# NREC-MD Meeting Minutes

**17th July 2025**

## Attendance

| Name | Role | Attendance/ Apologies |
|---|---|---|
| Prof. Barry O'Sullivan | Chair | Attended |
| Prof. Mary Sharp | Deputy Chair | Attended |
| Prof. Declan Patton | Deputy Chair | Attended |
| Dr Alyson Bailey | Member | Attended |
| Dr Caitriona Cahir | Member | Attended |
| Dr Daniel Coakley | Member | Attended |
| Dr Mireille Crampe | Member | Attended |
| Dr Ruth Davis | Member | Apologies |
| Prof Roisin Dwyer | Member | Attended |
| Dr Owen Doody | Member | Apologies |
| Dr Frank Houghton | Member | Apologies |
| Dr James Gilroy | Member | Apologies |
| Prof Suzanne Guerin | Member | Apologies |
| Ms Orla Lane | Member | Attended |
| Prof. Cara Martin | Member | Apologies |
| Mr Billy McCann (PPI) | Member | Attended |
| Dr Natalie McEvoy | Member | Attended |
| Prof. Tom Melvin | Member | Attended |
| Prof. Therese Murphy | Member | Apologies |
| Dr Declan O'Callaghan | Member | Attended |
| Dr Clare O'Connor | Member | Attended |
| Prof Paul O'Connor | Member | Attended |
| Dr Joanne O'Dwyer | Member | Attended |
| Mr Damien Owens | Member | Attended |

| | | |
|---|---|---|
| Prof. Mahendra Varma | Member | Attended |
| Mr Peter Woulfe | Member | Apologies |
| Ms Simone Walsh | Member | Attended |
| Louise Houston | Project Officer, National Office for Research Ethics Committees | Attended |
| Dr Sarah McLoughlin | Programme Officer, National Office for Research Ethics Committees | Attended |
| Dr Lucia Prihodova | Programme Manager, National Office for Research Ethics Committees | Attended |
| Dr Emily Vereker | Head of Office, National Office for Research Ethics Committees | Attended |
| Ciaran Horan* | Administrative Assistant, National Office for Research Ethics Committees | Attended |

**Quorum for decisions:** Yes

| **Agenda, discussion and decisions** | |
|---|---|
| 1. Welcome and apologies | The Chairperson welcomed the Committee, acknowledged apologies and opened the meeting. |
| 2. Report on Committee business | Noted |
| 3. Minutes of previous meeting | Adopted |
| 4. Declarations of interest | Mr Damien Owens: 25-NREC-MD-015<br>Mr Damien Owens stepped out of the meeting for the discussion of the application. |
| 5. 24-NREC-MD-011-SM2-R1 | • Principal Investigator (Lead Institution): Dr Noel Horgan (St Vincent's Hospital)<br>• Sponsor: Aura Biosciences |

| | |
|---|---|
| | • Study title: A Phase 3 randomized, masked, controlled trial to evaluate efficacy and safety of belzupacap sarotalocan (AU-011) treatment compared to sham control in subjects with primary indeterminate lesions or small choroidal melanoma<br>• NREC-MD decision: Favourable |
| 6. 25-NREC-MD-015-R1 | • Principal Investigator (Lead Institution): Prof Damien Kenny & Prof Kevin Walsh (Mater Misericordiae University Hospital)<br>• Sponsor: Medtronic Bakken Research Center<br>• Study title: Harmony TPV EMEA Post-Market Study<br>• NREC-MD decision: Favourable with conditions<br>• Associated conditions:<br>1. The participant information leaflet / informed consent form to be revised to reflect that this is a post-market clinical follow-up study and to clearly distinguish between procedures that are part of standard care and those that are specific to the study.<br>2. Due to some inconsistencies in the application documentation when it comes to the recruitment process, only those who have been determined to be treated with this device as part of standard of care to be informed about the study. |
| 7. 25-NREC-MD-019 | • Principal Investigator (Lead Institution): Prof Gabor Szeplaki (Mater Private Hospital)<br>• Sponsor: Boston Scientific International S.A<br>• Study title: A Registry on the FARAVIEW Technology of the OPAL HDx Mapping System When Used With the FARAWAVE NAV Ablation Catheter in the Treatment of Atrial Fibrillation (OPALISE)<br>• NREC-MD decision: Request for further information<br>• Further information requested:<br>1. The NREC-MD noted that Mater private aims to recruit 50 participants, however the protocol states that no site should recruit more than 40 participants to minimise centre effect bias. Clarify if the site received approval from the sponsor to recruit higher participant number than the maximum number per site specified in the protocol.<br>2. The NREC-MD noted from the Participant Information Leaflet/ Informed Consent Form that participants will need to inform their doctor about any changes to their medication, all other medical |

| | |
|---|---|
| | treatments and any medical problems or concerns that might have, including any admissions to the hospital or clinic visits, even if they are not related to this study. The NREC-MD requests clarification of how participants are expected to do this e.g. phone, in person visits or another method. The process should be then outlined in the participant information leaflet / informed consent form (PIL/ICF).<br>3. Clarify the sequencing of screening and recruitment procedures. Namely, clarify:<br>- The sequence of identifying prospective participants, approaching them about participation, screening and consenting.<br>- Who will undertake the actions listed in point 3a – study doctor or arrythmia nurse specialist.<br>4. As the recruitment will be undertaken by the clinical team, please outline how will it be ensured that participants have a good understanding of what activities are care related and what activities are study specific and therefore optional?<br>5. Given that this study is being conducted to "*continuously assess acute and long-term safety and effectiveness outcomes in subjects undergoing an ablation procedure for the treatment of atrial fibrillation in a standard of care setting"* the NREC-MD requests clarification / justification as to why are following groups excluded from the study:<br>- people with cognitive impairment<br>- pregnant<br>- of childbearing age.<br>Confirm if these patient population undergo treatment with the FARAVIEW technology as standard of care and if yes, justify their exclusion from the study.<br>6. The NREC-MD noted that translated copies of documents will be provided to participants who a non-native English speaker. Clarify what additional supports will be provided to participants who are not fluent in English language throughout the study to ensure they remain fully informed of the study procedures and their rights? In addition, note that if the study seeks to enrol a participant who requires a translated documentation, translations must be completed by a certified translation provider, and the translation certificates submitted to the NREC-MD.<br>7. The NREC-MD requests the PIL/ICF it is extensively revised to minimise technical language and to increase accessibility as in its current form it is not accessible to a layperson. |

| | |
|---|---|
| | 8. Furthermore, the PIL/ICF must be revised for Ireland, eg the reference to the UK arm of this study should be removed.<br>9. The NREC-MD noted that the PIL/ICF indicates participants will be informed of the study results via a website and through the study investigators. Clarify the specific process by which participants will be informed.<br>10. The NREC-MD requests that the information on withdrawal from the study is simplified and clarified and that if requested by the participant, full withdrawal of data is facilitated with the exception of any data required under the EU 2017/ 745 Medical Device Regulation.<br>11. Under the GDPR if data is to be anonymised a specific consent line for this must be included in the ICF. Update the ICF accordingly.<br>12. The NREC-MD noted number of inconsistencies in the description of data processing activities across the documentation and that the documentation would benefit from a review by the site DPO. Clarify if the sponsor has/ intends engaged with the site DPO on this application.<br>13. The NREC-MD noted that pseudonymised data will be held for 75 years. Clarify why this duration has been chosen.<br>14. Furthermore, review participant facing documentation clarity on the data retention period, currently ranging from 20-75y.<br>15. The PIL/ICF as it is currently written implies that future research may be carried out on participant data. If future research is to be carried out, then this should be outlined clearly in the documentation and a specific consent line for this should be included in the ICF.<br>Note that In line with regulations/best practice future use of personal data must be clearly explained to participants in the PIL/ICF so as to constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,<br>- it should be confined to a specified disease, related diseases or drug under study in this trial. Consent can only be obtained where future use of samples and data is defined such that participants are fully informed,<br>- and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies,<br>The PIL/ICF should also make it clear to participants that subsequent research ethics review will be sought for specific |

| | |
|---|---|
| | research once clearly defined. For further guidance, see: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/ |
| 8. 25-NREC-MD-020 | • Principal Investigator (Lead Institution): Prof Sherif AH Sultan (University of Galway Ireland)<br>• Sponsor: Feeltect Ltd<br>• Study title: Randomised control study of using a pressure monitoring technology for improving the targeted application, monitoring, and maintenance of compression therapy in patients with Venous Leg Ulcers<br>• NREC-MD decision: Request for further information<br>• Further information requested:<br>1. Note that the NREC-MD discussed this application at length and noted the potential benefit of this device, the importance of this clinical investigation and that as such it is a straightforward study.<br>However, the Committee noted that the application documentation raised number of queries regarding the recruitment procedures, management of the study, study implementation and the study teams' experience in the conduction of clinical investigations in terms of data processing and protection in the context of a clinical investigation.<br>To that end, the NREC-MD strongly recommends that you engage with the HRB Clinical Research Facility Galway, the Institute of Clinical Trials at University of Galway or another institution / organisation with experience in undertaking clinical investigations in relation to support in undertaking this clinical investigation. Additionally, the National Office would be happy to take arrange a call to discuss this decision letter and the queries raised by the Committees.<br>2. The NREC-MD noted that Section D6 of the application form states that the device is in the validation and verification phase while Section D7 states that the device is CE marked as a Class 1 device. Clarify this discrepancy.<br>3. The NREC-MD noted only five iPads will be available for use by 20 participants. Clarify how the study be carried out in practical terms as this suggests that the study will need to be conducted in four separate cohorts of five participants each, with each cohort requiring 90 days to complete. As a result, the total duration would extend to approximately 12 months, which exceeds the originally planned 9-month study period. |

| | |
|---|---|
| | 4. The NREC-MD noted a discrepancy between the participant information leaflet/informed consent form (PIL/ICF) and the application form (Section F13) in terms of frequency of transmission of data. The PIL/ICF indicates that data transmission will occur twice weekly for five minutes, whereas the application form states that data will be uploaded daily, with participants being contacted by phone if uploads do not occur. Clarify this.<br>5. Following up on previous point, the NREC-MD also requests that if participants may be contacted via phone daily, this is clearly stated in the PIL/ICF. Where possible, a pre-agreed time should be arranged to avoid burden to participants.<br>6. The NREC-MD noted in response to Q4 of the site suitability form that the same bandages will be used only 'where possible'. However, existing literature highlights significant variability in the pressure applied by healthcare professionals when using compression bandages to treat venous leg ulcers. To ensure consistency, it would be advisable to use the same type of bandage throughout the study. If this is not feasible, provide a detailed justification.<br>7. The NREC-MD noted in Section E4 of the application form (page 13) that *"The control group will receive standard care and use the pressure-sensing device with a blinded application (no feedback provided), with data transmitted for monitoring".* This appears to suggest that the clinical team may be aware of suboptimal pressure readings while the participant is wearing the device but will not intervene. Confirm whether this interpretation is correct? If so, this should be clearly communicated in the PIL/ICF.<br>8. The NREC-MD requests that Section G5 of the application form is completed.<br>9. The NREC-MD requests clarification as to whether it is possible to inform participants of the research results from this study. If possible, this information should be included in the PIL/ICF.<br>10. The NREC-MD noted that the device will no longer be available after the end of the study. If the results show a significant improvement with the use of the device, is there scope to provide the device to participants?<br>11. The NREC-MD requests more information on the Principal Investigator's (PIs) knowledge and understanding of data protection in clinical research e.g. experience in this area, training courses. Clarify if there will be an expert in this area supporting the PI in his duties (see also Q35).<br>12. The NREC-MD requests confirmation if the PI completed GCP training as per ISO 14155:2020 and if not, how will he be |

| | |
|---|---|
| | supported to ensure compliance with the ISO throughout the clinical investigation.<br>13. The email address provided for Prof Sultan should be a professional working email address rather than a personal one.<br>14. The NREC-MD noted that pregnant participants, those with intellectual disability and with dementia will be excluded from this study. Given that leg ulcers can affect this cohort of patients, and the study design allows for the involvement of carers, clarify/justify why these populations will be excluded.<br>15. The NREC-MD requests that reasonable efforts are made to allow access to the study for participants for whom English is not their native language, or who do not speak English. In the event that the study seeks to enrol a participant who requires a translated PIL/ICF, translations must be completed by a certified translation provider, and the translation certificates submitted to the NREC-MD as a non-substantial modification in advance of the distribution of translated documents.<br>16. The NREC-MD noted that informed consent will be obtained by the study PI, who also appears to be the treating clinician. Given the potential power imbalance involved in this situation, clarify if a member of the study team, other than the PI, can undertake this role.<br>17. The NREC-MD noted in Section E4 of the application form (page 13) that "*eligible patients will be identified through a combination of ankle brachial index measurements, venous duplex ultrasound, comprehensive wound assessment, and a review of their care plans*". These procedures constitute participant screening and therefore require prior informed consent. Clarify whether these assessments are already documented in the patients' medical records. If not, update the relevant documentation accordingly to reflect this.<br>18. The NREC-MD requests the PIL/ICF is extensively revised to minimise technical language to increase accessibility as in its current form it is not accessible to a layperson. The document should also be reviewed for spelling and grammatical errors.<br>19. The NREC-MD requests the PIL/ICF is updated to clearly explain to the participants what procedures the participants will undergo if in the active as well as control arm of the study.<br>20. The NREC-MD noted that the "What will happen to me if I agree to take part?" section needs to be revised to clearly state what activities the participant will take part in / undertake and what they need to do. Flow charts and diagrams may be useful here.<br>21. The NREC-MD noted that the PIL/ICF consistently refers to stages (i.e. stages 3 and 4). The stages, what they are and what |

| | |
|---|---|
| | they consist of, should be explained to participants and clearly outlined in the PIL/ICF.<br>22. The NREC-MD requests that the PIL/ICF is updated to clearly explain to the participant that they can leave at any time, and how they can do this.<br>23. The NREC-MD noted the following statement "… *and the research team believes you may benefit from advances in how this condition is monitored and managed".* As this implies a benefit that cannot be guaranteed and directly contradicts the benefits section of the PIL/ICF, rephrase or delete this.<br>24. The NREC-MD noted from the benefits section that "*there will be no direct benefit to your involvement".* As participants may benefit from the use of this device, correct this contradiction.<br>25. The NREC-MD noted that there are some risks associated with this study included in the application form but not the PIL/ICF. Update the PIL/ICF to include all associated risks.<br>26. The NREC-MD noted that the PIL states that if the bandage feels too loose "*extra compression can be added by your nurse".* However, as patients / their carers will be shown how to apply extra compression if needed, correct this discrepancy.<br>27. The NREC-MD noted the following discrepancy on page 3 of the PIL/ICF (45 minutes vs 1 hour). "*If you join the study, you'll have a 45-minute training session with a nurse during your next clinic visit. You're welcome to bring a family member or carer, especially if they'd like to take part. Participants receive a €50 One-For-All voucher for the hour-long training*". Update.<br>28. In relation to the participant training session, confirm that this will be lengthened if the participant requires more time to learn how to properly use the device.<br>29. Further to point 27, revise the PIL/ICF to clarify the role of family member or carer in the clinical investigation.<br>30. The NREC-MD noted that participants can contact the study nurse for a review of treatment if they feel any discomfort (page 4 of the PIL/ICF). Standard of care would not involve a patient calling an out of hours number to adjust bandage pressure and, as per the PIL/ICF, the patient or a carer may adjust the pressure. Confirm if this is correct, and if so, provide a 24/7 contact number for participants to contact.<br>31. In addition to the above revision, the NREC-MD requests that special attention is given to revision of the language used when discussing data protection and data processing. The NREC-MD have provided a non-exhaustive list of examples below. This |

should be applied to the PIL/ICF but also to relevant sections of the application form and other documentation as appropriate.

- The term 'Data Processor' is a legally defined role and is typically not assigned to an individual. This is because, in the event of a data breach, both the Data Controller and the Data Processor can be held legally accountable, responsibility that is not usually borne by a single person. In this study, Merlin Park University Hospital appears to be the appropriate entity to designate as the Data Processor.
- For the same reason, a single person (Dr Andrew Cameron) should not generally be listed as the Data Controller in a study. In this study, FeelTect Ltd. appears to be the data controller.
- A full list of the participants data protection rights should be given.
- The contact information for the sponsors DPO should be provided.
- The contact information for the Irish Data Protection Commissioner should be provided.
- The NREC-MD noted that the 'Data Protection' section of the PIL/ICF states that "*FeelTect Ltd. Will not have access to your information*". As the sponsor will be receiving pseudonymised data, this statement is not accurate and should be corrected.
- The company CEO should be removed as a contact person for this study, as it is generally not appropriate. A more suitable contact would be a research nurse.
- As this study is for validation and verification, participant data is generally not deleted should a participant withdraw from the study.

32. The NREC-MD noted that insurance is not yet in place for this trial. Note that adequate insurance must be in place prior to study commencement as per the State Claims Agency guidance.
33. The NREC-MD noted that the study budget only lists the cost of medical supplies required for the study and does not include staffing or overhead cost. Clarify if there are any payments to investigators, study staff or overhead payments for Merlin Hospital and confirm that financial arrangements are in place to cover this cost.
34. The NREC-MD noted that the PI for this study may encounter some potential participants through his private practice clinic. Confirm whether the PI will receive any form of payment for enrolling participants into this study. Furthermore, clarify if

| | |
|---|---|
| | participants will incur any cost for the study procedures if carried out in the private clinic.<br>35. The NREC-MD noted that there appears to be a grave misunderstanding of what constitutes personal data and thus a lack of knowledge and awareness surrounding data processing and data protection. Throughout the application, particularly in Section K, there appears to be inconsistency.<br>- The application refers to the use of pseudonymised data yet also states in Section K1 that 'only the study PI will have access to patient records (i.e. personal data)' and that 'the only personal data collected will be names of participants during the obtaining of consent.' However, Section K2 states 'personal data will not be used or included in this study,' which seems contradictory, especially given the later mention in Section K1 of collecting data and pressure data within a cloud database and pseudonymised wound images.<br>- The PI is listed as a data processor but will be reviewing clinical charts during the recruitment process, which means they will be acting as a data controller.<br>The NREC-MD requests clarification on this and in particular requests information on data protection knowledge of the study team and any supports in place in this area (as per question 11 of this letter).<br>36. The NREC-MD noted that the application mentions the use of ‘processed’ pseudonymised data for publications. However, best practice would be to fully anonymise personal data before using it in published material. The NREC-MD requests clarification on how personal data will be safeguarded in this context, especially given the difficulty of fully anonymising a small sample size.<br>37. The NREC-MD noted that Section G3 of the application form states that no personal data will be included in this study. However, the process of obtaining informed consent and collecting participant data constitutes the handling of personal data. Additionally, the study team will be contacting participants during the study (e.g., by phone) in response to pressure-related issues, which also involves the use of personal data. Review and revise Section G3 to accurately reflect the types of personal data being collected and processed, in line with data protection requirements.<br>38. The NREC-MD requests confirmation that the research study nurse has undertaken data protection training.<br>39. The NREC-MD noted in Section K16 of the application form that the study nurse will contact the participant for ‘check-ins’. However, elsewhere it states that the study nurse will have no |

| | |
|---|---|
| | access to the patient's name or phone number. How will these checks be undertaken in this case. Clarify this discrepancy and update the application accordingly.<br>40. The NREC-MD noted that the application form refers to data storage in the cloud with Galen Data, Dropbox in addition to the use of independent data firms. Provide the name and location of the independent data firms and include this information in the PIL/ICF.<br>41. The NREC-MD requests clarification as to whether data will be transferred outside of the EEA. If so, this information should be included in the PIL/ICF and a specific consent line should be added to the ICF for this. If applicable, the NREC-MD also requests confirmation that standard clauses and arrangements are in place to ensure that this transfer of data is in line with GDPR.<br>42. The NREC-MD noted in Section K19 of the application form (page 33) that "*Any published/presented data will be stored for at least 5 years, in accordance with standard practice for answering related queries*". However, as per GDPR, any data that is used for validation and verification should be stored for 15 years. Clarify this discrepancy. |
| 9. 25-NREC-MD-021 | • Principal Investigator (Lead Institution): Prof Ronan Collins (Tallaght University Hospital)<br>• Sponsor: The University of Nottingham, UK<br>• Study title: Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)<br>• NREC-MD decision: Request for further information<br>• Further information requested:<br>1. The NREC-MD noted the importance of this study. However the Committee noted the extensiveness of follow up data collection and queried the relevance of all of the data to the study objectives, eg use of statins and other medication (document 42), nighttime behaviour, depression, anxiety (document 30), etc. Justify the collection of such extensive data, explain the relevance to the study questions and aims and how is the current study approach aligned with data minimisation principles but more importantly with respect for participants, many of whom may not be in a position to consent for the study themselves.<br>2. Further to point 1, the NREC-MD requests clarification on how is the Cognitive sub study related to the aims and objectives of the clinical investigation aimed at assessment of the safety and |

| | |
|---|---|
| | efficacy of Pharyngeal Electrical Stimulation (PES) in people with post-stroke dysphagia (PSD).<br>3. The Committee noted that, while MDR Article 64.1.g requires a 'direct benefit' for incapacitated participants, this study acknowledges that a direct benefit may not arise for enrolled participants. The preliminary data from the 355+ participants enrolled so far may support the understanding of any benefit. Provide any such preliminary data related to benefit from the investigational device, if available. If not, please justify undertaking of the study.<br>4. The Committee noted that the investigator has to 'look for visual clues that the participant is uncomfortable' (Document 32, page 4). Explain the effectiveness of this method of determining the tolerability of the device, especially in participants who may have altered cognition, altered facial control or facial expressions, and altered abilities due to stroke and/or dementia.<br>5. Given that upwards of 355 participants have already been enrolled to date, the Committee noted that there may be preliminary data on the dropout rate in the study, particularly related to tolerability and threshold levels. If this data were available, the Committee is of the opinion it may help inform the acceptability of the PIL/ICF language concerning discomfort when the device is used. Provide any such preliminary data related to drop out rate and/or tolerability of the investigational device, if available.<br>6. The Committee noted that the statistical analysis plan for the study stated that linear regression to assess the rating scales across groups will be carried out. The Committee request clarification on what other, if any, statistical methods will be used to answer primary and secondary study objectives. Furthermore, given the large volume of data proposed to be collected as a part of the study, provide comprehensive statistical analysis plan.<br>7. The NREC-MD noted that it is unclear whether the outcome assessor is blinded, as the documentation supplied gives contradictory information. Clarify.<br>8. Clarify:<br>- where the outcome assessment will occur,<br>- if the University of Nottingham is responsible for any follow up, and<br>- provide information about all involvement of the national coordinator, and any nominees in Ireland, in follow up.<br>9. In Section F12(a) of the Application form 'Will any participants recruited to this study be simultaneously involved in any other |

| | |
|---|---|
| | research project?' the answer selected is 'No', however in the next section F12(b) 'If yes, please comment' the answer stated contradicts this: 'There are co-enrolment agreements in place with the following trials: ReCAST-3, TICH-3, MAPS-2 and GEKO. No other co-enrolment is allowed at the current time'. Clarify if participants may also be simultaneously enrolled and provide information on the potential impacts of this.<br>10. The application documents state that follow up will be made by 'phone/email/post'. Clarify why three methods may be used and if applicable when will each method be used.<br>11. NREC-MD request an explanation on how participants who lack capacity and/or have dementia will be expected to complete questionnaires and answer follow up questions and provide information on the possible reliability of such data.<br>12. The application Site Suitability forms states that 1 participant per month will undergo the procedure at two sites. As the study is due to take 14 months and aims to enrol 40 participants, it does not appear that the two sites will be able to complete the study. Clarify how the study will be completed with the study sites in the time frame indicated.<br>13. In section F10 of the application form 'What criteria exist for withdrawing research participants prematurely (if relevant)?, the applicants state that 'Site and trial staff may discuss with the participant the importance of collecting the primary outcome and so limiting the effect of withdrawal.' As participants must be allowed and enabled to withdraw unimpeded, this discussion and process is unethical as it may place undue pressure on a participant not to withdraw. The NREC-MD requests the removal of the stated process from the study.<br>14. The NREC-MD request more information regarding temporary withdrawals, including whether treatment is resumed after withdrawal, for how long will the intervention be resumed, will the full treatment still be for 6 days, and whether there is a cutoff where participants would not resume. If possible, provide a flowchart clarifying the process.<br>15. Section F10 of the application form does not outline the withdrawal options available to participants who regain capacity during the study, including whether they can request the destruction of all data collected up to that point. Clarify.<br>16. The NREC-MD noted that in the submitted application form, section F11(a) 'Will the participants be from any of the following groups?' the option for 'Prisoners' is selected. As there is no other reference to prisoners being enrolled in the study, provide clarification on whether prisoners will be recruited, and, if so, |

| | |
|---|---|
| | provide information on the processes surrounding prisoner recruitment and participation in the study.<br>17. Complete application form section F11(b) is not completed and is required. Update as required.<br>18. The Committee noted that people with dementia may be enrolled. Given that participants will also have had a stroke, the Committee requests justification for inclusion of people who may have additional cognitive and capacity challenges of dementia, and requests further information on the processes and procedures for the recruitment and participation of people with dementia who have had a stroke.<br>19. The NREC-MD noted that information in Section F10 of the Application form 'What criteria exist for withdrawing research participants prematurely (if relevant)?, the applicants state that 'Site and trial staff may discuss with the participant the importance of collecting the primary outcome and so limiting the effect of withdrawal.' As participants must be allowed and enabled to withdraw unimpeded, this discussion and process is unethical and it may place undue pressure on a participant not to withdraw. The NREC-MD requests the removal of the stated process from the study.<br>20. Information in application form section F5 is limited. This section asks about how participants will be identified, recruited and selected and the answer states "Patients will be identified by relevant members of their clinical team". The Committee requests further information on this process.<br>21. Section G(8) of the Application form states that 'participant information sheets, and consent forms, will be available printed in other languages as appropriate for the recruiting countries'. Clarify if the study intends to enrol participants who are not fluent in English language and note that if any translated participant-facing documentation will be used at the Irish sites, provide translation certificates to NREC-MD.<br>22. Clarify who on the clinical research team will consent participants, their role(s) and suitability for the process.<br>23. The NREC-MD noted that the documentation refers to different days post stroke for/ when the participant may be consented. Clarify the time window post-stroke that recruitment can take place.<br>24. The application states that a considerable percentage of participants may lack capacity. The NREC-MD noted that throughout the application documentation number of different terms is being used, eg 'proxy consent' or 'relative consultee' and a 'nominated consultee'. Clarify the roles and where applicable |

| | |
|---|---|
| | the Committee requests that the terminology is revised and aligned as per the NREC Guidance on Legally Designated Representatives Legally designated representatives - NREC.<br><br>25. Application form Section H2(b) states 'Where the participant lacks capacity and no personal legal representative can be identified then a nominated consultee may be approached. This must be an independent physician…'. This process is not provided for in Article 64 of the MDR nor is not in line with the HSE consent policy. To that end the NREC-MD request this mechanism is removed from the study protocol.<br><br>26. The NREC-MD noted that the consent processes, procedures and documentation are not in line with the HSE National Policy for Consent in Health and Social Care Research https://assets.hse.ie/media/documents/ncr/20250107_HSE-National-Policy-for-Consent-in-Health-and-Social-Care-Research-V2.0.pdf nor do they meet MDR Article 64 requirements for people who may lack capacity to consent. For example:<br><br>- The study process for consent as outlined in the application is either the person is deemed capable of consenting independently and so would be invited to give their consent, or the person is not deemed capable of consenting and so another person would give assent for them to enrol.<br><br>- There is no reference to potential conflict of interest in the documentation which could arise as the clinical research team will be determining a potential participant's capacity to consent.<br><br>- There is no provision for supporting potential participants to enable and maximise their capacity to make their own decisions whenever possible.<br><br>- There is no indication that special measures will be taken to protect potential participants' fundamental rights and interests<br><br>- There is no indication that there are sufficiently trained personnel on the clinical research team who can support potential participants to enable and maximise their capacity to make decisions<br><br>- There is no reference to a record of the consent given to the participant in a method that best suits their abilities, e.g. audio, videorecording.<br><br>- If a participant regains capacity during the study, there is not a reference in the withdrawal options that includes destruction of all of the participant's data collected for the research study to date |

| | |
|---|---|
| | - There is no reconsent form submitted. This form would be presented to a participant who initially lacked capacity to consent and then regains the capacity during the study, in order to consent to continue participation in the study.<br><br>The NREC-MD request the consent process is extensively revised and aligned with the HSE National Policy for Consent in Health and Social Care Research. Additionally:<br><br>27. An assent form for the participant, in the instances that a Legally Designated Representative (LDR) is required to give consent on behalf of a participant who lacks capacity to consent, was not submitted. A copy of the form must be provided for NREC-MD review.<br><br>28. The HSE National Policy for Consent in Health and Social Care Research states that participants should be supported to make their own decisions whenever possible and that 'information should be presented in a manner to facilitate this'. The Committee noted that, while an Aphasia Friendly PIL and ICF (document 9) was submitted, it was not considered accessible with confusing or irrelevant imagery and lack of sufficient information for a potential participant to be clear about the study. Update this document to make it more accessible and relevant so that it can enable informed consent.<br><br>29. It was not clear in what instances the Aphasia Friendly PIL and ICF (document 9) would be used, for whom and with what supports. Clarify.<br><br>30. It was not clear in what instances the Short Pictorial PIL (document 10) would be used, for whom and with what supports. Provide information about the use of the Short Pictorial PIL (document 10).<br><br>31. The participant-facing documents refer to the effects of the electrical stimulation as a 'tingling or warm sensation' and 'not painful' (Document 9 'tingling or warm sensation in the back of the throat, participants do not report this to be painful', Document 10 'a warm or tingling sensation during treatment', Document 11 'a moderate warm sensation at the back of the throat but this sensation is not painful', Document 52.0 'a moderate warm sensation at the back of the throat but this sensation is not painful.'). However, other documentation (e.g. CIP, Document 32) instruct the investigator that the threshold is the lowest level stimulation a participant can feel in their throat, that tolerability is 'the highest level the participant can tolerate' (Document 32) and that the investigator has to 'look for visual clues that the participant is uncomfortable' (Document 32, page 4). The Committee request that all participant facing documents are rewritten to fully inform the potential participants of any potential |

| | |
|---|---|
| | risk of any discomfort or other negative sensations or experiences, as well as how the investigator will determine the tolerability, so that the descriptions of procedures, risks and burdens of the study in the participant-facing documents fully reflect the reality of the study, and how participants can withdraw from further exposure to the device if they feel discomfort or pain.<br>32. The images used in the participant-facing documents are sometimes unclear, confusing and unrelated to the information, and require updating.<br>33. The use of the term 'subject' is not in line with the World Medical Association Declaration of Helsinki.<br>34. Minor typos were noted in some documents, e.g. 'Willl' on page 5 document 11.01<br>35. The Committee noted that in Document 10, some language is not appropriate on Page 1 'This will test the effect of a small electrical stimulation, within a nasogastric feeding tube, to improve your ability to swallow.' The phrase 'to improve your ability to swallow' could be leading. Review all participant facing documentation to more neutral statements and remove definitive statements implying that the electrical stimulation will improve the ability to swallow.<br>36. Documents 9 and 10 both state regarding follow up 'If you are not well enough to talk we will try to ask your family, friend or GP'. There is no reference to supporting the participant to communicate themselves first before asking someone else to speak for them and must be revised.<br>37. In line with Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018, the consent forms must be revised to facilitate unbundled consent for each individual item, including optional items such as participation in the cognitive sub study.<br>38. There is no reference in Document 9 or 10 to the Cognition Substudy or the role of the informant. The NREC-MD request that the PILs are revised to clearly describe the sub study, the role of the informant and include optional consent line for participant's consent as per point 44.<br>39. In Document 11, consent line 7 contains blanket consent for future research and an isolated reference to anonymous data 'agree to the information collected about me in this study may be used to support other research in the future and may be shared anonymously with other researchers'. Furthermore, the NREC-MD noted that the future use of data/samples is not described in line with regulations/best practice in the participant information leaflet and request that future use of samples/personal data is sufficiently explained to participants in the PIL/ICF so as to |

| | |
|---|---|
| | constitute broad informed consent, as required under the Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,<br>- it should be made optional<br>- it should be confined to a specified disease, related diseases or drug under study in this trial. Consent can only be obtained where future use of samples and data is defined such that participants are fully informed,<br>- and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies,<br>- optional future research is made into a separate and explicit consent item in the Informed Consent Form so it is distinct from the main consent to participate in the research,<br>- The PIL/ICF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. For further guidance, see: NREC guidance on use of biological samples and associated data - https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data/<br>- Under the GDPR if data is to be anonymised a specific consent line for this must be included in the ICF. Update the ICF accordingly.<br>40. There is no reference in Documents 9 and 10 about consenting after a participant regains capacity. Update the document accordingly.<br>41. In Document 9, the total sample size is incorrectly stated and must be revised.<br>42. It is unclear what the purpose of the consent form section is in Documents 9 and 10 and whether participants who lack capacity will sign the consent form of Document 9 or 10 as well as the LDR signing an assent form, or as well as the long PIL/ICF Document 11. Clarify.<br>43. Document 11.0, Page 5, states 'Participation in the trial is free of charge.' The NREC-MD request this sentence is removed.<br>44. In the Application form Section K1 there is reference to the UK data protection act that is not relevant for research in Ireland. Update to include information relevant to data protection in research in Ireland.<br>45. In the Application form Section K21 the section for access to healthcare records should be marked yes. |

| | |
|---|---|
| | 46. There is no reference to local site DPO input. Clarify if a local site DPO has been or will be consulted prior to the study beginning.<br>47. Clarify if all contractual agreements that are in place for sharing of personal information.<br>48. The Application form Section Q2 must be completed.<br>49. Clarify if the insurance policy for University of Nottingham (document 14) extends to the Irish arm of the study as the Irish specific policies do not meet the State Claims Agency guidance.<br>50. The NREC-MD noted that document 16 is a funding application, not a separate budget document. Provide a budget for the study.<br>51. It was not clear to the NREC-MD if any of the follow up appointments will be per clinical follow up appointments or if there would be added inconvenience for the participants due extra follow ups related to the study related procedure. Clarify if there is any added inconvenience as part of study participation and if compensation will be provided to participants because of it. |
| 10. 23-NREC-MD-037-SM2 | • Principal Investigator (Lead Institution): Prof Seamus O'Reilly (Cork University Hospital)<br>• Sponsor: Astrazeneca<br>• Study title: Clinical Performance Study Plan for Ki-67 IHC MIB-1 pharmDx (Dako Omnis) on early breast cancer specimens used to identify subjects for enrolment in AstraZeneca's Phase III CAMBRIA-2 trial (D8535C00001-IVD)<br>• NREC-MD decision: Favourable |
| 11. 24-NREC-MD-023-SM1 | • Principal Investigator (Lead Institution): Prof Robert Byrne (Mater Private Network)<br>• Sponsor: RCSI<br>• Study title: Randomised trial of dual device treatment involving drug-coated balloon angioplasty and drug-eluting stent implantation compared to single device treatments in patients with diabetes mellitus<br>• NREC-MD decision: Favourable |
| 12. 25-NREC-MD-011-SM1 | • Principal Investigator (Lead Institution): Dr Christina Fleming (University Hospital Cork) |

| | |
|---|---|
| | • Sponsor: Qufora<br>• Study title: A randomized clinical investigation to assess efficacy of low volume Transanal Irrigation by Qufora® Irrisedo Minigo versus conservative treatment for Low Anterior Resection Patients<br>• NREC-MD decision: Favourable |
| 13. AOB | • 25-NREC-MD-010 - This application was given the condition "The NREC-MD requests confirmation that the app used for the study is self-contained and that cybersecurity of the app is periodically assessed". They applicant has come back to say "The RiSolve App is not self-contained as it relies on external services to deliver emails, store logs, send notifications. It also relies on Azure to host the infrastructure".<br>• August meeting<br>• December meeting date<br>• NREC-MD application forms<br>• 2026 dates |