National Research Ethics Committee

NREC-CT Meeting

7th May 2025

Attendance

Name	Role
Prof Mary Donnelly	Chairperson, NREC-CT C
Prof John Faul	Deputy Chairperson, NREC-CT C
Dr Jean Saunders	Deputy Chairperson, NREC-CT C
Dr Susan Finnerty	Committee Member, NREC-CT C
Dr Steve Meaney	Committee Member, NREC-CT C
Dr Dervla Kelly	Committee Member, NREC-CT C
Dr Deborah Wallace	Committee Member, NREC-CT C
Ms Paula Prendeville	Committee Member, NREC-CT C
Mr Gerry Eastwood	Committee Member, NREC-CT C
Mr Philip Berman	Committee Member, NREC-CT C
Prof Anne Mathews	Committee Member, NREC-CT C
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
Dr Emma Heffernan*	Project Officer, National Office for RECs
Ms Deirdre Ní Fhloinn	Project Officer, National Office for RECs

Apologies: Prof Fionnuala Breathnach, Prof Andrew Smyth, Ms Susan Kelly

Quorum for decisions: Yes

Agenda

- Welcome & Apologies
- 2024-517190-24-00
- 2024-516036-94-00
- 2022-500031-37-00 SM11
- 2024-514173-22-00 SM5
- 2022-501522-38-00 SM4
- 2022-501050-11-01 SM1
- AOB

- The Chair welcomed the NREC-CT C.
  - The minutes from the previous NREC-CT C meeting on 2nd April 2025 were approved.
  - The NREC Business Report was discussed and noted.

Applications

2024-517190-24-00

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

Study title: A Phase 2 Study Evaluating the Efficacy and Safety of TORL-1-23 in Women With Advanced Platinum-Resistant Epithelial Ovarian Cancer (Including Primary Peritoneal and Fallopian Tube Cancers) Expressing Claudin 6 (CLDN6) (CATALINA-2)

Dossiers Submitted: MSC Part I & II

- **NREC-CT Decision:**

  Request for Further Information

- **Additional Information Required**

Part II Considerations

1. Subject information and informed consent form

- The NREC-CT requested that the relative frequency (i.e. uncommon, common, very common, rare, very rare etc.) of the adverse risks/discomforts for participants should be highlighted on pgs.10-11 of the L1_TORL123-002_IRL_Main-PICF PISCF, so participants are fully informed (suggested using data from stage 1 to inform this).
- The NREC-CT noted that pg. 15 of the L1_TORL123-002_IRL_Main-PICF, pg. 4 of the L1_TORL123-002_IRL_Pregnancy-PICF, pg. 6 of the L1_TORL123-002_IRL_Prescreen-PICF and pg. 5 of the L1_TORL123-002_IRL_TBDP-PICF PISCFs lists legitimate interest as the legal basis for data processing The NREC-CT requested that participants are informed that explicit consent is required as an additional safeguard for the processing personal data as per the Data Protection Act 2018 (Section 36(2) (Health Research) Regulations 2018 (it should be made clear that legitimate interests alone are not a sufficient legal basis to process personal data as described).
- The NREC-CT noted that pg.22 of the L1_TORL123-002_IRL_Main-PICF, pg. 8 of the L1_TORL123-002_IRL_Pregnancy-PICF, pg. 10 of the L1_TORL123-002_IRL_Prescreen-PICF state that participants should contact NREC should they have any questions, concerns, or complaints about the study or questions while taking part in this study. The NREC-CT requested that the reference to contacting NREC should be removed, and suggest the following or similar is added, as applicable:
  - The Principal Investigator (PI) should be the primary contact for the participant with any queries.
  - For questions or concerns regarding participants data protection rights that have not been addressed by the PI or study team, they should be provided with the contact details of the Hospital site DPO and the Data Protection Commission.

    - For questions or concerns about their rights as a research participant, each site should provide the details of relevant department to contact.
- The NREC-CT noted that an impartial witness is included pg. 24 of L1_TORL123-002_IRL_Main-PICF, pg. 13 of the L1_TORL123-002_IRL_TBDP-PICF, pg. 11 of the L1_TORL123-002_IRL_Pregnancy-PICF, pg. 12 of the L1_TORL123-002_IRL_Prescreen-PICFand pg. 8 of the L1_TORL123-002_IRL_Leftover-Samples-PICF documents. The Committee requested that this should include a statement to clarify that the impartial witness is not consenting on the participant's behalf, and that participant consent is still required.
- The NREC-CT requested that pg. 24 of L1_TORL123-002_IRL_Main-PICF, pg. 13 of the L1_TORL123-002_IRL_TBDP-PICF, pg. 11 of the L1_TORL123-002_IRL_Pregnancy-PICF, pg. 12 of the L1_TORL123-002_IRL_Prescreen-PICFand pg. 8 of the L1_TORL123-002_IRL_Leftover-Samples-PICF documents are updated with a placeholder for the qualification of the person performing the informed consent interview.
- 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.

2024-516036-94-00

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

Study title: MK-2400-01A Substudy: A Phase 1/2, Open-label Umbrella Substudy of MK-2400-U01 Master Protocol to Evaluate the Safety and Efficacy of Ifinatamab Deruxtecan-based Treatment Combinations or Ifinatamab Deruxtecan Alone in Participants With Metastatic Castration-resistant Prostate Cancer (mCRPC) (IDeateProstate02)

Dossiers Submitted: MSC Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations
1. Proof of insurance
• The NREC-CT noted the insurance expires on 26 July 2026. Please confirm that insurance will be in place for the duration of the trial.
2. Subject information and informed consent form

- The NREC-CT noted that pg. 21 of the L1_ICF_Main consent_IRL_EN_IN states that participants may have photographs taken. The NREC-CT requested the following is explained to participants in the PISCF:
    - Specifically, what is being photographed.
    - Why these photos need to be taken and what they will be used for
    - Details of the data protection measures related to the use, access and storage of these photographs.
- The NREC-CT noted that the future use of data/samples (including biomarker / genetic research) is not described in line with regulations/best practice on pg. 10 ('Your samples may be used to improve and develop tests to support clinical trials') and pg. 29 ('it might help people in the future because the goal of this research is to help develop better treatments and to learn more about human disease and health' and 'The Sponsor may use information from this additional research together with any other information collected about you for scientific research') of the L1_ICF_Main consent_IRL_EN PISCF. 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 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 Main PISCF, 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 noted that pg. 10 of the L1_ICF_Main consent_IRL_EN PISCF states that participants may undergo whole genome / whole exome sequencing and requested the following:
    - Genomic sequencing is confined to genes involved in the disease being treated 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. 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/

- The NREC-CT requested confirmation that if participants decide to withdraw from the trial that they are reminded that they must also request to withdraw from optional future research, should they prefer not to continue participating in any optional future research.
- The NREC-CT requested that pg. 28 & pg. 30 of the L1_ICF_Main consent_IRL_EN PISCF is updated with a placeholder for the qualification of the person performing the informed consent interview.
- 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.

2022-500031-37-00 SM11

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

Study title: A randomised phase III trial with a PET response adapted design comparing ABVD +/- ISRT with A2VD +/- ISRT in patients with previously untreated stage IA/IIA Hodgkin lymphoma (RADAR)

Dossiers Submitted: MSC Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

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

- The NREC-CT noted that the reference to high blood sugars has been removed from the pg. 13 of the PISCF and requested that it is clarified why this has been removed (it is noted that pg. 3 of the cover letter states 'Hyperglycaemia was removed from the list of SARs associated with brentuximab vedotin combination therapies', but it is not clear if this is the reason why it was removed from the PISCF).
- The NREC-CT requested clarification as to why the wording 'alone and' on pg. 24 of the L1_ SIS and ICF combined adults_TC has been removed.

- The NREC-CT noted that the future use of data (PET-CT scans) is not described in line with regulations/best practice on pg. 18 & pg. 31 of the ('improving services and refining techniques for PET-CT scan review') of the L1_ SIS and ICF combined adults_TC. The NREC-CT requested that future use of 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 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 Main PISCF, 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
- 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.

2024-514173-22-00 SM5

Institutions: CHI Temple St, St Vincent's University Hospital, Our Lady's Children's Hospital Crumlin, University Hospital Limerick, Cork University Hospital

Study title: A Phase 3, Open-label Study Evaluating the Long-term Safety and Efficacy of VX-121/TEZ/D-IVA Combination Therapy in Subjects With Cystic Fibrosis

Dossiers Submitted: MSC Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

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

- The NREC-CT noted that the future use of data/samples is not described in line with regulations/best practice on pg.24 of the L1_SIS and ICF Adult Part A_IE_eng_tc, pg. 23 of the L1_SIS and ICF Adult Part B_IE_eng_tc, pg. 24 of the L1_SIS and ICF Parent Guardian Part A_IE_eng_tc, and pg. 23 of the L1_SIS and ICF Parent Guardian Part B_IE_eng_tc. 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 made clear that it is optional
    - optional future research is made into a separate and explicit consent item in the Informed Consent section of the Main PISCF, with separate signatures section, so it is distinct from the main consent to participate in the research. 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/
- 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.

2022-501522-38-00 SM4

Institutions: Beaumont Hospital

Study title: An Extension Study of Venetoclax for Subjects Who Have Completed a Prior Venetoclax Clinical trial

Dossiers Submitted: MSC Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part II Considerations

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

- The NREC-CT noted that participants are advised on pg. 3 of the L1 M19-388 IE ICF Main Tracked MS to refer to the optional research section to see which samples are optional, however the PISCF does not seem to contain an optional research section. The NREC-CT requested that this is amended in line with regulations /best practice.
- Furthermore, the NREC-CT noted that the future use of data/samples is not described in line with regulations/best practice on pg.15 ('in continued medical research projects or scientific research purposes' and 'analysis of how AbbVie can improve its clinical research processes.'), and pg. 23 ('use of coded data for continued research') of the Main PISCF. 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 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 Main PISCF, 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 noted that pg. 18 of the L1 M19-388 IE ICF Main Tracked MS states that participants will not be 'punished' or lose any benefits to which they are otherwise entitled if they wish to withdraw from the trial. The NREC-CT requested that the word 'punished' is revised to be less harsh and more participant friendly.
- 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.

2022-501050-11-01 SM1

Institutions: University Hospital Galway, CHI Crumlin, Cork University Hospital, St James's Hospital

Study title: ALLTogether1 - A Treatment Study Protocol of the ALLTogether Consortium for Children and Young Adults (0-45 Years of Age) with Newly Diagnosed Acute Lymphoblastic Leukaemia (ALL)

Dossiers Submitted: MSC Part I & II

- **NREC-CT Decision:**

- Request for Further Information

- **Additional Information Required**

Part I Considerations

1. It was noted that the following statement in the below documents does not align. Please clarify details with regard to the recruitment of participants in Ireland - "R3-TEAM is the only R3-randomisation for patients with T-cell ALL and is open to patients from all countries [ ] adults in Ireland."
   - Section 8.4.2.4 of D1_Master Protocol 2022-501050-11-01 Summary of Changes
   - pg. 90 of D1_Master Protocol 2022-501050-11-01 TC

Part II Considerations

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

- The NREC-CT requested that the S1_ Compliance with Member State applicable rules for the collection, storage and future use of human biological samples document is updated to align with relevant changes made to the PISCF/ assent documents regarding future use of samples.
- The NREC-CT requested that section 2.1 on pg. 2 of the S1_ Compliance with Member State applicable rules for the collection, storage and future use of human biological samples document is updated to include cerebrospinal fluid, as archival samples of cerebrospinal fluid may be used in the study as detailed in the L1_SIS_SUS4_CSF Flow_For Parents_Ireland_TC.PDF and the L1_SIS_SUS4_CSF Flow_For Adult_Ireland_TC.PDF documents.

2. **Proof of insurance**

- The NREC-CT noted that the insurance expires at the end of 2025 and requested confirmation that insurance is in place for the duration of the trial.

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

- The NREC-CT noted that the letter ‘s’ has been removed from the word ‘old’ on pg. 1 of the L1_SIS and ICF_R3 Randomisation InO and TEAM_7 to 12 Years_Ireland_TC.PDF and requested this is reinserted for clarity and consistency with the rest of the documents.
- The NREC-CT noted that new text has been added to the section “What are the possible benefits of taking part?” on pg.3 of the L1_SIS and ICF_SUS5_Maintenance Therapy_13 to 15 Years_Ireland_TC .PDF which does not state that there may be no direct benefits to the participant as a result of participation. The Committee requested that an applicable statement be included.

- The NREC-CT noted that a section has been added to pg.3 of the L1_SIS and ICF_SUS5_Maintenance Therapy_13 to 15 Years_Ireland_TC .PDF entitled “What are the possible benefits of taking part?” which appears to address the parent/guardian as it refers to “your child’s doctor”. The Committee requested that the text be reassessed and edited as this PISCF is intended for the 13-15 year old cohort (suggest that the child is addressed directly i.e. ‘your doctor’).
- The NREC-CT noted that a section has been added to pg.3 of the L1_SIS and ICF_SUS2_MainBrain_ArmA_Age_13 to 15 _Ireland_TC.PDF entitled “What are the possible benefits of taking part?” which appears to address the parent/guardian as it refers to “benefit to your child/your child’s participation”. The Committee requests that the text be reassessed and edited as this PISCF is intended for the 13-15 year old cohort (suggest that the child is addressed directly).
- The NREC-CT noted the language used to describe the antileukaemic effect of maintenance therapy on pg. 21 of the L1_SIS and ICF_R3 Randomisation TEAM_For Parents_Ireland_TC.PDF (Appendix A Treatment Schedule TEAM), pg. 25 of the L1_SIS and ICF_R3 Randomisation InO and TEAM_For Parents_TC.PDF, pg. 24 of the L1_SIS and ICF_R3 Randomisation InO and TEAM_For Adults_Ireland_TC.PDF & pg. 20 of the L1_SIS and ICF_R3 Randomisation TEAM_For Adults_Ireland_TC.PDF may be difficult for participants to understand and requested that this section is simplified using plain English suitable for a lay audience.
- Due to character limit on CTIS this consideration has been split into two parts. The NREC-CT noted that the future use of data/samples (including genetic research) is not described in line with regulations/best practice on pg. 32 (‘I agree to make the blood and bone marrow sample(s) from my diagnostic blood tests, bone marrow aspirate and lumbar puncture and/or from the same tests at follow-up timepoints available for use in research related to this study. I understand that making my samples available for this research is voluntary and that I am free to withdraw my approval for their use at any time without giving any reason and without my medical treatment or legal rights being affected, providing the samples have not already been used up.’ & ‘I agree that any remaining samples can be stored for use in future ethically and scientifically approved research in Ireland or overseas, including genetic studies. This research may involve private or commercial companies.’; pg. 33 (‘I give permission for my leukaemic bone marrow, blood and other samples to be used for research projects, approved by the ALLTogether consortium science committee, on the prevention, diagnosis and/or treatment of leukaemia; including those projects based outside my country’); & pg. 34 ‘I consent to the bio banking of my biological samples at CHI Crumlin and to the subsequent transfer of the stored samples to the UK based Biobank called the Vivo Biobank as outlined in the provided information sheet.’) of the L1_SIS and ICF_MasterProtocolRegistration_Adults_Ireland_TC.PDF, pg. 8 (‘Stored samples may be used in future research studies or for specific projects also’); pg. 32 (‘I agree to make the blood and bone marrow sample(s) from my child’s diagnostic blood tests, bone marrow aspirate and lumbar puncture and/or from the same tests at follow-up timepoints available for use in research related to this study. I understand that making my child’s samples available for this research is voluntary and that I am free to withdraw my approval for their use at any time without giving

any reason and without my child's medical treatment or legal rights being affected, providing the samples have not already been used up.'); pg. 34 ('I consent to the bio banking of my child's biological samples at CHI Crumlin and to the subsequent transfer of the stored samples to the UK based Biobank called the Vivo Biobank, as outlined in the provided information sheet') of the L1_SIS and ICF_Master Protocol Registration_For Parents_Ireland_TC.PDF & pg. 16 (''I understand that information collected about my child will be used to support other research in the future, and may be shared with other researchers, in which case items that could directly identify my child would be removed and a code used to link information. I give permission for my child's data to be shared in this way.'), pg. 17 ('I understand that my child's data, and biobanked blood and bone marrow samples will be sent to the Princess Máxima Centre for Paediatric Oncology, Utrecht, in The Netherlands and to Copenhagen University Hospital, Rigshospitalet, Denmark for the research outlined and explained in the participant information sheet for this study. I give permission for my child's samples and data to be sent and shared in this way') of the L1_SIS and ICF_NRI1_ABL_Parents_Ireland_TC.PDF.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 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 Main PISCF, with separate participant information section and signatures section, so it is distinct from the main consent to participate in the research. It is recommended that a new Future Biological Research PISCF is developed.

Updates to this consideration should be aligned in the following documents:

L1_SIS and ICF_Randomisation 3_INO_For Parents_Ireland_TC.PDF, Pg. 24

'I understand that information collected about my child will be used to support other research in the future, and may be shared with other researchers, in which case items that could directly identify my child would be removed and a code used to link information. I give permission for my child's data to be shared in this way.'

'I understand that my child's collected data, tissue and blood samples may be used for research related to the study, in which case items that could directly identify my child

would be removed and a code used to link information. I give permission for my child's data to be shared in this way.'

L1_SIS and ICF_R3 Randomisation InO and TEAM_For Parents_TC.PDF, Pg.31

'I understand that information collected about my child will be used to support other research in the future, and may be shared with other researchers, in which case items that could directly identify my child would be removed and a code used to link information. I give permission for my child's data to be shared in this way'

'I understand that my child's collected data, tissue and blood samples may be used for research related to the study, in which case items that could directly identify my child would be removed and a code used to link information. I give permission for my child's data to be shared in this way.'

L1_SIS and ICF_Randomisation 1_For Parents_Ireland_TC.PDF, Pg.16

'I understand that information collected about my child will be used to support other research in the future, and may be shared with other researchers, in which case items that could directly identify my child would be removed and a code used to link information. I give permission for my child's data to be shared in this way.'

L1_SIS and ICF_Randomisation 2_For Parents_Ireland_TC.PDF

'I understand that information collected about my child will be used to support other research in the future, and may be shared with other researchers, in which case items that could directly identify my child would be removed and a code used to link information. I give permission for my child's data to be shared in this way.'

L1_SIS and ICF_SUS5_Maintenance Therapy_For Parents_TC.PDF

Pg. 9: 'I understand that information collected about my child will be used to support other research in the future, and may be shared with other researchers, in which case items that could directly identify my child would be removed and a code used to link information. I give permission for my child's data to be shared in this way.'

Pg.10: 'I understand that my child's collected data, tissue and blood samples may be used for research related to the study, in which case items that could directly identify my child would be removed and a code used to link information. I give permission for my child's data to be shared in this way.'

L1_SIS and ICF_Master Protocol Registration_13 to 15 Years_Ireland_TC.PDF, Pg. 4

'If you and your parent(s)/guardian(s) agree, your doctor will take a little extra blood, bone marrow and cerebrospinal fluid on two to three occasions when you are having your regular tests done. These samples will be stored, and would be used to find out more about ALL. You don't have to give any of these samples, but it would be helpful. Whilst we already know a lot, it is important that we learn more about how and why cells become 'sick' causing ALL. This knowledge will help us develop even more effective treatments, with fewer side effects, for children and young adults in the future'

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/

- 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.

- **AOB:**

N/A