NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

13 October 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 Caitriona Cahir	Member, NREC-MD
Dr Mireille Crampe	Member, NREC-MD
Dr Ruth Davis	Member, NREC-MD
Ms Orla Lane	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Dr Sarah McLoughlin	Member, NREC-MD
Dr Declan O'Callaghan	Member, NREC-MD
Prof. Susan O'Connell	Member, NREC-MD
Dr Clare O'Connor	Member, NREC-MD
Dr Catherine O'Neill	Member, NREC-MD
Mr Damien Owens	Member, NREC-MD
Ms Riona Tumelty	Member, NREC-MD

Prof. Mahendra Varma	Member, NREC-MD
Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees
Ms Megan O'Neill	Project Officer, National Office for Research Ethics Committees

*Drafted minutes

*Observer role

Apologies: Dr Owen Doody, Dr Frank Houghton, Dr Gloria Kirwan, Prof. Tom Melvin, Prof. Therese Murphy, Dr Paul O'Connor, Prof Anne Parle McDermott, Mr Peter Woulfe,

Quorum for decisions: Yes

Agenda

- Welcome (Chairperson)
- Report on Committee business
- Minutes of previous meeting
- Declarations of interest
- 22-NREC-MD-031
- 22-NREC-MD-003-SA3
- 22-NREC-MD-030
- 22-NREC-MD-032
- 22-NREC-MD-034
- 22-NREC-MD-035
- AOB

- The Chairperson welcomed the Committee and opened the meeting.
- NREC Committee Business Report: The Committee *noted* the report.
- Minutes of previous meeting (15 & 23 September 2022) & matters arising: The minutes were *approved*.
- Declarations of interest:
    - Prof Declan Patton (22-NREC-MD-034). Prof Patton left the meeting for the review of 22-NREC-MD-034.
    - Dr Catherine O'Neill (22-NREC-MD-034). Dr O'Neill left the meeting for the review of 22-NREC-MD-034.

Applications

22-NREC-MD-031

- Principal Investigator: Prof. Michael J Kerin
- Study title: An open-label, single site, pilot clinical investigation to assess the detectability and sizing of invasive breast cancers, the detectability of benign breast lesions, as well as the differentiation between malignant and benign breast lesions using the Wavelia #2 Microwave Breast Imaging system (Wavelia #2 Pilot #1 Study)
- Lead institution: NUI Galway and Galway University Hospital, Newcastle Road, Galway, H91 YR71.
- NREC-MD comments
  - The Committee noted that this was a response to request for further information issued following the 15 September 2022 NREC-MD meeting NREC-MD decision.
- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions
  - Due to the importance of this information, data on race is included in the Case Report Form as initially planned, but instead of the original wording, the ethnicity categories listed in the 2022 Census are used.
  - The NREC-MD noted the progress made in making the device more accessible, nonetheless, in its current form it is not accessible for those with more severe disability, and therefore does not offer equitable access. The Committee would like to encourage a further consideration is given to further improvements in accessibility in the next iteration of the device.
  - A completed and signed financial disclosure for the PI is provided.

22-NREC-MD-003-SA3

- Principal Investigator: Prof. Faisal Sharif
- Study title: Global SYMPLICITY Registry (GSR) Denervation Findings in Real World (DEFINE) is referred to as the GSR DEFINE study, Including Irish Country Addendum (IMPROVE) – Substantial Amendment.
- Lead institution: University College Hospital Galway, Newcastle Road, Galway, H91 YR71.
- NREC-MD comments
  - The NREC-MD noted that this is an application for substantial amendment of appointing Dr James Shand as the site Principal Investigator at St Vincent's University Hospital.

  - The Committee noted that this was a response to request for further information issued following the 15 September 2022 NREC-MD meeting NREC-MD decision.

- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions
  - Prof. Sharif, the National PI, will ensure that necessary training is provided for Dr Shand to carry out all necessary study procedures and that Dr Shand undertakes training in Good Clinical Practice before the study commences.

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 was a response to request for further information issued following the 18 August 2022 NREC-MD meeting NREC-MD decision.
- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions
  - A clarification is provided to the National Office on whether Section H of the application form needs to be completed.
  - A clarification is provided to the National Office regarding the purpose of the summary participant information leaflet and consent form. All participants should be provided by the full participant facing documentation before enrolment into the study.
  - Applicants are reimbursed for all reasonable expenses.
  - Participants can withdraw from the study by informing the study doctor/ gatekeeper, rather than having to discuss their decision with the study doctor.
  - The NREC-MD noted the updates Section G3 of the application form and noted some ambiguity in the description of the process. Therefore, the Committee requests that the role of gatekeeper is introduced in the recruitment and consenting process.
  - The NREC-MD noted the response on the question regarding participant vulnerability. Whilst the study does not meet all conditions set out in Article 68 of the Medical Devices Regulation (EU 2017/745), the Committee noted that given the acuity of the pulmonary embolism and urgency of the medical procedure, all prospective participants in the study are to some degree in a vulnerable position. The Committee requests that due consideration is given to the process of identifying and recruiting participants. Furthermore, the Committee noted that the circumstances of enrolling

participants in this study further underline the importance of a gatekeeper to minimise the perception of any undue influence.

22-NREC-MD-032

- Principal Investigator: Mr Peter Lonergan
- Study title: ProVee Urethral Expander System IDE Study
- Lead institution: St. James's Hospital, James Street, Dublin 8, D08 NHY1
- NREC-MD comments
  - The Committee noted that this was a response to request for further information issued following the 15 September 2022 NREC-MD meeting NREC-MD decision.
- NREC-MD decision
  - *Favourable with conditions*
- Associated conditions
  - The NREC-MD noted the response to the request to implement a gatekeeper in the recruitment and consenting process, and requests that the gatekeeper also undertakes the consenting process.
  - Information on the collection, use and all data protection issues of video data is comprehensively included in the participant information leaflet and the consent form. The data protection issues associated with the video data should be also considered in future iterations of the study data protection impact assessment (DPIA).
  - The consent form is truly unbundled in line with the requirements of the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018) and the Department of Health Guidance on Information Principles for informed consent for the processing of personal data for health research.
  - In relation to the query regarding study expenses, the NREC-MD acknowledges the practicalities of the flat rate. However, given the duration of the study and the rising cost of living, the Committee request that participants are offered an option of receipted claims vs flat rate which would be appraised periodically in relation to inflation.

22-NREC-MD-034

- Principal Investigator: Prof. John McDermott
- Study title: Wound Assessment Using Spectral Imaging (WAUSI).
- Lead institution: Connolly Hospital Blanchardstown, Mill Rd, Abbotstown, Dublin, D15 X40D.
- NREC-MD comments
  - The NREC-MD noted that this was application for an observational clinical investigation investigating a medical imaging device called DeepView SnapshotTM (DeepView), and its ability to predict Diabetic Foot Ulcer (DFU) healing times.

- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD noted that section E4 of the application form lists ankle brachial pulse measurements as one of the procedures that the study participants will undergo and that this procedure is not listed in the Participant Information Leaflet. The Committee requests a clarification on when, how and why this information will be collected and that all study procedures are detailed in the Participant Information Leaflet.
  - The NREC-MD requests a clarification on whether the study related assessments have any influence on the clinical management of the participants.
  - The Committee requests clarification on the study team members and their individual roles in the study.
  - The Committee a clarification on PI's experience in studies of similar scale.
  - The NREC-MD requests a clarification on whether the study gatekeeper has been identified and if yes, that their details and CV are provided.
  - The NREC-MD noted that page 4 of the Participant Information Leaflet states that "Your study doctor or sponsor can also remove you from the study at any time without your consent, for any of the following reasons:… for medical or business reasons." The Committee requests a clarification on what falls under "business reasons."
  - The NREC-MD noted that section F9 of the application form lists "Cannot speak or understand English" as one of the exclusion criteria. The Committee requests a clarification on how this will be determined. Furthermore, the Committee queried whether inclusion of such prospective participants should be considered given that the study related assessments are carried out as a part of standard care, and that there is likely a certified interpreter present for the appointment.
  - The Committee requests a clarification on personal data that will be shared with the sponsor and that relevant documentation is updated accordingly.
  - The NREC-MD noted that section K7 of the application form states that following the study completion, the data will be archived with Iron Mountain. The Committee requests more information on the provider, including location and relevant ISO certification.
  - The NREC-MD requests a clarification on whether data will be included in the analyses or discarded following participant's withdrawal/ death/ undergoing limb amputation.
  - Finally, the NREC-MD noted that the informed consent form does not include consent for data transfer outside of the EU and requests this is amended accordingly.
  - The NREC-MD requests a clarification on the study budget.
  - The NREC-MD noted that section S1 indicates that participants will not be reimbursed for lost earnings, travel costs and other expenses incurred and requests a justification.

- Finally, the NREC-MD noted that as the study device is an AI algorithm, the Committee highly encourages that due consideration is given to the Ethics guidelines for trustworthy AI and requests a comment on if and how it is intended to apply these Guidelines to the algorithm development.

22-NREC-MD-035

- Principal Investigator: Prof. Faisal Sharif
- Study title: Product Surveillance Registry (PSR) Coronary
- Lead institution: University College Hospital Galway, Newcastle Road, Galway, H91 YR71.
- NREC-MD comments
  - The NREC-MD noted that this application is a resubmission of a clinical investigation focused on the Product Surveillance Registry (PSR) that previously received an unfavourable decision. The Committee acknowledged the effort put into the revised application and noted that the application documentation is much improved.
- NREC-MD decision
  - *Request for further information*
- Further information requested:
  - The NREC-MD noted that the purpose of the study is not entirely clearly outlined in the application documentation and requests a confirmation that this application only pertains to the study of to the four devices listed in the form, rather than general inclusion in the existing registry.
  - The NREC-MD noted that the justification for recruiting participants up to 30 days post procedure is well described, along with the preference for inclusion pre procedure whenever possible. The Committee requests a clarification on any measures taken to minimise the potential bias stemming from this recruitment strategy and that the potential bias of this recruitment strategy is clearly stated in all future reporting from the registry findings.
  - The NREC-MD requests that prospective participants are allowed at least 24hours to consider their participation in the study, and that this is clearly stated in participant facing documentation.
  - The NREC-MD requests clarification on whether inclusion of prospective participants who do not speak English should be considered given that the follow-up visits are intended to align with routine clinical care practices, and that there is likely a certified interpreter present for the appointment.
  - The NREC-MD noted that section J of the application form on the inclusion of pregnant/ breastfeeding participants contains conflicting information. The Committee requests a clarification and justification for inclusion/ exclusion of child-bearing potential or pregnant or breastfeeding participants from a registry study.

- The NREC-MD requests that the number of participants from Ireland is to be included in the Participant Information Leaflet.
- The NREC-MD noted that only limited information on the study termination is provided and requests that study termination criteria are clearly set out in the application documentation, including in the participant information leaflet.
- The NREC-MD noted that the information on access to personal records in the application form provide conflicting information and request clarification.
- The NREC-MD requests clarification on what data might be collected from the participant's family members, justification for this approach and any relevant assent forms required to facilitate this.
- Similarly, the NREC-MD requests a clarification on what data might be collected from the participants healthcare providers, other that their cardiac team, and that a copy of any relevant letters/ forms is provided, eg GP letter. Furthermore the Committee requests that participant's explicit consent is sought for such data collection.
- The NREC-MD noted that page 10 of the Participant Information Leaflet states that "Your personal data will be processed at all times in accordance with applicable legal requirements and will be used only for the following purposes:… For future compatible scientific research in similar or related medical conditions and/or therapies," implying broad consent is being sought, and requests that this is amended. Please note that in line with best practice and Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018), both participant consent and independent research ethics review should be sought for specific research proposals once they are clearly defined. To that end, in the consent form, the participants should be asked for a consent to be contacted in the future for such purposes or for the data to be fully anonymised. Alternatively, "future compatible scientific research in similar or related medical conditions and/or therapies" should be more clearly defined in the current documentation.
- The NREC-MD noted that while an itemised study budget has been provided, no total budget estimate was listed in the documentation and requests clarification.
- The NREC-MD noted that page 3 of the Participant Information Leaflet states that "All costs are part of your usual medical care that would have been provided if you were not in the registry and therefore will be covered by the national healthcare coverage or your medical insurance," is revised to reflect that participant's insurance policy will not be charged for any of the study specific procedures.
- The NREC-MD noted that the provided Certificate of Liability insurance is not in line with the guidance issued by the State Claims Agency and requests clarification if this policy has been approved by the study site. The NREC-MD requests clarification whether there are any other policies in place, such as manufacturer's insurance for the individual study devices of site indemnity policy.

AOB

- The NREC-MD discussed whether there is a need to revise the current NREC-MD application form to accommodate the diverse types of applications, eg registry studies,

studies focused on AI/ software. Dr Prihodova invited the Committee to contact the National Office with proposed changes to the form.

- Dr Ruth Davis noted that she will be delivering a presentation to the NREC members on data protection and invited members to raise any topics that they feel would be of interest.
- The Chairperson thanked the Committee and closed the meeting.