NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

21 July 2022

Attendance

Name	Role
Prof. Barry O'Sullivan	Chairperson, NREC-MD
Prof. Mary Sharp	Deputy Chairperson, NREC-MD
Dr Caitriona Cahir	Member, NREC-MD
Dr Mireille Crampe	Member, NREC-MD
Dr Ruth Davis	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Dr Gloria Kirwan	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Dr Sarah McLoughlin	Member, NREC-MD
Prof. Tom Melvin	Member, NREC-MD
Dr Declan O'Callaghan	Member, NREC-MD
Prof. Susan O'Connell	Member, NREC-MD
Dr Catherine O'Neill	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD

Mr Peter Woulfe	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
Dr Susan Quinn**	Programme Manager, National Office for Research Ethics Committees
Ms Ayesha Carrim**	Project Officer, National Office for Research Ethics Committees
Dr Philip Kelly[×]	The Health Products Regulatory Authority (HPRA)
Dr Gearoid McGauran[×]	The Health Products Regulatory Authority (HPRA)
Dr Michele Meagher[×]	The Health Products Regulatory Authority (HPRA)
Dr Donal O'Connor[×]	The Health Products Regulatory Authority (HPRA)
Dr Gearoid O'Connor[×]	The Health Products Regulatory Authority (HPRA)

*Drafted minutes

**Attended the meeting in observer capacity

[×] Attended HPRA presentation only

Apologies: Dr Owen Doody, Mr Billy McCann, Prof Therese Murphy, Dr Clare O'Connor, Dr Paul O'Connor, Prof Anne Parle McDermott, Prof. Declan Patton, Ms Riona Tumelty

Quorum for decisions: Yes

Agenda

- Welcome (Chairperson)
- Presentation from the Medical Devices team of the HPRA
- Report on Committee business
- Minutes of previous meeting
- Declarations of interest
- 22-NREC-MD-016-SA1-R1
- 22-NREC-MD-017-R1
- 22-NREC-MD-018-R1

- 22-NREC-MD-005-SA1
- 22-NREC-MD-019
- 22-NREC-MD-020
- 22-NREC-MD-021
- 22-NREC-MD-022
- 22-NREC-MD-023
- AOB

- The Chairperson welcomed the Committee, welcomed new members who weren't able to attend the previous meeting and opened the meeting.
- Presentation from the Medical Devices team of the HPRA: the Medical Devices team of the HPRA presented on performance studies of in vitro diagnostic medical devices and clinical investigations of medical devices.
- NREC Committee Business Report: The Committee *noted* the report.
- Minutes of previous meeting (16 June 2022) & matters arising: The minutes were *approved*. The Committee acknowledged the recently published 2021 National Office for Research Ethics Committees annual report.
- Declarations of interest: none.

Applications

22-NREC-MD-016-SA1

- Principal Investigator: Prof. Carel LeRoux
- Study title: A Prospective, Randomized, Double-Blind, Sham-Controlled, Multi-Center Pivotal Study to Evaluate the Efficacy and Safety of Duodenal Mucosal Resurfacing Using the Revita® System in Subjects with Type 2 Diabetes on Insulin therapy – Substantial Amendment.
- Lead institution: University College Dublin, Belfield Downs, Conway Institute / Diabetes Complications Research Centre, Dublin, D14 YH57.
- NREC-MD comments
  - The NREC-MD noted that while the Participant Information Sheets and Participant Study Guide have been amended following the request from the Committee, the updated documents remain overly technical and not fully tailored specifically for participants in Ireland.

  - The NREC-MD noted that three participant facing documents were withdrawn from the submission and the remaining documents, aside from Participant Information Sheets and Participant Study Guide remain unchanged.
  - The NREC-MD noted additional information about future data and sample use has been included in the Participant Information Sheet. The Committee were not satisfied with the level of detail provided in this section and noted that overall, this section was phrased in broad terms, implying blanket consent.
  - The NREC-MD noted that unless justified and outlined in the Participant Information Sheet and protocol, samples should be destroyed once consent is withdrawn. The Committee found the wording too broad, general and not in line with informed consent guidance or with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
  - The NREC-MD also noted that no specific consent was sought for the participant data to be transferred outside of the EU.
- NREC-MD decision
  - *Unfavourable*

21-NREC-MD-017

- Principal Investigator: Prof. Rustom Manecksha
- Study title: Real world evidence observational study to evaluate performance and safety of intravesical sodium hyaluronate (Cystistat®) in the treatment of patients with interstitial cystitis (IC)/bladder pain syndrome (BPS).
- Lead institution: Department of Urology, Tallaght University Hospital, Tallaght, Dublin D24 NR0A, Ireland.
- NREC-MD comments

  The NREC-MD noted that this was an application for a study conducted with the aim of ensuring the continued acceptability of the benefit-risk ratio of Cystistat and confirming the safety and performance of the device throughout its expected lifetime.
- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions
  - A role of gatekeeper is introduced into the recruitment and consenting process.
  - The consent form is revised to ensure compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018), eg provide for unbundled consent, seek specific consent for data processing, data transfer outside of EU, etc.
  - As the NREC-MD will never request to access participant data, the relevant line on Page 6 of the Subject Information and Informed Consent document is removed.

- Given the structure of the Subject Information and Informed Consent, any data generated from this research can only be used for this study and for any other future research or processing.
- When it comes to participant requests to withdraw data from the study, every effort should be made to accommodate such requests.

22-NREC-MD-018

- Principal Investigator: Prof. Seamus Linnane
- Study title: A wearable in-phase chest wall vibration device for relief of dyspnoea in COPD: a first-in-human exploratory study.
- Lead institution: Beacon Hospital, Beacon Court, Bracken Rd, Sandyford Business Park, Sandyford, Dublin 18, D18 AK68.
- NREC-MD comments
  - The NREC-MD particularly noted and appreciated the clarity and quality of the application documentation and of the response to request for further information.
- NREC-MD decision
  - *Favourable*

22-NREC-MD-005-SA1

- 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.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD requests a clarification on what constitutes “a satisfactory outcome”,
  - and an example of actions/ treatment options that could be taken to resolve the most commonly anticipated adverse events listed in the protocol.
  - The NREC-MD requests more information on what the process for follow up will be
  - The NREC-MD requests a clarification on what constitutes "until resolved".
  - The NREC-MD requests a clarification on whether all potential adverse events will be followed up.

- The NREC-MD requests a clarification on the study termination criteria and on how does the proposed amendment impact on the criteria.
- The NREC-MD requests a clarification on whether all data processing carried out as a part of this amendment will be in line with original plan and DPIA.
- The NREC-MD requests a clarification on whether this proposed amendment has any cost implications.
- The NREC-MD requests a clarification on whether this proposed amendment has any implications on the study insurance and indemnity policies.

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.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD requests a clarification it is the intention to set up an all-comer registry and if so, exactly what other devices not listed in the current application are to be included in the registry in the future.
  - The NREC-MD requests a clarification on whether the data generated from this study will be sufficient to adequately address the objectives of this study.
  - The NREC-MD requests a clarification on the study termination process and a list of termination criteria based on which participants could be withdrawn from the study.
  - The NREC-MD requests clarification on the study duration and the duration of the follow up.
  - The NREC-MD requests that any safety issues which are highlighted through this study, are highlighted to the participants.
  - The NREC-MD requests more detail on how participants will be recruited and selected, and what steps will be undertaken to minimise any potential selection bias.
  - Furthermore, the NREC-MD requests that a role of gatekeeper is introduced into the recruitment and consenting process.
  - The NREC-MD requests a justification for consent to be given up to 24 hours after the procedure being carried out. While the study is observational, consideration should be

given to whether potential participants may be in a particularly vulnerable position at this time.

- The NREC-MD requests that the emphasis of participant facing documentation is placed on the purpose of the registry and associated advantages/disadvantages/risks of participation and how participant data will be managed as part of the study.
- 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.
- The NREC-MD noted that the consent form is seeking a broad consent by seeking consent for future use of information without further consent and requests this is amended in line with Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
- The NREC-MD requests a clarification for the following consent item: “I understand that results from analysis of my personal information will not be given to me” and how does this align with the right of the participant to access their personal data processed for this study.
- The NREC-MD noted that the Data Protection Impact Assessment describes the study as a “clinical trial” although this is an observational study, and requests this is amended.
- The NREC-MD noted that the Data Protection Impact Assessment does not specifically refer to the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) 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.
- The NREC-MD requests clarification on the data retention period and whether the data collected as a part of this study will be discarded at the end of the study.
- The NREC-MD requests more information on the “storage system” used for transfer of the data.
- The NREC-MD requests justification for the collection of equality data (race).
- The NREC-MD requests more information on the “affiliates & third-party providers” involved in processing of the 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).
- The NREC-MD requests a justification for no study specific insurance policy in place, given that participants are undergoing additional procedures as a part of the study, and risks associated with processing of personal data.
- The NREC-MD requests clarification whether the manufacturers insurance will cover the study site.
- The NREC-MD noted that the submitted insurance certificate expired in April 2022 and requests an up to date policy is provided.

- The NREC-MD requests a copy of itemised study budget to be provided.

22-NREC-MD-020

- Principal Investigator: Prof. David Burke
- Study title: A single-centre, investigator-led, observational clinical investigation to evaluate the performance of ECG gathered from a single arm for the detection of heart rhythm abnormalities, as compared to hospital telemetry ECG.
- Lead institution: Beacon Hospital, Beacon Court, Bracken Rd, Sandyford Business Park, Sandyford, Dublin 18, D18 AK68.
- NREC-MD comments
  - The Committee noted that this application was for a study designed to provide early information on the performance of an armband health tracker gathering ECG data from a single arm.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD requests a clarification of the rationale for this study and what the findings from the study will be used for.
  - The NREC-MD requests a clarification on the study device and whether there are currently comparable options available on the market.
  - The NREC-MD noted inconsistencies in the study team across the application and requests a clarification on the study team and their roles.
  - The NREC-MD noted that the sponsor Electronic Data Distribution Ltd. is a data company and requests more information on the role in this particular study and whether they will have access to any data stemming from the study.
  - The NREC-MD noted that currently there is no site agreement in place and the justification for this is the scale of the project and requests a confirmation on whether this approach has been agreed upon with the relevant governance bodies in the lead site.
  - The NREC-MD noted that no specific termination criteria has been set out in the Clinical Investigation Plan and requests a clarification on the study termination process and a list of termination criteria.
  - The NREC-MD requests clarification on whether there was any PPI input in the development of the study and study documentation.
  - The NREC-MD requests more detail on how participants will be recruited and selected, and what steps will be undertaken to minimise any potential selection bias. In particular, the NREC-MD noted that no information has been provided on how healthy volunteers will be recruited to take part in the study.
  - The NREC-MD requests more information on the process of identification of potential participants for the study.

- The NREC-MD requests a clarification on whether all potential participants will be under the care of the Principal Investigator and if not, who and how will access the site records to screen potential participants.
- The NREC-MD requests that a role of gatekeeper is introduced into the recruitment and consenting process.
- In line with section D5 of the application form on inclusion of pregnant participants, whilst notable, the NREC-MD requests a clarification on how this aligns with Article 66 of the Medical Devices Regulation (EU) 2017/745.
- The NREC-MD requests clarification on the process for dealing with complaints.
- The NREC-MD requests that participants are given a minimum of 24 hours to consider their participation in the study.
- 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 Participant Information Leaflet is overly technical and needs to be revised to improve accessibility.
- The NREC-MD noted that page 5 of the consent form states: “I give my permission for data to be stored and for possible future research unrelated to the study without further consent”, implying broad consent is being sought, and requests that this is amended in line with best practice and Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
- In line with points raised above in the section ‘Study team and study site’, the NREC-MD requests that the study team and their roles are clearly defined in the Participant Information Leaflet to minimise any confusion.
- The NREC-MD noted that the application lacked detail in terms of proposed data processing and requests more information:
- In relation to data retention, the NREC-MD noted that it is unclear if the data generated from this study is intended to be used in further development of this device, and if so, how long will this data be stored for, and will it be used for secondary analysis?
- The NREC-MD noted that the Participant Information Leaflet states that in the event of the data being transferred outside of EU or to an international organisation, the participants will be informed and advised of safeguards. As per the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018), participants would need to provide their consent for their data to be transferred outside of the EU for a specific purpose. The NREC-MD requests the document is amended accordingly.
- The NREC-MD noted that the data will be analysed at NUIG. The Committee requests more information on who will have access to the data, their role in the project and their relevant experience, and clarification on whether a data sharing agreement is in place.
- 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 funding for the study is not in place yet. The Committee requests a clarification on what will happen if the anticipated funding sum is not secured.
- Finally, the NREC-MD noted that the financing descriptions of the are not clear and requests an itemised budget, clarifying the cost of the various study fees.
- The NREC-MD noted that a quote for a study specific insurance has been provided and requests clarification whether there are any other policies in place, such as manufacturer's insurance.

22-NREC-MD-021

- Principal Investigator: Prof. Robert Byrne
- Study title: LiquID Guide Catheter Extension Safety Study.
- Lead institution: Mater Private Network, Eccles St, Dublin 7, D07 WKW8.
- NREC-MD comments
  - The Committee noted that this application was for a study exploring the LiquID Guide Catheter Extension in persons with potential or proven coronary artery disease to further determine the safety and performance characteristics of this device after obtaining market approval.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD noted that a reference is made in relation to procedure-related cost information, which is not outlined in the study objectives and requests clarification on if and how will this be assessed.
  - Based on the information provided in the application dossier, the NREC-MD noted only limited information on the experience of the study team and site. To that end, the NREC-MD requests further information.
  - The NREC-MD noted that the Chief Investigator for this study does have a financial interest in the company that manufactures the LiquID device and that the results of this study are not directly tied to that financial interest. The Committee requests clarification on what measures have been put in place to minimise any potential bias or undue influence.
  - The NREC-MD requests clarification on what sites of the Mater Private Network will be involved in this study.
  - The NREC-MD requests clarification on the number of participants to be enrolled in the study.
  - The NREC-MD requests a clarification on whether the cohort of potential participants includes all those with CAD scheduled for PCI, or only those where the use of a guide catheter is anticipated e.g., distal lesions.

- The NREC-MD noted that section D2.1 of the application form states that "only native English speaking subjects will be enrolled". The NREC-MD deems this as unjustifiable and requests that the inclusion/ exclusion criteria is revised to reflect desired proficiency in English language instead.
- To that end, the NREC-MD requests more detail on how participants will be identified, recruited and selected, and what steps will be undertaken to minimise any potential selection bias. The NREC-MD requests that the participant recruitment process is clearly defined and provided as a part of the response.
- The NREC-MD requests that no study-related assessments are done until participant's consent is obtained.
- Furthermore, the NREC-MD requests that a role of gatekeeper is introduced into the recruitment and consenting process.
- The NREC-MD noted, that the sponsor will have access to participant's medical records for verification purposes. The NREC-MD requests justification for this approach.
- The NREC-MD requests more clarification on how long will the key be retained for.
- The NREC-MD requests more information on the Trium clinical consultancy and any other third-party providers" involved in processing of the data, including their role, location, qualification and arrangement with the applicants in terms data sharing agreements.
- The NREC-MD noted that in section F2.3 a reference is made to the privacy shield as a safeguard for transfer of data outside of the EEA. As of June 2020, the EU-US Privacy Shield is therefore no longer a valid mechanism to transfer personal data from the European Union to the United States. The Committee requests updated information on safeguards in place to ensure that any Study Data transferred is processed compliant with the EU GDPR.
- 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 there is no named contact to answer questions on the study or to contact if experiencing potential side effects on the provided version of Participant Information Leaflet and requests this is updated.
- The NREC-MD requests that the Informed consent form is revised to facilitate unbundled consent.
- The NREC-MD requests that when it comes to participant requests to withdraw data from the study, every effort should be made to accommodate such requests.
- The NREC-MD noted that while the participant's GP will be informed about their participation in the study, no copy of GP letter was included in the application documentation.
- The NREC-MD noted that as a part of the study, the participants will undergo ionising radiation. The NREC-MD requests a confirmation that the study proposal was reviewed by the site's medical physicist.

- The NREC-MD requests an itemised budget.
- The NREC-MD noted that no study specific insurance policy has been included in the submission.

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.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD noted that no information on EU representatives of the sponsor and manufacturer in section B2 & B3 of the application form was provided and request this is rectified.
  - The NREC-MD requests more detail on how participants will be recruited and selected, and what steps will be undertaken to minimise any potential selection bias.
  - The NREC-MD requests that a role of gatekeeper is introduced into the recruitment and consenting process.
  - The NREC-MD requests clarification how long will the participants have to decide about their participation and recommends this is set at minimum of 72 hours.
  - The NREC-MD noted that participant's GP/ health care provider will not be informed about their participation in the study and requests a justification for this approach.
  - The NREC-MD noted that as a part of the study, the participants will undergo an additional X ray at 90 days or 6-12 months. The NREC-MD requests a confirmation that the study proposal was reviewed by the site's medical physicist.
  - The NREC-MD requests an itemised study budget to be provided.
  - 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 and a confirmation that the Principal Investigator has undertaken Good clinical practice / ISO 14155 training.
  - The NREC-MD requests a clarification on whether the timeline follow up is sufficient for meaningful conclusions to be drawn up.

- The NREC-MD requests that in addition to any patient reported episodes all event monitors occurring as a part of this study, are recorded and analysed, including those prior to 90 days.
- The NREC-MD requests clarification on whether this treatment is currently provided in the study site as part of standard practice.
- The Committee requests a justification for such broad and unspecified information being sought in some case report forms.
- The NREC-MD requests a clarification on whether any study data will be transferred outside the EU/EEA, and if so, which arrangements are in place to ensure that personal data will be processed as is necessary; a) to ensure the data being processed is safeguard under terms and conditions; b) to achieve the objective of the study and; c) to ensure that it shall not be processed in such a way that damage or distress to the data subject?
- The NREC-MD noted that no study specific insurance policy has been included in the submission.
- The NREC-MD requests that the Participant Information Leaflet and Consent Form are revised to ensure that the participants understand what it is they are consenting to as both the benefits and risks focus on the procedure rather than participation in the study itself.
- The NREC-MD noted that the site Data Protection Officer provided feedback on the Participant Information Leaflet and Consent Form and requests a clarification on whether the documents were updated in line with the feedback.
- The NREC-MD requests that details of the site Data Protection Officer are listed on the Participant Information Leaflet.
- The NREC-MD noted that the data protection section of the Participant Information Leaflet needs to be revised to ensure that participants rights under GDPR are clearly explained.
- The NREC-MD noted that the consent form is seeking a broad consent by seeking consent for future use of information without further consent and requests this is amended in line with best practice and Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
- 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).

22-NREC-MD-023

- Principal Investigator: Dr Danny Cheriyan
- Study title: Multi-Centre Prospective Observational Cohort Study: To assess the performance of single use duodenoscope.
- Lead institution: Beaumont Hospital, Beaumont Road, Dublin 9, Ireland.
- NREC-MD comments

  - The Committee noted that this application was for a study aimed to assess the technical success of a single use duodenoscope.

- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD noted that the application documentation could be revised to communicate more clearly that the technical aspects of using the single use duodenoscope, rather than any evaluation of their ability to reduce infection, are the focus of the study.
  - The NREC-MD requests a justification of the proposed study population size in Ireland within the context of the whole study.
  - The NREC-MD noted that this study is described as non-commercial study, funded by a grant secured by Dr Vasan, with Boston Scientific providing the devices. The NREC-MD requests a clarification if Boston Scientific contributed to the grant for this study and if they will have access to any of the data generated by the study.
  - 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. Additionally, the NREC-MD requests a confirmation that the Principal Investigator has undertaken Good clinical practice / ISO 14155 training.
  - The NREC-MD noted that throughout the application documentation, references are made to the Principal Investigator, and that it is unclear whether this always referring to the National Principal Investigator Dr Cheriyan or the study Principal Investigator Dr Vasan. The Committee requests this is specified throughout the documentation, and in particular in the participant facing documents.
  - The NREC-MD noted that as proposed in the application, the study specific procedures are linked with planned standard care procedures, eg the Participant Information Leaflet is being sent out with the endoscopy appointment to prospective participants or consenting for the procedure is done at the same time as for the study. The NREC-MD noted that this could lead to confusion among the prospective participants and requests that the study specific processes are differentiated from the standard care processes.
  - The NREC-MD requests that a role of gatekeeper is introduced into the recruitment and consenting process.
  - The NREC-MD requests that the number of participants taking part in the study in Ireland is highlighted in the Participant Information Leaflet.
  - The NREC-MD noted that the details of the Data Protection Officer listed in the Participant Information Leaflet direct the participants to the main study Data Protection Officer based in the UK and requests that details of the site Data Protection Officer are also included.
  - The NREC-MD noted that there are a number of formatting errors in the Participant Information Leaflet, eg space on page 6, and requests the form is revised.

- The NREC-MD noted that the data should not be considered anonymised as it is potentially identifiable.
- The NREC-MD noted that the consequences/ actions to be taken in the event of a data breach are not clearly outlined or differentiated between data breach at Beaumont Hospital and a data breach in UK. This should be revised with references made to Beaumont Hospital data breach protocols.
- The NREC-MD noted that the Data Protection Impact Assessment or participant facing documents do not specifically refer to the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) 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.
- The NREC-MD noted that the Case Report Form includes a question on participant ethnicity and requests a justification for a collection of equality data.
- The NREC-MD requests that when it comes to participant requests to withdraw data from the study, every effort should be made to accommodate such requests.
- The NREC-MD noted that the Informed Consent Form offers consent for future data use for “research related to the study” and “research unrelated to the study” implying that broad consent is being sought and requests this is updated in line with Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018).
- The NREC-MD noted that the Informed Consent Form does not seek specific consent for their data being transferred outside of the EU/EEA and requests the document is amended accordingly.
- 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 as a part of the study, the participants will be exposed to ionising radiation as a part of the procedure. The NREC-MD requests a confirmation that the study proposal was reviewed by the site’s medical physicist/ radiation safety board.
- The NREC-MD noted that no study specific insurance policy has been included in the submission.
- The NREC-MD noted that all but one member of the Data Monitoring Committee are directly involved in the study and requests a clarification of to what the degree will the Committee be independent.
- The NREC-MD requests an itemised study budget is provided.
- The NREC-MD noted that currently the tripartite agreement between the parties involved in this study was not provided and requests a copy is provided as a part of the response.

AOB

- Dr Lucia Prihodova, Programme Manager at the National Office for Research Ethics Committees informed the Committee about the 2023 meeting dates.
- The Chairperson thanked the Committee and closed the meeting.