# National Research Ethics Committee

## NREC-CT Meeting

**9th October 2024**

### Attendance

| Name | Role |
|---|---|
| Prof David Brayden | Chairperson, NREC-CT D |
| Prof David Smith | Deputy Chairperson, NREC-CT D |
| Prof Andrew Green | Committee Member, NREC-CT D |
| Prof Cathal Walsh | Committee Member, NREC-CT D |
| Dr Geraldine O'Dea | Committee Member, NREC-CT D |
| Prof Lina Zgaga | Committee Member, NREC-CT D |
| Mr Gerry Daly | Committee Member, NREC-CT D |
| Ms Deirdre McLoughlin | Committee Member, NREC-CT D |
| Prof Tina Hickey | Committee Member, NREC-CT D |
| Dr Mary McDonnell Naughton | Committee Member, NREC-CT D |
| Ms Chanel Watson | Committee Member, NREC-CT D |
| Emily Vereker | Head of Office, National Office for RECs |
| Dr Laura Mackey | Programme Officer, National Office for RECs |
| Dr Susan Quinn | Programme Manager, National Office for RECs |
| Emma Heffernan | Project Officer, National Office for RECs |
| Ms Patricia Kenny* | Project Officer, National Office for RECs |
| Ciaran Horan | Administrative Assistant, National Office for RECs |

**Apologies:** Christina Skourou, Jeff More, Deirdre Murray, Geraldine O'Sullivan Coyne

**Quorum for decisions:** Yes

### Agenda

- Welcome & Apologies
- 2024-512536-29-00
- 2024-516530-36-00 SM-1
- 2023-506288-33-00 SM-2
- AOB

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- The Chair welcomed the NREC-CT D.
  - The minutes from the previous NREC-CT D meeting on 11th September 2024 were approved.
  - The NREC Business Report was discussed and noted.

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## Applications

**2024-512536-29-00**

Institutions: Beaumont Hospital

Study title: A phase 2, randomized, double-blind, placebo-controlled parallel group study of VHB937 in Amyotrophic Lateral Sclerosis (ALS) over 40 weeks followed by an Open-label Extension (ASTRALS)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

**Part II Considerations**

1. **Compliance with national requirements on data protection**

- The NREC-CT requested that evidence of DPO input into the DPIA is provided.

2. **Compliance with use of biological samples**

- The NREC-CT noted the Collection, storage and future use of human biological samples document pg. 5 refers to *"Samples consented for future research by the Optional Genetics ICF, or by the Additional Research portion of the main ICF".* It was not clear to the Committee if the *"additional Research portion of the main ICF"* mentioned is
    - the "Optional consent for Additional Research" detailed on pg. 19 Main ICF for which there is a separate optional FSR ICF
      or
    - if the sponsor is also wishing to conduct additional research as part of the main study protocol.

  The Committee requested the Collection, storage and future use of human biological samples document section 4.1 be updated to clarify. The Committee advised that if there is to be future use of the samples/data as part of the main study protocol, and not part of the optional future research, then the Main ICF would need to be updated to include detail about this additional use/ future research and that future research is restricted to ALS or the drug under study and this is clearly stated in the main body and informed consent section of the PISCF. • The Committee also requested that if there is no future use of samples/data as part of the main study other than the Optional future research then the SIS and ICF Main pg 21 should be updated to remove the consent statement "I agree to my Personal Data and Coded Data, including my biological samples (such as blood and tissue) to be stored for future use".

3. **Subject information and informed consent form**

- The NREC-CT requested that the SIS and ICF Main ICF be updated to move the optional consent statement on pg 22 to another page with separate signature

sections for participant to be able to explicitly consent or not to this optional component separate from their consent for the main study.

- The NREC-CT requested that the SIS and ICF Main ICF pg 19 be updated to remove the word “not” from the following sentence “If you do not want to participate in this Additional Research, please refer to the separate Patient Information Sheet and Informed Consent Form for Future Scientific Research.”
- The NREC-CT requested that the signature section on SIS and ICF Main ICF pg 20 be moved to the end of the document as signature sections should be in consent form and not the information sheet.
- The Sponsor is requested to submit any Part 2 documentation that require updates as a result of the Part 1 Assessment. Please include detail of the Part 1 consideration that triggered the update to the Part 2 documentation
- The National Office requests that all documentation provided in response to RFI is presented in an accessible and searchable format (Word or original PDF). We are unable to accept scanned documents (including documents modified using Optical Character Recognition) as these documents cannot be optimised for use with assistive software.
- The NREC-CT noted that some of the sections on future research in the FSR ICF pg. 2 and Genetic ICF pg 3 are seeking blanket consent for future use of samples for unspecified purposes without further consent. This consent is not described in line with regulations and best practice as it is not confined to the disease or drug under study ie. *“It is not possible to predict the needs of future scientific research projects. The specific details of such Additional Research are not known right now”, “Future scientific research may provide new information about a disease, how to prevent it, or how to treat it. It may also help identify people likely to develop a disease” and “The purpose of this genetic research is mostly to better understand the safety and efficacy (how well it works) of a treatment. It may also be to learn more about human diseases or to help develop ways to detect, monitor and treat diseases.”*

  This type of consent is not in line with best practice, the Declaration of Taipei 2016 and not in compliance with the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018), where informed participant consent is a mandatory safeguard. The NREC-CT requested that future research is restricted to specified health research, either in relation to ALS or the drug under study and that this is clearly stated in the main body and informed consent section of the PISCF. The NREC-CT advised that consent can only be obtained where future use of samples and data is defined such that participants are fully informed. Furthermore, the NREC request confirmation that subsequent research ethics review will be sought for specific research once clearly defined.

  For further guidance, please see: NREC guidance on use of biological samples and associated data. https://www.nrecoffice.ie/guidance-on-use-of-biological-samples-and-associated-data
- The NREC-CT requested the SIS and ICF Main ICF pg 19 be updated to refer to the potential future use of biological samples as well as data.
- The NREC-CT requested clarification on the requirement of a legally designated representative for participants lacking decision making capacity, and that this information is added to the Main ICF, including a signature line for the legally

designated representative, if required. Further guidance is available here: Legally designated representatives - NREC (nrecoffice.ie).

- The NREC-CT requested that the witness signature section on Main ICF consent form pg. 22 be updated to include detail of the nature, independence and relationship of the witness to the participant.
- The NREC-CT requested that the Pregnancy ICF pg 6 be updated to include consent statement for the investigators to contact the health professionals involved in the care of the pregnancy, to get objective information on the pregnancy and its outcome.

**2024-516530-36-00 SM-1**

Institutions: St James's Hospital

Study title: A Randomized Phase III, Two-Arm Trial of Paclitaxel/Carboplatin/Maintenance Letrozole Versus Letrozole Monotherapy in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum.

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

**2023-506288-33-00 SM-2**

Institutions: Tallaght University Hospital, Cork University Hospital, St Vincent's University Hospital

Study title: MK-5684-01A Substudy: A Phase 1/2 Umbrella Substudy of MK-5684-U01 Master Protocol to Evaluate the Safety and Efficacy of MK-5684-based Treatment Combinations or MK-5684 Alone in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

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- AOB:
  - None