National Research Ethics Committee

NREC-CT B

25th of May 2022

Attendance

Name	Role
Dr Cliona McGovern	Chairperson, NREC-CT B
Dr Jean Saunders	Deputy Chairperson, NREC CT-B
Prof. John Faul	Deputy Chairperson, NREC CT-B
Mr Philip Berman	Committee Member, NREC-CT B
Dr Lorna Fanning	Committee Member, NREC-CT B
Dr John Hayden	Committee Member, NREC-CT B
Dr Mary McDonnell Naughton	Committee Member, NREC-CT B
Ms Paula Prendeville	Committee Member, NREC-CT B
Prof. Colm O'Donnell	Committee Member, NREC-CT B
Ms Mandy Daly	Committee Member, NREC-CT B
Dr Eimear McGlinchey	Committee Member, NREC-CT B
Prof. Abhay Pandit	Committee Member, NREC-CT B
Dr Mark Robinson	Committee Member, NREC-CT B
Dr Susan Quinn*	Programme Manager, National Office for RECs
Dr Jane Bryant*	Project Officer, National Office for RECs
Dr Emily Vereker	Acting Head of Office, National Office for RECs
Dr Emma Heffernan	Project Officer, National Office for RECs

*Drafted minutes

Apologies: Ms Serena Bennett, Ms Caoimhe Gleeson, Dr Enda Dooley, Prof. David Smith, Mr Gavin Lawler

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- Application 22-NREC-CT-095
- Application 22-NREC-CT-096
- Application 22-NREC-CT-098
- AOB

- The Chair welcomed the NREC-CT B.
  - The Minutes from the NREC-CT B meeting on the 27th of May were approved.
  - The NREC Business Report was discussed and approved.

Applications

22-NREC-CT-095

Principal Investigator: Professor John Richard Kelly

Study title: Efficacy and safety of COMP360 psilocybin therapy in anorexia nervosa: a proof-of-concept study

Lead institution: Tallaght Adult Mental Health Services

  - NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a multinational study, measuring the efficacy and safety of the combination of an investigational medicinal product and therapy, in patients with anorexia nervosa.
- The NREC-CT B commented that this was overall an interesting, well put together application.
- The NREC-CT B agreed that additional information was required to inform its deliberations and therefore, was not yet in a position to return a final ethics decision.

  - NREC-CT Decision:

- Request for Further Information

- Additional Information Required

- The Committee noted that section D.8 of the NREC Application form should be completed to include populations included in the study.
- The Committee requested further detail on inclusion of vulnerable patients in the study, and information regarding the interruption of treatment and restart of treatment.
- The Committee requested additional comment is provided justifying the recruitment of participants on psychotropic medicines. They noted the required wash out period from antidepressants and antipsychotics, with monitoring for withdrawal effects, and request justification is provided for not recruiting from patients who are not currently taking antidepressants and antipsychotics.
- The Committee considered that some lines in the Patient experience video script constitutes undue influence on participant to participate in the study and requested that this is omitted, or a significant justification given.
- The Committee requested further information on the study Recruitment Poster, and where this is proposed to be displayed. Furthermore, the email address provided is incomplete, and appears to be that of the sponsor and not the study doctor. This should be corrected.
- The Committee requested that the community pharmacist is copied on the GP letter to ensure that they are informed, particularly in relation to interruption to treatment.
- The Committee requested the applicant confirm details of access to emergency medicines in case of unexpected adverse reactions and provide further information on emergency pathways and rescue medication availability, specifically how an emergency is managed at this non-hospital site.
- The Committee noted that the study doctor will advise on tapering baseline meds, will create a treatment plan, and will share this with the participants GP. The NREC-CT B requested that the patient's own psychiatrist (originally referring) should also be included in this care plan to the GP, if applicable.
- The Committee requested that the DPIA should be reviewed and signed by a DPO. If this is not available, further justification is required.
- The Committee notes the insurance certificate is valid until March 2023, and requested the applicants please submit any additional certificates if study proceeds longer.

22-NREC-CT-096

Principal Investigator: Professor Peter J Conlon

Study title: A multicenter, randomized, double-blind, parallel group, placebo-controlled study to assess safety, tolerability, pharmacokinetic and pharmacodynamics of BI 764198 administered orally once daily for 12 weeks in patients with focal segmental glomerulosclerosis

Lead institution: Beaumont Hospital

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a double-blind, placebo-controlled study, measuring effects of the investigational medicinal product in patients with focal segmental glomerulosclerosis.
- The NREC-CT noted that this was a clearly presented study.
- The NREC-CT B agreed that additional information was required to inform its deliberations and therefore, was not yet in a position to return a final ethics decision.

- NREC-CT Decision:

- Request for Further Information

- Additional Information Required

- The Committee requested that the applicants justify why SARS-CoV-2 infection is considered a reason for discontinuation of trial treatment.
- The Committee requested that if the week two genetic screening is to determine inclusion or exclusion of a participant in the trial, that this should be carried out before their commencement on the trial. In addition, details on the purpose of the genetic testing should be more clearly explained to participants in the PIL and ICF.
- The Committee requested that side effects should be listed in the main consent form rather than in the appendix, to ensure accessibility.
- The Committee noted that the side effect of eye damage is not clearly explained in the PIL and ICF in order to clarify the reason for the eye exams, and this must be amended.
- The Committee noted the Biobanking PIL/ICF is not ready at this point. Until the Biobanking PIL/ICF is approved, and the patient has consented, sampling cannot be carried out. The NREC-CT requested that the reference to optional biobanking consent in PIL be removed.

- The Committee requested that consent for urine analysis testing for illicit substances is to be included in the PIL/ICF consent section.
- The Committee requested clarification on the statement in the ICF that describes the combination of anonymised data from the trial with data from other trials for the purposes of health research.
- The Committee noted that the layout for consent is not in line with best practice and requests that participants are provided with layered consent offering participants specific choices with initial boxes.
- The Committee requested clarification as to whether advertising material provided is to be used in Ireland.
- The Committee queried whether input from an Irish data controller is available on the DPIA. If not, justification is requested.

22-NREC-CT-098

Principal Investigator: Professor Damien Kenny

Study title: A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group, Event-Driven, Group-Sequential Study with Open-Label Extension Period to Assess the Efficacy and Safety of Selexipag as Add-On Treatment to Standard of Care in Children Aged ≥2 to ,18 years with Pulmonary Arterial Hypertension

Lead institution: Children's Health Ireland at Crumlin

- NREC-CT comments:

- The NREC-CT B noted this clinical trial application represents a double-blind, placebo-controlled study to assess the efficacy and safety of the addition of the investigational medicinal product to the standard of care for children with pulmonary arterial hypertension.
- The NREC-CT commented on the quality of the application and the study team.
- The NREC-CT B agreed that additional information was required to inform its deliberations and therefore, was not yet in a position to return a final ethics decision.

- NREC-CT Decision:

- Request for Further Information

- Additional Information Required

- The Committee noted additional visits may be required before the analysis of study data and requested that the applicants outline approximately how many visits may be required.
- The Committee requested that further information is provided on the Tanner Scale (which contains illustrations with stages of sexual maturation), to indicate which children will be given these illustrations, and requested that parental consultation is sought in advance to obtain their approval for such illustrations to be given to their child.
- The Committee requested information is provided on male contraception. Specifically, if this is not a requirement for study participants, information should be provided as to why the participants are required to inform the study team if they become pregnant.
- The Committee noted that the child is required to walk 6 minutes, and requests further information as to what is the process if the child is unable to complete this duration of walking.
- The Committee requested further information on sharing of research data, and requests that this is also updated in the consent section.

- AOB:

- Dr Susan Quinn gave an overview of the EU CTIS system for submission of clinical trial applications, including the format for requesting further information after review. It was noted that Dr Laura Mackey will give a presentation elaborating on same at the next NREC CT-B meeting. The Committee further discussed the format of applications submitted under the CTR through CTIS.
- The Chair gave an update on the addition of new members to the NREC CT-B, an update from a meeting with the Department of Health, and an update to the Substantial Amendment Bootcamp process. The members involved in Bootcamp were thanked for their work on the project.
- The Chair closed the meeting.