HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting – APPROVED

Date: 28th January 2025

Location: Zoom videoconferencing

HRCDC Attendance:

Brigid McManus
Evelyn Mahon
Alyson Bailey
Sheelah Connolly
Dan Rea
Mary Tumelty
Barry Lyons
Patricia O'Beirne
Susan Smith
Aisling McMahon
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

Returning Applications - For Consideration

Applicant: Alain Cariou
Ref No.: 24-010-AF1
Title: AfterROSC-2

New Applications – For consideration

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

Opening

The Chair opened the meeting and welcomed the members.

Apologies

Aideen Hartney, Zubair Kabir, Simon Furney, Kathy Brickell, Cornelius Cooney, John Woods, Paul Stynes

Disclosure of Interest

Aisling McMahon (AMcM) 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 the consensus that AMcM did not need to be absent when this agenda item is considered.

Minutes of the last meeting

Draft minutes of 10th December 2024 were circulated were circulated in advance of the meeting and were approved by the HRCDC, subject to the correction of a minor typo.

Chairperson Approvals

Ref ID: 19-016-AF2/AMD1 (CERVIVA HPV Primary Screening Pilot Study): The HRCDC were informed that amendment request 19-016-AF2-AMD1 was approved via the Chairperson approval process. The amendment covers the removal of the Coombe Hospital as one of the joint data controllers of the study.

Returning Applications

Reference ID:

24-010-AF1

Lead Applicant:

Alain Cariou

Lead Data Controller:

Association AfterROSC

Title:

AfterROSC-2

Research Objective:

See HRCDC Meeting minutes of 12th November 2024.

HRCDC Comments:

The Chairperson introduced the application and outlined the HRCDC's previous decision to request further information, specifically that requested changes to the study information leaflets. The HRCDC were provided with the updated study information leaflets from the Applicant. Following discussion, it was the consensus of the HRCDC that a consent declaration, subject to conditions attached, should be made.

Study documents:

- The HRCDC was of the view that the documents had been updated to address the points outlined in its request for further information.
- It was also noted that the consent and proxy assent forms include a broad statement asking the participant/proxy to agree to allow personal data to be shared with third parties, with reference to international hospitals, and academic research institutions, for the purposes of completing the research. It was discussed that the proxy assent and consent

forms should refer to the specific parties named in the HRCDC application who will receive and process the personal/pseudonymised data i.e., the data controller Association AfterROSC
- It was noted that the term 'consent', rather than 'assent', is used in some parts of the proxy assent documentation and that it should be recommended that this is addressed.
- It was further noted that the study information leaflets reference that patients participating in studies have better outcomes than those not participating in research. It was discussed if this wording could unintentionally pressurise the proxy or the participant to agree to enrol in the study. It was commented that the wording of this statement could be reviewed and include a statement that the patient's treatment will not be affected if they don't participate in the study.

Data anonymisation:
- The Secretariat highlighted the Applicant's updated response clarifying that the personal/pseudonymised data will be fully anonymised immediately after the study concludes; personal/pseudonymised data will not be stored for 15 years after the end of the study, as was described in the Applicant's previous responses.
- The HRCDC asked for clarification on the anonymisaiton of the data so soon after the study ended; it was commented that personal/pseudonymised data would often be retained for auditing or review purposes. It was asked if REC approval was in place for this change in the period of data retention. It was discussed that the Secretariat will discuss this with the Applicant, prior to confirming the outcome of the HRCDC meeting.

Other:
- The HRCDC previously discussed that data agreements/arrangements should be in place and that the study could consider enhancing transparency measures and PPI.

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 1st January 2028, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:
Condition 1. The required data agreements and arrangements must be in place between the relevant parties prior to the sharing of data.

Condition 2. With regards the response from the Applicant that the personal/pseudonymised data from St James's Hospital will be anonymised soon after the study ends, the Applicant must ensure that if REC approval is needed for this change in data retention, that it has been obtained. The consent declaration will not be in effect until the requisite REC approval is in place.

Condition 3. The proxy assent and consent form include the following broad statement on sharing data with third parties for the purpose of the AfterROSC-2 study:

'I agree to allow personal information about my relative to be shared with third parties including, national and international hospitals, and academic research institutions for the purposes of completing the research as laid out in this information leaflet'.

Based on the responses provided by the Applicant, the only parties processing personal/pseudonymised data from Ireland for this study are St James's Hospital and the Association AfterROSC. The Applicant is therefore requested to revise/amend the above option in the proxy assent and consent forms to outline that personal data is only shared with Association AfterROSC.

HRCDC Recommendations:

Recommendation 1. The Applicant is requested to consider reviewing and amending the following points with regards the proxy assent and participant consent documentation:

- The study information leaflets reference that patients participating in studies have better outcomes than those not participating in research. The HRCDC discussed if this wording could unintentionally pressurise the proxy or the participant to agree to enrol in the study. The Applicant is therefore asked to review the wording of this statement and consider including that the patient's treatment will not be affected if they don't participate in the study.
- The term 'consent', rather than 'assent', is used in some parts of the proxy assent documentation; 'assent' rather than 'consent' should be used when referring to permission from a proxy to process the participant's personal data for health research.

Recommendation 2: The Applicant is requested to consider including if transparency measures for this study can be further enhanced; for example, by providing information on this study on relevant websites or sharing information with relevant groups. In addition, the Applicant is requested to consider if public and patient engagement can also be enhanced during this study.

New Applications

Reference ID:
24-014-AF1

Lead Applicant:
Dr Patrick O'Sullivan & Prof Alistair Nichol

Lead Data Controller:
University of Warwick & University Hospitals Bristol and Weston NHS Foundation Trust

Title:
Airways-3

Research Objective:
AIRWAYS-3 is being conducted to find out whether insertion of a supraglottic airway device is more effective than tracheal intubation for adults who have suffered a cardiac arrest in hospital. It is not known what is the best way for hospital staff to provide rescue breathing (airway management) during an in-hospital cardiac arrest, and this study will be comparing the traditionally used tracheal intubation, placing a breathing tube in the windpipe, to the

newer alternative a supraglottic airway device, which is placed just above the voice box. Patients involved in the study be allocated to one of these two types of airways management in a process called randomisation. The study will then measure and compare the degree of disability, survival and quality of life for every patient included in the trial during their hospital stay and at 3 and 6 months after the cardiac arrest.

Reason for Declaration:

Due to the nature of the medical emergency, participants will not have the capacity to provide consent; a consent declaration is requested to process their personal/pseudonymised data for the purpose of this study (i.e., collection, transfer, analysis, storage)

HRCDC Comments:

Susan Smith was assigned as the Primary Reviewer for this application, with Dan Rea and Mary Tumelty 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:

- It was the view of the HRCDC that, on balance, there is a strong public interest case in this research.

Proxy Assent and consent:

- The HRCDC noted and discussed the deferred proxy assent and participant consent to continue process that will be implemented in this study. It was the view of the HRCDC that this approach was appropriate in the context of this emergency care study.
- The HRCDC noted and discussed the response from the Applicant on who is a ‘substitute decision maker’. It was highlighted that they are someone who a family member or another proxy might wish to defer to when they are asked for proxy assent on behalf of the participant who lacks decision-making capacity.

Study information leaflets:

- It was commented that the deferred proxy and participant consent to continue information leaflets notes that the proxy or participant does not have to agree for the participant to continue to take part in the study and that they can withdraw at any time; however it was noted that the leaflets do not reference what will happen the data already collected if they do not provide assent or consent or later decide to withdraw.
- On the separate study withdrawal form, it was commented that the first page of this document provides clear information on the three options for withdrawal; however, it was further commented that the options provided on the second page, which the proxy/participant are asked to choose their preferred option, do not fully correspond with the options on page 1, and this may be confusing.
- The proxy assent form includes an option asking the proxy to provide permission for storage/use of the data for possible future research related to the current study without further consent being required. It was highlighted that the consent declaration does not

cover the processing of the data of those who lack decision-making capacity for future research studies; it will only cover the processing of data for the Airways-3 trial. It was discussed that text in the proxy assent form for future studies should therefore be updated with text previously agreed by the HRCDC.

- It was noted that proxy assent form asks: 'Do you believe your friend/relative would wish to take part in this study?'; however, the proxy information leaflet refers to participant's being included 'If there is no known objection by your relative/friend'. It was commented that this statement in the proxy study information leaflet should be reframed to ask whether the relative/friend would wish to be included in this study.
- On the section of the study information leaflets relating to data protection, it was discussed that some of the language used is quite technical and legalistic in nature and therefore the Applicant should consider if this can be reviewed and revised to provide this information in more lay-person language.
- It was commented that in addition to 'yes' and 'no' tick boxes, that some options in the assent and consent form could include a 'don't know' option as well. It was also noted that the proxy assent form refers to the proxy providing their 'consent', rather than their 'assent'.

Public and Patient Involvement:

- The HRCDC noted the Applicant's response that PPI engagement on this study had been undertaken in the UK and that, in Ireland, the study will be discussed at the next ICC-ITN PPI meeting.
- The HRCDC welcomed the PPI undertaken in the UK, however it was also commented that the Applicant could have provided more detail on this activity, including what was the feedback provided.
- On the Irish PPI engagement, the HRCDC queried if this has been undertaken yet. It was commented that it would be expected that such PPI engagement would have been undertaken already, given that the Applicant had indicated that this study would be tabled for discussion at the next ICC-CTN PPI meeting. It was discussed that PPI in Ireland should be undertaken before this study commences. It was also discussed that PPI engagement in Ireland could consider matters such as study transparency measures and dissemination of research findings.

Other:

- The UK DPIA that was submitted further made reference to the potential for extending this study; it was highlighted that the Applicant confirmed that the end date for Ireland remains December 2025.
- It was commented that the Applicant's replies on the duration of the data archiving and the duration of the consent declaration requested were not very clear; the Secretariat highlighted the reference made that the consent declaration is requested to include the archiving of personal/pseudonymised data for 10 years.
- The HRCDC also noted data agreements and arrangements should be in place and the submission of the outstanding signatures and DPO feedback.

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 31st December 2025 and for 10 years thereafter until 31st December 2035, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The required data agreements and arrangements, including joint controller arrangement, must be in place between the relevant parties prior to the sharing of data.

Condition 2. The Applicant is requested to undertake PPI engagement in Ireland with regards the AIRWAYS-3 study and to provide information about this activity, including details on the PPI feedback that was received, prior to the study commencing. The Applicant is requested to respond to this condition as soon as possible and within 2 months.

Condition 3. With regards the study information leaflets and assent/consent documents, the following points must be addressed prior to the study commencing:

- The deferred proxy and participant consent to continue information leaflets notes that the proxy or participant does not have to agree for the participant to continue to take part in the study and that they can withdraw at any time; however, it was noted that the leaflets do not reference what will happen the data already collected if they do not provide assent or consent or later decide to withdraw. It should be outlined in the PILs what will happen if assent or consent is refused or is later withdrawn i.e., that options will be provided including the option to delete the data already collected, where possible.
- On the references to future research included in the proxy assent documentation, the current text outlined in the documentation should be amended to the following: 'If my relative does not regain decision-making capacity, I give assent for my relative's material/data to be stored/used for XXX years for possible future research only related to the current study without further assent being required but only if the research is approved by a Research Ethics Committee and the Health Regulation Consent Declaration Committee (HRCDC) if required'.

Condition 4. The submitted consent declaration application form has been signed on behalf of the University of Warwick. It is a condition that the outstanding signature on the application form from the other joint data controller, the University Hospitals Bristol and Weston NHS Foundation Trust, is submitted prior to the study starting.

HRCDC Recommendations:

Recommendation 1.

- The HRCDC commented that the section of the study information leaflets relating to data protection (i.e., Section 5), uses quite technical and legalistic language. The Applicant is asked to consider if this text can be reviewed and revised to provide such information in more-lay person language, where possible. Consideration should be given to engaging with public and patient groups or individuals on this matter.

- The proxy assent form includes the statement: 'Do you believe your friend/relative would wish to take part in this study?'; however, the accompanying proxy information leaflet refers to the participant being included 'If there is no known objection by your relative/friend'. It was commented that this statement in the proxy study informaiton leaflet should be reframed more positively to ask whether the relative/friend would wish to be included in this study.

Recommendation 2: On the separate study withdrawal form, it is the view of the HRCDC that the options on the second page with regards to what will happen the data already collected and the potential continued collection of data post-withdrawal, do not fully correspond with the options on page 1, and this may be confusing. The Applicant is therefore requested to review and amend the options provided on the second page to ensure they fully correspond with the first page of the withdrawal form.

Condition replies from 19-075-AF2 (University of Galway-Saolta Cancer Biobank)

- The HRCDC were provided with an overview of the progress that has been made by the Applicant to date to address Condition 1 and Condition 2 which relate to reconsenting the breast cancer and colorectal cancer patients who have been enrolled in this biobank, and whose data and associated samples continue to be stored.
- In addition, the Applicant outlines that the biobank is committed to requesting reconsent from patients still attending the hospital for follow-up, but they do not envisage it to be practicable to contact former patients outside of their routine hospital visits for the purpose of reconsent. The reasons referenced in the correspondence on why reconsenting patients who are not attending the hospital for follow-up include causing distress for patients, resource challenges, documented research in this area and feedback from a patient liaison group
- The Secretariat is of the view that Condition 1 has been met for 2024. However, the HRCDC was asked to consider if the response provided from the Applicant is sufficient to address Condition 2. The HRCDC were reminded that the scope of the consent declaration is for the continued storage only, of the personal data of specific cohorts of patients recruited to the biobank between 1998-2008; it does not cover the further processing of the personal data in specific studies. Further processing will require a new application or amendment request to be submitted for consideration.
- The HRCDC noted and discussed the extensive work undertaken to date with regards reconsenting the relevant participants. It also noted and acknowledged the difficulties and challenges faced by this biobank in contacting participants outside of their routine hospital visits to obtain their reconsent.
- On balance, and in the context of this specific biobank and the efforts undertaken by the Applicant, the HRCDC was of the view that Condition 2 could be deemed met. It was also discussed that the biobank should continue to seek reconsent from those patients still attending the hospital for follow-up and that transparency measures for the biobank continue to be maintained, including measures outlining the data rights of participants.

HRCDC Topics for Discussions

The HRCDC were provided with a summary of proposed topics for discussion on matters that have arisen following discussions with applicants and other stakeholders. It was discussed that there may be benefits to discuss some specific topics in more detail, for example to help ensure consistency and also to help the secretariat to engage with researchers at an earlier stage with the aim of preventing issues from arising at HRCDC meetings and preventing delays. The following topics were discussed initially at this meeting:

Responsible party question in the application form:

- The HRCDC discussed the question presented in the application form that is applicable to studies where the data controller is based outside Ireland: 'If controller(s) based outside Ireland, please confirm the party/parties in Ireland responsible for implementation of the consent declaration, if made'. Feedback from Applicants state that this poses a difficulty in that one hospital site cannot be responsible for the implementation of conditions / agreements etc in another site or legal entity.
- The aim of including this question was outlined to the HRCDC; it was discussed that the purpose was to ensure that the HRCDC would have a party in Ireland that could co-ordinate with the Data Controller outside of Ireland, and who would be responsible for communications and annual review reporting.
- The HRCDC discussed this matter, and it was of the view that this wording of this section of the application form would be revised.

Public and patient involvement (PPI):

- With many international studies, PPI will be completed as part of the study design and development. This consultation will be done in countries other than Ireland. The question from applicants is whether PPI specifically from Ireland is necessary, in addition to this.
- It was discussed that public and patient involvement has been regarded by the HRCDC as an important component in the consideration of the public interest case for each application, and that it is also considered a data protection safeguard when consent from the participant cannot be obtained. It was also commented that PPI is a useful approach of helping to ensuring that documentation such as informaiton leaflets, are user-friendly to the participant and/or their proxy and that it can help enhance the dissemination of results of the research. It was further noted that PPI is important in a wider context with regards to enhancing trust and transparency in research; it was highlighted that the 2024 updates to the Declaration of Helsinki encourage more community engagement and involvement in heath research.
- It was agreed in principle that it is acceptable to submit the PPI completed outside Ireland, for international studies. If this is the case the Applicant should provide further detail on this engagement including the feedback that has been received.
- While international PPI engagement is welcomed, it was also the consensus of the HRCDC that it may still be important to see PPI conducted in Ireland in an international study, depending on the sensitivity, scope and context of the application that is being considered by the HRCDC; therefore, the need for local PPI engagement will be considered on a case-by-case basis. It was also discussed that local Irish PPI

engagement could include discussions on the consent model in place, study transparency and dissemination of research findings in Ireland.

- It was also discussed that the sections on PPI engagement in the HRCDC application forms would be revised to differentiate between international and local PPI engagement, if applicable.

Annual Reviews

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

- **Ref ID:** 19-022-AF2 (TILDA)
- **Ref ID:** 20-022-AF1 (PHIND study)
- **Ref ID:** 19-005-AF2 (SJHCB)
- **Ref ID:** 23-012-AF1 ('Research Use of Diagnostic Genomic Testing Data for Epilepsy')
- **Ref ID:** 19-045-AF2 (DISCOVARY BIORESOURCE)
- **Ref ID:** 23-019-AF1 (TICH-3)
- **Ref ID:** 19-016-AF2 (HPV CERVICA Pilot)
- **Ref ID:** 22-011-AF1 (SENSE-Cog)

Activities report and events of interest

The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting. A summary of the Expression of interest (EOI) campaign was provided. A total of 21 expressions of interest were obtained and following meetings with applicants, 6 names have been forwarded to the Minister for Health for consideration for appointment. The Chairperson thanked the Secretariat Programme Manager for the work undertaken during this EOI campaign.

2024 HRCDC Annual Report

The HRCDC were provided with a draft of the 2024 Annual Report to be submitted to the Minister for Health, as required in the Health Research Regulations. The HRCDC were asked to submit any comments or feedback they had on this draft report within two weeks.

The Chair closed the meeting