

Date: 27th February 2024

Location: Zoom videoconferencing

Minutes of the Meeting

HRCDC Attendance

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

Quorum for Decisions

YES

New Amendments - For Consideration

Applicant	Ref No.	Title
Nikola Sprigg	23-019- AF1/AMD1	Tranexamic acid for hyperacute spontaneous IntraCerebral Hemorrhage (TICH-3)

Meeting Items

1. Opening

The Chair opened the meeting and welcomed the members. The Chair introduced and welcomed a new member to the HRCDC, Prof Paul Stynes, Dean of the School of Computing at the National College of Ireland.

2. Apologies

Evelyn Mahon, John Woods, Cornelius Cooney, Mary Tumelty (Maternity Leave)

3. Disclosure of Interest

- **23-019-AF1/AMD1:** Kathy Brickell (KB) had previously noted that St Vincent's University Hospital is one of the sites involved in this study, however KB confirmed that she is not involved in this study. It was agreed that there was no conflict of interest.

4. Minutes of the last meeting

Draft minutes of 30th January 2024 were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

The Secretariat confirmed that it had provided clarity to the Applicant on a recommendation that was attached to HRCDC application 23-012-AF1, as was requested by the HRCDC at 30th January 2024 meeting.

6. For discussion

19-086-AF1 (*Sepsis Immunosuppression in Critically Ill Patients*)

- Following the correspondence that was issued to the Applicant/data controller informing them that the HRCDC would consider revoking the consent declaration on the basis that the condition to undertake public and patient involvement (PPI) activities had not been satisfactorily progressed or met, the HRCDC were provided with the latest responses from the study on PPI engagement.
- The submitted replies included positive PPI feedback on this study from ICU Steps Dublin and the Irish Sepsis Foundation. In addition, the study informed the HRCDC that further PPI review and discussion of this study is scheduled to occur on 28th February, at the meeting of the St James's Hospital General PPI Committee.
- In the context of the progress that had been made to undertake PPI engagement, it was proposed and agreed that the revocation of the consent declaration would not need to be considered. Subject to the Secretariat receiving further information on the PPI engagement that is scheduled for 28th February, condition 3 could be deemed met.
- It was also discussed that a member of the research team should be involved in PPI engagement, where possible. The Applicant/data controller should therefore be asked to confirm who on the research team is included in PPI engagement activities.

General points discussed

- The HRCDC discussed that PPI engagement should be considered and undertaken by research studies in advance of submitting a consent declaration application. If this is not possible, then a clear pro-active plan or pathway for PPI engagement, including timelines, should be outlined.
- It was discussed that the PPI section of the HRCDC application forms will be reviewed to ensure it is clear on what is meant by PPI engagement and what is generally expected with regards PPI from Applicants/data controllers seeking a consent declaration
- It was noted that a review of the monitoring of attached conditions via the Annual Review process will also be undertaken by the Secretariat to help identify areas where common issues arise and whether the monitoring process can be enhanced or improved.

7. Chairperson Approvals

- **23-016-AF1/AMD1 (*PEGASUS study*)**. The Chairperson approval letter for this amendment request was uploaded to Decision Time and noted by the Committee. The approved amendment request was for the addition of the Mater Misericordiae University Hospital as another study site and as a data processor.

8. Amendments

Reference ID:	23-019-AF1/AMD1
Lead Applicant:	Nikola Sprigg
Lead Data Controller:	University of Nottingham
Title:	Tranexamic acid for hyperacute spontaneous IntraCerebral Hemorrhage (TICH-3)
Research Objective:	See HRCDC Meeting minutes of 17 th October 2023
Purpose of Amendment:	<p>Where the participant lacks decision-making capacity, the original consent declaration application outlined an assent/consent process that involves independent doctor permission followed by family/friend deferred proxy assent.</p> <p>Following the making of the consent declaration, the Applicant/data controller noted that there may be rare cases where it is not possible to obtain such deferred proxy assent and where the participant does not regain decision-making capacity. If this rare situation occurs, only the initial permission from the independent doctor permission would be obtained.</p> <p>It is requested that the scope of the consent declaration would cover the continued processing of personal data for this study in the rare situation where proxy assent from a relative/friend is not obtained despite adequate efforts being made, and only the initial permission for enrolment from the independent doctor is in place. The processing of personal data in such a scenario was not outlined in the original HRCDC application form.</p>
HRCDC Comments:	<p>The Chair requested each HRCDC member if they approved the amendment.</p> <p>The HRCDC noted the reasons outlined by the Applicant/data controller on why they wished to continue to process personal data for this study in situations where it is not possible to obtain deferred proxy assent. Based on information provided and following a detailed discussion, the consensus was that the amendment should not be approved.</p> <p>Participant cohorts and study design</p> <ul style="list-style-type: none"> • The Applicant/data controller outlined that it is important that research does not exclude populations such as those who are homeless or who are from poorer socio-economic circumstances or who have no relatives. • The HRCDC discussed the value of including the personal data of this cohort, in the context that it would already be collected up until the point where it was determined by the researchers that deferred proxy assent cannot not be obtained. • The HRCDC also discussed and considered that this study aims to investigate the efficacy of a treatment for hyperacute spontaneous Intracerebral Haemorrhage patients. It was commented that is the study is not designed to draw out information on vulnerable or marginalised participant cohorts and whether they experienced better, or worse treatment outcomes compared to other cohorts who are enrolled in this research. • Overall, in this context the public interest case for processing the personal data of this cohort was not deemed to be strong when

	<p>balanced against the data rights and the need for appropriate safeguards.</p> <p>Study bias</p> <ul style="list-style-type: none"> • The Applicant/data controller stated that not processing the data of this cohort could bias the result of the trial and this was also discussed by the HRCDC. • In its discussion, the HRCDC also noted the response from the Applicant/data controller outlining that it would be a rare scenario where deferred proxy assent cannot be obtained and where the participant does not regain decision making capacity. In this context, it would seem that the effect of omitting the data of the participant cohort in question might not be significant. <p>Proxy assent safeguard</p> <ul style="list-style-type: none"> • It was commented that proxy assent from an individual who understands the will and preferences of the participant who lacks capacity, such as a relative, is an important data protection safeguard. It was noted that relying only on the permission of an independent doctor is not a process that is typically undertaken in studies in Ireland. In addition, while some participants may be deemed to be more vulnerable or marginalised, the HRCDC would not want different cohorts of participants to be treated differently in terms of the process for determining their will and preferences. • It was also mentioned that a specific protocol for when proxy assent could not be obtained was not specifically outlined by the Applicant/data controller. <p>Public interest</p> <ul style="list-style-type: none"> • While the reasons outlined by the Applicant/data controller for seeking to process the personal data of this small cohort were acknowledged, it was the view of the HRCDC that there isn't sufficient public interest to approve the amendment request, when weighing the public interest against the importance of ensuring that the will and preferences of participants is being taken into account via obtaining proxy assent from a suitable individual such as a relative.
<p>HRCDC Consensus:</p>	<p>The consensus of the HRCDC at the meeting was that the amendment should not be approved.</p> <p>Following the meeting, the HRCDC secretariat, in reviewing previous applications, noted additional information that was relevant to the application (23-019/AMD1).</p> <p>In light of the fact that the Committee was not in a position to review this information at the time of this meeting, it was agreed the application would be further discussed at the March meeting, in advance of a final decision being made</p>

9. HRCDC Annual Report 2023

An updated version of the HRCDC Annual Report for 2023, encompassing the feedback that was received following the January meeting, was circulated to the HRCDC. At the meeting some additional feedback and comments on the Annual Report were provided. The Secretariat will update the draft text based on the feedback from the meeting. The report will then be forwarded to the proof-reader and designer. Once finalised the completed, designed report will be circulated to the HRCDC for final feedback and sign-off in advance of the 31st March deadline.

10. HRCDC SOPs and HRCDC Website

- **SOPs:** The HRCDC were provided with the latest version of the HRCDC Standard Operating Procedures. Members had additional minor comments and feedback that they would forward to the Secretariat after the meeting. Subject to making these minor amendments and that no further material changes arise, the HRCDC agreed that the revised SOPs are approved. The final version will be uploaded to the HRCDC website.
- **Website document:** The updated document for the HRCDC website detailing the commonly occurring issues that the HRCDC identities in study information leaflets and assent/consent forms was circulated to the HRCDC in advance of the meeting. There was a brief discussion relating to the point on future research and issues raised by certain applications. It was discussed that this website document is a living document that will be reviewed and updated over time.
The Secretariat also noted that this document will be presented as helpful guidance for researchers but is not considered legal advice; this will be made clear when it is uploaded to the HRCDC website.
The HRCDC approved this document, and it was confirmed that will be published on the HRCDC website in the coming days.

11. Annual Reviews

The Secretariat has received 3 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID: 19-045-AF2;** Sharon O'Toole, *The Gynaecological cancer bioresource (DISCOVERY Bioresource)*
- **Ref ID: 20-012-AF1/COV;** Clíona Ní Cheallaigh, *COVID-19 Bioresource [Note: Declaration no longer required]*
- **Ref ID: 22-013-AF1;** David Williams, *Maximising equity and accessibility of acute stroke care pathways in Ireland (Part C): Patient outcome and experience.*

12. Activities report and events of interest

- The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting. The Secretariat gave a brief update on recent and upcoming events.
- The Secretariat also informed the HRCDC that it has scheduled information sessions on the consent declaration application process for researchers and DPOs in both March and April 2024. Subject to demand, additional sessions may also be held later in the year, including sessions outside of Dublin.

- The following upcoming event of interest was also noted: Webinar: 'Let's Talk Ethics: Ethics Committees and Patient Engagement'; Wednesday 28th February 2024, 14:30 to 16:00. Link to register: <https://patientengagement.synapseconnect.org/events/lets-talk-ethics-ethics-committees-and-patient-engagement>.

13. Any Other Business

- N/A

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

APPROVED