HRCDC
Health Research Consent
Declaration Committee

Minutes of the Meeting – APPROVED

Date: 24th March 2026

Location: Zoom videoconferencing

HRCDC Attendance:

Aideen Hartney
John Woods
Patricia O'Beirne
Susan Smith
Paul Stynes
Aisling McMahon
Sarah Barnes Aabo
Antoinette O'Connor
Jim Blighe
Ross McMullan
Barbara Clyne
Fionnuala Gough
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

Opening

The Chair opened the meeting and welcomed the members.

Apologies

Evelyn Mahon, Mary Tumelty, Jonathan Briody.

Disclosure of Interest

Aisling McMahon (AMcM) declared her interest in application 26-005 (ERUPT study). AMcM was absent during the meeting when this application was considered.

Minutes of the last meeting

Draft minutes of 24th February 2026 were circulated in advance of the meeting and were approved by the HRCDC.

Chairperson approvals

- **25-011-AF1/AMD3 (EXTUBE)**: The HRCDC were informed that amendment request 25-011-AF1/AMD3 was approved via the chairperson approval process. The amendment covers the addition of Beaumont Hospital, Naas General Hospital, Sligo University Hospital and University Hospital Limerick as study sites and data processors.

New Applications

Reference ID:

26-004

Lead Applicant:

Dr Sarah Power

Lead Data Controller:

Neuravi Ltd

Title:

A Prospective, First In Human Pivotal Study To Evaluate The Adaptive Tip Catheter Used To Treat Acute Ischemic Stroke Patients During Mechanical Thrombectomy (PHAST).

Research Objective:

PHAST will evaluate the Adaptive Tip Catheter (ATC) in treating acute ischemic stroke (Blockage in a blood vessel in the brain caused by a clot). The ATC is a small flexible tube and works to capture the clot(s) by using suction. The ATC is then removed from the body. The aim of the study is to assess the safety and effectiveness of the ATC. Data generated will support CE-mark application. Due to the emergent nature of stroke, and the time sensitive nature of treatment, prospective informed consent may not always be feasible prior to enrolment. In such cases, participants may be enrolled under Article 68 of the Medical Device Regulation (MDR). Informed consent will be sought from the participant as soon as capacity returns, or from a legally designated representative (LDR) if the participant does not regain capacity. This will occur by discharge or day 7 (whichever occurs first).

Reason for Declaration:

The consent declaration is requested to process personal data of participants who lack decision-making capacity for the purpose of the PHAST study.

Due to the emergent nature of stroke, and the time sensitive nature of treatment, prospective informed consent may not always be feasible prior to enrolment. Where participants lack decision-making capacity to consent prior to the procedure, assent will be sought from a family member or medical practitioner prior to the procedure. In some scenarios, the participant may be enrolled under Article 68 of the Medical Device Regulation (MDR) for emergency inclusion, and deferred participant consent or proxy assent will then be sought within 7 days or by discharge. Informed consent will be sought from the participant as soon as capacity returns.

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. Following detailed discussions, 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, and it was the view of the HRCDC that there is a strong public interest case in this research.

Exit strategy:

- It was discussed that it is not yet clear whether the data will be fully anonymised or deleted after the archiving period of 25 years has concluded. It was commented that this should be reported on by the Applicant and that the study information should also note that the data will be deleted or fully anonymised by the controller and processors by the end of the study.

Public and Patient Involvement (PPI) and PILs:

- The HRCDC noted the Applicant's reply that no PPI has been undertaken or is planned for this study. The HRCDC discussed the importance of PPI and was of the view that a strong recommendation should be made with regards PPI in future research studies related to this device.
- On the study information leaflets, it was the view of the HRCDC that the language used in places was quite technical in nature and grammatical errors were also noted. It was commented that a lay-person friendly information sheet that describes the study in a non-technical manner could accompany the main information leaflet and assent/consent form for the Irish site, and the development of such a sheet could involve appropriate PPI engagement. It was also recommended that the PILS could also be explained by a member of the study team to the participant before assent is obtained.
- On the list of risks to the participant noted in the information leaflet, it was also commented that the list of risks could be organised by category or degree of seriousness to help the participant/proxy's understanding.
- In addition, it was commented that the information leaflets were not fully clear on whether data can be removed from the study if a proxy or participant withdraws and wishes to have their data deleted.
- It was further noted that the forms do not include a specific tick-box option to affirm permission for the use of personal/pseudonymised data in future research. It was also commented that a tick-box allowing the use of brain imaging for other purposes could be made clearer; it was discussed that the scope of the consent declaration will be limited to the PHAST study only and it was further highlighted that the research ethics committee had attached a condition with regards to the description of future research within the PILs that must be complied with by the study.

Other:

- It was noted that pseudonymised data will be transferred and processed outside of Ireland, including to countries outside the EEA. It was commented that necessary arrangements such as Standard Contractual Clauses and Transfer Impact Assessments will be completed.

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 31st March 2027 and for 25 years thereafter, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The conditions attached to the NREC approval letter must be complied with; this includes conditions relating to the assent/consent process and changes to the PILs with regards future research.

Condition 2. The necessary data arrangements/arrangements must be in place prior to the transfer/processing of data. This includes necessary agreements/arrangements for transfer of data outside the EEA, such as Standard Contractual Clauses and Transfer Impact Assessments.

Condition 3. The Applicant must report on whether the data will be deleted or fully anonymised by the controller and processors in the annual review.

HRCDC Recommendations:

Recommendation 1. It is noted that public and patient involvement (PPI) will not be undertaken in Ireland or other countries with regards this specific study. The HRCDC strongly recommends and encourages that future studies to be undertaken by the data controller in Ireland undertake appropriate PPI engagement.

Recommendation 2. The HRCDC recommends that the following points are considered by the Applicant with regards to the study information leaflet and assent/consent form:

- it was the view of the HRCDC that the study documentation for the participant and their proxies utilise quite technical language in places that may be difficult for some individuals to understand; some grammatical errors were also noted in the leaflets. It is therefore recommended that the Applicant review the study documentation and utilise more lay-person language. Consideration should also be given to developing and using a separate lay-person friendly information sheet that describes the study in a non-technical manner, that could accompany the main information leaflet and assent/consent form for the Irish site; the development of such an information sheet could involve Irish PPI engagement.
- On the list of risks to the participant noted in the information leaflet, it was commented that these could be organised by category or level.
- the information leaflets are not fully clear on whether data can be removed from the study if a proxy or participant withdraws and wishes to have their data deleted; they refer to

using all data collected unless consent/assent is withdrawn but they also state that a request to delete data may not be allowed. Further the replies provided to the HRCDC also stated that data can't be removed but is also considered on case-by-case basis. The applicant should review the study documents to make it clearer to individuals whether data can or cannot be removed from the study, if requested.

- The assent/consent forms do not include a specific tick-box option to affirm permission for the use of personal/pseudonymised data in future research; this should be reviewed by the Applicant.
- the study information leaflets should note that the data will be deleted or fully anonymised by the controller and processors by the end of the study and data archive period.

Further to the above it was also recommended that the PILS could also be explained by a member of the local study team to the participant before assent is obtained.

Reference ID:

26-005

Lead Applicant:

Dr. Yvelynne Kelly

Lead Data Controller:

Medical University of Vienna
Tallaght University Hospital

Title:

ERUPT: Early rehabilitation of intensive care unit patients - a multinational prospective observational study on dosage and outcome

Research Objective:

The ERUPT Study is an international observational study looking at how early rehabilitation and mobilisation is provided for patients in intensive care units (ICUs). Patients in ICU often spend long periods confined to bed, which can cause muscle weakness and delayed recovery. Early rehabilitation (e.g. sitting up, standing, or walking in ICU) may help recovery, but current practices vary widely around the world. In this study, ICU patients will be observed during their hospital stay. Information will be collected on patient characteristics, the timing and type of mobilisation they receive, and outcomes including length of ICU stay, survival, and recovery. Patients will also be contacted 90 days after enrolment to ask about their health and daily activities. The study involves only collection of information from medical records, daily observations, routine performance-based standardised tests and questionnaires. The results will help to understand how mobilisation is delivered in ICUs worldwide, and whether differences in practice affect patient outcomes.

Reason for Declaration:

For the processing of personal/pseudonymised data of those who lack decision making capacity for the purpose of the ERUPT study only.

The consent declaration is required for patients who lack decision-making where they are mechanically ventilated, as well as for those who are not mechanically ventilated, but who lack capacity due to other reasons. There is a process for obtaining deferred proxy assent/participant consent; they aim to seek deferred proxy consent within 72 hours of patient enrolment – if not obtained then the data is deleted.

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. Following detailed discussions, 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, and it was the view of the HRCDC that there is a strong public interest case in this research.

Deferred proxy assent:

- The Applicant confirmed that a deferred proxy assent process will be implemented and that if such proxy assent is not obtained within 72hrs of participant enrolment their data will be deleted. It was discussed that if data is uploaded to the electronic capture system, it should not be further processed, including analysed, prior to obtaining deferred assent within 72hrs.

Study information leaflets:

- It was commented that the study information leaflets could be clearer that data, including pre-hospital function, will be collated from medical records, observations as well as interviews with the participants or their proxies. It was also discussed that they should also be clear on the time points when the data will be collected.
- Further, it was noted that the leaflets do not reference TUH as a joint controller of the study and under the section 'Your rights', the rights related to erasure and automated decision-making/processing are not listed. The leaflets also state that the data is 'stored securely for 10 years and then deleted or anonymised'; it was commented that it should be clear in the PILs if the data is anonymised or deleted. Further, there are inaccurate references to the data being anonymised during the study rather than pseudonymised.
- It was also noted that consent for future research was not provided as a separate option within the consent form but was bundled with permission for other processing activities.

Other:

- It was discussed that the declaration at present will only cover Tallaght University Hospital and that the other named sites of the Mater Misericordiae University Hospital, Beaumont Hospital, St. Vincent's University Hospital and University Hospital Galway would only be covered by the consent declaration once they have obtained the necessary research ethics approval.
- It was commented that where a participant is withdrawn from the study and the researchers wish to continue to keep and process their data in the study, then permission for this should be requested from the proxy or the participant; if a request is made to remove/delete the data form the study, then this should be acted upon, subject to any GDPR derogations that may apply.

- It was noted that the Applicant plans to continue engagement with the international public and patient representatives during the course of the study; it was queried whether they could engage with Irish PPI representatives as part of this.
- It was confirmed that the data protection officer feedback on the DPIA from the Medical University of Vienna needs to be submitted.

HRCDC Decision:

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

Duration of Declaration:

The consent declaration is made until 28th February 2038, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. It is a condition that while data can be collected and uploaded to the ClinCase system, it cannot be further processed (including analysed) by any party prior to obtaining proxy assent by the 72hr deadline; if proxy assent is not obtained within 72hrs then the data uploaded to the ClinCase must be fully deleted.

Condition 2. The other named study sites of the Mater Misericordiae University Hospital, Beaumont Hospital, St. Vincent's University Hospital and University Hospital Galway are not covered by this consent declaration until they have obtained the necessary research ethics approval and confirmation of this has been submitted to the HRCDC.

Condition 3. The Applicant must report in the Annual Review whether the personal/ pseudonymised data will be anonymised or deleted after 10 years.

Condition 4. Where a participant is withdrawn from the study and the researchers wish to continue to keep and process their data in the study, then permission for this must be obtained from the proxy or the participant; if a request is made to remove/delete the data from the study, then this should be acted upon, subject to any GDPR derogations that may apply. ***Note:*** a withdrawal form is included in one of the versions of the study documents submitted to the HRCDC, but it is not included in all the versions.

Condition 5. Data protection officer feedback on the DPIA from the Medical University of Vienna remains outstanding and must be submitted by **30th April 2026 or before any patient enrolment.**

HRCDC Recommendations:

Recommendation: The Applicant is requested to address the following with regards the study information leaflets for the participant and the proxy:

- it should be clear that data, including pre-hospital function, will be collated from medical records, observations as well as interviews with the participants or their proxies. The leaflets should also be fully clear on the time points when the data will be collected.
- The leaflets should reference Tallaght University Hospital as a joint data controller of this study with Vienna.

- Under the section 'Your rights', the right to erasure and the rights with regards to automated decision-making/processing are not listed and should be included.
- The leaflets also state that the data is 'stored securely for 10 years and then deleted or anonymised'; it should be clear in leaflets whether the data is anonymised or deleted.
- There are inaccurate references to the data being anonymised during the study rather than pseudonymised, for example 'details of the mobilisation that you receive in the ICU to be recorded anonymously as part of this study'.
- The option to provide consent for future research is bundled (i.e., not a separate option) in the consent forms submitted; for example a consent form submitted states: *'I give permission for my data to be stored anonymously in a cloud-based electronic data collection system hosted by the Medical University of Vienna for analysis as part of this study* ***and*** *for my data to be used for possible future research related to the current study without further consent being require*d'. The option to provide consent/assent for future research should be provided as a separate and unbundled option in the consent/assent forms.

Recommendation 2. It is noted that the Applicant plans to continue engagement with the international public and patient representatives during the course of the study; the Applicant is asked to consider if they could engage with Irish PPI representatives as part of this ongoing process.

Annual Reviews

The Secretariat has received 6 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 25-001-AF1 (AKI-EPI-2)
- **Ref ID:** 24-012-AFI (T4P)
- **Ref ID:** 20-005-AF1 (AIID study)
- **Ref ID:** 19-075-F2 (University of Galway-Saolta Cancer Biobank)
- **Ref ID:** 19-085-AF1 (Blood Biomarkers to Predict Recovery from Ischaemic Stroke
- **Ref ID:** 20-006-AF1/COV (A randomized double-blind placebo-controlled trial of intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness)

An update was also provided on the overdue Annual Review for 24-013-AF1 that was discussed at the February HRCDC meeting.

Activities report and events of interest

The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting and discussed the key points at the meeting.

Any Other Business

- The Secretariat provided an update on the HRCDC 2025 Annual Report. The HRCDC were informed that the final draft will be circulated to the members shortly and the report will then be submitted to the Department of Health by the statutory deadline.
- The HRCDC were reminded that the next meeting is scheduled for 28th April 2026.

The Chair closed the meeting