NATIONAL OFFICE FOR RESEARCH ETHICS COMMITTEES

National Research Ethics Committee

NREC-MD Meeting Minutes

15 August 2024

Attendance

Name	Role
Prof. Declan Patton (Deputy Chair)	Deputy Chair, NREC-MD
Prof. Mary Sharp (Deputy Chair)	Deputy Chair, NREC-MD
Dr Daniel Coakley	Member, NREC-MD
Dr Ruth Davis	Member, NREC-MD
Dr Frank Houghton	Member, NREC-MD
Dr James Gilroy	Member, NREC-MD
Dr Gloria Kirwin	Member, NREC-MD
Mr Billy McCann	Member, NREC-MD
Dr Sarah McLoughlin	Member, NREC-MD
Prof. Tom Melvin	Member, NREC-MD
Dr Joanne O'Dwyer	Member, NREC-MD
Mr Damian Owens	Member, NREC-MD
Prof. Mahendra Varma	Member, NREC-MD
Ms Simone Walshe	Member, NREC-MD
Dr Lucia Prihodova*	Programme Manager, National Office for Research Ethics Committees

*Drafted minutes.

Apologies: Prof. Barry O'Sullivan, Dr Caitriona Cahir, Dr Mirielle Crampe, Dr Owen Doody, Ms Orla Lane, Prof. Cara Martin, Prof. Therese Murphy, Dr Declan O'Callaghan, Dr Clare O'Connor, Dr Paul O'Connor, Prof. Mahendra Varma, Mr Peter Woulfe

Quorum for decisions: Yes

Agenda

1. Welcome (Chairperson) and apologies:
2. Report on Committee business
3. Minutes of previous meeting
4. Declarations of interest
5. 24-NREC-MD-003-R1
6. 24-NREC-MD-016-R2
7. 24-NREC-MD-018-R1
8. 24-NREC-MD-019-R1
9. AOB

- Prof. Barry O'Sullivan welcomed the Committee and acknowledged apologies sent and opened the meeting.
- Declarations of interest: None

Applications

24-NREC-MD-003-R1

- Principal Investigator: Prof. Briain MacNeill
- Study title: A Post-Market Registry of the BioFreedomTM Ultra CoCr Biolimus A9TM coated coronary stent system
- Lead institution: Dept. of Cardiology, Galway University Hospital, Newcastle Rd, Galway, H91 YR71.
- NREC-MD Decision
  - *Favourable with Conditions*
- Associated conditions

- Given the nature of the study, participants are presented with the participant information leaflet and consent form after the procedure.
- The participating sites Data Protection Officers review and approve the proposed data processing and the study Data Protection Impact Assessment.
- Data breach insurance policy is in place for the study.

24-NREC-MD-016-R1

- Principal Investigator: Prof Ray McDermott
- Study title: An interventional, prospective clinical study protocol for testing RNA extracted from FFPE tumor tissue specimens taken from patients with Intermediate risk Non-Muscle-Invasive Bladder Cancer (IR-NMIBC) for FGFR alterations, using the QIAGEN therascreen® FGFR RGQ RT- PCR Kit, to determine molecular eligibility (FGFR gene alterations detected) for enrolment onto Janssen's Phase 3 clinical trial of the FGFR inhibitor, erdafitinib (MoonRISe-1 number 42756493BLC3004).
- Lead institution: St. Vincent's University Hospital, Dublin
- Sponsor: Qiagen Manchester Ltd.
- NREC-MD Decision
  - *Favourable*

24-NREC-MD-018-R1

- Principal Investigator: Dr Austin Duffy
- Study title: Clinical performance study for use of the FOLR1 (2.1) Clinical Trial Assay in Study IMGN853-0424: A Randomized Phase 2 Study of Ocular Toxicity Evaluation and Mitigation During Treatment with Mirvetuximab Soravtansine in Patients with Recurrent Ovarian Cancer with High Folate Receptor-Alpha Expression
- Lead institution: Mater Misericordiae University Hospital
- Sponsor: Immunogen Inc.
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions:
  - The NREC-MD noted that in response to the Committee request for explicit consent for future use an additional consent item relating to future testing based on regulatory requirements was added to the ICF. This implies that no future research, eg research not outlined in current protocol, will be carried out on the samples and data collected for the purpose of this study.
  - Any testing carried out due to regulatory requirements for the purposes of current study generally does not require specific consent and that the added consent line may be removed.

- As IHC protein assay is not considered a source of genetic information, the PIL/ ICF and the NREC-MD application form are to be revised to remove references to genetic material. If there are plans to carry out future genetic research with the samples/ data from the current study, these are subject to specific explicit consent from the participant and separate Research Ethics Committee review.

- Finally, page 4 of the updated PIL/ICF states that “Since the objective of clinical studies is to encourage scientific research to discover new treatments, the Sponsor is required to combine your Coded Personal Data with other participants´ Coded Personal Data. The Sponsor will use the combined data to assess the safety and efficacy of MIRV on ocular health and submit it to health agencies for the approval of the drug.” This section is to be revised to relate to the IVD under exploration rather than the drug.

24-NREC-MD-019-R1

- Principal Investigator: Dr Rajendra Ramsamooj
- Study title: Oncomine™ Dx Express Test Clinical Performance Study Protocol (NTRK), Solid Tumor (FFPE), Danube, Project Number PRJ0003987
- Lead institution: Life Technologies Clinical Service Lab Inc.
- Sponsor: Life Technologies Corporation, part of Thermo Fisher Scientific
- NREC-MD Decision
  - *Favourable with conditions*
- Associated conditions:
  - The NREC-MD application form is revised to clearly outlined the role of Bayer Group in the performance study as per previous email communication.

AOB

- Dr Sarah McLoughlin informed the Committee that she is stepping down from the NREC-MD. Dr McLoughlin will be joining the National Office for Research Ethics Committees as the new Programme Officer. The Chairperson thanked the outgoing member for their commitment to the Committee to date.
- The Chairperson thanked the Committee and closed the meeting.