

# National Research Ethics Committee

## NREC-CT A Meeting

**28 June 2023**

### Attendance

Name	Role
Prof. Alistair Nichol	Chairperson, NREC-CT A
Dr Heike Felzmann	Deputy Chairperson, NREC-CT A
Ms. Erica Bennett	Committee Member, NREC-CT A
Prof. Tina Hickey	Committee Member, NREC-CT A
Dr Dervla Kelly	Committee Member, NREC-CT A
Prof. John Wells	Committee Member, NREC-CT A
Mr Gerard Daly	Committee Member, NREC-CT A
Prof. Catherine Hayes	Committee Member, NREC-CT A
Ms Muireann O'Briain	Committee Member, NREC-CT A
Prof. David Brayden	Committee Member, NREC-CT A
Dr Darren Dahly	Committee Member, NREC-CT A
Prof. Gene Dempsey	Committee Member, NREC-CT A
Prof. Austin Duffy	Committee Member, NREC-CT A
Mr Gerald Eastwood	Committee Member, NREC-CT A
Dr Geraldine Foley	Committee Member, NREC-CT A
Ms Evelyn O'Shea	Committee Member, NREC-CT A
Ms Ann Twomey	Committee Member, NREC-CT A
Dr Emily Vereker	Head, National Office for RECs
Ms Patricia Kenny	Project Officer, National Office for RECs
Dr Jane Bryant	Project Officer, National Office for RECs

Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Susan Quinn*	Programme Manager, National Office for RECs

\*Drafted minutes

**Apologies:** Prof. Mary Donnelly

**Quorum for decisions:** Yes

## Agenda

- Welcome & Apologies
- 2022-500536-11-01
- 2023-505874-14-00
- 23-NREC-CT-009\_Mod-1

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- The Chair welcomed the NREC-CT A.
    - The minutes from the previous NREC-CT A meeting on 24 May 2023 were approved.
    - The NREC Business Report was discussed and noted.
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## Applications

### 2022-500536-11-01

Study title: A randomized, double-blind, placebo-controlled, multicenter phase III study to evaluate the efficacy and safety of ABX464 once daily for induction treatment in subjects with moderately to severely active ulcerative colitis.

EudraCT: 2022-500536-11-01

Principle Investigators and Institutions: Portiuncula Hospital (Dr Gerard Clarke), St Vincent's University Hospital (Prof. Glen Doherty), Connolly Hospital (Dr Orlaith Kelly), Our Lady of Lourdes Hospital (Dr John Keohane), Regional Hospital Mullingar (Dr Murat Kirca), University Hospital Galway (Prof. Laurence Egan)

- **NREC-CT comments:**
- The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required**

- The NREC-CT requested that the information related to database searches performed as part of pre-screening, be added to the DPIA.
- The NREC-CT noted that participants with limited understanding of English and those lacking capacity to consent are excluded from the study. The Committee requested justification for the exclusion of these cohorts.
- The NREC-CT requests that all reimbursed expenses participants are entitled to should be added to the Participant Information and Consent Form documents.
- The NREC-CT requested that the planned recruitment number of participants in Ireland and in total, is added to all Participant Information and Consent Form documents.
- The NREC-CT noted that information on reproductive risks (Page 9 of the Participant Information Leaflet) relates to both participants and partners of participants who become pregnant. This is not reflected in the statement of consent on Page 19. The Committee requested that the consent statement is amended to include partners of participants if required.
- The NREC-CT noted that the information related to the potential risks is on Page 10 of the Participant Information Leaflet. The Committee requested that a brief summary of the potential risks is included on Page 3 of the Participant Information Leaflet to ensure participants are informed of the risks early in the document.

## **2023-505874-14-00**

Study title: A Pilot Study to Assess the Use of Methylone in the Treatment of PTSD

EudraCT: 2023-505874-14-00

Principal Investigators and Institutions: Tallaght University Hospital (Dr John Richard Kelly),  
La Nua Day Hospital, Galway (Dr Shane McInerney)

- **NREC-CT comments:**

- The NREC-CT A agreed that additional information was required to inform its deliberations before a final ethics position could be returned.

- **NREC-CT Decision:**

- Request for more information

- **Additional Information Required**

- The NREC-CT requested that the information related to database searches performed as part of pre-screening, be added to the DPIA.
- The NREC noted that compensation for participants is based on minimum wage and the number of hours per dosing visit (i.e., 8 hours). The sponsor is asked to consider whether provisions for out-of-pocket expenses outside the dosing visit are required, for example, compensation for public transport 24 hours post dosage.
- The NREC requested justification is provided regarding collection of participants' PPS and passport number. However, if this information is not pertinent to the management of the trial, the Committee requests that it is removed.
- The NREC noted that the participant's GP will be notified of their involvement in this trial and requested that the GP letter is submitted as part of the Request for Further Information to Part 2 clarifications.

### **23-NREC-CT-009\_Mod-1**

Study title: A Phase IIIb, Open Label Extension Study Evaluating The Safety And Tolerability of AMX0035 Up To 108 Weeks In Adult Participants with Amyotrophic Lateral Sclerosis (ALS) Previously Enrolled In Study A35-004 (PHOENIX)

Principal Investigator: Prof Orla Hardiman

- **NREC-CT Decision:**

- Favourable with conditions

- **Additional Conditions Applied**

- The committee requested that further explanation is provided to the participant (page 20, Main ICF) regarding the purpose for collection of race and ethnicity data in the study. Race and ethnicity data comes under GDPR special category data. For this reason, the committee requests that justification for its collection is provided.
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