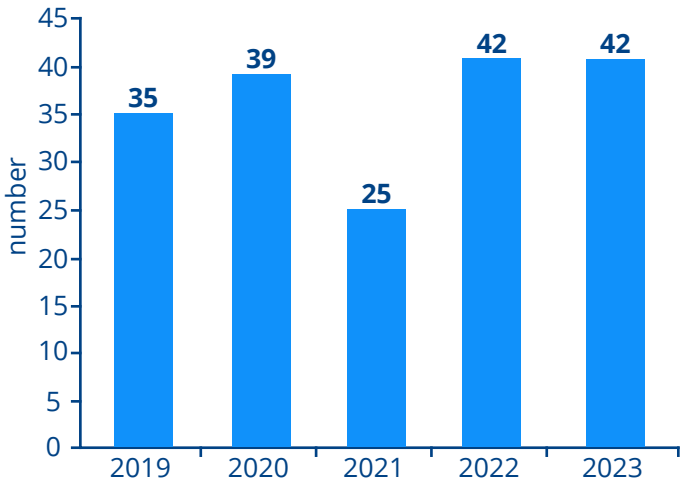

Figure 6: Number of sub-biobank and release protocols amended at least once in 2023 compared to 2019 2022.

6.5 Incidental findings

The term "incidental findings" refers to unforeseen individual donor results that raise issues regarding the obligation to return the results to the donor. Per the Committee's Standard Operating Procedure Reporting of Findings published on the Committee's website here, all reports of incidental findings are subject to review, in order to provide guidance on the return of the results to the donor. Despite the availability of a clear procedure on the reporting and review of incidental findings, no reports of an incidental finding were received, in 2023. This lack of reports is unexpected and worrisome.

6.6 Final reports

After approval of their release protocol, researchers are asked to report results within one year of completion of the study. Similar to previous years, only a few final reports were received in 2023. As it is considered the responsibility of the researcher the submit the final report, there has been no active follow-up by the Committee to ascertain study results,

6.7 Submission procedures

Information on the background of the UMC Utrecht Central Biobank and the role of the committee's review of sub-biobank and release protocols are provided on the Committee's website . In addition, forms and templates for researchers as well as instructions for submissions are provided there. The templates facilitate the Committee's review per UMC Utrecht Biobank Regulations.

The information on the website is provided in both Dutch and English. The website is accessible from outside the UMC Utrecht systems and can therefore be reached by both UMC Utrecht researchers and external parties wishing to collaborate with the UMC Utrecht.

The employees of the Department of Research Review can be contacted daily by e-mail and telephone for questions and advice on review procedures and requirements. When necessary, researcher are re-contacted by telephone or given the opportunity for video consultations.

7 Appeal against committee decisions

No formal appeals were received.

8 Other review activities

Besides the reviews under the UMC Utrecht Biobank Regulation reported above there are no other review activities to report for 2023.

9 Requests for information under the Freedom of Information Act

As in previous years, no requests for information under the Freedom of Information Act (in Dutch: Wet openbaarheid van Bestuur, Wob) or its successor as of 1 May 2022, the Open Government Act (in Dutch: Wet Open Overheid, WOO) were received in 2023.

10 Internal quality assurance and training

In order to support committee members to enhance the quality of their review, two training sessions were organised in 2023:

10.1 Committee's 10th Anniversary

As mentioned in section 5.1, the Committee celebrated its 10th anniversary with a small meeting for Committee members with presentations by invited speakers on:

"Ethics of Biobanks: past, present and the future challenges".

The program was as follows:

Prof. dr. J. van Delden, Committee Chair.
The (long) road to a governance structure for human biological material.

Dr. E. Niemantsverdriet, projectleader NFU project Mutual Recognition
How do we achieve mutual recognition of review of multicenter biobanks?

Dr. S. Muller, assistant professor Ethically and Socially Responsible Health Research Governance, Julius Centrum
Futureproof governance of Biobanks – What is the role for patients?

10.2 Annual meeting MERC NedMec

In the annual meeting of MREC NedMec, to which members of the Committee are invited, relevant developments regarding research ethics and national and or international regulations are discussed. Attendance facilitates training of the Committee members.

The theme of the 2023 meeting was:
"Review of research in Europe."

The program was as follows:

Prof. dr. A.F.A.M. Schobben
MERC developments in the past years.

Dr. R. van der Graaf
Ethical questions at het international review of medical scientific research.

Dr. Ir. M.D.M. Al
European review of clinical studies.

Mr. Drs. I.R. Kist
Sharing patient data at an (inter)national level.

10.3 Training of members of Staff

As part of continued education, the following meetings were also attended by secretaries of the Committee:

- 12 October 2023: "Connecting the dots", conference organized by Health-RI regarding secondary use of health data.
- 9 November 2023: National Biobanks and Collections Day, organized by Health-RI

Presentations by the secretaries to train members of staff of the Department of Research Review:

- 6 December 2023:
  - non-WMO research, A. van den Oetelaar
  - Review of biobanks , W.A. Groenewegen

Home - Toetsingscommissie Biobanken (umcutrecht.nl)

11 Attachments

Attachment 1

Committee members and office staff

Committee members in 2023

Prof. J.J.M. (Hans) van Delden MD PhD	Ethicist, chair
Mr. M. (Martin) Bootsma PhD	Epidemiologist
Mrs. B.C. (Claire) Collins LLM	Lawyer
Prof. R. (Roel) Goldschmeding MD PhD	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 (from 25-04-2023)	Geneticist
Mrs. N.A. (Kiki) Tesselaar PhD	Immunologist
Mr. T. (Terry) Vrijenhoek PhD	Geneticist
Mr. P.M.J. (Paco) Welsing PhD	Epidemiologist
Mrs. J.M.L. (Jeanine) Roodhart MD PhD	Medical Oncologist

Substitute members in 2023

Mrs. M. (Marieke) Bakker MD	On behalf of donors
Mrs. M. (Marieke) Hollestelle MA	Ethicist

Staff from the Department of Research Review that supported the Committee in 2023

Mrs. A.C. (Anna) Bakker LLM	Head of Department Research Review
Mr. R.P. (Rutger) Chorus MA	Senior review procedure coordinator
Mrs. W.A. (Antoinette) Groenewegen PhD	Secretary
Mrs. M. (Mandy) Koppes MSc	Senior review procedure coordinator
Mrs. A.H.M. (Anita) van den Oetelaar MSc	Secretary
M. (Michael) de Ridder	Advisor on information and archive

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Attachment 2: Abbreviations

BREC Biobank Research Ethics Committee
(in Dutch: Toetsingscommissie Biobanken, TCBio)

MREC Medical Research Ethics Committee
(in Dutch: Medisch-Ethische Toetsingscommissie, METC)

UMC University Medical Center

WMO Medical Research Involving Human Subjects Act
(in Dutch: Wet Medisch-Wetenschappelijk Onderzoek met Mensen)

Colophon
Text and graphics: R. Chorus
Text and editing: W.A. Groenewegen
Contact: tcbio@umcutrecht.nl

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