National Research Ethics Committee

NREC-CT Meeting

18th June 2025

Attendance

Name	Role
Prof David Brayden	Chairperson, NREC-CT D
Prof David Smith	Deputy Chairperson, NREC-CT D
Dr Christina Skourou	Deputy Chairperson, 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
Dr Mary McDonnell Naughton	Committee Member, NREC-CT D
Prof Geraldine O'Sullivan Coyne	Committee Member, NREC-CT D
Ms Chanel Watson	Committee Member, NREC-CT D
Dr Jeff Moore	Committee Member, NREC-CT D
Ms Chita Murray	Programme Manager, National Office for RECs
Dr Laura Mackey	Programme Officer, National Office for RECs
Dr Jane Bryant	Programme Officer, National Office for RECs
Dr Susan Quinn	Programme Manager, National Office for RECs
Ms Patricia Kenny*	Project Officer, National Office for RECs

Apologies: Deirdre McLoughlin, Deirdre Murray, Andrew Green and Gerry Daly

Quorum for decisions:

Agenda

- Welcome & Apologies
- 2024-518749-35-00
- 2024-516805-22-00
- 2025-520665-47-00
- AOB

- The Chair welcomed the NREC-CT D.
  - The minutes from the previous NREC-CT D meeting on 14th May 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2024-518749-35-00

Institutions: University Hospital, Tallaght University Hospital, Beaumont Hospital, Misericordiae University Hospital, Wexford General Hospital

Study title: SODium BICarbonate for Metabolic Acidosis in the Intensive Care Unit (SODa-BIC): A multicentre, randomised, double-blind clinical trial

Dossiers Submitted: RMS Part I and II

- **NREC-CT Decision:**

  Request for Further Information

- **Additional Information Required RFI**

Part I Considerations (RFI) for addition to CTIS

1. The Sponsor is requested to clarify how timing of administering this treatment in this trial compares to standard of care.

Part II Considerations

1. Recruitment arrangements

- The NREC-CT requests that pg 2 Recruitment arrangements telephone assent document be updated to remove reference to Skype as an option for communication as this will no longer be available.
- The NREC-CT notes the use of telephone assent from participants legal representative in this trial due to the emergency nature of the treatment. The Committee requested more information be provided in relation to the telephone assent including how the appropriate person will be identified on the call and how their own capacity to assent will be identified, how they will be informed of the emergency nature of the situation and whether this phone conversation will be recorded.

2. Subject information and informed consent form

- The NREC-CT stated that the term 'Next-of-Kin' is not recognised under Irish law and should not be used in participant information leaflets, consent and assent documentation for Irish research participants. The Committee requests that SIS and ICF deferred Assent and Recruitment arrangements telephone assent be updated to replace "Next of Kin" with "legally designated representative". Please refer to NREC Guidance on use of legally designated representatives https://www.nrecoffice.ie/guidance-on-legally-designated-representatives/
- 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 the SIS and ICF Patient Consent to Continue and SIS, ICF Deferred Assent pg 9 and pg 2 ICF Telephone Assent be updated to include specific statement that the participant/legally designated representative (use as applicable) confirms that a copy of the signed and dated Informed Consent Form will be provided to them and that a copy will be retained by the study doctor.
- The NREC-CT requested that the SIS and ICF Patient Consent to Continue pg 1 be updated to include the EU trial number for participants.
- The NREC-CT requested that the SIS and ICF Patient Consent to Continue and SIS and ICF Deferred Assent be updated to provide information about the availability of the clinical trial results at the end of the trial and location of same.
- The NREC-CT requested the duplicate statement “I am aware of the potential risks, benefits and alternatives of this research study” be deleted from pg 9 SIS and ICF Patient Consent to Continue.
- The NREC-CT requests clarification on what the next steps are if a family member, or someone with a personal relationship with the participant cannot be identified or located in a timely manner to provide assent .If a medical practitioner who is primarily responsible for the medical treatment of the participant and not involved in the conduct of the clinical trial or investigation would act as the legally designated representative as per Clinical Trial Regulation Article 35, the ICF Deferred Assent document should be updated accordingly.
- The NREC-CT noted that there is reference to storage and future use of information on pg 9 of SIS and ICF Patient Consent to Continue, pg 9 SIS and ICF Deferred Assent and pg 2 of ICF Telephone Assent however there is no detail on the future research in the information sheet. The Committee request that detail be provided in the information on the future use of data which is in line with regulations / best practice. It should be 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 made optional
    - 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 SIS and ICF Patient Consent to Continue, with separate participant information section and signatures section, so it is distinct from the main consent to participate in the research.

  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/

- The NREC-CT were unclear what will happen to the participants data and/or samples already collected if:
    - The participant does not wish to consent to continue when they regain decision making capacity
    - The participant does not regain decision making capacity
    - If the legal representative does not assent to enrolment

  The Committee requests SIS and ICF Deferred Assent pg 3 and SIS and ICF Patient Consent to Continue pg 3 be updated to clarify each of the above situations.
- The NREC-CT notes that SIS and ICF Deferred Assent pg 7 and SIS and ICF Patient Consent to Continue pg 6 states that data will be anonymised/coded. The Committee requests that both SIS and ICF's be updated to replace the following "anonymised/coded once leaving" with "pseudonymised/coded prior to leaving".
- The NREC-CT requests that the SIS and ICF Deferred Assent pg 6 and SIS and ICF Patient Consent to Continue pg 7 Sharing of personal data Section 5.1 and 5.2 references to "personal data" and be updated to "pseudonymised personal data".
- The NREC-CT requests that the SIS and ICF Deferred Assent pg 7 Assent Form and SIS and ICF Patient Consent to Continue pg 7 Section 6.1 references to "personal information" and "personal data" be updated to "pseudonymised personal information" and "pseudonymised personal data".
- The NREC-CT requests that the SIS and ICF Patient Consent to Continue pg 1/2 "Why have I been chosen" section be updated to include a detailed description of procedure took place, subsequent assent process, what data was collected, what frequency etc.
- The NREC-CT requests SIS and ICF Patient Consent to Continue pg 2 be updated to include detail on what medical data will be used, at what time intervals etc.
- The NREC-CT requests that SIS and ICF Deferred Assent pg 3 and SIS and ICF Patient Consent to Continue pg 3 be updated to explain
    - how withdrawal can take place
    - if there is any stage of the trial at which the participant or their legal representatives cannot withdraw the data already collected
    - what happens to the data if it is a full withdrawal.

  The Committee requests that the SIS and ICF Deferred Assent pg 3 and SIS and ICF Patient Consent to Continue pg 3 be updated to clarify.

- The NREC-CT requests that SIS and ICF Deferred Assent and SIS and ICF Patient Consent to Continue be updated to provide information on how checks will be conducted for Advance Healthcare Directive, living will Decision making agreement or Co-decision making agreement. The Committee also request that the SIS and ICF Deferred Assent and SIS and ICF Patient Consent to Continue be updated to explain how the Irish Legislation on Co-Decision Maker will be addressed.
- The NREC-CT would remind the sponsor that while under the Clinical Trial Regulation a legally designated representative can give permission for the participants enrolment in the trial, under General Data Protection Regulation they

cannot give permission for the use of the participants data. Under Health Research Regulations 2018 (HRR); it is a requirement to obtain the explicit consent of the individual to process their personal data in that health research study. Where it is determined that the participant consent cannot be obtained, the HRR provides for a statutory process where the researchers apply for a 'consent declaration' for their health research study from the Health Research Consent Declaration Committee (HRCDC). The Committee requests that

- ICF Deferred Assent be updated to be clear that the legally designated representative is only assenting to the participants enrolment in the trial and that an application will be made to the HRCDC for consent declaration.
- ICF Deferred Assent pg 9 and ICF Telephone Assent pg 1 be updated to replace *"I give permission for data to be stored for possible future research related to the current study without further consent being required but only if the research is approved by a Research Ethics Committee"* wiith *'If my relative does not regain decision-making capacity, I give assent for my relative's material/data to be stored/used for XXX years for possible future research only related to the current study without further assent being required but only if the research is approved by a Research Ethics Committee and the Health Regulation Consent Declaration Committee (HRCDC) if required'.*

2024-516805-22-00

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

Study title: A Phase III Long-Term Extension Trial with Optional Additional Doses of CYB003 to Assess the Safety and Long-term Efficacy in Participants with Major Depressive Disorder (EXTEND)

Dossiers Submitted: RMS Part I and II

- **NREC-CT Decision:**

  Request for Further Information

- **Additional Information Required RFI**

Part II Considerations

1. Financial arrangements

- The NREC-CT notes there are two eight-hour visits and queried whether the sponsor could consider compensation for accommodation for participants and carers (designated person) if required. The NREC-CT also notes that a designated support person is required to attend with the participant and requests that compensation for out of pocket expenses including meals is provided for the designated support persons also. Please update the Main ICF Section 9 pg 11 as appropriate.

- The NREC-CT requests the Main ICF be updated to make it clear whether receipts are a condition of reimbursement

2. Proof of insurance

- The NREC-CT noted the insurance certificate was with Lloyd's Insurance Company, the Main PISCF states that the insurance is through Berkley Canada. The NREC-CT requests clarification on the details on insurance for Irish participants and if applicable for the insurance details to be updated. The NREC-CT also requests that insurance details be added to the pregnancy and pregnant partner PISCFs.
- The NREC-CT requests information regarding La Nua Day Hospital Mental Health Centre and if the centre is covered under the HSE public liability insurance

3. Recruitment arrangements

- The NREC-CT requests that the recruitment arrangements document Sections 1.5 and 1.11 be updated to include detail regarding when the invitation to participate in EXTEND will be brought to participant's attention.

4. Subject information and informed consent form

1. 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

2. 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.

3. The NREC-CT requests that the Main ICF be updated to provide reassurance to participants around legal aspects of this IMP including the legal status of this substance in Ireland.
4. The NREC-CT notes that participants who complete either the APPROACH or EMBRACE trial will be eligible to enrol in this extension trial however throughout the Main ICF there are only references to the preceding EMBRACE study. The Committee requests that the Main ICF pg 2 be updated to include reference to this preceding APPROACH study also to ensure clarity and consistency for all potential participants.
5. It was unclear to NREC-CT if all participants who took part in EMBRACE and APPROCH trials will be eligible to participant in the EMBRACE trial. The NREC-CT requests that Main ICF pg 2 Section 2 be updated to include detail about inclusion / exclusion criteria for EXTEND trial.
6. The NREC- CT requests that the Main ICF pg 2 be updated to include the dose of CYB003 to be used in the EXTEND study.
7. The NREC-CT requests that Section 2.2 What happens if new information becomes available during the study? Main ICF pg 3 be updated to provide more detail on what kind of new information this refers to.
8. The NREC-CT requests that the duration of study visits is made clearer to participants in the Main ICF. In Section 3 "What will happen if I take part in this study" it states remote visits may take "up to 90-120 min" this should be changed to "up to 120 mins". The Committee also notes that the Main ICF page 5 "Questionnaire administered by central rater" states "The calls may take about 40

minutes" and requested that this is updated to 120 minutes, if this is referring to the same visit as above. It should be clear to the participant how long each visit/call will take.

9. The NREC-CT notes that "dosing visit will last a minimum of 8 hours". The Committee requests that the Main ICF pg 3 be updated to detail the maximum length of time dosing visits may last.
10. The NREC-CT notes the dosing visits take a long time and requests the Main ICF be updated to include detail on the following:
    a. If and when participants will be given food and drink during the dosing visit particularly given that they will arrive having fasted for these visits.
    b. Who will be with them for the dosing period?
    c. What can they expect to occur over the period of dosing and if there are any limitations to what they can and can't do during this period
    d. Details of anything participants should bring with them.
    e. Describe the setting where these visits will happen and what participants will have access to during this time.
11. The NREC-CT notes that the "designated support person" is essential for participation in the study however this is not made clear in the ICF. The Committee requests that the Main ICF be updated to make it clear a designated support person is mandatory and to provide more information around what their role and responsibilities are, including whether this will be the same person each time, and whether they will sign a consent form to agree to attend.
12. The NREC-CT requests that pg 4 Main ICF be updated to include the duration for each of the study tests and procedures.
13. The NREC-CT notes reference to "Clinician administered interviews" for completion of assessments related to psychological status on pg 4 and 5 of the Main ICF. Given the sensitive nature of the interviews, the Committee requests that the Main ICF be updated to provide more detail on the following:
    a. who will be the conducting the interviews,
    b. are they part of the study team or external to the study team,
    c. are they an external company; if so are they independent or are they being paid by the sponsor
    d. what is their training and qualifications.
14. The NREC-CT notes in the Main ICF reference to "Session Monitors" in several locations. Given the sensitive nature of the interviews, the Committee requests that the Main ICF be updated to provide more detail on the following:
    a. who will be the session monitors,
    b. are they part of the study team or external to the study team,
    c. are they an external company; if so are they independent or are they being paid by the sponsor
    d. what is their training and qualifications.
15. The NREC-CT notes reference to "Questionnaire administered by central rater:" on pg 5 of the Main ICF. Given the sensitive nature of the interviews the Committee requests that the Main ICF be updated to provide more detail on the following:
    a. who will be the central rater
    b. are they part of the study team or external to the study team,
    c. are they an external company; if so are they independent or are they being paid by the sponsor

    d. what is their training and qualifications.
16. The NREC-CT notes reference to “At least 1 session monitor (lead) will be a licensed therapist.” on pg 6 of the Main ICF. The Committee requests that the Main ICF be updated to provide more detail on who will be the licenced therapist. The Committee is specifically requesting details on their qualifications, licensing, details of the specialised EMBARK training and safety measures that will be taken.
17. The NREC-CT notes that the “Study Tests and Procedures” table in the Main ICF pg 4 and pg 6 states that up to 11 sessions (pre and post) will be provided by the study session monitors. The Committee requests clarification if any other sessions will be provided by the study session monitors and if there are other sessions, for those sessions to be listed in the “Study Tests and Procedures” table.
18. The NREC-CT requests that the Main ICF pg 6 Pre-dose psychological support session reference to EMBARK be updated to:
    a. describe the EMBARK model in plain language.
    b. to clarify when the first session of post dose psychological support will be provided
    c. how the participants will access such support.
19. The NREC-CT requests that the Main ICF pg 8/9 Side effects of CYB003 be updated to include the frequency of the listed side effects.
20. The NREC-CT notes pg 9 of the Main ICF details the risk of allergic reactions. The Committee requests the Main ICF be updated to confirm if any allergic reactions to CYB003 have been observed to date. The Committee also requests details are included as to the mitigation or response in the event of allergic reaction.
21. The NREC-CT notes on pg 9 of the Main ICF “Potential Loss of Privacy” The NREC-CT requests the Main ICF be updated to include details of efforts to be undertaken by the research team to mitigate potential loss of privacy.
22. The NREC-CT advises that the wording Main ICF pg. 11 Section on incidental findings “The results of incidental findings (e.g., from clinical tests) have no significance for the individual participant” and would state that this definition is incorrect as incidental findings would be significant for individuals and should be shared with them as appropriate. The Committee requests that this wording be amended. The Committee also requests that a lay language explanation be provided for participants as to what constitutes an incidental finding.
23. The NREC-CT noted that future use of data/samples pg 12 Main ICF “*Your personal data will be processed for scientific research purposes (e.g., for the purposes of identifying biomarkers, and for further research into specific conditions/therapeutic areas) related to this study”,* pg 16 Main ICF *“The deidentified recordings and/or transcripts may also be used for quality control and research purposes (e.g., for the purposes of identifying biomarkers, and for further research into specific conditions/therapeutic areas)”* is not described in line with regulations / best practice. It should be 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,
    a. it should be made optional
    b. 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,

c. and/or that an option is provided to enable participants to consent to be contacted in the future about other research studies,
d. optional future research is made into a separate and explicit consent item in the Informed Consent section of the SIS and ICF Patient Consent to Continue, with separate participant information section and signatures section, so it is distinct from the main consent to participate in the research.
e. The PISCF should also make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. The NREC-CT ethics opinion is limited to the clinical trial protocol and application dossier that has been assessed. Any future research conducted beyond the protocol and application dossier will require a separate ethics approval from a recognised research ethics committee once that future research question is 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/

24. The NREC-CT were unclear what the role of the Patient Engagement Services is. The Committee requests that the Main ICF pg 15 Patient Engagement Services be updated to include:
    a. detail that this navigator service is optional (as per consent page 21).
    b. explanation of what Patient Engagement Services means and their role in the trial
    c. clarify if this is a private entity and if so whether they are linked to the sponsor, and/or study doctor.
    d. who do they serve and what does having this service add for participants?
    e. which metrics will be tracked and which trends monitored?
25. The NREC-CT notes confusion on the Main ICF pg 15 regarding Patient Engagement Services as there is a section to add the contact details for the Patient Navigation Service which is followed by a paragraph advising that medical concerns should be directed to the Study Doctor/team, “who can provide you with more details and contact information for the navigation service”. The Committee requests that the “who can provide you with more details and contact information for the navigation service” be deleted as it is superfluous.
26. The NREC-CT notes on page 15 of the Main ICF and Pregnant Partner ICF the list of people/organisations who are authorised recipients of personal data. The NREC-CT requests clarification of why each named organisation needs personal data and not coded data. The NREC-CT requests that the list be divided into who will receive participants’ personal information as defined under GDPR and who will receive coded information.
27. The NREC-CT notes discrepancies in the Main ICF regarding the use of Block Clinical Reimbursement Services. The Main ICF pg 16 states “Opt-in is mandatory to receive stipend” however pg 21 lists use of Block Clinical as optional. The Committee requests that the Main ICF be updated to align. The Committee requests that the Main ICF pg 16 be updated to clarify what is meant by stipend and to include detail as to whether use of Block Clinical reimbursement company is mandatory for stipend and incidental reimbursement payments, and recommended that an alternative option is available for participants who do not wish to use this service. The Committee also request that Compensation for trial participant document be updated to align if a stipend is being offered as, at present, the

document does not list monetary payment as being one of the compensation options available during the trial for participants or carers.

28. The NREC-CT notes on page 16 of the Main ICF video recordings are processed by AI. The Committee requests that the Main ICF be updated to provide detail on:
    a. what this AI processing entails
    b. why it is being done.
    c. details of the AI tool being used, including the name and vendor supplier details.
    d. assurance that the content won't be shared with a commercial source
    e. details of how the sponsor will manage the data and maintain data protection for the participant including details of any future use either related or unrelated to the trial.
29. It is not clear to the NREC-CT for pre-dose, dosing and post-dosing sessions which sessions will be audio recorded and which sessions will be video recorded. The Committee requests the Main ICF pg 16 be updated to clarify.
30. The NREC-CT notes that participants are only asked to consent to video and audio recordings for the dosing sessions on pg 21 of Main ICF. The Committee requests that Main ICF pg 21 be updated to include consent for recording of pre or post dosing sessions.
31. The NREC-CT notes on pg 16 of the Main ICF that the video recordings will be stored for 7 years. The Committee requests the Main ICF be updated to provide clarification regarding the storage time of 7 years, the details on the vendor who will be storing the video file and how the sponsor will maintain data protection for the participant. The Committee also requests that the consent form pg 21 be updated to include a specific consent statement for the processing and storage of the video recordings for participants to be able to provide explicit consent.
32. The NREC-CT notes reference to "Your personal data will only be shared with and disclosed to authorised third parties and recipients" on pg 17 of the Main ICF. The Committee requests clarification for the identity of these authorised third parties and if they are the same third parties listed on pg 13. If they are the same third parties, the Committee requests that reference to the list on pg13 is included on pg 17 in the relevant paragraph. If they are not the same third parties listed on pg 13 then the Committee requests that the third parties concerned are listed on pg 17, along with the reason for the sharing of personal data with these third parties.
33. The NREC-CT requests that Main ICF pg 21 be updated to move all optional components onto a separate page with separate signatures section, so it is distinct from the main consent to participate in the research.
34. The NREC-CT notes the future research on pg 3 Pregnant Partner is limited to the drug under study. The Committee requests that the Pregnant Partner ICF pg 7 be updated to insert a separate and explicit consent item in the Informed Consent section to make future research optional and to have a separate signatures section, so it is distinct from the main consent to participate in collection of data on the pregnancy.
35. The NREC-CT requests that the Pregnancy Follow up ICF Section 9 pg 3 be updated to remove the section "What new information might become available that investigators would need to share with pregnant woman?" as this would not apply to the female partner of a male participant.

36. The NREC-CT requests that the GP letter be updated to make it clear who is responsible for patient's depression treatment.

2025-520665-47-00

Institutions: Royal Victoria Eye and Ear Hospital

Study title: An Open-Label Dose-Escalation Study to Assess the Safety and Tolerability of a Single Intravitreal Injection of SPVN20 Gene Therapy in Subjects with No Light Perception Due to End-Stage Rod-Cone Dystrophy, and Who Retain Dormant Foveal Cone Photoreceptors (NYRVANA)

Dossiers Submitted: Add MSC

- **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 notes that the sponsor is proposing that the study team will read the contents of the informed consent to the participant with an impartial witness also present during the process. The Committee were unclear if all potential study participants will be unable to read the information sheet due to sight issues or if some may be able to read, please clarify. If some may be able to read then please provide an information sheet and consent form for use in this situation.
- The NREC-CT requested further information on the supports in place to accommodate participants with sight issues and allow sufficient time to listen to and digest the information such as ICF being provided in braille if applicable, providing an accessible version for use with screen readers etc. Please provide information on the options available to the participant in the ICF such that the participant is informed e.g. stating that an audio recording is available if required.
- The NREC-CT notes reference to "the way SPVN20 and agents of the same group work" on pg 25 of Main ICF. The Committee requests that the references to "agents of the same group work" be updated to clarify for participants what this means. For further guidance on future use 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 notes that future use of data/samples pg 25 Main ICF *"The trial doctor and the Sponsor can only use the encoded personal data for research purposes in connection with scientific publications within the context of the trial that you participate in, or for a broader use of the encoded data if described below.", "In addition, the Sponsor may provide access to the encoded data to external researchers (that are not involved in this trial)" and* "*These activities may concern the way SPVN20 and agents of the same group work, the disease/condition for which SPVN20 is evaluated in this trial or other diseases and health problems which could benefit from SPVN20, or from related diagnostic tests"* is not described in line with regulations / best practice. It should be sufficiently and explicitly 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 made optional
    - it should be clearly 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 ICF with separate participant information section and signatures section, so it is distinct from the main consent to participate in the research.

  If the option is not provided to enable participants to consent to be contacted in the future about other research studies then please remove reference to word *"may"* on section 12.8 and update to *"These activities are limited to".*

  The PISCF should also be updated to make it clear to participants that subsequent research ethics review will be sought for specific research once clearly defined. The NREC-CT ethics opinion is limited to the clinical trial protocol and application dossier that has been assessed. Any future research conducted beyond the protocol and application dossier will require a separate ethics approval from a recognised research ethics committee once that future research question is 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 requests that pg 30 Main ICF Consent form be updated to include either initial or tick boxes beside each consent statement for impartial witness (or participant if applicable) to tick/initial when the participants indicates consent for each statement, such that informed consent is recorded in line with best practice.
- The NREC-CT requests that the Main ICF pg 7 reference to "must be paid for by your health insurance" and pg 23 "charged to you or your mutual insurance fund" be updated as standard of care services in public hospitals are coved by Health Service Executive in Ireland.

- The NREC-CT requests that the Main ICF pg 23 Section 11.2 be updated to provide more detail on what expenses will be covered. The Committee also requests that the Main ICF pg 23 be updated to include details of alternative options for reimbursement if participants do not wish to use Greenphire.
- The NREC-CT notes that Main ICF pgs 24, 26 and 28 refers to anonymised data. The Committee requested that the Main ICF pg 31 be updated to include a specific statement for the participant to explicitly consent to the processing of their personal data from coded to anonymised data as per Article 4 (2) and (6) General Data Protection Regulation (GDPR).
- The NREC-CT requests that the Pregnant Partner ICF pg 2 Section 2 be updated to detail specific length of time follow up on the new born will occur.

2. Suitability of the investigator

- The NREC-CT noted that [redacted] CV shows she has not had previous experience as a Principal Investigator on a clinical trial. The Committee requests detail of supports in place from other suitably qualified clinicians if required.

- AOB:
  - None