

Biobank Research Ethics Committee

Annual report 2022



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Content

Preface	3
Summary	4
1 Competent authority BREC	5
2 Committee members	6
3 Committee secretariat	6
4 Committee's operating procedure	7
5 Results of 2022 and aims for 2023 5.1 Results in 2022 5.2 Aims for 2023	8 8 9
6 Review of sub-biobanks and release protocols 6.1 Sub-biobank submissions 6.1.1 Number of new sub-biobanks submitted 6.1.2 Number of recommendations to the Board of Directors issued on sub-biobanks 6.1.3 Sub-biobanks submitted by UMC Utrecht Divisions 6.2 Release protocols 6.2.1 Number of new release protocols submitted	10 10 10 10 10 11 11
6.2.2 Number of decisions regarding release protocols6.2.3 Release protocols submittedby UMC Utrecht Divisions	11 12
6.3 Review time	12

6.4 Amendments		
6.5 Incidental findings	13	
6.6 Final reports		
6.7 Submission procedures	13	
7 Appeal against committee decisions	14	
8 Other review activities	14	
9 Requests for information under the Freedom		
of Information Act	14	
10 Internal quality assurance and training	15	
11 Attachments	16	
Attachment 1: Committee members and office staff	16	
Attachment 2: Abbreviations		

Preface

This annual report describes the results of the reviews by the Biobank Research Ethics Committee (BREC, in Dutch: TCBio) in 2022. 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.

With the support of the Board of Directors, the meeting frequency and Committee support was increased during 2021. This resulted in faster review of release protocols for the whole of the year 2022. In addition, it allowed more focus on complex protocols and issues.

The UMC Utrecht biobank policy applies only to protocols within the UMC Utrecht. 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. The lack of a national framework may result in differences in protection of rights of patients taking part in the same biobank in different hospitals. Harmonization of the ethical framework for the collection and use of human tissues in the Netherlands is urgently needed. A national framework should lead to better protection of the rights and interest of patients nationwide while facilitating UMC Utrecht researchers collaborating in multicenter research activities.

We thank the Board of Directors for their continued support of the Committee.

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

Summary

In the reporting year 2022, release protocol reviews were completed in less time than in previous years and on average were reviewed within the time set by the Committee's Rules of Procedure. The increased meeting frequency and increase of supporting staff as of April 2021 are the most likely factors that have contributed to the decreased review time. Release protocol reviews comprise the majority of the Committee's review procedures.

In addition, the template release protocol was further optimized with special focus on the sections concerning handling and storage of data with the aim to reduce the number of rounds of questions. To support both researchers before submission and committee members during their deliberations on privacy issues, documents detailing background information were finalized. Further, attention to privacy aspects was given by publishing Frequently Asked Questions on the website and during a seminar for Committee members. New sub-biobank submissions comprise a smaller number of the Committee's review procedures. As in previous years, the review time for sub-biobanks submissions remained above the time set by the Committee's Rules of Procedure. To optimize the quality of the sub-biobank submissions with the aim to decrease the number of rounds of questions and thereby the review time, the template sub-biobank protocol will be updated in 2023.

In 2022, while the number of sub-biobank submissions and reviews remained stable, release protocol submissions and reviews decreased compared to the previous year. By contrast, the number of amendments to approved protocols increased substantially in 2022. As the number of release protocol submissions has shown variation in the previous years, it is too early to conclude that the decrease noted in 2022 constitutes a downward trend.

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 Regulations¹ 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 medicalscientific research only.

In cases where 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), the Committee has requested the MREC Utrecht to perform the review of the establishment of the sub-biobank in parallel with the WMO review in order to avoid that researchers have to deal with two separate ethics committees at the same time.

2 Committee members

The UMC Utrecht divisions propose new Committee members to replace members that leave. In 2022, geneticist dr. M. Siemelink, geneticist prof. J.K. Ploos van Amstel and privacy officer D.A.H. Gulikers-Schoonderbeek left the committee. The committee was happy to welcome geneticist dr. T. Vrijenhoek as a new member. In addition, two substitute members joined the Committee: Mrs. M. Hollestelle (ethicist) and Mrs. M. Bakker (on behalf of donors).

A complete list of the Committee members in 2022 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. Following the merger of the MREC (see below), Mrs. A. Bakker was appointed as Head of Department in May 2022, replacing Mrs. J. van Luipen who temporarily filled the position of Head of Department.

The Department's staff also supports the Medical Research Ethics Committee (MREC, in Dutch: METC) Utrecht that is facilitated by the UMC Utrecht and the Princess Maxima Center of Pediatric Oncology. On 1st January 2022, the MREC Utrecht merged with the MREC Antoni van Leeuwenhoek (AvL) hospital to form MREC NedMec. As part of this merger, the supporting staff were also merged to form a new Department of Research Review. This new Department continues to support the Committee. 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 2022, there were no changes in the members of staff who support the Committee. A list of the staff member who support the Committee can be found 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 <u>here</u>. Committee meetings take place every two weeks on Mondays. Twenty-four committee meetings were held in 2022. During the pandemic years 2020-2022 all meetings took place online via video conferencing. Starting May 2022, committee meetings were held alternating online and on location in UMC Utrecht. 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 2022 and aims for 2023

5.1 Results in 2022

- A) In 2022 the procedures to facilitate the Committee's review process were further optimized by the following:
 - i. During review of release protocols, privacy aspects of linking human tissue material to medical data frequently lead to committee questions, prolonging the review process. The revision of the template release protocol that started in 2021 was finalized and published on the Committee's website on 1st June 2022. As of 1st September 2022, the use of the new template became compulsory for new submissions. In the new version, the questions regarding the privacy aspects were restructured. In addition, the template includes clarification of the information researchers need to provide on data protection and handling in the protocol. These explanations are aimed at reducing the necessity to ask for additional information or arguments.
 - ii. To further support committee members and researchers, the following documents with background on privacy aspects were completed:

- Background information on privacy legislation and genetic methods aimed at members that are not experts in these fields. Information on genetics methods was included since using or generating genetic information in a study also can raise privacy issues. As of May 2022, this document is attached to every committee meeting's agenda.
- A decision tree outlining the criteria for exemptions for use of identifiable data in research without patient's consent. This document was published on the Committee's <u>website</u> for researchers on 1st June 2022.
- A list of frequently asked questions (FAQs) regarding privacy issues. The list is available on the Committee's <u>website</u> from 24 October 2022.
- iii. In November 2022, a seminar was organized by and for committee members to discuss issues regarding privacy legislation. The seminar focused on the legal requirement of access to medical data for research in the absence of patients consent. Discussed were questions such as who has the right to access medical data (treating physician or researcher) and for what purpose (see also section 10).

- iv. In addition to the results for aims set for 2022, a simplified procedure was drawn up to facilitate researchers that wish to directly use fresh residual material from routine care in a single study. When specific criteria are met, no sub-biobank protocol review is required before collection and immediate use of the material. The procedure was published on the <u>website</u> on 8th August 2022. In addition, typically a patient's specific consent is needed. As the available patient information leaflets in practice are not suitable for these situations, further development of the patient consent letter is in progress.
- B) The Central Committee on Research Involving Human Subjects (CCMO) is increasing its focus on Patient participation in research. To start exploring ways to strengthen patient participation in the Biobank Research Ethics Committee, on 8th March 2022 both secretaries attended the online UMC Utrecht symposium on patient participation in research. In addition, both secretaries attended the CCMO secretaries working group on 29th March 2022 where an update of the CCMO program Patient Participation was presented.

5.2 Aims for 2023

In 2023 we aim to achieve the following:

- a) Further development of a patient information leaflet to obtain specific consent for direct use of fresh residual material (see section 5.1 under A iv).
- b) Reduce the review time for sub-biobank files. The average review time for sub-biobanks in 2022 exceeded the time in which the committee aims to complete the procedure (see section 9.3). As privacy aspects of sub-biobank protocols frequently lead to Committee questions, the template sub-biobank protocol will be updated with focus on the sections on handling and storage of data.
- c) Increase the awareness of patient participation for researchers and Committee. As the CCMO is introducing questions on patient participation as part of the research files reviewed by MREC's, the possibilities will be explored to incorporate comparable questions in the files submitted for review by the Committee.
- d) Explore the possibilities for electronic consent (eConsent) for sub-biobanks. Since eConsent is now legally possible under the WMO, based on the questions formulated by the CCMO, the criteria and conditions for eConsent for sub-biobanks will be explored.



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).

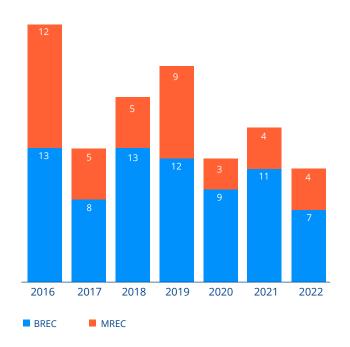
6.1 Sub-biobank submissions

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 one, the MREC Utrecht 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 2022 is therefore reflected by the sum of sub-biobank submissions received for review by either the Committee or the MRFC.

The total number of sub-biobank submissions decreased in 2022 compared to 2021. However, the number of submissions has varied in the past few years. There is no clear reason known for this variation. The majority of the sub-biobanks (7 out of 11) were received by the Committee (Figure 1) while the remaining four sub-biobank protocols were submitted by UMC Utrecht departments to the MERC in parallel with clinical research that was subject to the WMO as described in section 1.

Figure 1

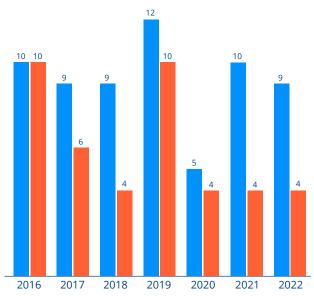
Number of sub-biobank protocols submitted to the Committee (blue) the MREC (orange) in 2022 compared to 2016-2021.



6.1.2 Number of recommendations to the Board of Directors issued on sub-biobanks For all thirteen sub-biobank review procedures completed in 2022, the Committee/MREC recommended the Board of Directors to approve the sub-biobank (Figure 2). There were no recommendations for rejection. Similarly to the decreased number of sub-biobank submissions in 2022 (Figure 1), the total number of recommendations for approval was also decreased slightly in 2022 (Figure 2).

Figure 2

Number of sub-biobanks recommended by the Committee (blue) and MREC (orange) for approval by the Board of Directors in 2022 compared to 2016-2021.



BREC MREC

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 seven sub-biobank protocols submitted by UMC Utrecht divisions to the Committee (Figure 1), three protocols were submitted by the division Images & Oncology, two by the division of Internal Medicine & Dermatology and one each by divisions Brain and Laboratories and Pharmacy & Biomedical Genetics. The Committee received no new sub-biobank protocols from the divisions Children, Women & Babies, Heart & Lung, Julius Center, Surgical Specialties and Vital Functions.

In addition, the MREC received four sub-biobank protocols for review in parallel with a WMO review (Figure 1), which were submitted by the UMC Utrecht divisions Internal Medicine & Dermatology (2), Children (1) and Laboratories and Pharmacy & Biomedical Genetics (1).

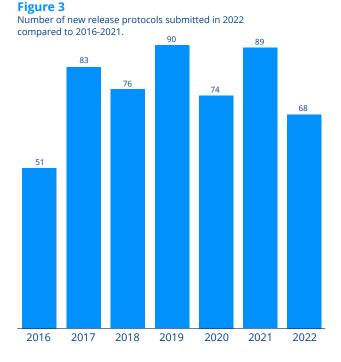
6.2 Release protocols

6.2.1 Number of new release protocols submitted The total number of new release protocol submissions in 2022 decreased compared to 2021 to about the level of 2020 (Figure 3). Of the total number of submissions (68), the majority (44) originated from UMC Utrecht divisions. The number of new release protocols submitted by UMC Utrecht researchers have shown yearly variations. For example, from 2019 to 2021 the number of UMC Utrecht submissions were 69 (2019), 41 (2020) and 57 (2021). After the lower number in the pandemic year 2020, when almost all research was suspended in the UMC Utrecht, the increase in 2021 may have been due to a catch up effect after the pandemic. The factors contributing to the lower number of release protocol submissions in

the reporting year 2022 are unclear. By contrast, the number of amendments to approved protocols increased in 2022 (see section 6.4). A breakdown of the release protocol submissions by UMC Utrecht division in 2022 is discussed in section 6.3.2.

As in previous years, a substantial number of release protocol submissions originated from HUB Organoids Technology (HUB). Founded by Hubrecht Institute, UMC Utrecht and Royal Academy of Arts and Sciences (KNAW), HUB aims to refine organoid development and foster organoid adoption globally². HUB manages the HUB sub-biobanks in cooperation with the UMC Utrecht Central Biobank. As for all UMC Utrecht sub-biobanks. release requests from the HUB sub-biobanks are reviewed by the Committee. HUB facilitates release protocol submissions from the HUB sub-biobanks. These submissions therefore also include release requests for studies by UMC Utrecht researchers although the vast majority of submissions concern requests not directly related to UMC Utrecht research. In 2022, 24 of the 68 release protocol submissions were submitted by HUB. In line with the decreased number of total submissions, this number is also decreased compared to the number of HUB submissions in 2021 (31).

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 2022 no request from such external parties were received.

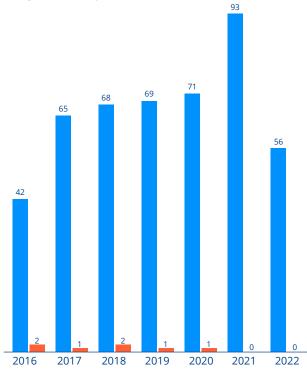


6.2.2 Number of decisions regarding release protocols

Similarly to the decrease in the total number of release protocols submitted, the number of release protocols approved by the Committee in 2022 decreased compared to 2021 (Figure 4). No release protocols were rejected by the Committee. The decreased number of approvals reflects primarily the decreased number of release protocol submissions (Figure 3).

Figure 4

Number of release protocols approved (blue) and rejected (orange) in 2022 compared to 2016-2021.



approved rejected

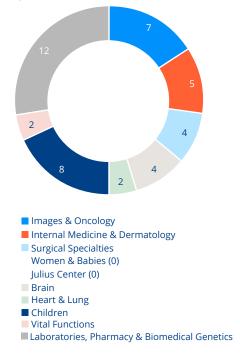
Review procedures may extend into the next calendar year. Therefore, the sum of the approvals and rejections within a calendar year may differ from the total number of submissions in that year shown in Figure 3.

6.2.3 Release protocols submitted by UMC Utrecht Divisions

The number of release protocol submissions per UMC Utrecht division varied in 2022 from 0 and 12 (Figure 5). Similar to the year 2021, the highest number of release protocols were submitted by the division Laboratories, Pharmacy and Biomedical Genetics (12) although this number was more than 50% reduced compared to the peak year 2021.

Figure 5

Number of release protocols submitted in 2022 by UMC Utrecht divisions.



6.3 Review time

The average total time the committee needed for protocol reviews in 2022 is shown in Table 1. Compared to 2021, the average number of days for release protocols decreased to well within the committee's time limit of 42 days. This decrease is likely largely due to the increased meeting frequency introduced in April 2021. 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)

Table 1

Average duration of committee review (in calendar days) for the recommendations and approvals given in 2022 compared to 2019-2021. 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, 4 out of the 9 files were reviewed within the time limit of 56 days (number of days needed by the committee: 34, 52, 54 and 55 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.

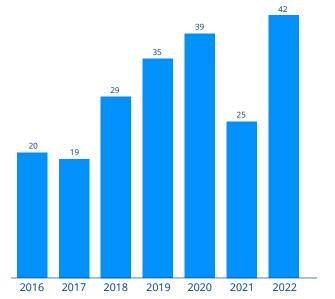
6.4 Amendments

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 next meeting as weekly listings.

By contrast to the reduction in the number of new release protocols submitted (Figure 6), the number of amendments to sub-biobank or release protocols increased in 2022 after a decrease in 2021. When this increased number of amendments is taken into account, the total number of letters sent to researchers for all types of review procedures were comparable for both years (311 letters in 2022 and 316 letters in 2021).

Figure 6

Number of sub-biobank and release protocols amended at least once in 2022 compared to 2016-2021.



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, all reports of incidental findings are subject to review, in order to provide guidance on the return of the results to the donor. At the end of 2022, one report of an incidental finding was received. The finding had already been reported back to the donor as the finding was considered of immediate relevance. In the first committee meeting in 2023 the committee discussed the nature of the finding and reviewed whether it was correct to inform the donor of the result immediately. This possibility of immediate return of the result to the donor is also laid down in the Committee's Procedure Reporting of Findings. The committee agreed that due to the nature of the finding, the procedure of immediate return to the donor was correct.

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 2022. As it is considered the responsibility of the researcher, 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 <u>website</u>. 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 2022. 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 2022.

10 Internal quality assurance and training

In order to train committee members with the aim to enhance the quality of the review, a seminar was organised in November 2022 as already mentioned in section 5.1. As the use of medical data without specific consent frequently leads to discussions during the review process, the legal aspects of access to medical data, such as who has the right to access medical data (treating physician or researcher) and for what purpose, were presented and discussed. As aspects of the legislation need further clarification, this discussion will be followed up in future seminars.

About once or twice a year, the Committee's secretary (re)trains UMC Utrecht employees on the UMC Utrecht biobank policy. However, in 2022 there were no presentations to UMC Utrecht employees.

As an exception, a request for a presentation on biobank review was accepted from an external party with interest in setting up a biobank: the Association of Dutch Burn Centres (ADBC; in Dutch Vereniging Samenwerkende Brandwondencentra Nederland VSBN). This association is not affiliated to a hospital with a biobank research ethics committee. Therefore one of the secretaries presented the background in biobank review and present procedures that are operational within the UMC Utrecht. From January 1st 2022, the MREC Utrecht has merged with the MREC Antoni van Leeuwenhoek hospital to form MREC NedMec. In November 2022, the 1st annual meeting of MREC NedMec was held at a location between Amsterdam and Utrecht. The meeting was held together with members of the Committee, as was the case previously for the Annual meetings of METC Utrecht. During the annual meeting, relevant developments regarding research ethics and national and or international regulations are discussed. Attendance facilitates training of Committee members.

The topic of the 2022 meeting was: "Review of human-related research in the future."

The program was as follows:

Prof. M.C. Ploem LLM PhD

(Amsterdam UMC)

Power of control over human biological material Act (Wet zeggenschap lichaamsmateriaal (Wzl))

Prof. C.M. Zwaan, MD PhD (Princess Maxima Center Pediatric Oncology and chair MREC NedMec) Thematic MREC's versus all round MREC's

Mrs. E. Vroom MSc

(Founder and director Duchenne Parent Project, co-founder and chair World Duchenne Organization) **Developments from a patient's perspective**

Members of both committees attended the meeting in large numbers.

11 Attachments

Attachment 1

Committee members and office staff

Committee members in 2022 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 Mrs. D.A.H. (Dennie) Gulikers-Schoonderbeek BSc Privacy officer (until 1-11-2022) Mr. I. (Imo) Höfer MD PhD Mrs. H.E. (Titia) van Lier LLM MA Mrs. G.V. (Gaby) Minasian LLM Lawyer Prof. J.K. (Hans Kristian) Ploos van Amstel PhD Geneticist (until 1-12-2022) Mrs. N.A. (Kiki) Tesselaar PhD Mr. T. (Terry) Vrijenhoek PhD (from 01-04-2022) Geneticist Mr. P.M.J. (Paco) Welsing PhD Mr. M. (Marten) Siemelink MD PhD Geneticist (until 01-04-2022) Mrs. J.M.L. (Jeanine) Roodhart MD PhD

Substitute members in 2022

Mrs. M. (Marieke) Bakker MD (from 01-04-2022) Mrs. I.E. (Irene) de Bruijne Mrs. M. (Marieke) Hollestelle MA (from 01-04-2022) Mrs. A.M. (Jenny) Zijlmans LLM

Pathologist Physician/scientist On behalf of donors Immunologist Epidemiologist

Medical Oncologist

On behalf of donors On behalf of donors Ethicist

On behalf of donors

Staff from the Department of Research Review that supported the Committee in 2022

Mrs. A.C. (Anna) Bakker LLM (from 01-05-2022) Mr. R.P. (Rutger) Chorus MA Mrs. W.A. (Antoinette) Groenewegen PhD Mrs. M. (Mandy) Koppes MSc Mrs. J. (Jolande) van Luipen MA (until 01-05-2022)

Mrs. A.H.M. (Anita) van den Oetelaar MSc M. (Michael) de Ridder Mrs. P.B. (Pauline) de Vries Bed (until 01-02-2022) Management assistant

Head of Department Research Review Senior review procedure coordinator Secretary Senior review procedure coordinator Acting Head of Department Research Review Secretary Advisor on information and archive

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

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