HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting – APPROVED

Date: 25th June 2024

Location: Zoom Videoconference

HRCDC Attendance:

Brigid McManus
Evelyn Mahon
Alyson Bailey
Sheelah Connolly
Simon Furney
Aideen Hartney
Zubair Kabir
Dan Rea
Barry Lyons
Patricia O'Beirne
Susan Smith
Paul Stynes
Aisling McMahon
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

New Applications – For consideration

Applicant: Prof Alistair Nichol
Ref No: 24-003-AF1
Title: Early Sedation with Dexmedetomidine vs. Placebo in Older Ventilated Critically Ill Patients (SPICE IV)

Returning Applications – For consideration

Applicant: Dr Vincenzo Russotto
Ref No: 24-007-AF1
Title: International observational study on airway management in operating room and non-operating room anaesthesia (STARGATE)

Opening

The Chair opened the meeting and welcomed the members.

Apologies

Cornelius Cooney, John Woods, Kathy Brickell, Mary Tumelty (Maternity Leave).

Disclosure of Interest

Aisling McMahon (AM) noted that she was a collaborator on other studies with Principal Investigators from 24-003-AF1 (SPICE IV) and 24-007-AF1 (STARGATE). It was agreed that AM did not need to be absent during these items in the meeting and that AM would be invited to comment last on these items.

Minutes of the last meeting

Draft minutes of 28th May 2024 were circulated in advance of the meeting and were approved by the HRCDC.

Updates on previous applications

24-001-AF1: Exploring MALDI-TOF MS data to improve the diagnosis and treatment of Staphylococcus aureus bacteraemia.

- The HRCDC were provided with an overview of the responses submitted to date from the applicant on the efforts made to enhance transparency measures beyond hospital notices, as requested in Condition 1 that was attached to the consent declaration. In their responses the Applicant had outlined that they had contacted relevant parties to request that information on this study be provided/disseminated by other channels such as social media and email bulletins; evidence of this communication was submitted to the Secretariat. Unfortunately, despite their efforts, the Applicant was unable to enhance the study transparency measures.
- The HRCDC discussed the replies from the Applicant, including the responses they received when they sought to utilise social media and email bulletins. It was noted that the Applicant had made efforts to try and meet Condition 1 and was engaging with the Secretariat on this matter since the declaration was made.
- The HRCDC accepted the response from the Applicant on Condition 1. They also commented that they should explore if other avenues for enhancing transparency could be implemented during the course of the study, for example sharing information on the study and/or study findings with relevant advocacy groups.

New Applications

Reference ID:

24-003-AF1

Lead Applicant:

Prof Alistair Nichol

Lead Data Controller:

Monash University

Title:

Early Sedation with Dexmedetomidine vs. Placebo in Older Ventilated Critically Ill Patients (SPICE IV)

Research Objective:

Most ICU patients who need a breathing machine (ventilator) to help them breathe require sedation with one or more sedative (calming) drugs, given as continuous drip into a vein. Currently, there is no agreement amongst doctors around the world about the best choice of sedative drug or the best way to manage sedation. Many of the commonly used sedative drugs have side effects and are thought to be associated with longer time on the ventilator, longer stay in the ICU, leading to delirium (a confused state often including hallucinations) and decreased mental awareness after recovery from critical illness. Dexmedetomidine is a commonly used sedative drugs that can be used alone or in combination, to keep ICU patients comfortable while on a ventilator. The purpose of this study is to evaluate dexmedetomidine, which might improve survival and recovery for older patients who require sedation in ICU.

Points to Discuss:

Please see HRCDC meeting minutes of 30th April 2024.
A consent declaration was made for 24-003-AF1 (SPICE IV) on 30th April 2024, with the decision letter issued on 7th May 2024.
Regulation 9 of the Health Research Regulations sets out the following: 'A person who has been notified by the Committee that a declaration has been made in respect of his or her application under these Regulations shall confirm in writing to the Committee his or her acceptance of the declaration within 30 working days of the date of the notification of the decision and where such confirmation is not received by the Committee within that period the declaration shall lapse'.
The Applicant did not provide confirmation that they accepted the HRCDC's decision within the prescribed 30 working day and therefore the consent declaration has lapsed, as per the Health Research Regulations.
The HRCDC were asked to issue a new consent declaration on the same terms as the original decision for the SPICE IV study. The Applicant confirmed, post-30-day deadline, that they accept the HRCDC's decision and the attached conditions. The HRCDC were also informed that the study remains unchanged, and the conditions attached to consent declaration would remain unchanged.

HRCDC Comments:

The HRCDC noted why it was requested to issue a new consent declaration for the SPICE IV study. The communication between the Applicant and the Secretariat was outlined during the meeting.
The HRCDC issued a new consent declaration for the SPICE IV study, with the same scope and conditions that were attached to the original declaration applying. It was also noted that the Applicant would have to formally confirm acceptance of this re-confirmed declaration within the required 30 working deadline.

Returning Applications

Reference ID:

24-007-AF1

Lead Applicant:

Dr Vincenzo Russotto

HRCDC
Health Research Consent Declaration Committee

Lead Data Controller:
University of Torino

Title:
International observational study on airway management in operating room and non-operating room anaesthesia - STARGATE.

Research Objective:
Please see HRCDC minutes of 28th May 2024.

Reason for Declaration:
Please see HRCDC minutes of 28th May 2024.

HRCDC Comments:
The Chairperson introduced the study and noted the HRCDC's request for further information and provided an overview of the Applicant's response. Based on the information provided and following an in-depth discussion, it was the decision of the HRCDC that a consent declaration, subject to conditions, could be made.

Study bias
- As part of their replies to the HRCDC's request for further information, the Applicant further stated that requesting consent could impact the scientific integrity of the study by potentially introducing a risk of population and study bias. The Applicant submitted supplemental journal articles on this matter to the HRCDC.
- The HRCDC reviewed the information provided by the Applicant. The HRCDC did not accept the Applicant's rationale that requiring informed consent would create additional issues with regards study and population bias. In the discussion, members noted the nature of the population sampling within this study which is based on first-come patient model. Some members also noted that the supplementary articles were related to a patient register and a review of 17 studies on bias published prior to 2008.

Participant Consent and Opt-out
- The HRCDC discussed the Applicant's replies to its queries on whether, where feasible, efforts can be made to approach patients and seek their explicit consent, or deferred consent, before or after their surgical procedure. The HRCDC also noted and discussed some additional information that was provided on the proposed opt-out process that the study would implement, however it was commented that a robust protocol on the opt-out process was not detailed.
- The Applicant also stated that it was not clear how they could seek consent prior to enrolment into the study due to logistical issues, specifically that the patients enrolled into the study will be treated in multiple locations in the hospital. On the matter of seeking deferred consent after the patient has undergone their procedure, the Applicant also outlined that many patients will likely be day cases and may only spend a relatively short time in hospital; however, their replies indicated that deferred consent may be possible in some cases.
- It was the consensus of the HRCDC that there is a public interest in this international study, and it was commented that the clinical data to be collected and processed is that generated

from standard care and treatment, but at more regular intervals. However, the HRCDC was of the view that there will likely be opportunities where it would be practicable for the study to attempt to obtain deferred participant consent at an appropriate time following their surgical procedure, and that it would be appropriate to do so in the context of this research; it was the consensus of the HRCDC that seeking deferred participant consent for data processing should also be the default where this it is possible. Therefore, the HRCDC determined that the study must develop a process for obtaining deferred consent, with the aim of seeking to obtain deferred consent from as many of the 50 study participants as possible.

- Where efforts to obtain deferred consent are not successful, the HRCDC consensus was that a clear opt-out process should then be implemented, offering such participant a clear option to opt-out of the study and have their personal data deleted. It was also commented that the timeline of 7 days for the participant to opt-out, as outlined by the Applicant's responses, must be 7 days, or longer where possible, from the date the participant is informed of their ability to opt-out and not 7 days from their enrolment in the study. The collected data cannot be transferred from the Irish hospital site to the data controller of the study before this minimum 7-day period lapses.
- It was the view of the HRCDC that the consent declaration will not become operational until a detailed response on the deferred consent and opt-out process is submitted and deemed satisfactory. As part of the response, the Applicant is also required to submit relevant study documents such as the deferred consent information leaflet and consent form, and the relevant opt-out process materials for the participant.
- Further to implementing a deferred consent and opt-out process, it was discussed by some HRCDC members that it could be possible, in some cases, for the study to obtain prospective consent from the patient prior to their procedure; it was also commented that doing so may, in some cases, be more convenient than implementing the deferred consent or opt-opt process. The HRCDC discussed that this should be highlighted to the Applicant and, although not a condition, it should be suggested that prospective patient consent should be sought where possible and appropriate, prior to their procedure.

HRCDC Decision:

The decision of the HRCDC was that a Consent Declaration, subject to conditions attached, should be made.

Duration of Declaration:

The consent declaration is made commencing 25th June 2024 and is valid until 31st July 2030, or until the personal data is deleted or fully anonymised.

Conditions Attached:

Condition 1.

- It is a condition of this consent declaration that the study must develop a process for obtaining deferred consent from participants who are enrolled into this study; this process should be developed with the aim of seeking to obtain deferred consent from as many of the 50 study participants as possible. It is expected that the process for seeking deferred consent will be the default procedure undertaken by this study; only where deferred consent cannot be obtained from a participant should the study then provide the individual with an option to opt-out of the study (please see bullet point below).

- For those participants whose deferred consent cannot be obtained, then the study must implement a clear opt-out mechanism, providing everyone whose deferred consent could not be obtained with an option to opt-out of the study and have their personal data deleted. The suggested timeline of 7 days for the participant to opt-out, as outlined by the Applicant's responses, must be 7 days, or longer wherever possible, from the date the participant is informed of their ability to opt-out and not 7 days, or longer wherever possible, from their enrolment in the study. The collected data cannot be transferred from the Irish hospital site to the data controller of the study before this minimum 7-day period lapses.
- The Applicant must submit a detailed protocol for seeking deferred consent and for the direct opt-out process to the HRCDC; in addition, relevant documents such as the deferred consent information leaflet and consent forms and the opt-out documents for the participant, including study informaiton leaflets, must also be submitted.

Condition 2. The Irish hospital sites must, together with the data controller University of Torino, be responsible for the implementation of and compliance with the consent declaration and data protection requirements; there should also be a point of contact in Ireland for participants if a participant has queries or otherwise wishes to exercise their rights.

Condition 3. The required data agreements and arrangements must be in place for this study. The transfer of data between parties cannot occur prior to the necessary agreements being in place.

Annual Reviews

The Secretariat has received three annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID 20-027-AF1**: Immune Dysfunction in Acute Brain Injury
- **Ref ID 19-021-AF1:** National Self Harm Register
- **Ref ID 19-025-AF1:** Alpha-1 Register

Activities report and events of interest

The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting. The Secretariat informed the HRCDC that it observed a meeting of the UK's Confidentiality Advisory Group (CAG) and there was a brief discussion on how the CAG operated, including alternative practices the HRCDC could potentially trial at its meeting. The Secretariat will be meeting with the Health Research Authority, UK in July and will follow up on any findings at a future HRCDC meeting.

Any Other Business

- The HRCDC were provided with a draft of the accessible HRCDC minutes template that will be used for future meeting minutes to help better comply with EU accessibility standards.
- The HRCDC were informed that there is no July meeting and that the next HRCDC meeting is scheduled for 13th August 2024.

The Chair closed the meeting