National Research Ethics Committee

NREC-CT Meeting

2nd July 2025

Attendance

Name	Role
Dr Cliona McGovern	Chairperson, NREC-CT B
Dr John Hayden	Deputy Chairperson, NREC CT-B
Ms Serena Bennett	Committee Member, NREC-CT B
Prof. Michaela Higgins	Committee Member, NREC-CT B
Ms Jasmine Joseph	Committee Member, NREC-CT B
Dr Ciaran Lee	Committee Member, NREC-CT B
Dr Andrew Lindsay	Committee Member, NREC-CT B
Dr Niall McGuinness	Committee Member, NREC-CT B
Mrs Ann Twomey	Committee Member, NREC-CT B
Mr Edward McDonald	Committee Member, NREC-CT B
Dr Emily Vereker	Acting Head, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Emma Heffernan	Project Officer, National Office for RECs
Ms Deirdre Ní Fhloinn	Project Officer, National Office for RECs
Ms Chita Murray	Programme Manager, National Office for RECs
Dr Peadar Rooney	Project Officer, National Office for RECs

*Drafted minutes

Apologies: Dr Aine de Roiste, Ms Evelyn O'Shea, Prof John Wells, Dr Karina Halley

Prof Seamus O'Reilly, Prof Colm O'Donnell

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2024-518296-56-00
- 2025-520538-49-00
- 2023-505268-12-00 SM-3
- 2023-505699-31-00 SM-4
- 2023-508265-33-00 SM-7
- 2023-503209-13-00 SM-7
- 2023-504816-14-00 SM-21
- 2024-512701-11-00 SM-3
- AOB

- The Chair welcomed the NREC-CT B.
  - The minutes from the previous NREC-CT B meeting on 28th May 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2024-518296-56-00

Institutions: St Vincent's University Hospital, Beaumont Hospital

Study title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Program to Evaluate the Efficacy and Safety of Tulisokibart in Participants with Moderately to Severely Active Crohn's Disease

Dossiers Submitted: Part I & II

  - **NREC-CT Decision:**
- Request for Further Information

  - **Additional Information Required RFI**

Part II Considerations

1. Recruitment arrangements

- The NREC-CT noted that recruitment materials listed on page 2 of the Recruitment Arrangement Form (e.g poster, brochure, patient invitation letter, banner ad) have not been submitted. The Committee request that all recruitment material is submitted for review if available along with an outline of the procedures proposed for handling responses to the advertisement.

2. Subject information and informed consent form

- 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 page 17 of the Main PISCF includes a witness signature line. The Committee requested information be added explaining the context where a witness signature would be needed in all relevant PISCF's.
- The NREC-CT noted that the optional future biological research (FBR) PISCF states that 'the data protection laws outside of the Republic of Ireland may not be as comprehensive as Ireland' (pg4). The Committee requested that the FBR PISCF is updated to align with the Main ICF (pg 13) which states 'the Sponsor will ensure adequate safeguards are in place to protect your data and will abide by Irish and EU data privacy laws'.
- The NREC-CT noted in the Protocol (pg 170) that 'Depression or suicidal ideation and behavior are adverse events of special interest' but that this is not mentioned in the PISCF's. The Committee requested that these potential adverse events are included in all relevant PISCF's and that a proposed care strategy is detailed if such adverse events are reported.
- The NREC-CT noted that a GP letter is mentioned in the Main ICF (pg5) but has not been submitted. The Committee requested that the GP Letter is submitted if available.
- The NREC-CT noted that there is a lack of information regarding the cessation of treatment in the Main PISCF. The Committee requested further information is provided in the Main PISCF regarding IMP discontinuation and study end e.g. clarification on a tapered or sudden withdrawal of IMP, the risk of relapse and options regarding subsequent alternative treatments.

2025-520538-49-00

Institutions: Rotunda Hospital, Cork University Maternity Hospital, Coombe Women and Infants University Hospital

Study title: Phase I Dose Escalation and Cohort Expansion study to affirm the safety of pharmacological doses of a novel formulation of intravenous melatonin in babies with hypoxic-ischaemic encephalopathy (HIE) to augment therapeutic hypothermia (HT) treatment; to reduce the incidence and severity of disability in babies with moderate-severe HIE (ACUMEN)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Compliance with use of biological samples

- The NREC-CT noted that future research samples will be 'initially' stored for 5 years (Biological Samples Form, pg 7). The Committee requested that the wording is amended such that the intended duration for sample storage is clear and to ensure compliance with data retention periods as per the CTR in both the Compliance with Biological Samples Form and relevant PISCF's.
- The NREC-CT noted a discrepancy in blood sample volume between the Main SIS (pg7) and the Compliance with Biological Samples Form (pg 3). The Committee requested that the sample volume is aligned in both the Main SIS and the Compliance with Biological Sample Form.

2. Proof of insurance

- The NREC-CT noted the submission of an insurance quote rather than a study specific certificate of insurance. The Committee requested confirmation that the insurance cover will comply with the list below:
    - Scope of policy consistent with trial
    - Covers the total number of participants.
    - Exclusions do not conflict with study e.g. pregnant participants, minor and genetic testing.
    - Minimum Limit of €6.5 million in annual aggregate.
    - Territorial limit includes the Republic of Ireland.
    - Insurer is authorised to operate by Central Bank of Ireland.

3. Subject information and informed consent form

- If applicable, 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 requested that all relevant PISCF's be updated to provide information about the availability of the clinical trial results at the end of the trial and location of same (e.g. https://www.ClinicalTrials.gov and https://euclinicaltrials.eu/)
- The NREC-CT noted that page 4 of the Main ICF (written consent) and page 5 of the Maternal Data ICF include a witness signature line. The NREC-CT requests information be added explaining the context where a witness signature would be needed.
- The NREC-CT noted the sentence 'By now, the doctors will be cooling your baby for 72 hours' in the Summary Leaflet. The Committee requested that this sentence be amended to 'By now, the doctors will be cooling your baby' as babies will be less than 6 hours old when parents receive this information.
- The NREC-CT noted that p2 of the Main SIS states 'Melatonin is a natural hormone our body makes to help regulate sleep. It is safe and is used in children to treat sleep problems when taken by mouth'. The Committee requests that the language be amended to 'It is used in children…'.
- The NREC-CT noted that data (including videos) will be stored for 33 years. The Committee requested that participants on attaining 16 years of age should be reconsented for future research (Main SIS p8,13).
- The NREC-CT noted opposing statements regarding data amendments in the Main SIS (p14), where the content of the section 'Your Rights' contradicts the statement 'we won't be able to let you see or change the data we hold about your baby'. The Committee requested clarification in the Main SIS that clinical data collected as part of the study cannot be altered, while personal information may be updated if necessary.
- The NREC-CT noted that p17 of the Main SIS states 'The normal National Health Service complaints mechanisms will still be available to you'. The Committee requests removal of reference to the National Health Service (NHS) in the UK and that the document is amended as applicable for the reporting of complaints in the Republic of Ireland.
- The NREC-CT noted that the ASQ-3 questionnaire collects personal information such as names, addresses and phone numbers. The Committee requested confirmation that this identifiable information will be pseudonymised before being transferred to UCL.
- The NREC-CT noted the information relating to data handling and protection in the Maternal Data PISCF has not been adequately adapted for use in Ireland (e.g. 'this means that we know their laws offer a similar level of protection to data protection laws in the UK' (pg 2). The Committee requested that the Maternal Data PISCF be updated to align with the Irish context and to include information relating to the transfer of data from Ireland to the UK.
- The NREC-CT noted that the future use of data / samples is not described in line with regulations / best practice in the Main SIS (pg14), Main ICF (pg4) Maternal ICF (pg4) or Biological Samples Form (pg7). The NREC-CT requested that future use of samples / personal data is sufficiently explained to participants in the PISCF documents so as to constitute broad informed consent, as required under the

Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,

- it should be confined to a specified disease, related diseases or drug under study in this trial. Consent can only be obtained where future use of samples and data is defined such that participants are fully informed (e.g. pg14 of the Main SIS states 'This future related research may be but not limited to early brain injury and development' while pg 4 of the Main ICF states 'I agree to my baby's samples, being stored for use in future ethically approved research')
- and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies,

4. Suitability of the clinical trial sites facilities

- The NREC-CT noted that a 3T MRI machine is required to perform the MRI/MRS imaging secondary outcomes. The Committee requested i) clarification on whether each site will have a 3T MRI ii) clarification on where the imaging will be performed, on transport logistics and whether the imaging could be done in the required time frame if the site does not have a 3T MRI iii) clarification on whether the requirement of access to a 3T MRI is essential for this study.

2023-505268-12-00 SM-3

Institutions: La Nua Day Hospital Mental Health Centre, Tallaght Adult Mental Health Service

Study title: A Phase III, multicentre, randomised, double-blind, controlled study to investigate the efficacy, safety, and tolerability of two initial administrations of COMP360 in participants with treatment-resistant depression

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-505699-31-00 SM-4

Institutions: St Vincent's University Hospital, Beaumont Hospital, University Hospital Galway

Study title: A Phase 3 Multicenter, Long-Term Extension Study to Evaluate the Safety and Efficacy of Upadacitinib (ABT-494) in Subjects with Ulcerative Colitis (UC)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

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

- If applicable, 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 the Compliance of Biological Samples (pg5) states that withdrawal of permission for future use of samples must be done in writing and that the option to verbally withdraw permission from study participation and from future use of samples has been removed from the Main ICF (pg 27). The Committee request that the option to verbally withdraw permission from study participation and from future use of samples is reinstated in the Main ICF and that the Compliance with Biological Samples form is updated to include verbal withdrawal so that both documents are aligned, and so that participants are given the choice whether to withdraw verbally or in writing.

2023-508265-33-00 SM-7

Institutions: University Hospital Galway, Mater Misericordiae University Hospital, University Hospital Waterford, St Vincent's University Hospital, St James's Hospital

Study title: A double-blind, randomized, placebo-controlled multicenter study to investigate efficacy and safety of elinzanetant for the treatment of vasomotor symptoms caused by adjuvant endocrine therapy, over 52 weeks and optionally for an additional 2 years in women with, or at high risk for developing hormone-receptor positive breast cancer (21656)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2023-503209-13-00 SM-7

Institutions: Rotunda Hospital

Study title: Co-administration of Acetaminophen with Ibuprofen to Improve Duct-Related Outcomes in Extremely Premature Infants (The ACEDUCT Trial)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations raised

3. Suitability of the investigator

- The NREC-CT noted that the ICH-GCP certificate which was submitted for [redacted] was dated 2018. The Committee requested the submission of an up-to-date ICH-GCP certificate for [redacted] This document must be 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.

2023-504816-14-00 SM-21

Institutions: Mater Misericordiae University Hospital, St James's Hospital, Cork University Hospital

Study title: A Phase 3, Randomized, Active-controlled, Open-label, Multicenter Study to Compare the Efficacy and Safety of MK-2870 Monotherapy Versus Treatment of Physician's Choice in Participants With Endometrial Cancer Who Have Received Prior Platinum-based Chemotherapy and Immunotherapy (MK-2870-005/ENGOT-en23/GOG-3095)

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Favourable

2024-512701-11-00 SM-3

Institutions: Our Lady's Children's Hospital

Study title: An Open-label, Sequential, Ascending, Repeated Dose-finding Study of Sarilumab, Administered with Subcutaneous (SC) Injection, in Children and Adolescents, Aged 1 to 17 Years, with Systemic Juvenile Idiopathic Arthritis (sJIA), Followed by an Extension Phase

Dossiers Submitted: Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Subject information and informed consent form

- If applicable, 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 requested that all relevant PISCF's be updated to include the EU clinical trial number for participants' information.
- The NREC-CT noted an administrative error on page 27 of the PISCF for 18+ Years and page 25 of the PISCF for Parents "because in this study adopt as needed by providing the scientific rationale the doctor will not have access to some of the data". The Committee requested that this administrative error is corrected to ensure readability for the participant.
- The NREC-CT noted that there is no recommendation for male participants to use contraception, but that sperm donation must be avoided during the study and for 3 months afterwards (pg 11 PISCF for 18+Years, pg 10 PISCF for Parents). The Committee request clarification on the absence of a recommendation for male participant contraception and for the relevant PISCF's to be updated with this requirement if applicable.
- The NREC-CT noted the submission of a PISCF for 18+ Years but not the submission of a PISCF for 16+ years. The Committee wish to advise of a recent national policy change informed by discussions at a national level with relevant authorities: participants aged 16yrs+ may consent to both participation in a regulated study and associated data processing. Therefore, the consent for participation in the study and use of personal data for the study, should not be treated separately. As such, there is now no requirement to seek consent from a parent/guardian for data processing for participants aged 16 and17. We acknowledge that this 'decoupled' change to the consent process was initially incorporated by Sponsors at the request of the NRECs. We hope this policy change is viewed as more pragmatic and facilitative for those involved in the recruitment process. The Committee request the submission of a PISCF for 16+ Years with applicable updates.
- The NREC-CT noted no Tracked Change Version of PISCF for Parents has been submitted or listed in the Modification Description. The Committee requested that a Tracked Change Version of PISCF for Parents be submitted on CTIS.
- The NREC-CT noted that the future use of data / samples is not described in line with regulations / best practice on pg. 29/ 30/37/38 of the PISCF for 18+ Years and pg 21/28/29 of the PISCF for parents. The NREC-CT requested that future use of samples / personal data is sufficiently explained to participants in the PISCF documents so as to constitute broad informed consent, as required under the

Health Research Regulations (Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018). Furthermore,

- it should be confined to a specified disease, related diseases or drug under study in this trial. Consent can only be obtained where future use of samples and data is defined such that participants are fully informed
- and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies,
- optional future research is made into a separate and explicit consent item in the Informed Consent section of the Main PISCF with separate participant information section and signatures section, so it is distinct from the main consent to participate in the research. (Information on future research is currently included in the main text body of both the PISCF for 18+Years and the PISCF for Parents. In addition, there is currently a future research tick box amidst the other ICF questions on page 28 of the Parents PISCF and on page 37 of the PISCF for 18+ Years)
- It should be clarified that the previously approved PISCF's for Future Research is obsolete if optional consent for future research is included in the PISCF for 18+Years and PISCF for Parents.
- The PISCF should also make it clear to participants 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/
- Alternatively, to all the above, the section on future research which has been inserted into the PISCF for 18+Years and PISCF for Parents could be removed and the previously approved Future Research PISCF (which is already separate, optional and limits the scope of future use to the drug/disease) could continue to be utilized.

- The NREC-CT noted that consent for genetic analyses had been inserted into the PISCF for 18+ Years and the PISCF for Parents. The Committee requested the following:
  - Genetic analyses are confined to genes involved in the disease being treated or related diseases and /or genes involved in the metabolism of the medicines being used in the trial and this elucidated in the PISCF.
  - Explicit consent, including outlining the risks entailed in such analysis being performed, is added to the PISCF.
  - The possible ownership of such data by private or commercial interests and that this elucidated in the PISCF.
  - The right to withdraw genetic data, and clear information on how to do so, must also be provided in the PISCF.
  - Clarification is provided in the PISCF on the mechanism for anonymisation, storage and security and transfer of genetic material and its associated data.
  - Clarification in the PISCF on how the sample will be obtained for genetic analyses

- optional genetic research is made into a separate and explicit consent item in the Informed Consent section of the PISCF for 18+ Years and PISCF for Parents with separate participant information section and signatures section, so it is distinct from the main consent to participate in the research. (Information on genetic analyses is currently included in the main text body of both the PISCF for 18+Years and the PISCF for Parents. In addition, there is currently a tick box for genetic analyses amidst the other ICF questions on page 28 of the Parents PISCF and on page 37 of the PISCF for 18+ Years)
- It should be clarified that the previously approved PISCF for Genetic Research is obsolete if consent for genetic analyses is included in the PISCF for 18+Years and PISCF for Parents.
- For guidance, please see HSE National Policy for Consent in Health and Social Care Research (V2.0, 2024). Dublin: Health Service Executive https://www2.healthservice.hse.ie/organisation/national-pppgs/hse-national-policy-for-consent-in-health-and-social-care-research
- Alternatively, to all the above, the section on genetic analyses which has been inserted into the PISCF for 18+Years and PISCF for Parents could be removed and the previously approved Pharmacogenetic Analysis PISCF (V2- which is already separate, optional and limits the scope of use to the drug/disease) could continue to be utilized.

- AOB:

  None