HRCDC
Health Research Consent Declaration Committee

# Minutes of the Meeting – APPROVED

**Date**: 10th December 2024

**Location:** Zoom video conferencing

## HRCDC Attendance:

Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Sheelah Connolly
Aideen Hartney
Zubair Kabir
Dan Rea
Mary Tumelty
John Woods
Patricia O'Beirne
Susan Smith
Paul Stynes
Aisling McMahon
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

## Quorum for Decisions

**YES**

### New Amendments - For Consideration

**Applicant:** Emily Changa
**Ref No.:** 23-010-AF1/AMD1
**Title:** ESsCAPE Trial

### New Applications – For consideration

**Applicant:** Lorraine Schwanberg
**Ref No.:** 24-013-AF1
**Title:** Learning from Incidences

**Applicant:** Dr Patrick O'Sullivan & Prof Alistair Nichol
**Ref No.:** 24-014-AF1
**Title:** AIRWAYS-3

***Note:*** due to time constraints, new application 24-014-AF1 was deferred to the next HRCDC meeting.

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## Opening

The Chair opened the meeting and welcomed the members. The HRCDC were reminded that the pilot process of primary and secondary reviewers is being undertaken at today's meeting.

## Apologies

Cornelius Cooney, Simon Furney, Barry Lyons

## Disclosure of Interest

- Kathy Brickell (KB) declared an interest in applications 24-012-AF1, 23-010-AF1/AMD1 and 24-014-AF1 application. It was agreed that KB would be absent when these items are considered.
- Aisling McMahon (AMcM) declared an interest in application 23-010-AF1/AMD1 and also noted that she had previously collaborated with the researcher noted on 24-014-AF1, however she is not involved in this specific study. It was agreed that AMcM would be absent during the discussion for 23-010-AF1/AMD1. For application 24-014-AF1, it was the consensus that AMcM did not need to be absent when this agenda item is considered.

## Minutes of the last meeting

Draft minutes of 12th November 2024 were circulated in advance of the meeting and were approved by the HRCDC, subject to the correction of a minor typo.

## Matters arising

- **COI policy**: following the discussion on the conflict-of-interest policy from the November meeting, where a HRCDC member may have commercial/competitive interest and where the documentation circulated might contain pertinent commercial or competitive information, it was discussed that the HRCDC member concerned should inform the Secretariat so that the permissions to view the relevant documents can be removed.
- **24-012-AF1 (Platelets study):** the HRCDC were provided with an update on the discussion with Applicant on whether the participant is informed about the threshold treatment they received in this study.
- **24-010-AF1 (AfterROSC2):** the HRCDC were provided with an update on their request for further information from the November meeting. It was noted that the Applicant is in the process of addressing the HRCDC's queries.

## Chairperson Approvals

- **Ref ID: 23-020-AF1/AMD2.** The HRCDC were informed that amendment request 23-020-AF1/AMD2 was approved via the Chairperson approval process. The amendment covers the extension of the consent declaration until 31st December 2034 to cover future waves/cohorts for this study.

- **Ref ID: 19-006-AF3/AMD2.** The HRCDC were informed that amendment request 19-006-AF3-AMD2 was approved via the Chairperson approval process. The amendment covers the extension of the consent declaration until 31st December 2025.

## New Amendments

### Reference ID:
23-010-AF1/AMD1

### Lead Applicant:
Emily Changa

### Lead Data Controller:
Biotest AG

### Title:
ESsCAPE Trial

### Research Objective:
See HRCDC Meeting minutes of 22nd August 2023

### Purpose of Amendment:
The amendment is requested to include independent doctor proxy assent.

### HRCDC Discussions:
Alyson Bailey was assigned as the Primary Reviewer for this application; John Woods and Aideen Hartney were assigned as the Secondary Reviewers.
The Chairperson requested the primary and secondary reviewers to outline the proposal contained in the amendment and any issues arising. There was then a discussion on the amendment application by the HRCDC.
Following detailed discussions, it was the consensus of the HRCDC that the amendment request should be approved.

**Assent/consent process:**
- It was noted that a condition was attached to the original consent declaration for 23-010-AF1 that proxy assent for data processing as a safeguard should be sought from a relative/friend and not an independent doctor.
- The Applicant outlined the reasons why they were requesting an amendment to cover proxy assent from an independent doctor, specifically, while the default process will be to obtain proxy assent from the relative/friend prior to enrolment, the study treatment intervention needs to be administered within a 24-hour window. For some participants, it may not be possible to obtain relative/friend proxy assent within this timeframe. If proxy assent cannot be obtained from the relative/friend, it will be sought from an independent doctor. It was noted that the Clinical Trials Regulations allow for an independent doctor to provide permission to enrol and treat a patient in a trial and that ethics approval for this has been obtained.
- The HRCDC discussed the process for identifying an independent doctor to seek proxy assent. It was commented that a clear and consistent process for identifying an independent doctor should be in place at the local Irish sites if proxy assent from a relative/friend cannot be obtained in the first instance.

- The HRCDC further discussed if, after obtaining independent doctor assent, efforts would be made to continue to seek proxy assent from a relative/friend before data is transferred.

**Study Information Leaflets**

- It was noted that the same study documents are used when requesting proxy assent from the relative/friend and from an independent doctor.
- It was discussed it is important to outline and be clear in the study documents that data will be transferred outside the EEA and acknowledge the potential risks for such transfer, however the documents should be clear that it is not requesting or suggesting that the independent doctor is being asked to waive the participants data rights and protections. It was discussed that proxy assent can be considered an appropriate data safeguard; however, no one can consent to data processing or waive a participant's data protection rights other than the participant themselves. Accordingly, the HRCDC was of the view that some sections of the study documents should be revised to reflect this.
- It was also discussed that the study documents use the term 'consent' rather than 'assent' when referring to seeking permission from the relative/friend or independent doctor. It was acknowledged that the term 'consent' is accurate with regards the relative/friend or independent doctor providing permission to enrol a participant onto the trial, although it is not 'consent' for the data processing, but proxy assent as a data safeguard. It was commented that the use of assent rather than consent could be reviewed and considered by the Applicant.

**Withdrawal**

- It was noted that the study withdrawal form provided, outlines that the data and associated samples collected to date will continue to be used in this study unless the participant requests for them to be deleted/destroyed; however, the HRCDC noted that the withdrawal form does not provide an option for the participant to confirm if they want their data and samples deleted/destroyed.

**Other**

- It was not clear from the amendment application what efforts would be made to obtain assent from a relative/friend following initial assent from an independent doctor, and it was commented that it would have been beneficial to get a sense of how many participants the Applicant envisioned would require independent doctor assent in the absence of relative/friend assent.

## HRCDC Decision:

The consensus of the HRCDC was that the amendment request should be approved, subject to conditions.

## Conditions Attached:

**Condition 1.** With regards data processing, seeking proxy assent from a relative/friend in the first instance must continue to be the default. Where this is not possible and independent doctor permission is therefore obtained in the first instance, then the study should continue to make reasonable efforts to obtain proxy assent from a relative/friend or, if they regain decision-making capacity, the participant's consent to continue. The personal/ pseudonymised data collected for the study where only independent doctor assent has been obtained and where the participant continues to lack capacity, should not be uploaded/transferred from the hospital site until sufficient efforts are made to obtain proxy

assent from the relative. For clarity, if proxy assent from a relative/friend cannot be obtained after sufficient efforts are made, then the data can be transferred from the hospital site and analysed for this study.
As part of the Annual Review, the Applicant is requested to report on the number of participants in Ireland (as a proportion of total participants in Ireland) where data processing is taking place on the basis of independent doctor assent in the absence of deferred assent from the participant relative/friend proxy assent.

**Condition 2.** A clear and consistent process for identifying an independent doctor should be in place and implemented at the local Irish sites if proxy assent from a relative/friend cannot be obtained.

## HRCDC Recommendations:

**Recommendation 1.** The following references are made regarding the transfer of data outside the EU or EEA in the study information leaflet and assent/consent form for the independent doctor:

- *'The provision of your personal data is voluntary. However, you cannot participate in this study without your express consent to the processing of your data'.*
- *'Your coded data can only be transferred to these countries if you have expressly consented to this. Without your explicit consent to the transfer of your data to countries without an adequacy decision and appropriate safeguards, you cannot participate in this clinical research study'.*

The following references are also made towards the end of the study information leaflet and assent/consent form for the independent doctor, in the section entitled 'Data protection consent' under point 2, followed by 'tick-boxes' and the signature section.

- *'I have been informed that my data may also be transferred to people and organizations outside my country and the European Union (EU) or the European Economic Area (EEA), where personal data protection laws may be less constraining than those in my own country or in the EU or EEA. I have been informed that I cannot participate in this study without my consent to the transfer of my data to these countries'*
- *'I expressly consent to the transfer of my data to countries outside my country and the European Union and the European Economic Area where the protection of my data cannot be guaranteed in a comparable manner. I am aware of the considerable personal disadvantages that such a transfer of data may entail'*
- *'I understand I cannot participate in this study, or my data cannot be processed if my permission/consent is not provided for this transfer'*

It is important that the independent doctor is informed that data will be transferred to other counties/parties and that there may be risks; however the wording of the above references suggest that the independent doctor is being asked to agree to 'waive' the data rights and protections of the participant who lacks decision-making capacity with regards the transfer of their data to third countries outside the EEA - a data subject's rights and protections cannot be waived by an independent doctor.
The Applicant is therefore requested, at the next available opportunity, to amend the study document for the independent doctor so that they are not asked to waive the data rights and

protections of the participant who lacks capacity with regards the transfer of data outside the EEA.

**Recommendation 2.** The independent doctor/relative/friend study documents use the term 'consent' rather than 'assent' when referring to seeking permission from the relative/friend or independent doctor with regards data processing The term 'consent' is accurate with regards the relative/friend or independent doctor providing permission to enrol a participant onto the trial, although it is not 'consent' for the data processing but proxy 'assent' as a data safeguard. It was commented that the use of 'assent' rather than consent could be reviewed and considered by the Applicant to avoid confusion.

**Recommendation 3.** The study withdrawal from provided, outlines that the data and associated samples collected to date will continue to be used in this study unless the participant requests for them to be deleted/destroyed; however, it is noted that the withdrawal form does not provide an actual option for the participant to confirm if they want their data and samples deleted/destroyed; this should be considered

## New Applications

### Reference ID:
24-013-AF1

### Lead Applicant:
Lorraine Schwanberg

### Lead Data Controller:
Health Service Executive and Trinity College Dublin

### Title:
Learning from Incidences – a mixed method study of incident reviews

### Research Objective:
The Health Service Executive (HSE) is seeking to optimise its learning function from incident reporting. Since the revision of the Incident Management Framework (IMF) in 2018, the HSE has further broadened its scope in terms of investigative tools. In particular, the HSE strives to better understand how, and how well the learning is extracted and applied from the incident management review process. Thus, the revised IMF (2020) defines a 6-step incident management process. Step 6 focuses on the "Improvement Planning and Monitoring", that involves developing and monitoring an action plan and sharing learning within and across the service. The purpose of the study is to evaluate the effectiveness of the different incident review methods in embedding the 6 principles of the IMF, explore staff, patient/service user and family/ carers experiences in incident reviews and to evaluate and improve the human factors analysis (e.g. fatigue, poor procedures, understaffing etc. that contributed to an incident), in a systematic and comprehensive way. In addition, to evaluate and improve the recommendation generation in incident reviews to determine whether recommendations are clearly based on the contributory factors that have been identified and address them effectively.

## Reason for Declaration:

Consent will be obtained for the personal data obtained via the participant survey and interview stages; however, consent will not be obtained for Stage C of the study i.e., processing personal data from the incidence reports. 200 incident reviews/reports will be extracted from NIMS and each report could involve the data of at least 6 people including the patient, staff, family members and others. The applicant outlines the reasons why consent cannot be obtained including the number of individuals involved.

## HRCDC Discussion:

Sheelah Connolly was assigned as the Primary Reviewer for this application; Kathy Brickell and Patricia O'Beirne were assigned as the Secondary Reviewers.
The Chairperson requested the primary and secondary reviewers to outline the proposal contained in the application and any issues arising. There was then a discussion on the application by the HRCDC.
Following detailed discussions, it was the consensus of the HRCDC that a consent declaration should be made, subject to conditions attached.

### Public interest case

- The HRCDC discussed the study activities, aims and objectives. On balance, it was the view of the HRCDC that there is a strong public interest case in this research; it was commented that there could potentially be great benefits arising from this study and that it would be important for patients, the public and the health service in better understanding learnings from incident reports.
- While it was the consensus of the HRCDC that there is a strong public interest case, the HRCDC also considered that this study involves the processing of quite a large volume of data and that this data was sensitive in nature. There were significant concerns raised about sensitive data relating to staff being processed and the possible data identification risks, even with the data being pseudonymised; there were also concerns raised that no engagement with staff had occurred to date.

### Consent

- It was highlighted that the study will extract the NIMS reports and invite the individuals involved in the report to complete a survey and an interview; the Applicant confirmed that consent will be sought for the surveys and interviews.
- The HRCDC discussed the Applicant's rationales for why consent cannot practicably be obtained for the processing of data from the NIMS reports; the Applicant outlined that many of the individuals will be lost to follow-up as the reports go back to up to 5 years and that it is important that the study is able to include all the reports in its sample. The HRCDC noted this and on balance it was of the view that it would not be mandatory to obtain consent for the use of the NIMS reports.
- It was also commented that consideration should be given to exploring if a consent mechanism could be added to NIMS reports to allow individuals to consent for the use of their NIMS data in future health studies.

## Transparency

- On the transparency measures, the Applicant's response is that the information leaflets for the survey and interview will be updated to state that the research team will also be analysing the NIMS review report associated with that individual and that they can contact the study for more information. It was discussed that the survey and interview information leaflets must make it clear that personal/pseudonymised data from the NIMS reports will be processed in this study, including transferred to Trinity College.
- In addition, information must also be provided regarding the data rights of the individual and how they can exercise their rights; this includes clearly outlining that they can request that their information within the NIMS incident review is not included in this study, who to contact to request this and outline what limits there could be to such rights e.g., is there a point where they can no longer request their NIMS data to be excluded from the study.
- It was further commented that individuals may not engage with or see the information leaflets for the survey and interview. It was therefore discussed that transparency measures should be further enhanced such as providing information about this study and data rights on the HSE website.
- On the information leaflets for the survey, it was also noted that the leaflet states that individuals will be asked to confirm their willingness to take part in the survey by email, a survey link will be sent, and that consent to participate in the survey will be deemed given on completion of the online survey. While the processing of the survey and interview data is not within the scope of this consent declaration, it was discussed that this description may be confusing and that the information leaflets must provide clear information to individuals on the consent process.
- It was further noted that there is missing information on the information leaflets.

## Stakeholder engagement

- The HRCDC noted the replies from the Applicant on the public and patient involvement undertaken to date; it was outlined that a patient group had been contacted and a meeting held with one of their patient representatives to provide an overview of the study. It was noted that further engagements are planned, and it was commented that PPI engagement should be undertaken during the study, where practicable, such as with those who complete the study interviews.
- In addition, the HRCDC was of the view that it is important that there is engagement with health service staff about this research, not just patients, and that this should occur prior to the study progressing, given the sensitive nature of the data involved.

## Other:

- It was noted that the data would be pseudonymised before it is transferred to Trinity College, including the NIMS reports. However, it was also noted that even after pseudonymisation, the reports may be identifiable due to the nature of their content. It was commented that the study could consider having a 'gatekeeper' check the data before it is transferred to ensure it is pseudonymised to be best extent possible and to limit the risk that the information may be identifiable.

- The HRCDC noted the data transfer process, and it was queried if this process involving sharepoint was sufficiently secure. It was commented that further details could be provided by the applicant on the security measures in the Annual Review.
- It was confirmed that the data collected for this study will be deleted after the archiving period.

## 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 until **10th December 2033** (2 years study duration and 7 years data archiving), or until the personal data is deleted or fully anonymised, whichever occurs first.

## Conditions Attached:

**Condition 1.** Based on the information provided, it is the HRCDC's understanding that all individuals from the extracted NIMS report will be contacted and asked if they wish to complete the study survey and that individuals will have the ability to withdraw such data from this research.
It is a condition of this declaration that (i) the individuals must be clearly told in the initial contact about the study survey that their information contained in the extracted NIMS report will be used in this study, including transferred to Trinity College, and (ii) that they can withdraw their NIMS data from the study; this includes clearly outlining who to contact to request this and outline what limits there could be to such rights e.g., is there a point where they can no longer request their NIMS data to be excluded from the study.
The applicant should also explore and consider if other transparency measures could be implemented, such as providing information about this study and data rights on a relevant section of the HSE website. Transparency measures should be considered as part of Condition 2 below.

**Condition 2.** As this study involves the processing of data relating to health service personnel, and given the sensitive nature of this research, it is important that there is also engagement with health service staff about this study. Matters that should be considered for discussion with staff include their views of the study, the study design as well as transparency measures and dissemination of findings. It is a condition that engagement with health service personnel is undertaken prior to the study undertaking the surveys, interviews and review of NIMS reports. The Applicant is requested to report on the progress of engagement with health service personnel (and with patients) within 4 months. Consideration should also be given to continue to undertake public and patient engagement during the study, where practicable, such as with those who complete the study interviews.

**Condition 3.** As part of the Annual Review, the Applicant must inform the HRCDC of the security arrangements in place with regards the use of Sharepoint, including considering the potential risks to the data, of human error such as sharing the data with the wrong individuals via this platform.

**Condition 4.** The required data agreements and arrangements must be in place between the study parties. Data cannot be transferred prior to such agreements being implemented.

### HRCDC Recommendations:

**Recommendation 1:** It is noted that the data would be pseudonymised before it is transferred to Trinity College, including the NIMS reports. However, it was also noted that even after pseudonymisation, the reports may be identifiable due to the nature of their content. The applicant is asked to consider having a 'gatekeeper' to check the data before it is transferred to ensure it is pseudonymised to be best extent possible and to limit the risk that the information may be identifiable.

**Recommendation 2.** Consideration should be given to exploring if a consent mechanism could be added to future NIMS reports to allow individuals to consent for the use of their NIMS data in future health studies.

## Annual Reviews

The Secretariat has received 8 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID: 21-010-AF1,** A Phase 3, Multi-Arm Multi-Stage Covariate-Adjusted Response Adaptive Randomised Trial to Determine Optimal Early Mobility Training after Stroke (AVERT DOSE)
- **Ref ID: 19-012-AF2,** Breast Cancer Proteomics and Molecular Heterogeneity
- **Ref ID: 20-005-AF1,** The All-Ireland Infectious Diseases Cohort Project (AIID Cohort)
- **Ref ID: 19-060-AF3,** National Kidney Disease Surveillance System and Quality Assurance Programme
- **Ref ID: 23-021-AF1,** Patient-Reported Outcomes in Cemented and Uncemented Total Hip Replacements*******
- **Ref ID: 20-024-AF1,** Genetics of Mortality in Critical Care (GenOMICC)
- **Ref ID: 22-012-AF1,** TRAUMA study
- **Ref ID: 19-033-AF3,** MERIT Study***

*** Declaration no longer required

## Feedback on Primary and Secondary Review Pilot

The HRCDC agreed that it would continue with the pilot review process at the next meeting in January 2025.

## Activities report and events of interest

The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting.

## Any Other Business

The Chairperson thanked the HRCDC and Secretariat for their work in 2024 and looks forward to the next meeting on Tuesday 28th January 2025.

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

*The HRCDC also attended a presentation from the CSO on the CSO Health Research Data Centre.*