NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

18 August 2022

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Prof. Declan Patton	Deputy Chairperson, NREC-MD
Dr Ruth Davis	Member, NREC-MD
Dr Owen Doody	Member, NREC-MD
Dr Gloria Kirwan	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Prof. Tom Melvin	Member, NREC-MD
Prof. Therese Murphy	Member, NREC-MD
Dr Declan O'Callaghan	Member, NREC-MD
Dr Paul O'Connor	Member, NREC-MD
Dr Catherine O'Neill	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Mr Peter Woulfe	Member, NREC-MD
Dr Gloria Kirwan	Member, NREC-MD

Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees
Dr Louise Houston	Project Officer, National Office for Research Ethics Committees
Dr Emily Vereker	Head, National Office for Research Ethics Committees

*Drafted minutes

Apologies: Dr Caitriona Cahir, Dr Mireille Crampe, Dr Frank Houghton, Ms Orla Lane, Dr Sarah McLoughlin, Prof. Susan O'Connell, Dr Clare O'Connor, Prof Anne Parle McDermott, Ms Riona Tumelty, Prof. Mahendra Varma

Quorum for decisions: Yes

Agenda

- Welcome (Chairperson)
- Report on Committee business
- Minutes of previous meeting
- Declarations of interest
- 22-NREC-MD-024
- 22-NREC-MD-025
- 22-NREC-MD-026
- 22-NREC-MD-007-SA2
- 22-NREC-MD-027
- 22-NREC-MD-028
- 22-NREC-MD-029
- 22-NREC-MD-030
- 22-NREC-MD-019-R1
- 22-NREC-MD-005-SA1-R1
- 22-NREC-MD-022-R1
- AOB

- The Chairperson welcomed the Committee, welcomed new members who weren't able to attend the previous meeting and opened the meeting.

- NREC Committee Business Report: The Committee *noted* the report.
- Minutes of previous meeting (21 July 2022) & matters arising: The minutes were *approved*.
- Declarations of interest:
    - Prof. Declan Patton (22-NREC-MD-028, 22-NREC-MD-007-SA2). Prof. Patton left the meeting for the review of 22-NREC-MD-028 and 22-NREC-MD-007-SA2.
    - Dr Lucia Prihodova (22-NREC-MD-027). Dr Prihodova left the meeting for the review of 22-NREC-MD-027.

Applications

22-NREC-MD-024

- Principal Investigator: Mr Gerry O'Sullivan
- Study title: Evaluation of the GOREÂ® VIAFORT Vascular Stent for Treatment of Symptomatic Inferior Vena Cava Obstruction with or without Combined Iliofemoral Obstruction.
- Lead institution: University Hospital Galway, Newcastle Rd, Galway, H91 YR71.
- NREC-MD comments
    - The Committee noted that this application is for a first in human study with a primary objective to collect safety, clinical and imaging data for the GORE® VIAFORT Vascular Stent to establish if it is safe and effective in treating patients with symptomatic inferior vena cava obstruction.
- NREC-MD decision
    - *Request for further information*
- Further information requested:
    - As this is the first in human study with relatively unknown risk profile, the NREC-MD requests that more frequent follow ups are scheduled for the first six months, especially in the immediate period after treatment.
    - The NREC-MD requests clarification on when are the quality of life assessment scales (VEINES and EQ-5D-5L) administered.
    - As blood samples are taken as a part of the study, the Committee request section G of the application form is completed.
    - The NREC-MD requests that, in line with best practice a role of a gatekeeper is introduced into the recruitment and consenting process to avoid any potential imbalance of power and undue influence.
    - The NREC-MD noted that the PIL is very informative, but could be further improved for accessibility. To that end, the Committee requests that the PIL is revised, eg

medical terminology is reduced for accessibility and the document is made relevant to participants in Ireland.

- The NREC-MD requests that the PI's personal email is removed from participant facing documentation and replaced by his professional email.
- The NREC-MD requests that information on data retention is included in the Participant Information Leaflet.
- Further to point 1, given the unknown risks associated with the medical device, can any other information be provided to the participant to inform their decision to participate?
- The NREC-MD noted that the GP letter includes the following: "We would be very grateful if you could inform us of any medication changes, new illnesses and surgical procedures regarding our shared patient within the next five years." The Committee deemed this broad and unspecific list of information was not justified, and requests this is revised to ensure alignment with the principle of data minimisation.
- The NREC-MD requests an update on whether an input from the lead site DPO on the study Data Protection Impact Assessment was provided.
- The NREC-MD noted that the document "21. 908 VNS 21-05 hse-privacy-impact-assessment-form 2.0 JUN22" contains scrollable fields which are not reader accessible and requests an updated version is provided.
- The NREC-MD noted that the transfer tool is yet to be identified. The Committee requests an update and a list of criteria applied to the selection process.
- The NREC-MD requests a confirmation that neither participants nor their health insurance are charged for their participation in the study and any study specific procedures.
- The Committee requests a confirmation that the proposed budget is sufficient to carry out the study in its completeness.
- The NREC-MD requests a clarification on the proposed process for payments once a participant completes the study.

22-NREC-MD-025

- Principal Investigator: Prof Faisal Sharif
- Study title: A Prospective, Multi-Center, Open Label, Single Arm Clinical Trial Evaluating the Safety and Efficacy of the Cordella Pulmonary Artery Sensor System in New York Heart Association (NYHA) Class III Heart Failure Patients (PROACTIVE- HF Trial).
- Lead institution: University Hospital Galway, Newcastle Rd, Galway, H91 YR71.
- NREC-MD comments

  - The Committee noted that this application is for the third clinical study using the Cordella™ Pulmonary Artery Sensor System and aims to investigate the safety and efficacy of the study device in helping to reduce heart failure hospitalisations.

- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD noted that the implanted sensor remains active for up to 10 years and is not removed from the participant. The Committee requests clarification on:
    - The rationale for the duration of the participant's involvement (3 years).
    - The envisaged use of the device following the end of the study. Can participants continue to use the device and associated technology free of charge as a part of their routine care?
    - What will happen with the data gathered by the device following study end, who will have access to it and for what purpose.
  - The NREC-MD noted that the risk of worsening heart failure due to participation in the study is ranked at 30% and requests a clarification on whether the applicants deem that the potential risks are outweighed by potential benefits and the rationale for this.
  - In relation to the proposed radiation exposure, the NREC-MD noted that the radiation does appears to significantly exceed the standard dose and requests a clarification on how the proposed radiation aligns with the ALARA principles.
  - The NREC-MD noted that the sponsor might send representatives to participant's home to assist with installation of the devices. The Committee requests more detail on how participant's privacy and dignity will be respected in the process and about the qualifications/ training of the representatives in place to facilitate this.
  - The NREC-MD noted that one of the sites in this study is the Mater Misericordia University Hospital. The Committee requests a clarification if this includes the public and/ or the private site.
  - The NREC-MD noted that conflicting information on the number of participants from Ireland has been included in the application documentation and requests clarification on the number of participants to be recruited from the two listed sites.
  - The NREC-MD requests that a role of gatekeeper is introduced into the recruitment and consenting process.
  - The NREC-MD noted that the study imposes a lot of responsibility on the participant and requests this is made clear in the participant facing documentation.
  - The NREC-MD requests that the Participant Information Leaflet highlights that the implanted sensor remains in place permanently.
  - The NREC-MD noted that several references are made to Syneos Health throughout the participant facing documentation and requests that their role is clarified in the documentation.
  - The NREC-MD requests that the likelihood of risks/ adverse events is included in the Participant Information Leaflet.

- The NREC-MD noted that the consent form is seeking blanket consent for future use of information for unspecified purposes, without further consent. This type of consent is unlawful and not in line with best practice and the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018), where informed participant consent is a mandatory safeguard. To that end, in the consent form, the participants should be asked for a consent to be contacted in the future for such purposes. Subsequent research ethics review should be sought for specific research proposals once they are clearly defined.
- The NREC-MD requests a confirmation that neither participants nor their health insurance are charged for their participation in the study and any study specific procedures.
- The NREC-MD noted that section F4 of the application form “Access to healthcare records” was ticked as no. The Committee noted that this doesn’t appear appropriate given responses elsewhere in the application form and requests clarification.
- The NREC-MD noted that both application form and the DPIA provided only limited information on the data transfer from the participant to the clinician. To that end the Committee requests a clarification on the process and measures in place to minimise any unauthorised access.
- The NREC-MD noted that page 15 of the Participant information leaflet states that if a participant withdraws from the study but does not withdraw their consent, their data will still be used. The Committee requests that if participant withdraws from the study, their consent for data processing is also presumed as withdrawn and no further data is collected. Furthermore, every effort should be made to facilitate withdrawal of participant’s collected data, should they request it.
- The NREC-MD noted that the information on the proposed data processing and transfers needs to be revised for accessibility and clarification.
- The NREC-MD noted that the provided manufacturer’s liability expires in January 2023. The Committee requests a clarification on whether the policy will be extended for the anticipated lifespan of the device (10 years).
- The NREC-MD noted that participants will be offered a reimbursement of expenses associated with their study specific hospital visits. Given the duration of the participation and the rising cost of living, the Committee requests that the financial impact of participation is considered, eg cost of wifi, cost of electricity required to run the devices at home, and that participants are reimbursed for such expenses.
- The Committee requests a clarification on whether all members of Clinical Events Committee and Data Safety Monitoring Board are independent from the Sponsor and have no interest in the current study.

22-NREC-MD-026

- Principal Investigator: Dr Paul Kelly

- Study title: Effectiveness of the SpaceOAR Vue System in Subjects with Prostate Cancer being Treated with Stereotactic Body RadiothErapy (SABRE).
- Lead institution: Bon Secours Radiotherapy Centre Cork, Western Road Entrance, Cork, T12 DV56.
- NREC-MD comments
  - The Committee noted that this application is for a study examining the effectiveness of the SpaceOAR Vue System and its ability to reduce late (between 3 and 24 months) gastrointestinal toxicity in patients undergoing SBRT to treat prostate cancer.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD requests clarification on how many of the follow up appointments are study specific vs part of routine care.
  - The NREC-MD noted some of the follow up appointments will be facilitated through “remote contact visits.” The Committee requests more detail on how/ through which technology exactly these will be facilitated.
  - The NREC-MD noted that section F13 (activities, procedures or interventions that are study participants asked to undergo or engage in for the purposes of this study) of the application form was difficult to comprehend and requests a clarification.
  - The NREC-MD noted that there is no intention to directly inform the participants about the outcomes of the study. The NREC-MD requests that study team proactively informs participants about study findings.
  - The NREC-MD noted that the study site is affiliated with University of Pittsburgh Medical Center and queried whether this study is carried out in collaboration with the University. If so, please detail what role and responsibility it has in relation to the study, including detailing any insurance and data protection implications.
  - The NREC-MD requests more detail on the staffing arrangements in place to facilitate the study, especially over the follow up period.
  - The NREC-MD noted that no specific number of participants to be recruited from Ireland has been provided, instead a range of 15-75 is listed in the application form, and that an estimate for UK site is provided. The NREC-MD requests an estimate for the Irish site to be provided.
  - The NREC-MD noted lack of detail on the recruitment process in the application documentation and requests a detailed outline to be provided.
  - The NREC-MD requests that a role of gatekeeper is introduced into the recruitment and consenting process.
  - The NREC-MD requests clarification the study will be promoted online in Ireland and if yes, that a copy of all relevant promotional materials is provided.
  - The NREC-MD noted that members of Clinical Events Committee were not listed in the submitted documentation. The Committee requests a clarification on whether all

members are independent from the Sponsor and have no interest in the current study.

- The NREC-MD requests that the PIL is revised for accessibility and the document is made relevant to participants in Ireland.
- As the NREC-MD will never request to access participant data, the Committee requests that the Participant Information Leaflet and Informed Consent Form is amended accordingly.
- Finally, the NREC-MD noted some ambiguity in the mechanism for withdrawal of consent and requests that this is clearly defined.
- The NREC-MD noted that the Data Protection Impact Assessment is sponsor led, and does not specifically refer to the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) nor addresses any potential risks with the study data processor (Bon Secours Hospital Cork) and requests this is rectified.
- The NREC-MD requests clarification on whether an input from the lead site DPO was sought in completion/ sign-off of the study Data Protection Impact Assessment. If not, the Committee requests a justification for this approach and an assurance that relevant site approvals in accessing participant data are in place.
- Due to inconsistencies across the documentation, the NREC-MD requests a clarification on who/ what entities will have access to the participant's personal data and justification for the proposed data sharing.
- The timeline for the storage of data ranges from 15 to 75 years. A specific archive period must be clearly set out for participants. Please clarify the storage timeline with clear justification.
- Furthermore, the NREC-MD requests clarification on whether the data collected as a part of this study will be discarded at the end of the study.
- When it comes to participant requests to withdraw data from the study, the NREC-MD requests that every effort is made to accommodate such requests.
- To that end the NREC-MD requests an assurance that all data processing and management will be carried out in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
- The NREC-MD noted that the study insurance policy cover lower than the value recommended by the State's Claims Agency and requests this is justified.
- Furthermore, the NREC-MD requests a confirmation that the Bon Secours Cork study site is covered by the policy provided.
- The NREC-MD noted that participants will be reimbursed expenses up to €84. The NREC-MD requests that participants are offered a reimbursement for all reasonable expenses.

22-NREC-MD-007-SA2

- Principal Investigator: Prof. Caroline McIntosh

- Study title: A Pilot Study to Investigate the Use of Remote Thermovisual Monitoring in Patients with a Previous Diabetic Foot Ulcer, during the COVID-19 pandemic – Substantial Amendment.
- Lead institution: Discipline of Podiatric Medicine, Aras Moyola, NUI Galway, Newcastle Road, Galway.
- NREC-MD comments
  - The Committee noted that that the original study received a favourable opinion from the Galway University Hospitals Regional Ethics Committee. In this regard, the NREC-MD opinion pertains only to the substantial amendment of:
  - A software patch is to be applied to the DFS (Delta Foot Scanner) Software to address a functionality issue related to scan completion delays.

  NREC-MD decision
  - *Favourable*

22-NREC-MD-027

- Principal Investigator: Prof Richard Costello
- Study title: CONNected Electronic Inhalers Asthma Control Trial 3 (“CONNECT 3”).
- Lead institution: Beaumont Hospital, Beaumont Rd, Dublin 9, D09V 2N0.
- NREC-MD comments
  - The Committee noted that this application is for a study to test if using the BF Digihaler Digital System is effective in getting better control of asthma in adult patients compared to usual care.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD request clarification on whether the data obtained from this study may be used to support conformity assessment of the BF Digihaler in the future.
  - The NREC-MD requests that all relevant documentation clearly outlines the steps taken if a participant becomes pregnant while enrolled in the study. In particular, the NREC-MD requests steps taken to justify pregnant participants remaining in the study, as per Article 66 of the Medical Devices Regulation (EU) 2017/745. The NREC-MD also requires the inclusion of a detailed risk-benefit analysis for pregnant participants to remain in the study. Outcome of the risk-benefit analysis should also be included in the Participant Information Leaflet and other participant facing documentation as applicable.
  - The NREC-MD noted inconsistencies in the number of participants to be recruited in this study and requests a clarification on participant numbers in Ireland.

- The NREC-MD requests that further information is provided regarding recruitment to the study, including where and how participants will be recruited and determination of exclusion criteria.
- The NREC-MD requests that a role of gatekeeper is introduced into the recruitment and consenting process.
- The NREC-MD noted in Section D2.3 (b) of the application form that “A minimum of 24 hours will be allowed for the potential participant (or legal representative) to decide whether or not to take part in the study”. Given that one of the inclusion criteria for this study is the ability to give informed consent, the NREC-MD requests that reference to the legal representative is removed.
- The NREC-MD requests that participants are offered a reimbursement for all reasonable expenses incurred and should not be capped.
- Based on the information provided in the application dossier, the NREC-MD noted that only limited information on the Principal Investigator experience in clinical investigations/ trials was provided and request a full CV.
- The NREC-MD noted that the application lacked detail in terms of proposed data processing. In particular, the NREC-MD requests clarification on the following:
    - How long will participant data be retained for and what safeguards are in place to ensure the personal data is secure?
    - Is the data retention period aligned with the Medical Devices Regulation (EU) 2017/745?
- To that end the NREC-MD requests an assurance that all data processing and management will be carried out in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) and GDPR legislation.
- The NREC-MD requests clarification on exactly how the app will capture the data and how it will be transferred from the app and phone to the cloud. The NREC-MD also requests information on how data stored on the participants phone will be protected e.g. password protected, two factor authentication etc.
- The NREC-MD noted in Section 19 of Participant Information Leaflet / Informed Consent Form that “your right to access personal data about you may be suspended until the conclusion of the study”. The NREC-MD requests that adequate justification is provided for denying research participants access to their own personal data for any period of time.
- The NREC-MD noted the following in Appendix A of the Participant Information Leaflet / Informed Consent Form; “Your Rights in Relation to Your Data – Where applicable by law, in circumstances where it would not prevent or seriously impair the conduct of the study, you can ask the study doctor for a copy of your data, or to correct, delete or restrict (stop any active) processing of your data”. To that end the NREC-MD requests an assurance that all data processing and management will be carried out in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) and GDPR legislation.
- The NREC-MD noted the rationale provided for not using a data monitoring committee. However, given the potential risks to participants, in particular participants

who may become pregnant during the study, and as this device does not have a CE mark, the NREC-MD requests that a data monitoring committee/ clinical events committee is established.

21-NREC-MD-028

- Principal Investigator: Prof. Denis Harkin
- Study title: Preliminary testing of the Safety, Usability and Functionality of an innovative and smart medical device: Compression Therapy System Prototype for Venous Leg Ulcer treatment in healthy volunteers.
- Lead institution: RCSI University of Medicine and Health Sciences, 123 St. Stephens Green, Dublin 2, D02 YN77.
- NREC-MD comments

  The NREC-MD noted that this was an application for a study to assess the safety, usability and functionality of a new medical device called Compression Therapy System Prototype, designed for the treatment of venous leg ulcers in healthy study participants.

- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions
  - The NREC-MD noted that the study intends to enrol staff from the PI's institution and requests that every effort is taken to minimise any bias in the selection of the study participants by ensuring that participants represent various socio-demographic and socio-economic groups.
  - The NREC-MD requests that the Participant Information Leaflet is revised to reflect time commitment expected from participants in completing the Diary.
  - The NREC-MD noted that participants will undergo skin checks. The Committee requests participants are made aware of this in the Participant Information Leaflet, along with a rationale for the checks.
  - The NREC-MD requests that participants are offered a reimbursement for all reasonable expenses.
  - The NREC-MD noted that the participants will not be offered a compensation for participation in the study. Given the commitment on day one of the study, the Committee requests that further consideration is given to whether the participants should be offered a payment for earnings lost. Alternatively, at an institutional level, arrangements should be made to ensure that participants are enabled participation in the study without an impact on their work.

22-NREC-MD-029

- Principal Investigator: Prof. Andrew Davies
- Study title: Remote photo plethysmography for measuring vital signs: useability and acceptance within a specialist palliative care unit.
- Lead institution: Our Lady's Hospice & Care Services, Harold's Cross, Dublin, D6W RY72.
- NREC-MD comments
  - The NREC-MD particularly noted this was revised application for a study examining the Lifelight® technology in palliative care unit.
- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions
  - The Participant Information Leaflet highlights that participant data will be transferred outside of the EU for processing.
  - Given the varied length of each participant's involvement, the NREC-MD requests that for participants who's capacity decreases over time, checks to affirm assent for participation are considered. The timing of such checks should be determined by the PI based on clinical status of the participant.
  - A copy of the co-investigator's CV (Dr Jenny Power) is provided for the National Office records.

22-NREC-MD-030

- Principal Investigator: Dr Umer Salati
- Study title: A randomized trial of ultrasound-facilitated, catheter-directed, thrombolysis versus anticoagulation for acute intermediate-high risk pulmonary embolism: The higher-risk pulmonary embolism thrombolysis study.
- Lead institution: Mater Misericordiae University Hospital, Eccles St, Dublin 7, D07 R2WY.
- NREC-MD comments
  - The Committee noted that this application was an application for a substantial amendment pertaining to participants with an unresolved adverse event at the end of the investigation to be followed-up until a satisfactory resolution occurs.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD commented that due to the nature of the study being conducted in emergency care situations, participants are most likely to lack decision-making capacity to provide informed consent due to their physical health. This observation highlighted a series of inconsistencies and discrepancies throughout the application

form regarding the procedures and safeguards in place to obtain informed consent lawfully. In this regards, the NREC-MD have requested that the following points are addressed:

- Section F11 is not completed to indicate that Adults in emergency situations are included in the study, yet Section G6 states that this treatment is an emergency situation. The Data Protection Impact Assessment also does not reflect that this participant cohort is considered vulnerable due to the emergency care situation under which they are recruited. All inaccuracies must be revised and corrected.
- Section H2 states that a legally authorised representative may consent on behalf of a participants that lacks decision-making capacity and deferred consent will be sought thereafter. Under Irish data protection law, a legally authorised representative cannot lawfully consent on behalf of another individual for the processing/use of personal data for health research, but can provide assent as a safeguard. Please detail what procedures can be implemented to seek assent from the legally designated individual, or individual who understands the will and preference of the participant. Consideration should be given to the safeguarding principles outlined in the Assisted Decision-Making Act 2015 .
- Section H5 does not set out how a legal representative will be identified and should be revised for clarity.
- Section H7(a) and (e) of are contradictory. Please clarify whether a consent declaration will be sought from the Health Research Consent Declaration Committee , or, whether the study falls within the ‘deferred consent’ exemption set out in amendments to the Health Research Regulations .
- Details are requested, as to how Article 68 of the Regulation (EU) 2017/745 will be complied with and what safeguarding procedures are in place.
- Section G3 states that the Principal Investigator seek informed consent. In line with Good Clinical Practice, please detail who will act as a gatekeeper in this emergency and/or what procedures will be in place to mitigate against any potential imbalance of power and undue influence on the participant when seeing consent.
- Section G8 refers to participants requiring an interpreter and documents maybe translated upon request. To ensure participants have a record of what they consented to, confirmation is required that all documents will be translated and provided to the participant.
- The consent form provides for the participants to consent for their general practitioner (GP) to be notified about their participation in this study. It does not however, provide a consent option for information to provided by the GP to the study, as is set out in the letter template to the GP. The consent forms must be revised to correct this inaccuracy.
- Given that the participants and legally designated representative/family may be distressed at the time of presenting in an emergency situation, consideration should be given to initially providing brief synopsis PIL to avoid distress and potentially overwhelming the participants and their proxy which a lengthy document. Please comment on the possibility of developing a synopsis PIL for implementation.

- No detail has been provided as to how participants can withdraw from the study or who to contact. Please clarify and amend the PIL accordingly.
- Further to point 2, assent forms and information leaflets for individuals providing proxy assent should be submitted.
- No deferred consent/consent-to-continue forms and accompanying participant information leaflets have been provided. Please submit deferred consent/consent-to-continue forms and accompanying information leaflets.
- The PIL and consent form should be separated and presented as separate documents.
- The PIL should be carefully reviewed and revised to ensure readability and accessibility for participants as some content is technical and detailed.
- The PIL and consent forms refers to personal data being shared with the ethics committee. The NREC will never receive personal data from participants and requests this reference to be removed.
- Section K3 states that ‘patient-level data’ maybe shared with practitioners/researchers. Please elaborate on i) if or how the data will be safeguarded and pseudonymised and ii) if the patient-level data is intended for future research uses in this regard.
- The timeline for the storage of data ranges from 15y to 75 years. A specific archive period must be clearly set out for participants. The storage timeline must be clarified with clear justification.
- Furthermore, please clarify whether the data collected as a part of this study will be deleted at the end of the study.
- Section K10 does not specially address how data breaches and mitigating actions will be managed in the context of Irish participants and how they will be informed of any breaches.
- Section K9 and K12 sets out verbatim Article 5 of GDPR. Neither section addresses how the study will be conducted in a transparent manner, or how the principle of data minimisation is being complied with. These Sections must be revised and addressed giving specific regard to the study: eg how data minimisation has been considered given a significant amount of data is being requested in the quality of life questionnaires.
- Section K5 of the application form states that data will be ‘transferred to the US’ and ‘onwards from the US’, however the jurisdictions, legal basis and safeguards for such transfers are not outlined.
- All health research in Ireland must be in compliance with the Health Research Regulations. Irish legislation should be updated in Section 5 of the DPIA submitted.
- The readability of Section K13 is insufficient. Please revise and elaborate for accuracy.
- It is noted that the site Principal Investigator will hold the master list/link for pseudonymised participant data, however no details on the data security measures are provided.

- The PIL refers to ‘anonymised’ data being used for future research. Please outline how and when all personal/pseudonymised data will be fully and irrevocably anonymised (ie deletion of the master list/code). This information should also be reflected in the PIL.
- The site DPO has provided comprehensive feedback, some of which aligns with the comments from the Committee. Please detail how this feedback has been or will be addressed and reflected in the relevant documents submitted.
- For the purpose of understanding the scope of the insurance coverage, please confirm whether the study is being conducted in both the public and private Mater Misericordiae University Hospital.
- Please clarify and provide detail as whether both arms of the study are considered standard of medical care procedures.
- The protocol notes that participants will have follow up visits up to 12 months following treatment. The PIL further states that the participant maybe contacted to confirm their health status. In the event a participant becomes deceased prior to this timeline, detail is requested as to how this will be managed by the study team.
- Please outline will happen with incidental findings during the follow up and clarify whether will participants their healthcare team be informed of such findings.
- Further to point 28, the PIL sets out that standard of medical care treatments/test/exams as part of the study, may or may not be covered by the participants medical insurance. Clarity and certainty regarding unforeseen costs should be highlighted to the participant and should not be borne by the participant or their health insurers. How this will be addressed and reflected in the PIL?
- The PIL refers to compensation and costs covered. However, there are no provisions to reimburse participants for the 3 follow up visits to the hospital. The PIL must be revised to address and confirm reimbursement.

22-NREC-MD-019

- Principal Investigator: Prof. Faisal Sharif
- Study title: Coronary Product Surveillance Registry (PSR) Platform Base.
- Lead institution: University College Hospital Galway, Newcastle Road, Galway, H91 YR71.
- NREC-MD comments
  - The Committee noted that this application to set up a PSR registry to continuously record of the experience from people around the world treated with a Medtronic product and its performance. The NREC-MD noted that the application documentation is relies on overly technical language.
  - The Committee reviewed this application at its meeting convened on 21/07/2022, and after careful consideration, requested further information on the application.

- The NREC-MD noted that whilst the response clarified a number of queries raised by the Committee, a number of the queries were not adequately addressed, without providing a justifiable explanation. Without a complete and thorough response, the Committee is unable make a favourable decision on the application.
- The NREC-MD noted the query on whether the Committee was reviewing documentation submitted on 28 June 2022. The Committee was reviewing documentation submitted on 29 June 2022. The list of documents is provided in Appendix 1.
- The NREC-MD noted that the participant facing documentation has not been tailored to this specific section study population. Furthermore, the Committee noted the unwillingness to amend the PIL as it has been approved by the HPRA, notwithstanding that the NREC-MD would never receive participant data, contrary to what is set out in the leaflet. The Committee commented that this indicates a lack of regard for the NREC review process, an unwillingness to correct inaccurate information for participants, in order to ensure a participant-centered approach to informed consent.
- The NREC-MD noted that the response to the clarification request, to understand if the generated data would address the objectives of the study, did not provide further details to substantiate the answer.
- The NREC-MD noted that no response was provided on the request to i) amend the broad consent being sought, which is unlawful, and ii) consider that consent is sought for future subject communication to re-consent for future specified use of the data. The applicant states the Medtronic ICF team are on annual leave and a response will follow on their return (undated). All queries must be addressed to enable the NREC-MD to make a fully informed decision.
- The NREC-MD noted that while the response has clarified the situation regarding recruitment timing and that participants may be recruited before or up to 30 days after the index intervention. As mortality is a safety parameter, the Committee noted that recruitment after the index event has the potential to bias the data in this regards in favour of the safety of the device and therefore the overall study findings.
- The NREC-MD noted that “no copy of the DPIA is provided to the site as the content of the DPIA is confidential,” and that “the study site as data controller of the original medical records shall prepare their own data privacy impact assessment as required by the applicable data privacy legislation.” As both processes relate to the processing of data for the purposed of this study, both DPIAs are subject to the NREC-MD review and should be provided in future submissions.

- NREC-MD decision
  - *Unfavourable*

22-NREC-MD-005-SA2

- Principal Investigator: Mr S.Guan Khoo
- Study title: Treatment Evaluation of Neuromodulation for Tinnitus Stage A3 (TENT-A3) – Substantial Amendment.

- Lead institution: St. Vincent's Hospital, Elm Park, Dublin 4, D04 T6F4.
- NREC-MD comments
  - The Committee noted that this application was an application for a substantial amendment pertaining to participants with an unresolved adverse event at the end of the investigation to be followed-up until a satisfactory resolution occurs.
  - The Committee reviewed this application at its meeting convened on 21/07/2022, and after careful consideration, requested further information on the application.
- NREC-MD decision
  - *Favourable*

22-NREC-MD-022

- Principal Investigator: Dr Gabor Szeplaki
- Study title: A Prospective Open label single arm Post Market Clinical Follow-up trial of the FARAPULSE pulsed field ablation system in patients with paroxysmal Atrial fibrillation.
- Lead institution: Mater Private Network, Eccles St, Dublin 7, D07 WKW8.
- NREC-MD comments
  - The Committee noted that this application was for a study aimed to evaluate a device used to treat paroxysmal atrial fibrillation. The NREC-MD noted that the application documentation is relies on overly technical language.
  - The Committee reviewed this application at its meeting convened on 21/07/2022, and after careful consideration, requested further information on the application.
- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions
  - Adverse events listed in the Participant Information Leaflet include risk likelihood.
  - The Informed Consent Form is revised for clarification to indicate whether participants are expected to initial or tick the boxes.

AOB

- The Chairperson thanked the Committee for their ongoing commitment in review of large volume of applications and closed the meeting.