HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting – APPROVED

Date: 8th September 2026

Location: Zoom videoconferencing

HRCDC Attendance:

Aideen Hartney
Susan Smith
Paul Stynes
Aisling McMahon
Sarah Barnes Aabo
Jim Blighe
Barbara Clyne
Fionnuala Gough
Eben Stewart
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

Opening

The Chair opened the meeting and welcomed the members. The Chair also welcomed Eben Stewart as a new member of the HRCDC.

Apologies

John Woods, Antoinette O'Connor, Mary Tumelty, Ross McMullan, Jonathan Briody, Evelyn Mahon

Disclosure of Interest

Aisling McMahon (AMcM) declared her interest in application 26-015 (Prevention of REcurrent Vascular EVENTs after STROKE (PREVENT-STROKE) Study). AMCM was absent during the meeting when this application was considered.

Minutes of the last meeting

Draft minutes of 11th August 2026 were circulated in advance of the meeting and were approved by the HRCDC.

HRCDC
Health Research Consent Declaration Committee

Returning Applications

Reference ID:
26-010

Lead Applicant:
Daniela Tropea

Lead Data Controller:
Trinity College Dublin and St James's Hospital Dublin

Title:
EEG-Based Analysis of Brain Activity in patients with rare neuropsychiatric disorders and typical development (TD) controls (EBABArare)

Research Objective:
See HRCDC Meeting minutes of 26th May 2026

HRCDC Comments:
The HRCDC were reminded of their request for further information to the applicant and an overview of the applicant's responses were provided. The HRCDC was of the view that the responses addressed their queries and that a consent declaration could be made. However, it was discussed that some of points raised with regards changes to the study information leaflets and assent/consent forms had not been fully addressed and should be revisited by the Applicant. It was further commented that additional detail could be provided in the patient facing documents on what is meant by machine learning and to remove references to the use of a 'gatekeeper'
The applicant's reply to the question on the Assisted Decision-Making Act within the HRCDC application was also noted; it was discussed that the Applicant could be reminded to have due regard to this Act when undertaking this study.

HRCDC Decision:
The consensus of the HRCDC was that a Consent Declaration is made, subject to conditions attached.

Duration of Declaration:
The consent declaration is made until 31st July 2038 or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:
Condition 1. With regard the updated study information leaflets and assent forms submitted to the HRCDC, the following points, including some previously raised in Point 4 of the HRCDC's request for further information, remain incomplete or outstanding and must be addressed prior to the study commencing:

- Sections of the documentation for the proxy continues to be incorrectly written in the first person
- The study information leaflets still state that participants cannot withdraw after the data is pseudonymised; this is incorrect as participants can still be identified when the data is

pseudonymised and therefore be withdrawn from the study up until the data is anonymised.

- In addition, the term 'consent' should not be used in the study documents used to seek permission from the proxy; the term 'proxy assent' should be used instead. References to the 'gatekeeper' in the PILs should also be removed as they will not be used in this research.

Condition 2. The applicant must submit to the HRCDC secretariat, a signature from St James's Hospital (SJH) on the HRCDC application form. SJH data protection officer feedback on the DPIA must also be submitted. This condition must be addressed before the study commences.

HRCDC Recommendations:

Recommendation 1. Additional detail could be provided in the study information leaflets to describe what is meant by 'machine learning' beyond the current statement that *'Machine learning may be used to analyse the EEG data.'*

Reference ID:

26-015

Lead Applicant:

Dr. John McCabe

Lead Data Controller:

Mater Misericordiae University Hospital (MMUH)

Title:

Prevention of REcurrent Vascular EVENTs after STROKE (PREVENT-STROKE) Study

Research Objective:

See HRCDC Meeting minutes of 11th August 2026

HRCDC Comments:

The HRCDC were reminded of their request for further information to the applicant and an overview of the applicant's responses were provided. The HRCDC was of the view that the responses addressed their queries and that a consent declaration could be made.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration is made, subject to conditions attached.

Duration of Declaration:

The consent declaration is made until 31st October 2050 or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. Data agreements and arrangements must be in place, where required; this includes where data that is not part of routine care is collected by the Mater Hospital for the purpose of this study from the applicant's GP or from another hospital.

HRCDC Recommendations:

Recommendation 1. The following points must be addressed within the study information leaflets and assent/consent forms prior to the study commencing:

- It was noted that if insufficient clinical blood samples are left over from care and treatment, the participant may be asked to provide an additional sample for this research study. The study information leaflet and assent/consent forms should make this clearer.
- The study information leaflets should detail that data may also be collected from the participant's GP and other hospitals beyond the Mater, and why this will be processed in this study.
- The study information leaflets also outline that '*this study data will not be used for commercial purposes or shared with commercial organisations'*, however in the assent and consent forms there is a tick-box option for '*I understand that study results may be used to build medical tools. If those tools prove useful they may be shared or licenced, including for commercial use…'*. This inconsistency needs to be addressed.
- The assent/consent forms should provide a clear yes/no option with regards the processing of personal/pseudonymised data for this study.
- The information leaflets should be clear that participant data can be removed prior to anonymisation if a request to withdraw is made, subject to GDPR derogations that may apply.

New Applications

Reference ID:

26-019

Lead Applicant:

Dr James O`Byrne

Lead Data Controller:

Chiesi Farmaceutici S. p. A (Italy)

Title:

THE ALPHA-MANNOSIDOSIS REGISTRY: A multi-centre, multi-country, non interventional, prospective cohort, in alpha-mannosidosis patients (SPARKLE)

Research Objective:

This Registry is being conducted to gather additional data in the context of post marketing surveillance. As a condition of Lamzede marketing authorization and its Risk Management Plan, the Alpha-mannosidosis registry is requested to obtain long term data on effectiveness and safety; furthermore, the Registry will expand the current understanding of alpha-mannosidosis by collecting additional data on natural history and disease progression in alpha-mannosidosis patients despite the therapeutic treatment they are receiving. Human

alpha-mannosidosis is a rare genetic disorder, resulting in cognitive impairment, skeletal changes, hearing loss and recurrent infections. The epidemiology of alpha mannosidosis is poorly understood. The incidence of the disease ranges from 1 in 500,000-1:1,000,000 worldwide. Life expectancy in alpha-mannosidosis is highly variable. Individuals with early onset severe disease often do not survive beyond childhood, whereas those with milder disorders may survive well into adulthood. Clinical expression of alpha-mannosidosis varies from a few symptoms to death. The long-term prognosis of the disorder is poor, although some patients can reach over 50 years of age. Lamzede is the only authorised treatment for alpha mannosidosis in the EU. Prior to its approval, the only available treatment focused on the relief of symptoms, and prevention of complications and impairments. These treatments and procedures are designed individually based on symptoms and age. Bone marrow transplantation has been used as a therapeutic strategy for alpha mannosidosis but comes with a risk of mortality and morbidity. Palliative treatments include physiotherapy, respiratory physiotherapy or antibiotic treatment for recurrent infections. This study is a non-interventional prospective registry which aims to collect data from patients with alpha mannosidosis to improve understanding of treatment with Lamzede and of the disease itself. The duration of the observation period for each patient will be 15 years.

Reason for Declaration:

The consent declaration is requested to process the personal data of one eligible participant who lacks decision-making capacity.

HRCDC Comments:

The Chairperson requested the primary and secondary reviewers who were assigned to this application to outline the proposal contained in the application and any issues arising. There was then a discussion on the application by the HRCDC. It was the consensus of the HRCDC that a consent declaration should be made, subject to conditions attached.

Public interest case:

- The HRCDC discussed the study activities, including the baseline and follow-up data collection. It was noted that the study focuses on a rare disease and that individuals living with such conditions should not be excluded from research.
- It was also discussed that while most of the study data is already collected as part of standard care and treatment, it was queried whether the quality-of-life questionnaires are collected primarily for this study. However, the questionnaires are completed by the participant themselves or their family, and that data from other healthcare providers outside the MMUH will not be collected.
- It was also clarified that recruitment for this study had ceased and that only one participant from Ireland will be enrolled.
- Overall, it was the view of the HRCDC that there is a strong public interest case in this research.

Data Security:

- It was acknowledged by the HRCDC that security measures will be put in place.

PPI and dissemination:

- Based on the replies from the applicant, it was the view of the HRCDC that PPI engagement could be strengthened; the applicant's response was that PPI to date involved discussions with the data controller's patient engagement manager and not with patient representatives. It was noted that there are rare disease PPI organisations in Ireland who could be engaged with.
- On the dissemination of findings, it was also commented that this too could be strengthened via sharing of findings with Irish rare disease patient groups and not just via the Encepp website.

Study Information leaflets:

- It was discussed that the information leaflets should make it clear on what data to be collected for this study is and is not part of routine care.
- The study information leaflets appear to confuse the terms 'pseudonymised' and 'anonymised' data.
- It was discussed that separate information leaflets should be used for the proxy and not the same ones used to seek the consent of the participants themselves.
- On withdrawing from the study, the applicant outlines in their responses and in the PILs that the study will keep the data it has already collected; it was commented that personal/pseudonymised data should be deleted if requested unless there is a GPDR derogation that can apply.
- It was confirmed by the applicant that only data held by the MMUH, in addition to questionnaires and patient diaries, will be included in this study; however, it was noted that the PIL and assent/consent form refer and request permission to contact the participant's GP to seek medical information from them.

Other:

- On the processing of samples and the associated data, it was discussed that the declaration will not cover sample analysis that goes beyond that undertaken as part of standard care and treatment.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration, subject to conditions attached, should be made.

Duration of Declaration:

The consent declaration is made until 8th September 2067 (15 years observation period plus 25 years of data archiving).

Conditions Attached:

Condition 1. The required data agreements and arrangements must be in place for this study.

Condition 2. The following points must be addressed with regards the study information leaflet and assent/consent forms prior to the study commencing:

- A separate proxy information leaflet, and not the same one used to seek the consent of the participants themselves, should be used for the proxy when seeking their assent.
- The information leaflets confuse the terms ‘pseudonymised’ and ‘anonymised’ data; they also use the term ‘coded’ data which is not a term used in the GDPR. It should be made clear in the documents that pseudonymised data will be collected, transferred and analysed.
- It was confirmed by the applicant that only data held by the MMUH, in addition to questionnaires and patient diaries, will be included in this study; however, it was noted that the PIL and assent/consent form refer and request permission to contact the participant’s GP to seek medical information from them – this inaccuracy within the PILs must be addressed.
- On withdrawing from the study, the applicant outlines in their responses to the HRCDC and in the PIL that the study will keep the data it has already collected; please note that personal/pseudonymised data should be deleted if requested unless there is a GPDR derogation that can apply – this should be reflected in the study PILs.

HRCDC Recommendations:

Recommendation 1. The Applicant should enhance the level of PPI engagement undertaken for this specific study, and in particular undertake engagement with rare disease representative groups in Ireland (for example Rare Diseases Ireland). The applicant is requested to progress this prior to the study commencing.

Recommendation 2. The study should strengthen its strategy to disseminate the study findings beyond the Encepp website, with a focus on sharing the findings with those living with rare diseases such as through relevant representative groups.

Recommendation 3. Further to condition 2, the information leaflets could make it clearer on what data to be collected for this study is and is not part of routine care (i.e., the medical record data, the patient questionnaire and diaries).

Annual Reviews

The Secretariat has received 8 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 23-010-AF1 (ESsCAPE)
- **Ref ID:** 25-007-AF1 (Clinical Feasibility Study of a Prototype Device (SepTec) System for Early Detection of Sepsis in Critically Ill Patients)
- **Ref ID:** 23-004-AF1 (REACT SHOCK)
- **Ref ID:** 22-007-AF1 (OPTIMATE)
- **Ref ID:** 25-011-AF1 (EXTUBE)
- **Ref ID:** 25-006-AF1 (COALESCE-Brain)
- **Ref ID:** 19-004-AF2 (REMAP-CAP)
- **Ref ID:** 25-004-AF1/CSO (Impact of diabetes and co-morbidities on health status, economic activity and morality)

Any Other Business

- The HRCDC were provided with a draft of the updated confidentially agreement. The change was approved.
- The HRCDC were reminded that the next meeting is scheduled for 6th October.

The Chair closed the meeting