HRCDC
Health Research Consent Declaration Committee

Date: 17th October 2023
Location: Zoom videoconferencing

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Sheelah Connolly
Simon Furney
Aideen Hartney
Zubair Kabir
Cornelius Cooney
Patricia O'Beirne
Susan Smith
John Woods
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES

New Amendments - For Consideration

Applicant	Ref No.	Title
Professor Patricia Fitzpatrick	22-001-AF1/CSO/AMD2	Study of the impact of lifestyle factors on COVID-19 outcomes

New Applications – For consideration

Applicant	Ref No.	Title
Dr Lieuwe J. Bos	23-016-AF1	Personalized Mechanical Ventilation Guided by UltraSound in Patients with Acute Respiratory Distress Syndrome (PEGASUS).
Vincenzo Rusotto	23-017-AF1	Preventing cardiovascular collapse with Vasopressors during Tracheal Intubation: The PREVENTION Randomized Controlled Trial
Professor Ronan Collins	23-019-AF1	Tranexamic acid for hyperacute spontaneous IntraCerebral Haemorrhage (TICH-3)

HRCDC
Health Research Consent Declaration Committee

Meeting Items

1. **Opening**
   The Chair opened the meeting and welcomed the members.

2. **Apologies**
   Barry O' Sullivan, Dan Rea, Barry Lyons, Mary Tumelty (Maternity Leave)

3. **Disclosure of Interest**
   22-001-AF1/CSO/AMD2: Zubair Kabir (ZK) noted his professional relationship with the Applicant, however ZK is not connected to this study. It was discussed that there was no conflict of interest.
   23-019-AF1: One of the sites for this study is St Vincent's University Hospital. Kathy Brickell confirmed that she is not involved in this study. It was discussed that there was no conflict of interest.

4. **Minutes of the last meeting**
   Draft minutes of 19th September 2023 were circulated in advance of the meeting and were approved by the HRCDC.

5. **Matters arising**
   Application 23-011-AF1 (Building Circles of Support for People with Intellectual Disabilities). The HRCDC were provided with correspondence from the Applicant/data controller outlining that due to project deadlines the study will progress with only those participants who have decision making capacity to provide consent and for this reason the consent declaration made by the HRCDC has not been accepted as it is no longer required. The HRCDC noted this correspondence.

6. **Amendments**

Reference ID:	22-001-AF1/CSO/AMD2
Lead Applicant:	Professor Patricia Fitzpatrick
Data Controller:	University College Dublin
Title:	Study of the impact of lifestyle factors on COVID-19 outcomes
Research Objective:	Please see HRCDC Meeting minutes of 12th April 2022 and 13th December 2022.
Purpose of Amendment:	A request to extend the duration of the consent declaration to 30th June 2024.
HRCDC Comments:	The Chairperson highlighted that this was a technical amendment to extend the duration of the consent declaration. The HRCDC were asked if they approved the amendment. It was the consensus of the HRCDC that the amendment request should be approved.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved.

7. **New Applications**

Reference ID:	23-016-AF1
Lead Applicant:	Dr Lieuwe J. Bos

Data Controllers:	Amsterdam University Medical Centers (UMC)
Title:	Personalized Mechanical Ventilation Guided by UltraSound in Patients with Acute Respiratory Distress Syndrome (PEGASUS).
Research Objective:	Acute respiratory distress syndrome (ARDS) is a frequent cause of severe acute respiratory failure and has a mortality rate of approximately 30%. The identification of patients with different subtypes (termed 'phenotypes') of ARDS, based on whether the changes in their lungs are localized ('focal') or spread across the lungs ('diffuse), may be helpful to better target mechanical ventilation strategies. Lung ultrasound (LUS) is a non-invasive tool that can accurately distinguish 'focal' from 'diffuse' ARDS subtypes. This study will test the hypothesis that LUS-guided personalized mechanical ventilation will lead to a reduction in 90-day mortality compared to conventional mechanical ventilation in ARDS patients. This study will include 538 consecutively admitted invasively ventilated adult intensive care unit (ICU) patients with moderate or severe ARDS. There will be a predefined feasibility and safety evaluation after inclusion of the first 80 patients. Patients will receive a LUS exam within 12 hours after diagnosis of ARDS to classify lung morphology as focal or non-focal ARDS. Immediately after the LUS exam patients will be randomly assigned to the intervention group, with personalized mechanical ventilation, or the control group, in which patients will receive standard care.
Reason for Declaration:	The consent declaration is requested to process the personal data of participants who lack decision making capacity due to the nature of their critical condition (collection, transfer, analysis, storage etc.). In such circumstances deferred proxy assent will be obtained on their behalf, and consent to continue sought when the participant regains decision-making capacity.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a consent declaration with conditions attached should be made. **Public interest case:** • The HRCDC discussed the study activities, including the follow-up data collection, study outcomes, and how the researchers are monitoring the impact of the intervention on the patient. • It was the view of the HRCDC that this is an important research area and that there is a strong public interest case. **Public and patient involvement (PPI) and Transparency** • The HRCDC discussed the Applicant's response on the PPI engagement that has occurred with this study. It was noted that this study was discussed with PPI representatives in early 2023.

	It was discussed that some additional information could have been outlined on this PPI engagement and what was discussed in relation to the PEGASUS study specifically. • The HRCDC was of the view that the Applicant/data controller should consider further enhanced PPI via continued PPI engagement during the course of the study, including on disseminating the study findings to relevant PPI groups for the benefit of transparency. **Study Information Leaflets** • It was commented that the title of the proxy assent form should read 'deferred assent form' not 'assent form'. Further, it was discussed that it should be fully clear in the proxy information leaflets and assent form that they are being asked to provide permission for the participant's continued participation in this study. • The HRCDC also noted an omission in the information leaflets and assent/consent forms that should be highlighted to the Applicant. **Study and data withdrawal** • The HRCDC commented that it was not fully clear when the database would be locked, for example if this will occur when all participants are recruited. It was discussed that information on when the data lock will occur should be provided as part of the Annual Review. • It was also noted that the Applicant's response outlined that the data collected will be deleted if deferred proxy assent is not obtained within 72hrs of participant enrolment. It was discussed that the use of a deferred proxy assent process, followed by deferred participant consent to continue, is used in similar studies and that proxy assent should always be obtained. The HRCDC discussed that data deletion could occur in a reasonable period after 72hrs as agreed by the study team. **Other:** • It was queried which personnel at the local hospital site would be on local research team and therefore who would be noted on the study's delegation log. It was discussed that it could be assumed that all personnel involved in the local research team would be trained on the study and Good Clinical Practice. • It was further queried how the clinical frailty score could be administered in situations where the participant lacks decision-making capacity. It was commented that the frailty score is a relatively straightforward questionnaire that can be completed by a proxy where the participant is unable to complete it for themselves. • It was highlighted that the study protocol refers to what will happen the participant's personal data if they are deceased before deferred proxy assent can be obtained. It was discussed that the personal data of deceased individuals falls outside the remit of data protection legislation.

	• It was also discussed that there is no standardised tool for determining functional capacity and that this is based on the experience and skills of the clinical team. • Other items noted regarding technical and more standard safeguards that may need to be considered included clarity on the scope of the consent declaration (and what is excluded from the scope of the declaration), ensuring the required data agreements are in place, and clear information and processes on deleting data if an individual wishes to withdraw.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration should be made, subject to the conditions as detailed below.
Duration of Declaration:	The consent declaration is made on 17th October 2023 and is valid until 31st October 2025 and for 15 years thereafter (until 31st October 2040), or until the personal data has been irrevocably anonymised or destroyed. It will be made clear in the communications to the Applicant/data controller that the scope of the consent declaration covers data processing for this specific study only and subsequent data archiving; it will be outlined that other activities, for example future research purposes, sharing/disclosing personal data with other third parties, are not covered.
Conditions Attached:	**Condition 1.** The required data agreements/arrangements must be in place between the parties prior to personal data being transferred and processed. In this context, the data controller must ensure that the data agreements/arrangements meet the necessary GDPR requirements. **Condition 2:** Where an individual wishes to withdraw from the study and the study wishes to continue to process the existing personal data already collected up to that point, then permission for this should be sought from the proxy or participant, whoever is relevant, and appropriately recorded. If this permission to continue to process data after withdrawal is provided by the proxy, then consent to continue to process the data already collected should also still be obtained from the participant if they regain decision-making capacity. Where an individual requests that the personal data is deleted following withdrawal then it should be deleted up until the point where this is no longer practicable i.e., data lock. As part of the Annual Review, the Applicant/data controller is also requested to provide information on when the data lock will occur i.e., if it is after all participants have been recruited to study. **Condition 3.** The consent declaration does not cover data processing in a situation where deferred proxy assent is not provided; if proxy assent is not obtained in a short period after the 72hrs, then data deletion should occur.
HRCDC Recommendations:	**Recommendation 1.** The Applicant is requested to review and amend the study information leaflets and assent/consent forms as follows: (i) Parts of the documents refer to '90' and not '90 days'.

	(ii) The proxy assent form should be titled 'deferred proxy assent form' as opposed to only 'proxy assent form'. (iii) Linked to point (ii), it should be fully clear in the proxy information leaflets and assent form that the proxy is being asked to provide permission for the participant's continued participation and data processing. For example, the proxy assent form should state '*I assent to my relative/friend continuing to take part in this research study having been fully informed of the risks, benefits and alternatives'.*

Reference ID:	23-017-AF1
Lead Applicant:	Vincenzo Rusotto
Data Controllers:	University of Torino
Title:	Preventing cardiovascular collapse with Vasopressors during Tracheal Intubation: The PREVENTION Randomized Controlled Trial
Research Objective:	Tracheal intubation is the most commonly performed procedure in critically ill patients and is essential to facilitate invasive ventilation, or 'life support'. It is a high risk procedure, with severe complications seen in 45% of patients, in the recent INTUBE study. These adverse events appear to have long-term consequences, with patients experiencing at least one major peri-intubation event at higher risk of dying. Hemodynamic complications such as low blood pressure (i.e. shock) is the commonest severe complication seen, and even a short period of shock may lead to harm, and even cause death. Studies show that the need to deeply sedate patients to reduce discomfort from the procedure may play a key role in these complications. This randomized controlled clinical trial will investigate whether pre-emptively starting medications to maintain blood pressure (termed 'vasopressors') in patients undergoing tracheal intubation can reduce the risk of hemodynamic complications inpatients requiring urgent/emergent tracheal intubation compared to standard care.
Reason for Declaration:	The consent declaration is requested to process the personal data of participants who lack decision making capacity due to the nature of their critical condition (collection, transfer, analysis, storage etc.). In such circumstances deferred proxy assent will be obtained on their behalf, and consent to continue sought when the participant regains decision-making capacity.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the

	Applicant, it was the consensus of the HRCDC that a consent declaration with conditions attached should be made. **Public interest case:** • The HRCDC discussed the study's aims and objectives and was of the view that there is a strong public interest case in this research. **Public and patient involvement (PPI) and Transparency** • The HRCDC discussed the Applicant's response on the PPI engagement that has occurred with this study. It was noted that this study was discussed with PPI representatives in early 2023. It was discussed that some additional, information could have been outlined on this PPI engagement, i.e. what was discussed in relation to the PREVENTION study specifically. • The HRCDC was of the view that the Applicant/data controller should consider further enhanced PPI via continued PPI engagement during the study, including on disseminating the study findings to relevant PPI groups for the benefit of transparency. It was also commented that it would be beneficial for PPI feedback (e.g., ICU Steps) to be sought on the ICU research information poster made available in the hospital that was referenced by the Applicant. **Study Information Leaflets** • The HRCDC noted that the study information leaflets outlines inconsistent information on the length of data storage, referring to 15 or 25 years, while the Applicant's response to the Secretariat confirmed that personal data would be stored for 10 years. It was discussed that the study information leaflets should be amended to align with the 10-year data storage that was outlined to the HRCDC. • It was also discussed that the statement '*If a study has been published that included data linked to you/your relative, it may not be possible to alter this result'* may be confusing to the individual reading the document. Instead, the documentation should clearly outline that once the results have been published the participant can't be identified as the data published is anonymised. • The HRCDC also noted that references to using personal data in future research studies and requesting permission for this use was included in the study documents for the proxy. The Secretariat confirmed that the Applicant/data controller understood that the scope of the declaration does not extend to future studies. It was noted that references and requests to use data in future studies should be removed from the proxy study documents. • It was also highlighted that the Applicant's responses to the Secretariat's query letter outlined several changes that will be made to the study information leaflet. The HRCDC agreed that the Applicant/data controller must make these amendments to the documents.

	• Further, it was commented that it should be fully clear in the proxy information leaflets and assent form that they are being asked to provide permission for the participant's continued participation in this study. **Study and data withdrawal** • The HRCDC commented that it was not fully clear when the database would be locked, for example if this will occur when all participants are recruited. It was discussed that information on when the data lock will occur should be provided as part of the Annual Review. • It was also noted that the Applicant's response outlined that the data collected will be deleted if deferred proxy assent is not obtained within 48hrs of participant enrolment. It was discussed that the use of a deferred proxy assent process, followed by deferred participant consent to continue, is used in similar studies and that proxy assent should always be obtained. The HRCDC discussed that data deletion could occur in a reasonable period after 48hrs, as agreed by the study team. **Other:** • The HRCDC noted the differing use of terms pseudonymisation and anonymisation in the documents submitted. It was commented that the data remains pseudonymised as it is coded, and the master key is retained by the local hospital. • It was noted that one of primary and secondary study outcomes detailed in the application form were identical. • Other items noted regarding technical and more standard safeguards that may need to be considered included clarity on the scope of the consent declaration (including what is excluded from the scope of the declaration), ensuring the required data agreements are in place, clear information and processes on deleting data if an individual wishes to withdraw and other changes to the PILs.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration should be made, subject to the conditions as detailed below.
Duration of Declaration:	The consent declaration is made on 17th October 2023 and is valid until 30th November 2025 and for 10 years thereafter (Until 30th November 2035), or until the personal data has been irrevocably anonymised or destroyed. It will be made clear in the communications to the Applicant/data controller that the scope of the consent declaration covers data processing for this specific study only and subsequent data archiving; it will be outlined that other activities, for example future research purposes, sharing/disclosing personal data with other third parties, are not covered.
Conditions Attached:	**Condition 1.** The required data agreements/arrangements must be in place between the parties prior to personal data being transferred and processed. In this context, the data controller must ensure that the data agreements/arrangements meet the necessary GDPR requirements.

	Condition 2: Where an individual wishes to withdraw from the study and the study wishes to continue to process the existing personal data already collected up to that point, then permission for this should be sought from the proxy or participant, whoever is relevant, and this permission should be appropriately recorded. If this permission to continue to process data after withdrawal is provided by the proxy, then consent to continue to process the data already collected should also still be obtained from the participant if they regain decision-making capacity. Where an individual requests that the personal data is deleted following withdrawal then it should be deleted up until the point where this is no longer practicable i.e., data lock. As part of the Annual Review, the Applicant/data controller is also requested to provide information on when the data lock will occur i.e., if it is after all participants have been recruited to study. **Condition 3.** The Applicant/data controller is requested to amend the study information leaflets and assent/consent forms, as per the replies provided to the Secretariat query letter and to address other points highlighted by the HRCDC: (i) Remove references to collecting and using bio-sample *(ii)* It must be made clear who the data controller of the study is, i.e., University of Torino, and that personal/pseudonymised data will be shared with this controller in Italy (*Note: the responses provided states that PILs have been updated to reflect that data in 'an anonymised format' will be transferred. Based on the information provided the data is not fully anonymised but remains pseudonymised)* *(iii)* Aligned with the scope of the consent declaration, remove references to future research, sub-studies etc from the proxy information leaflet and assent forms. *(iv)* Ensure consistency of information in the study information leaflets and assent/consent forms confirming that data is held for 10 years, and not 15 or 25 years as referenced in some sections. (Note: the Applicant's responses to the Secretariat query letter stated a few of the above changes had been made, however the HRCDC did not receive a copy of the update documents that reflect these changes, therefore it is important that the above amendments are made. Confirmation that the above changes have been made is acceptable; the HRCDC do not need to receive copies of the updated leaflets). **Condition 4.** The consent declaration does not cover data processing in a situation where deferred proxy assent is not provided; if proxy assent is not obtained in a short period after the 48hrs, then data deletion should occur.
HRCDC Recommendations:	**Recommendation 1.** The Applicant is requested to review and amend the study information leaflets and assent/consent forms as follows: (i) It should be fully clear in the proxy information leaflets and assent form that the proxy is being asked to provide permission

	for the participant's continued participation and data processing. For example, the proxy assent form should state '*I assent to my relative/friend continuing to take part in this research study having been fully informed of the risks, benefits and alternatives'.* (ii) the statement '*If a study has been published that included data linked to you/your relative, it may not be possible to alter this result'* may be confusing to the individual reading the document. You are asked to look at this phrase to make it clear to the subject.

Reference ID:	23-019-AF1
Lead Applicant:	Professor Ronan Collins (TUH)
Data Controllers:	University of Nottingham
Title:	Tranexamic acid for hyperacute spontaneous IntraCerebral Haemorrhage (TICH-3)
Research Objective:	TICH-3 is a randomised clinical trial investigating the efficacy of tranexamic acid in treating hyperacute spontaneous intracerebral haemorrhage. This condition involves sudden bleeding within the brain, which can lead to severe health complications or death. The trial aims to determine if tranexamic acid can provide a beneficial treatment option for patients experiencing this type of haemorrhage.
Reason for Declaration:	The study involves emergency treatment for stroke patient. Wherever possible the study will obtain participant explicit consent prior to their recruitment to the study, however the consent declaration is requested to process the personal data of those who lack decision-making capacity to provide explicit consent upon recruitment due to the nature of their condition. If a patient does not have decision-making capacity, then proxy assent will be obtained on their behalf from a relative or from an independent doctor.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Secretariat provided an overview of the study, and the following points were noted, following clarifications from the Applicant: • The consent declaration will not cover St. James Hospital as a site / data processor or data collection from other sources not named in the HRCDC application form e.g., 'other databases. It will also not include any pilot phase as this has already been completed in countries other than Ireland. • Directly identifiable data (e.g., patient names) will not be sent to the UK and data collection will be done by Irish based personnel. The Applicant confirmed that data will be archived for 1 year after the study concludes, after which it will be fully anonymised.

	Follow up personal data collection will not be covered by a consent declaration, if a participant fully withdraws from the study • A consent declaration, if made, will not cover the further processing of personal data (including pseudonymised data) by unknown third parties or processing for other future studies. • The Health Economics part of this study is not applicable to Irish participants. • If proxy assent is initially obtained from an independent doctor for enrolment in the study, it was highlighted that proxy assent will always be sought from an appropriate patient representative i.e., relative or friend. • The Applicant has confirmed that the study information leaflets will be customised for each Irish site, i.e., name of hospital and PI contact. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a consent declaration should be made, subject to the conditions as detailed below. **Public interest case:** • The HRCDC discussed the study activities, including the follow-up data collection, aims and objectives of the study. • It was the view of the HRCDC that there is a strong public interest case in this research. **Data Transfer and agreements.** • The process of completing the follow up at day 180 was discussed by the HRCDC. The follow-up process will be undertaken by the local hospital site or by the co-ordinated by the National co-ordinator in TUH under the supervision of Dr Ronan Collins. The HRCDC considered it important that the transfer of data from the Irish Hospital sites to the central co-ordinator to enable TUH to undertake the follow-up, should be completed in a secure manner that protected the personal data of the participants. A suggestion was that the secure hospital to hospital system that is already in place could be used when transferring data between hospitals e.g., HEANet. It is suggested that the Applicant is asked to ensure a process for the secure transfer of data is in place prior to the start of the study and to inform the HRCDC within three months of the details of the process in place to address this condition. • The HRCDC also noted the response from the Applicant that indicates that local personnel on the study delegation log can set-up an account to enable them to access the study's designated web portal/electronic case report form. It was commented that the Sponsor of the study usually organises the set-up of researchers on the portal, not the local team. It was discussed that the local researcher set-up should be appropriately overseen and done in a secure manner.

	• The study will also involve uploading scans to the study site. A HRCDC member commented that the Applicant should be asked to ensure that only pseudonymised data accompanies these scan, names etc will need to be redacted. • It was also discussed that the necessary data agreements/arrangements must be in place between the relevant parties prior to data being transferred. **Consent / assent process:** • The Applicant has stated that when proxy assent is initially provided by an independent doctor, the study will always seek to obtain written proxy assent from a suitable relative/friend as soon as possible, if the participant continues to lack capacity. The HRCDC were of the view that this proxy assent should be obtained as soon as possible, however if after a reasonable period of time proxy assent cannot be obtained, the applicant could consider telephone assent, subject to REC approval. • The HRCDC also discussed how initial proxy assent may be provided by an independent doctor if a relative/friend is not available. The HRCDC was of the view that while such proxy assent can be sought for enrolment and participation in this study, it is not appropriate with regards the use of the participant's personal data; the HRCDC commented that proxy assent from a relative/friend is more appropriate and suitable for data processing as a safeguard. To this point the HRCDC was of the view that references to the use of personal data will need to be removed from the assent documentation provided to the independent doctor. **Public and patient involvement (PPI) and Transparency** • The HRCDC acknowledged the PPI already completed by the applicant with various groups as stated in the application form. While this was noted, it was also recommended that PPI groups in Ireland are consulted also on the study. An update at the annual review on activity in this area should be given. **Other** • The HRCDC noted minor comments in the study information leaflets that should be addressed. • Other items noted regarding technical and more standard safeguards that may need to be considered included, clarity on the scope of the consent declaration (including what is excluded from the scope of the declaration), ensuring clear information and processes on deleting data or continuing to collect follow-up data if an individual wishes to withdraw and other changes to the PILs.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration should be made, subject to the conditions as detailed below.
Duration of Declaration:	The consent declaration is made on 17th October 2023 and is valid until 1st April 2029 (i.e., 87 months following commencement of study on 1st January 2022) and for 1 year thereafter (until 1st April 2030), or until the personal data has been irrevocably anonymised or destroyed.

	It will be made clear in the communications to the Applicant/data controller that the scope of the consent declaration covers data processing for this specific study only and subsequent data archiving; it will be outlined that other activities, for example future research purposes, sharing/disclosing personal data with other third parties, are not covered.
Conditions Attached:	**Condition 1**. The process of completing the follow up at day 180 for each participant will be co-ordinated and undertaken by the National co-ordinator (i.e., TUH under the supervision of Ronan Collins), if it is not done by personnel form the local site. A secure process for transfer of data between the hospital sites to enable this follow up must be therefore documented and in place prior to the commencement of the study e.g., transfer of data via the secure hospital systems such as HEANet. The applicant is asked to provide details to the committee on this secure process within three months of receipt of this letter. **Condition 2.** References to the processing of personal data should be removed from the assent documentation provided to the independent doctor who may provide initial permission at study enrolment if no other suitable person is available i.e., from a relative/friend. Proxy assent as a safeguard for data processing should be sought from a suitable relative/friend. **Condition 3.** The necessary data agreements/arrangements must be in place between the relevant parties prior to data being transferred. This includes agreements/arrangements between the University of Nottingham and the Irish hospital sites including Standard Contractual Clauses if applicable, agreements for the transfer of personal data between the sites (e.g., local hospital and co-ordinating centre) and agreements with GP, if necessary. Data cannot be transferred prior to the necessary agreements/arrangements being in place. **Condition 4.** It is noted that local personnel on the study delegation log can set-up an account to enable them to access the study's designated web portal/electronic case report form. It must be ensured that the local researcher set-up is appropriately overseen and authorised and done in a secure manner. **Condition 5**. Where the study wishes to collect the 180- day follow-up data after an individual withdraws, then clear permission for this should be obtained and appropriately recorded, whether from the relative/friend or the participant. If this permission to continue to process data after withdrawal is provided by the proxy, then consent to continue to collect this follow-up data should also still be obtained from the participant if they regain decision-making capacity. The study information leaflets should therefore also be amended to reflect and provide clarity on this potential permission for follow-up data collection i.e., amend the statement/section '*If you withdraw, we will no longer collect any information about you or from you but*

	we will keep the information about you that we have already obtained…' Further, while it is acknowledged that the data collected to date cannot be deleted upon a request to withdraw from the study, it remains that data should be deleted where it is practicable and possible, subject to any GDPR derogations that may apply. For example, if all the data isn't needed post-withdrawal, then the data that can be deleted should be deleted.
HRCDC Recommendations:	**Recommendation 1**: Where initial permission is provided by the independent doctor, the response to the HRCDC stated that *'the study will still always seek to obtain written proxy assent from a suitable relative/friend as soon as possible if the participant continues to lack capacity, and this proxy assent will be done as soon as possible'*. In seeking subsequent assent from the relative/friend as soon as practicable, if after a reasonable period of time post enrolment (a couple of days) the relative/friend cannot be reached in-person then proxy assent should be obtained from them by telephone, subject to REC approval. A significant period should not lapse between initial doctor assent and deferred relative/friend assent. The HRCDC is agreeable that an amendment is not required for telephone assent (if implemented) and accordingly this would be covered by scope of the declaration made. The Applicant is also requested to report at the first Annual Review on the time it has generally taken to obtain deferred relative/friend assent. **Recommendation 2.** The committee recommend that PPI groups in Ireland are consulted also on the study, the documentation, consent / assent process etc. An update on this activity in this area can be provided at the annual review. **Recommendation 3:** The Applicant is requested to review and amend the study information leaflets as follows: - aligned with the duration of the consent declaration, it should be made clear in the study information leaflets that the personal data will be fully anonymised 1 year after the study concludes (note: the current versions state '*After this time your personal data will be disposed of securely*' this could be misunderstood that all data will be destroyed as opposed to anonymising the personal data). - Ensure the following is corrected in the information leaflet for the relative: '*The study will also involve giving you a drip for 8 hours'.* - More broadly, ensure that the documents are adapted for an Irish context i.e., relates to research and data processing of Irish based participants, does not refer to NHS data sources etc.

8. Annual Reviews

The Secretariat has received and fully processed 7 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID: 19-003-AF1**; Alistair Nichol, TEAM Study

- **Ref ID: 20-026-AF1/COV;** John Laffey, CHARTER IRL Trial* [*Consent declaration no longer required]
- **Ref ID: 19-016-AF2**; Cara Martin, CERVIVA HPV Primary Screening Pilot Study
- **Ref ID: 19-013-AF2**; Maeve Rooney, Irish OMEGA-3 study
- **Ref ID: 19-077-AF3;** David Galvin, IPCOR study
- **Ref ID: 21-013-AF1;** Maeve Mullooly, Mammographic breast density and breast cancer outcomes in a population-based breast screening programme
- **Ref ID: 19-026-AF2;** Deirdre Daly, MAMMI study

To discuss

Ref ID 19-086-AF1; Sepsis Immunosuppression in Critically Ill Patients.

The HRCDC were provided with a summary of the communications received from the Applicant in relation to Condition 3 (PPI engagement) of the consent declaration made in March 2020. From the information provided it was not possible to determine that the study has met or was adequately progressing the requirements of Condition 3. The HRCDC was asked to consider the responses provided by the Applicant and provide guidance on what further action, if any, is necessary.

It was noted by the Secretariat that study is actively recruiting participants and the consent declaration is in place until April 2029.

While it was noted that the Applicant is involved in broader PPI and transparency activities, the HRCDC expressed concern at the lack of progress on PPI engagement on this specific study, considering the resources in place in this area. ICU Steps, PPI ignite are examples of organisations the Applicant could contact and there is also a designated PPI officer in St. James that could be contacted.

The HRCDC agreed that a chairperson letter would be sent to the applicant outlining the concerns regarding compliance with Condition 3 and copy this communication to the DPO of the organisation. (St. James). The Applicant will be requested to reply to this correspondence by mid-January 2024.

9. Meeting dates for 2024

List of proposed dates uploaded to Decision Time. The members agreed on dates for 2024. The Secretariat will circulate the meeting invites for 2024 shortly.

10. Updated HRCDC application form

The Secretariat provided an overview of the updates made to the Application form. The HRCDC approved the form for release, with one minor change requested. Once updated, this form will be placed on the website for use for all applicants, after this time.

11. Activities report and events of interest.

The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting. Upcoming events of interest and other relevant updates where also noted.

12. Any Other Business

- Reminder that next meeting is in person, including guest speaker Alistair Nichol.
- The Chairperson informed the members that an expression of interest form will be uploaded to the HRCDC website in due course.

****The Chair closed the meeting****