HRCDC
Health Research Consent Declaration Committee

Date: 26th March 2024
Location: Zoom videoconferencing

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Zubair Kabir
Dan Rea
John Woods
Barry Lyons
Patricia O'Beirne
Susan Smith
Paul Stynes
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES

New Applications – For consideration

Applicant	Ref No.	Title
Dr Aaron Doherty	24-001-AF1	Exploring MALDI-TOF MS data to improve the diagnosis and treatment of Staphylococcus aureus bacteraemia
Prof Ger Curley	24-002-AF1	Brain Oxygen Neuromonitoring in Australia and New Zealand Assessment (The BONANZA Trial)

Meeting Items

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

2. **Apologies**
   Sheelah Connolly, Simon Furney, Aideen Hartney, Cornelius Cooney, Mary Tumelty (Maternity leave)

3. **Disclosure of Interest**
   Kathy Brickell declared her potential interest in application 24-002-AF1 application (The BONANZA Trial) highlighting to the HRCDC that she had previously worked with researchers on the study team. KB was absent during the meeting when this application was considered.

4. **Minutes of the last meeting**

Draft minutes of 27th February 2024 were circulated in advance of the meeting and were approved by the HRCDC.

5. **Returning Application:** 23-019-AF1/AMD1 (Tranexamic acid for hyperacute spontaneous IntraCerebral Hemorrhage: TICH-3).

Introduction

- This amendment application was considered by the HRCDC at its meeting of 27th February. Following this meeting, the HRCDC Secretariat, in reviewing previous applications, noted additional information that may have been of relevance but that the HRCDC was not in a position to review when first considering 23-019-AF1/AMD1. With the agreement of the Chairperson and HRCDC, it was decided that the issuing of the February decision would be deferred, and that the amendment would be tabled again at the March meeting.
- This deferring of the decision was communicated to the Applicant. They requested if they could provide further clarification to the HRCDC on their process for obtaining proxy assent within this study; this was agreed.
- It was confirmed at the meeting that the provision of this clarifying information and the deferment of the February decision was not an indication that the outcome of the previous HRCDC's discissions should change; it was also confirmed that this had been communicated to the Applicant.

Discussion

- The Chairperson introduced the application and the HRCDC were reminded what the scope of the amendment request was for; to cover the processing of personal data should it arise where deferred proxy assent or participant consent to continue cannot be obtained. It was noted that there was a detailed discussion on 23-019-AF1/AMD1 at the HRCDC meeting of 27th February 2024 that considered matters such as the participant cohort, potential for study bias and the proxy assent process. Following this discussion in February 2023, and considering the benefits and drawbacks of this amendment request, it was the consensus of the HRCDC, at that stage, that the amendment should not be approved.
- In returning this amendment request to the HRCDC, it was drawn to the committee's attention that in a separate full application recently considered by the HRCDC, the consent declaration made for that study covered the processing of personal data if it occurs that deferred proxy assent or participant consent to continue cannot be obtained. It was also highlighted that all HRCDC decisions are based on individual case circumstances and are not regarded as setting a precedent; therefore, a previous decision made by the HRCDC to cover continued data processing in the absence of deferred proxy assent, does not set a precedent for other applications.
- Some members of the HRCDC discussed the differences between 23-019-AF1 and the previous separate study that was granted a consent declaration to cover data processing in the absence of proxy assent or participant consent; matters discussed included the different aims and nature of each study, the different data safeguards that were noted, the duration of participant hospitalisation and follow-up, and information on identifying and obtaining deferred proxy assent or participant consent to continue. Other members of the HRCDC discussed the similarities between the request by 23-019-AF1/AMD1 to process personal data if deferred proxy assent or participant consent to continue cannot be obtained and the previous separate study whose consent declaration covered such data processing. As a general point, it was

further noted that many similar types of studies don't process personal data if they can't get proxy assent.

- On the additional clarifications submitted by the Applicant on 23-019-AF1/AMD1 in advance of this meeting, it was noted that only a minimum amount of participant data would be collected and processed in the rare scenario where deferred proxy assent or participant consent to continue cannot be obtained. It was also noted that the study will make every effort to obtain proxy assent and as part of this process they would contact the participant's family doctor or social worker.
- The HRCDC again discussed the matter that not obtaining deferred proxy assent or consent to continue for 23-019-AF1, would likely apply to those who may be considered more vulnerable. As was discussed at the February 2024 meeting, it was commented that the study is not designed to draw out specific information on vulnerable or marginalised participant cohorts, however the importance that health research should not exclude the data of more vulnerable populations was again highlighted and discussed.
- Following a detailed discussion, the HRCDC consensus was that the amendment request should be approved. In coming to this decision, the HRCDC noted the additional clarifications provided by the Applicant. In approving the amendment, the HRCDC discussed that the Applicant/data controller must undertake reasonable efforts to obtain participant consent to continue or deferred proxy assent, including in line with the additional clarifications they submitted to the HRCDC. It was also the view of the HRCDC that efforts made to obtain participant consent to continue or deferred proxy assent, should be tracked and documented.
- The following condition is attached to 23-019-AF1/AMD1:
  Condition: The Applicant/data controller must make every reasonable effort to obtain participant consent to continue if they regain decision-making capacity and make every reasonable effort to obtain deferred proxy assent where they have not yet regained capacity. Accordingly, a clear process outlining the efforts that will be made to obtain participant consent to continue/deferred proxy assent must be in place; as part of this process, the participant's social worker or family doctor should be contacted to identify and determine if there is a suitable relative who can provide proxy assent on behalf of the participant who lacks capacity. Efforts made to determine if the participant has regained capacity and efforts to then seek participant consent to continue, as well as efforts made to obtain deferred proxy assent, must be tracked by the Applicant/data controller and appropriately documented.
  The Applicant/data controller must also report in the Annual Review on the number of participants recruited to the study in Ireland where participant consent to continue or deferred proxy assent has not been obtained.

General point

- The HRCDC discussed and re-emphasised that obtaining proxy assent from a suitable individual who understands the will and preferences of the participant is an important data protection safeguard. In this context, when applying for a consent declaration, a request to continue to process personal data if it occurs that deferred proxy assent or consent to continue cannot be obtained, is considered by the HRCDC to be the exception**.** The HRCDC discussed that such requests to continue to process or use personal data in this type of rare scenario are and will continue to be considered on a case-by-case basis; it was discussed that there would have to be a strong case made by the study if they wish to continue to process personal data should it arise that deferred proxy assent cannot be obtained.

6. New Applications

Reference ID:	24-001-AF1
Lead Applicant:	Dr Aaron Doherty
Data Controllers:	Cork University Hospital
Title:	Exploring MALDI-TOF MS data to improve the diagnosis and treatment of Staphylococcus aureus bacteraemia
Research Objective:	Using a pre-existing platform, the MALDI-TOF MS, which is widely available and used by many laboratories for identifying microorganisms, the study intends to investigate its ability to identify toxin producing strains of *S.aureus* (a common skin organism that can cause severe and invasive infections), and then correlate this with patient demographics, site of infection and outcome, principally mortality.
Reason for Declaration:	The consent declaration is requested for the processing of personal data (collection, transfer, analysis etc) without the explicit consent of the participant for the duration of the study; the data is confirmed as pseudonymised during the study. The personal data to be processed has already been collected as part of patient care and treatment and includes data associated with/generated from the bio samples/isolates that were also collected as part of patient care and treatment. The study will involve the data of up to 300 patients.
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, subject to conditions attached, should be made. **Public interest case** • The HRCDC discussed the aims and objectives of this research and the study activities. • It was the view of the HRCDC that there is a strong public interest case in this research. **Obtaining consent** • The HRCDC discussed the reasons outlined by the Applicant on why consent, or efforts to obtain consent, would not be made for this study. The HRCDC noted the replies that patients would likely not be reattending the hospital, that the study did not wish to cause potential distress, that there may be resource issues and that there may be gaps with regards data on patient address, among others. • The HRCDC discussed if efforts to obtain consent should be made by the study, given the relatively small number of

participants to be included and that they were treated in hospital recently, between 2022 and 2023.

- On balance, the HRCDC commented that there is a low risk to the participant's data protection rights given that the study's primary focus is to re-analyse pre-existing samples to help determine if they can better predict patient outcomes. Given the strong public interest, as well as the study's time constraints the HRCDC was prepared to make a declaration. However, it was discussed that transparency measures and PPI engagement would be important data protection safeguards in the absence of explicit consent.

Public and patient involvement (PPI)

- The HRCDC noted that the study has contacted the Irish Sepsis Foundation and that a meeting will be arranged with their members to discuss this study and seek their feedback. The Applicant submitted a draft of the information and question form that will be provided to these PPI representatives.
- The HRCDC welcomed the plan to engage with the Irish Sepsis Foundation, however given the study's timescale it was the view of the HRCDC that PPI engagement needs to occur prior to the commencement of the study. In addition, given that consent would not be obtained for this study, it was discussed that PPI engagement should examine the issue of consent as well as enhancing the transparency measures and how to inform participants about this study and the use of their data and associated samples. On the PPI question and information form, it was commented that the question on consent should be made prominent and clear in this document.
- It was also highlighted that in addition to the Irish Sepsis Foundation, that there would likely be PPI groups in UCC or CUH who could also be consulted.

Transparency measures and study withdrawal

- It was commented that a clear method/process needs to be put in place to enable participants to contact the researchers and request to be withdrawn from the study. It was also commented that the poster provided does not refer to information on the participant's broader data protection rights.
- The HRCDC also queried if the use of posters was sufficient and suggested information on the study could be provided on the hospital's website to enhance the level of transparency.

Other:

- The Applicant outlined why the study wished to process retrospective data and associated samples, rather than to seek to recruit new participants who meet the study criteria, including the time that it would take to recruit sufficient participant. The HRCDC noted why the study wished to process retrospective data and samples.

	• It was noted that as the data is deemed to be coded/pseudonymised, that appropriate data agreements would be needed between the data controller of the study and UCC as a data processor. • The HRCDC discussed the reference made by the Applicant to using a pro-forma data collection tool and that data is held on HSE equipment.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration, subject to conditions attached, should be made.
Duration of Declaration:	The consent declaration is made commencing 26th March 2024 and is valid until 30th June 2024, or until the personal data is deleted or fully anonymised, whichever occurs first.
Conditions Attached:	**Condition 1.** • Engagement with public, patient and carer involvement (PPI) representatives must occur prior to the commencement of this study. PPI engagement should discuss and seek feedback on matters that may arise given this study will not seek to obtain participant consent. Importantly, PPI engagement should also discuss and seek feedback on how transparency measures for this study can be best developed so that participants who may be included in the study can be informed about this research, the use of their data and samples and how they can request to be withdrawn from the study. For example, the Applicant is requested to discuss other transparency measures with the PPI representatives that are beyond the hospital posters to include other methods such as the CUH website, social media accounts etc. Information provided on the transparency measures should be presented in a lay person language. • The transparency measures, including those beyond the hospital posters, must be in place prior to the study commencing. The Applicant is requested to report on the PPI engagement activities within 2 months, including on what other transparency measures will be undertaken. **Condition 2.** Where a participant contacts the researchers and wishes to have their data deleted from the study, then this should occur wherever this is possible and practicable, subject to any GDPR derogations that may apply. A consent declaration cannot override the decision of a particiapnt to withdraw from the study. **Condition 3.** Appropriate data agreements must be in place between the data controller of the study (CUH) and the data processor (UCC) with regards this study. Data cannot be transferred between these parties prior to the necessary agreements being in place. ***Note:*** based on the informaiton provided to the HRCDC, UCC is a data processor processing data on behalf of the study data controller (CUH) and the data to be processed during this study is pseudonymised. While UCC may not have access to directly identifiable data or to the key/link used to reidentify the participant, it remains that the data to be shared with the processor is still

	pseudonymised data and therefore appropriate data agreements must be put in place.

Reference ID:	24-002-AF1
Lead Applicant:	Prof Ger Curley
Data Controllers:	Monash University, Australia
Title:	Brain Oxygen Neuromonitoring in Australia and New Zealand Assessment (The BONANZA Trial)
Research Objective:	Brain injury which occurs due to trauma is a leading cause of death/disability and particularly affects young people. After the primary brain injury, additional brain damage often occurs, which can significantly affect patient survival/disability. The brain requires a continuous adequate supply of oxygen. Patients who die/have significant disability after a traumatic brain injury often have had low levels of oxygen in the brain. There are common interventions that can normalise the brain oxygen levels. However, none of the standard monitoring devices routinely used in the intensive care unit (ICU) measure brain oxygen levels. In the BONANZA study patients' brain oxygen levels are monitored and when a low level of oxygen is detected, clinicians provide treatments in an attempt to bring the brain oxygen levels back to normal. The study believes this close monitoring and ICU intervention to improve brain oxygen levels will reduce the amount of death/disability 6 months after injury.
Reason for Declaration:	The consent declaration is requested for the processing of personal data for this specific study (i.e., collection, transfer, analysis, storage) of the participants as they will lack decision-making capacity. The patient population for BONANZA are those who have suffered a severe traumatic brain injury, and as such will lack capacity to give informed consent on enrolment into the trial due to injury sustained. A process of deferred proxy assent will be implemented; due to the emergency nature of the study, it will not be possible to obtain proxy assent before study enrolment/data processing. Deferred proxy assent will be obtained as soon as possible and consent to continue will be sought from the participant if they regain 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 to request further information from the Applicant.

	Public interest case and participant groups. • The HRCDC discussed the study aims and objectives and data processing activities. Based on the information provided the HRCDC was of the view that there is public interest in this research study. • However, from the responses provided, including the study information leaflets, the HRCDC noted that brain oxygen monitoring, alongside brain pressure monitoring, is already used as part of patient care in Beaumont Hospital, while it is not part of the normal care in other hospitals involved in the study. According to the reply from the Applicant, the current use of brain oxygen monitoring in Beaumont for clinical care is based on clinical preference. • It was noted that participants recruited to the study would be assigned to one of two study groups (i) the optimisation strategy group that involves both brain pressure and brain oxygen monitoring and (ii) the control strategy that involved brain pressure monitoring alone. Based on this information, the HRCDC commented that participants recruited to the study's control strategy in Beaumont may not receive brain oxygen monitoring that would otherwise be used if clinically preferred and therefore may be at a disadvantage as a result of their enrolment in the trial. To fully determine the degree of public interest of this specific study, the HRCDC wishes to seek further informaiton from the Applicant on this matter. **Public and patient involvement (PPI)** • The HRCDC noted the initial replies from the Applicant/data controller with regards the PPI engagement that has been undertaken. It was commented that the Applicant's later replies provided more information on the PPI engagement that has occurred with regards this particular study. **Study data and proxy assent process** • The responses provided by the Applicant confirmed that in the event deferred proxy assent or consent to continue is not obtained, only data on participant month/year of birth and sex would have been transferred/uploaded to the study database. It was queried why this data would be transferred in the absence of proxy assent or participant consent. **Study Information Leaflets** • It was noted that the consent to continue form for those who regain capacity, could make it clearer whether their treatment has already been completed by the time they are asked to provide consent. It was also commented that the study documents could provide further details on the personal data that would be processed. • The HRCDC commented that the section on future use within the assent/consent documents was not clear and did not seem to outline any specific purpose as it simply states '*The results of this study may be used to inform future research'.*

	• The legal basis mentioned in the study information document was noted to be confusing, appearing to combine two different legal bases i.e., legitimate public interest. • The HRCDC also commented on the use of language within the proxy assent documents such as '*Are you aware of any objections your relative had to being included'*, seeking '*permission*' from the relative/next-of-kin, asking for relative assent to contact the participant. In addition, the use of the terms 'optimisation strategy' and 'standard strategy' to describe the two different intervention groups were discussed and that it would have the potential to cause confusion. • Linked to the matter on brain oxygen monitoring already being part of care in Beaumont Hospital, subject to the response provided by the Applicant, it was discussed that the study information leaflets will need to clearly highlight whether participants enrolled to the study may be included in the control group strategy and therefore they would not be receiving brain oxygen monitoring that is part of normal care in Beaumont Hospital. **Other:** • The HRCDC queried if proxy assent would only be obtained from a relative of the participant or whether proxy assent could be obtained from another suitable individual who understands their will and preferences if they do not have a relative. • It was discussed that the required data agreements and arrangements would need to be in place, including agreements/arrangements for sharing data outside the EEA. It was discussed that while the data may not be directly identifiable to researchers who do not have access to the master list, it remains pseudonymised. • The HRCDC also noted and agreed with technical and more standard safeguards that may need to be considered by the Committee, including that Beaumont must be jointly responsible for compliance if a consent declaration is made, clarity on the scope of any consent declaration made and seeking assent/consent to continue to process data if a participant is withdrawn.
HRCDC Decision:	The consensus of the HRCDC was to request further information from the applicant.
Request for further information:	**Query 1.** • From the information provided, brain oxygen monitoring, alongside brain pressure monitoring, is already used as part of patient care in Beaumont Hospital, while it is not part of the normal care in other hospitals involved in the study. According to the reply from the Applicant, the current use of brain oxygen monitoring in Beaumont for clinical care is based on clinical preference. Participants recruited to the study would be assigned to one of two groups (i) the optimisation strategy group that involves both brain pressure and brain oxygen monitoring and (ii) the control

	strategy that involved brain pressure monitoring alone. Based on this information, participants recruited to the study's control strategy in Beaumont may therefore not receive brain oxygen monitoring that may otherwise be utilised if clinically preferred and if they were not enrolled onto this study. The Applicant is requested to respond directly the following: (a) Please explicitly confirm if the use of brain oxygen monitoring alongside brain pressure monitoring, is part of the normal care of patients with brain injury in Beaumont Hospital; if yes, please also outline the proportion of these patients treated in Beaumont who would receive both brain oxygen and pressure monitoring (i.e., 25%, 50%, all patients etc.). versus those who would not receive brain oxygen monitoring. (b) If the use of brain oxygen monitoring is based primarily on the preference of the treating clinician, then please provide more information on this. (c) Subject to your response to point (a) and (b) above, where the use of brain oxygen monitoring alongside pressure monitoring may be part of normal patient care, please expand on the public interest case, specifically for participants from the Irish site, for this study, in the context that eligible participants from the Irish site may then not receive brain oxygen monitoring because of their enrolment. In answering this question please also refer to whether a participant, from the Irish site, may be at a disadvantage as a result of being enrolled into this study if they are enrolled into the control strategy group. **Query 2.** Please also provide informaiton on the following points: - confirm if proxy assent on behalf of the participant who lacks decision-making capacity would only be obtained from their next-of-kin or relative, or whether proxy assent could be obtained from another suitable individual who understands their will and preferences, if they do not have a relative or next-of-kin. - in the event deferred proxy assent or consent to continue is not obtained, only data on participant month/year of birth and sex would have been transferred/uploaded to the study database – no other data would be processed. Please outline why this data would still be transferred in the absence of proxy assent or participant consent.

7. Annual Reviews

No Annual Reviews were noted as completed. Annual Reviews have been received and reviewed; however, some additional information is required from the Applicants.

8. HRCDC Annual Report 2023

The final designed Annual Report for 2023 was circulated and approved by the HRCDC. The report will be furnished to the Minster and uploaded to the HRCDC website shortly.

9. Activities report and events of interest.

The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting. The following upcoming events of interest where also noted:

- **HRB NCTO International Clinical Trials Day Conference:** Thursday 9th May, O'Reilly Hall, UCD (9am-4:30pm) https://www.eventbrite.ie/e/international-clinical-trials-day-conference-2024-tickets-852306841707?aff=oddtdtcreator
- **Save the date - Irish Health Research Forum:** Thursday May 16th, Aisling Hotel Dublin. Invites to be issued in the coming weeks. The Secretariat will forward these on when available.

10. Any Other Business

- **19-023-AF2/AMD2** (*Effect of naïve and pre-activated MSCs on monocyte/ macrophage function in patients with pulmonary and non-pulmonary sepsis):* the HRCDC was informed that this amendment that was considered at the meeting of 9th May 2023 and where the HRCDC had requested further information, has been withdrawn by the Applicant. It was also confirmed that the consent declaration for 19-023-AF2 is no longer required.
- **Decision Time:** the Secretariat informed the HRCDC of important upcoming changes to the security features of Decision Time.

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