

Memorandum of Understanding: NMCB Data Access & Governance Framework

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Status: Memorandum of Understanding (MoU) supplementing the Joint Data Registry Agreement (JDRA) and Consortium Agreement

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Executive Summary

This Memorandum of Understanding (MoU) provides the overarching governance framework for access to and use of data and human biological materials from the Netherlands ME/CFS Cohort & Biobank (NMCB) consortium. It brings three resources under a single, uniform policy: the adult cohort (Amsterdam UMC), the paediatric cohort (UMC Utrecht), and the brain tissue biobank (NIN-KNAW).

The framework has two aims: to facilitate high-quality biomedical research into ME/CFS and post-acute infection syndromes (PAIS), and to protect participants' interests and integrity. The CCDC provides a recommendation that carries substantial weight; the EB makes the decision and may depart from that recommendation only with documented reasons. Additional safeguards apply to high-risk applications that could lead to stigmatising interpretations.

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1. Purpose, Scope and Status

1.1 Status of this Document

This document has the status of a Memorandum of Understanding (MoU). It has been endorsed by all institutions involved in the NMCB consortium. It provides the practical implementation of the data governance agreed in the Joint Data Registry Agreement (JDRA).

1.2 Scope

This framework applies to access to data and materials from the three biobanks and cohorts affiliated with NMCB:

1. **The NMCB Adult Cohort and Biobank** (*owned and managed by: Amsterdam UMC*).
2. **The NMCB Paediatric Cohort and Biobank** (*owned and managed by: UMC Utrecht*).
3. **The ME/CFS Brain Tissue Biobank** (*owned and managed by: the Netherlands Institute for Neuroscience, part of the Royal Netherlands Academy of Arts and Sciences (KNAW)*).

1.3 Legal Hierarchy

In the event of conflicts between provisions in the different documents governing this consortium, the following order of precedence applies (from highest to lowest):

1. **Local legal, institutional and institution-specific requirements and decisions¹**
2. **Participant consent (informed consent):** the specific consent and restrictions indicated by each individual participant take precedence at all times.
3. **Consortium Agreement:** the fundamental agreements between the partners.
4. **Joint Data Registry Agreement (JDRA):** the legal framework for data management and privacy.
5. **This Memorandum of Understanding (MoU):** the operational and ethical implementation of the access policy.

2. Governance Structure

2.1 Executive Board (EB)

The EB acts as the final decision-making body (the “Data Governance Committee” in the terminology of the JDRA) for all three cohorts.

- **Role:** The EB delegates the substantive review to the CCDC but retains ultimate responsibility for formal approval (Letter of Approval).

¹ The proposal's compliance with approval from the local Medical Research Ethics Committee (METC) and, where applicable, the local biobank (review) committee is a prerequisite and takes precedence over the governance provisions set out below. The CCDC relies on the assessment made by the METC or biobank committee and does not re-review approvals that have already been granted.

- **Veto:** The **Coordinator, acting on behalf of the EB**, retains an operational veto if legal requirements (such as a valid DTA/MTA) have not been met. The relevant **data or material holder** (Amsterdam UMC, UMC Utrecht or the Netherlands Institute for Neuroscience) also retains a veto where there are compelling reasons on the holder's side, for example scarcity of material or a conflict with ongoing or specifically planned analyses by the holder².

2.2 Consortium Cohort Data Committee (CCDC)

The CCDC is an independent review body that advises the EB on data (and/or sample) applications relating to all three cohorts. Its members are appointed by the EB.

CCDC composition:

- Required: Chair
- Required: At least one biomedical researcher.
- Required: One representative from each patient organisation represented on the EB.
- Preferred: Ad hoc experts (e.g. paediatrics, neurology/brain research, ethics), where relevant to the specific application.
- Preferred: A clinician with expertise in ME/CFS.

CCDC remit:

Review of scientific quality, feasibility, alignment with the NMCB mission³ and participant consent, and risk.

CCDC decision-making:

The CCDC provides a recommendation that carries substantial weight to the Executive Board (EB). The EB makes the formal decision ("Letter of Approval"). Any departure from the CCDC recommendation must be justified in writing, with explicit reference to the assessment criteria. Where appropriate, the EB may consult its advisory board in advance.

3. Access Criteria and Applicants

3.1 The Partner Principle

In accordance with the JDRA, only researchers affiliated with an NMCB Partner Institution may submit an application.

Route to external access: External parties may (i) apply through sponsorship/collaboration with an NMCB Partner acting as a co-applicant to safeguard quality and ethical integration (see Section 3.1), or (ii), where appropriate, join through the accession mechanism set out in the Consortium Agreement and the JDRA. Initial contact and preliminary discussions before formal submission must take place through the relevant project lead of the data or material holder, who oversees data collection and management⁴.

² In practice, this scenario is largely a formality, as initial contact and preliminary consultation prior to submission are required to take place through the project lead responsible for the relevant data or biobank holder. Formally, applications can only be submitted via this route.

³ See NMCB Mission and vision document

⁴ The collaboration with ME/CFS Lines occupies a special position. NMCB and ME/CFS Lines are part of the same ZonMw programme, collaborate on several projects, and are explicitly encouraged by ZonMw to work together. This close substantive relationship is taken into account when assessing applications. However, no overarching agreement formally

3.2 Commercial Parties

Commercial parties may be granted access, provided that:

1. They collaborate with an NMCB Partner.
2. The participant has given specific consent for collaboration with for-profit parties.
3. The data remain the property of the managing institutions (AUMC, UMCU or KNAW).

4. Assessment Framework and Protection Against Stigmatisation

4.1 Assessment Framework

NMCB distinguishes three types of application. The role of the CCDC and the level of review differ by type, ensuring proportionality: a light review where possible and a more rigorous review where necessary.

Type 1. Analyses within the ZonMw-approved project plan

When a consortium partner conducts research covered by the project plan approved by ZonMw, this is considered an already authorised research pathway. In this case, the CCDC is informed by reference to the project plan; no additional CCDC review is required. The researcher remains responsible at all times for conducting the research correctly, i.e. in accordance with the Medical Research Involving Human Subjects Act (WMO) and the General Data Protection Regulation (GDPR/AVG).

Type 2. Analyses outside the original ZonMw project plan

When a consortium partner wishes to conduct analyses outside the original ZonMw-approved project plan, the CCDC conducts a light review based on the two core criteria described in Section 4.2 and the appendix (see Appendix 1 and Section 4.2).

This review is intended to safeguard participants' interests and the trust they have placed in the consortium, without creating unnecessary administrative burdens.

Type 3. Projects initiated by external parties

External applications must describe the proposed research question, analytical framework, outcome measures and intended outputs in sufficient detail. Broadly formulated or open-ended applications without clear boundaries may be returned by the CCDC for further specification. Projects initiated by an external party or for which an external party is the primary applicant must always include one or more representatives of the relevant data/material holder (project lead) as co-applicants; see also Sections 3.1 and 5 (point 3). These currently include, at a minimum, Niels Eijkelkamp for the paediatric cohort, Jos Bosch for the adult cohort and Inge Huitinga for the brain bank. This is intended to ensure that an internal review has taken place before submission covering (i) scientific quality, (ii) alignment with participants' interests and consent, and (iii) consistency with the NMCB mission (see Section 4.2).

The CCDC assesses these applications against the same criteria as Type 2 applications. Additional review covers:

- **Patient involvement:** External applicants must demonstrate that patient consultation (e.g. through their own patient advisory board) is embedded in their project.

exists between the two consortia. Furthermore, some of the data held by ME/CFS Lines fall under the governance framework and conditions of Lifelines BV, a third party. Applications are therefore processed according to the procedure for external applications.

- **Quality and feasibility:** sufficiently developed and scientifically sound; practically and financially realistic, including capacity and timescale.
- **Overlap and prioritisation:** no unnecessary duplication or conflict with ongoing applications or core analyses planned by the data/material holder.
- **Formalisation through an MTA/DTA:** covering ethics, intellectual property, data minimisation and data security⁵.

If an application is rejected, applicants will be given the opportunity to improve their proposal.

4.2 High-Risk Review

For applications involving an elevated risk of communication-related harm or stigmatisation, the CCDC may impose additional requirements concerning the analysis plan, interpretative framework, plain-language summary, patient consultation, communication strategy and advance sharing of draft manuscripts with the relevant NMCB representative(s), insofar as this is compatible with academic independence.

To operationalise the concept of “high risk”, the CCDC uses a draft assessment rubric based on two core criteria (see Appendix 1). The following two specific clauses apply to high-risk applications (where either of the two criteria is rated “high”; see Appendix⁶):

1. **Consensus requirement:** The CCDC aims to reach consensus and gives substantial weight to the views of patient representatives⁷. A full committee, with input/representation from both affiliated patient organisations, is required for a quorum in this category. Once a quorum is reached, unanimity among the patient representatives present is the starting point for a positive CCDC recommendation. If consensus cannot be reached, no positive recommendation will be issued; the CCDC will document its considerations and any minority views for the EB’s decision.
2. **Right of reply:** If consensus cannot be reached, internal deliberation and a right of reply with the applicants will take place. If the application is ultimately rejected, applicants will be given the opportunity to revise their proposal.

4.4 Escalation in the Absence of Consensus

If consensus is not reached after internal deliberation and the right-of-reply process, the escalation steps set out in the NMCB governance regulations apply.

- **Step 1 – External advice:** The CCDC seeks advice from one or more independent external experts, preferably experts from the NMCB Advisory Board.
- **Step 2 – Executive Board:** If external advice does not lead to a CCDC recommendation supported by the committee, the CCDC submits a written summary to the EB setting out the majority and minority positions, including the reasoning against the assessment criteria. The EB then makes the formal decision; where appropriate, it may consult the General Assembly.

⁵External partners are not covered by the consortium JDRA; therefore, a separate DTA/MTA is required for data release. In principle, the standard DTA/MTA template and review procedure of the institute holding the data are used. The CCDC does not duplicate this review process; its role is limited to verifying that the process has been completed.

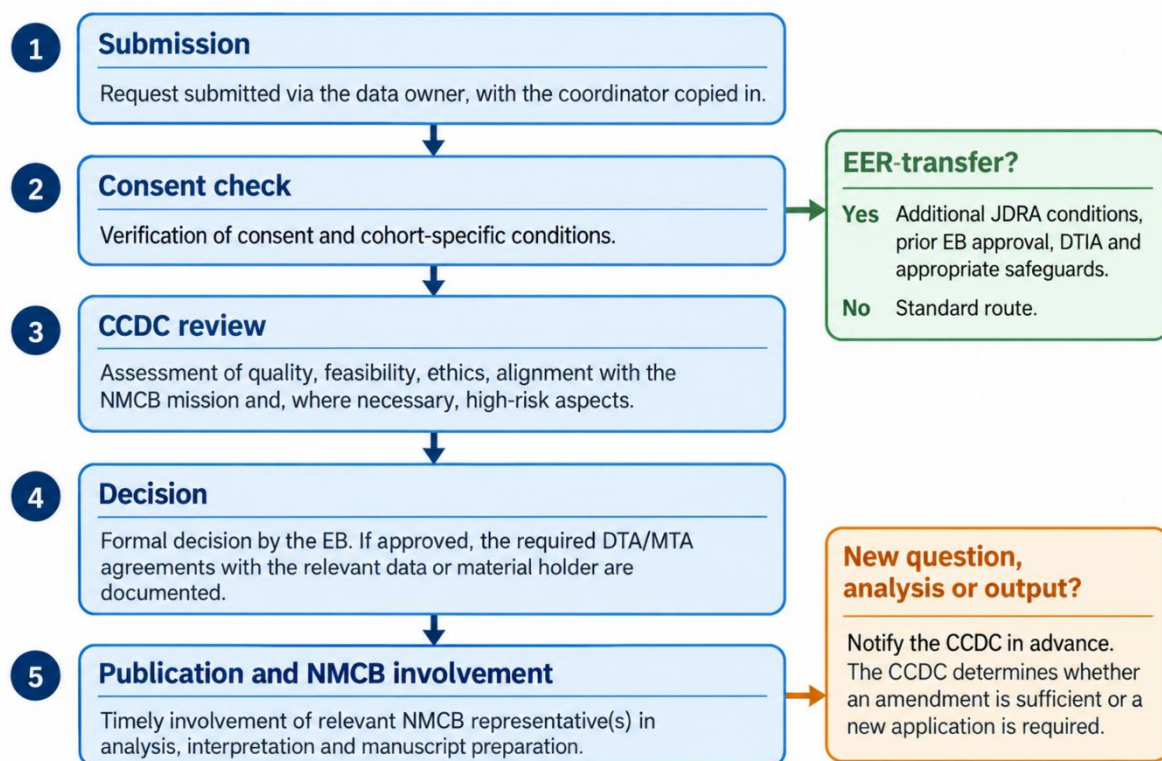
⁶ The CCDC may also classify an application as high-risk if both criteria receive a medium rating and, in the CCDC’s judgement, their combination poses a substantial risk of stigmatisation or communication-related risks.

⁷It is conceivable that a researcher’s reputation may be considered a communication risk; however, this alone must not constitute grounds for rejection.

5. Procedure and Release

Approval for the release of data and/or materials is always linked to a specific research objective, analysis plan or coherent publication package (in principle, two publications per application), as described in the application. Approval does not constitute blanket approval for other or future analyses, publications or secondary research questions. The CCDC must be notified in advance of materially new research questions, analyses, outcome measures or publication objectives; the CCDC determines whether an amendment is sufficient or a new application is required.

Figure 1. Schematic overview of the release procedure described in Section 5



The procedure has four layers: local eligibility and consent checks by the data holder, substantive review by the CCDC, a formal decision by the EB, and contracting through the relevant data holder.

1. **Submission:** Submit the central Data and Sample Request Form to the data owner, copying the coordinator.
2. **Consent Check:** Verificatie met de specifieke toestemmingen per cohort (Volwassenen, Paediatrisch, Hersenweefsel).
3. **CCDC review:** Assess scientific quality, feasibility, ethics and alignment with the NMCB mission, including high-risk review and the consensus/escalation procedure where applicable.
4. **Decision and contracting:** The EB makes the decision. If approved, a DTA/MTA is signed with the specific owner of the data/material (AUMC, UMCU or NIN-KNAW).
5. **Publication and NMCB involvement:** The receiving party must involve at least one relevant NMCB consortium researcher in a timely manner in the analysis, interpretation and manuscript preparation. This should normally include the representative of the relevant data or material

holder, giving them a genuine opportunity to contribute in accordance with applicable authorship criteria. If authorship is not established, NMCB, the relevant biobank/cohort infrastructure, the funding and relevant consortium contributions must be appropriately acknowledged and/or included in a collaborator or consortium statement, in accordance with the journal's policy.

Indicative timelines:

Completeness check by the data owner (copying the coordinator): within 15 working days. CCDC review: within a maximum of one month (or at the next meeting). Right of reply for high-risk applications: 15 working days. EB decision: within 10 working days of the CCDC recommendation. DTA/MTA contracting: dependent on the owner, with a target timeframe of one month. Stop-the-clock rule: timelines start only once the application is complete and are paused while additional information is outstanding.

Transfers outside the EU:

Every application must explicitly state whether data/materials will leave the EU. The consent check must address this category for each cohort and, where relevant, each participant. If transfer outside the European Economic Area (EEA) is requested, the conditions in the JDRA apply, including prior EB approval, a Data Transfer Impact Assessment (DTIA) and appropriate safeguards such as Standard Contractual Clauses (SCCs), where applicable.

Return of derived data:

Within a reasonable period after completion of the analyses or publication, the receiving party must return the generated derived data, analysis code/syntax and relevant metadata to NMCB, insofar as legally, ethically and technically possible, in accordance with the DTA/MTA.

6. Evaluation and Revisions

This framework will be reviewed annually by the CCDC and the EB, taking into account feedback from users, patient representatives and funders.

Appendix 1. High-Risk Assessment Rubric (draft, to be further developed)

The rubric below supports consistent and transparent assessment of applications that may be classified as “high risk”. The definitions for each level (low, medium, high) may be further developed in practice.

Criterion	Low	Medium	High	Assessment
Alignment with mission	Vraagstelling past duidelijk binnen de biomedische missie van NMCB, sluit aan bij consent en bevat geen impliciete blame of psychologische causaliteit.	The research question is partly aligned, but its scope, wording or rationale needs to be sharper.	The research question falls outside NMCB’s biomedical mission or is largely based on psychologising or stigmatising assumptions.	Assess the question, hypothesis, outcome measures, theoretical framework, biomedical rationale, consent and participants’ interests.
Communication	The title, abstract, context and plain-language summary are carefully worded; causal claims are cautious and a psychosomatic misinterpretation is unlikely.	There is a risk of misinterpretation or stigmatising framing, but this appears manageable through revisions or additional context.	There is a substantial chance that patients, stakeholders or the public will interpret the study as psychosomatic or stigmatising.	Assess the title, abstract, plain-language summary, causal claims, terminology, communication plan and mitigation measures.

Appendix 2. Data and Sample Request Form (indicative)

Use this form to request access to NMCB data and/or materials. The template is based on the NMCB Framework document and may be tailored further for each cohort/biobank.

	Description
Date of submission	
Project title	
Principal Investigator (PI) (Name, Institution, Department, Position, Email, Phone)	
Co-applicants (List names, affiliations, and roles)	
Institutional address for DTA/MTA	
Funding source(s) (Include grant number, if applicable)	
Has this request been discussed with an NMCB investigator?	Yes No
Intended start/end dates	
Intended outputs/publications	
Which new derived data will be generated, and how will it be returned to NMCB?	
Proposed arrangements for NMCB involvement in analysis, interpretation and publication.	

Lay summary A plain-language summary suitable for publication on the NMCB website. (max 200 words)	
Scientific abstract Include rationale, hypothesis, and methods. (max 300 words)	
Aims and objectives	
Type of request	Data only Samples only Data + Samples Collaboration proposal
Related ethical approval (Attach copy of ethics letter, if applicable)	
Link to existing NMCB study (e.g., sub-study, replication, secondary analysis)	
Expected public or patient benefit	
Patient engagement strategy	

Dataset(s) requested (specify domains, e.g. clinical, biomarker, omics, etc.)	
Variables / data fields required (Attach list, if extensive)	
Participant groups	Adult cohort Paediatric cohort Both

Participant subgroups (provide justification)	
Participant types	ME/CFS Post-COVID Lyme QFS Post-Sepsis Healthy controls
Number of participants	
Data linkage requested?	

Sample type(s) (e.g. plasma, serum, saliva, PBMCs)	
Number of participants/samples	
Volume per sample (µL)	
Intended analyses/assays	
Laboratory performing analyses (Name, address, contact)	
Will any material remain after analysis?	Destroy Return Discuss
Has similar work been done previously within NMCB?	No Yes, specify

Data storage location and security measures (describe IT infrastructure, encryption, access control)	
Will data leave the EU?	No Yes, specify country and legal basis
How will participant confidentiality be maintained?	
Plan for data destruction / return (specify timeline and method)	
Compliance confirmation	I confirm the research will comply with GDPR and the conditions of the NMCB DTA / MTA

Study design (cross-sectional, case-control, etc)	
Sample size justification	
Planned statistical analyses	
Expected outputs (tables, figures, derived variables, models, etc)	

Planned publications/conferences	
Proposed first and senior author(s)	
Proposed NMCB collaborator(s) (at least 1 recommended)	
Acknowledgement statement (confirm use of NMCB's standard wording)	
Timeline for manuscript submission	
Return of data and analysis syntax to NMCB	

Declaration	Tick
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All investigators have read and will adhere to the NMCB Access and Use Framework.	
No conflicts of interest exist, or any conflicts are disclosed here.	
All required ethical and institutional approvals will be obtained before data are released.	

Role	Name	Signature	Date
Applicant/PI			
Head of department/budget holder			
NMCB PI			
CCDC Chair (approval)			
CCDC Secretary (for the record)			

Application ID #	
Date received/reviewed	
Decision	Approved Approved with conditions Rejected
Summary of decision/conditions	
Follow-up actions	
Data communicated to applicant	