HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting – APPROVED

Date: 29th April 2025

Location: The Health Research Board

HRCDC Attendance:

Brigid McManus
Evelyn Mahon
Aideen Hartney
Patricia O'Beirne
Paul Stynes
Sarah Barnes Aabo
Jonathan Briody
Antoinette O'Connor
Jim Blighe
Ross McMullan
Barbara Clyne
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

New Applications – For consideration

Applicant: Patrick Murray
Ref No: 25-003-AF1
Title: Cirrhosis-Acute Kidney Injury Cohort Study

Opening

The Chair opened the meeting and welcomed the members. The Chair noted that, following the meeting, there will be a presentation from the Central Statistics Office on the data security of the Health Research Data Centre.

Apologies

Cornelius Cooney, Aisling McMahon, Barry Lyons, Mary Tumelty, John Woods, Susan Smith.

Disclosure of Interest

There were no disclosures of interest for this meeting.

Minutes of the last meeting

Draft minutes of 25th March 2025 were circulated in advance of the meeting and were approved by the HRCDC, subject to a minor clarification.

Chairperson Approvals

- **23-002-AF1/AMD3 (EAGER Register):** The HRCDC were informed that amendment request 23-002-AF1/AMD3 was approved via the Chairperson approval process. The amendment covers the extension of the duration of the consent declaration by 2 years.
- **22-001-AF1/CSO/AMD4 (Study of the impact of lifestyle factors on COVID-19 outcomes**): The HRCDC were informed that amendment request 22-001-AF1/CSO/AMD4 was approved via the Chairperson approval process. The amendment covers the extension of the duration of the consent declaration to 30th September 2025.
- **24-009-AF1/AMD1 (INCLUDE study):** The HRCDC were informed that amendment request 24-009-AF1/AMD1 was approved via the Chairperson approval process. The amendment covers a change in the data time periods cover by the consent declaration; specifically, the data time periods to be covered are 2024 for the HIPE data from the Mater Hospital and 2015-2024 data from the HSE Central Treatment list, PASS data and data from the Irish Prison Service.
- **23-023-AF1/AMD1 (STEPCARE trial):** The HRCDC were informed that amendment request 23-023-AF1/AMD1 was approved via the Chairperson approval process. The amendment covers a change in the study protocol involving the collection and storage only on additional pseudonymised blood samples and associated data for the optional bio-marker sub-study. The Chairperson highlighted to the HRCDC that blood samples were already being collected and stored under the previous protocol and that this amendment did not cover the processing of the samples and associated data. The amendment also covers a change in what may happen the personal data if proxy assent is withdrawn to align with the new study withdrawal form.

New Applications

Reference ID:

25-003-AF1

Lead Applicant:

Prof Patrick Murray

Lead Data Controller:

University College Dublin, St Vincent's University Hospital, Mater Misericordiae University Hospital

Title:

Cirrhosis-Acute Kidney Injury Cohort Study

Research Objective:

In patients with liver cirrhosis, acute kidney dysfunction (named acute kidney injury (AKI)) may occur. Various causes may explain these kidney dysfunction episodes, and specific management exists for some of them. However, clarification of the right diagnosis is sometimes difficult in this population and is associated with delayed diagnosis and associated management.
The objective of this study is to evaluate the ability of novel urinary biomarkers (proteins in the urine) to predict response/progression of acute kidney injury in patients with liver disease, using urine samples at the time of diagnosis. These discoveries could help to discriminate (more quickly) between various kidney injuries and therefore optimize the treatment and outcomes in this patient population.

Reason for Declaration:

To process the personal data of participants who lack decision-making capacity due to their medical condition; for those who lack decision making capacity, deferred proxy assent will be obtained within 48hrs.

HRCDC Comments:

The Chairperson requested the primary and secondary reviewers who were assigned to this application 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 study activities and objectives were discussed. It was commented that this is a observational study that involves the processing of personal data and associated samples that are already collected as part of care and treatment. It was discussed that this research area is of particular importance given the implications of this condition for patients and the health service.
- Overall, it was the view of the HRCDC that there is a strong public interest case in this research.

Scope of the declaration

- It was noted that this study had already commenced with a small number of participants already recruited, including a small cohort of those who lack decision-making capacity to provide explicit consent.
- It was discussed that the researchers have stated that they had previously relied on the deferred consent amendment to the Health Research Regulations to process personal data in the absence of explicit consent or a consent declaration for a small cohort of participants; however, the parties involved in the study have determined that a consent declaration is required now that the study has recently expanded to include additional sites who are not joint controllers of the study.
- The HRCDC discussed and confirmed that the consent declaration will not provide retrospective cover and accordingly the declaration does not cover the processing of

personal data of the small cohort of participants who lack decision-making capacity who have already been recruited to the study.

- It was further discussed that the consent declaration will not cover future research activities beyond the specific study described in the HRCDC application; accordingly an amendment request or new application will need to be submitted for further processing such as for other biomarkers beyond those that were listed in the application form and approved by the REC, other future studies, sharing personal data/samples with other unnamed parties, adding new hospitals etc.

Proxy Assent and Participant Consent:

- The HRCDC noted that participants would be enrolled in the study and have their urine samples collected and stored when their acute kidney injury first occurs and 48 hours later. If a participant lacks capacity, then deferred proxy assent will be sought within 48 hours; it was noted that if such proxy assent (or participant consent to continue if they regain capacity) is not obtained within 48 hours, then the participant will be withdrawn from the study and their urine samples for the study will be destroyed.
- The HRCDC also noted the Applicant's response on how a participant's decision-making capacity will be assessed to determine if their consent to continue could be obtained following proxy assent. It was also discussed that decision-making capacity should be re-assessed at the 3 month and 1 year follow-up points, where practicable, and that consent to continue should be sought if they have regained capacity.

Data Processing and Parties Involved:

- The responses from the Applicant confirmed which parties where joint data controllers of this study and which were considered data processors. It was also confirmed by the Applicant that data or samples are not processed outside of Ireland and that UCD, as one of joint controllers, will be the only party receiving and processing the pseudonymised data and associated samples for this study, with the pseudonymisation key securely stored at each local hospital site.

Data Security:

- The 'transport security protocol' of the data from the hospital site to the RedCap database was queried; it was discussed that specific detail on this matter was not detailed by the Applicant.
- The HRCDC discussed that follow-up data will be collected at 3 months and 1 year and that this may be requested from the participant's GP if the data required cannot be obtained from the hospital's own records. It was queried how data would be transferred/captured from the GPs, and it was also queried whether the details on the GP would be kept separate and secure from the participant's own data to further protect the participant's data, including protection from identification. It was noted that data agreements/arrangements would need to be in place with GPs if data will be shared/transferred from GPs.

Public and Patient Involvement (PPI):

- The HRCDC noted and discussed the Applicant's response on the PPI engagement that has occurred to date. It was the view of the HRCDC that PPI could be further enhanced

through engagement with appropriate patient organisations such as the Irish Kidney Association or other similar organisations.

- It was discussed that enhanced PPI engagement could include disseminating study findings or outcomes to relevant organisations and also request PPI feedback on the study information leaflets and assent/consent forms.

Study information leaflets and assent/consent forms:

- The Applicant submitted the separate study information leaflets and assent/consent forms for (i) the St Vincent's University Hospital (SVUH) site and (ii) the Mater, Galway and Wexford sites, which use the same version of the study documents. The Applicant had outlined that the study commenced first at SVUH during the COVID-19 pandemic and that the other three sites were approved for inclusion in the study more recently; the Applicant outlined that this explains the differences between the study documentation used at SVUH and the other three sites.
- The HRCDC acknowledged that the SVUH documentation was developed and used in the years prior to extending the study to the other sites, however it was discussed that the SVUH versions of the assent/consent documents are significantly different to what is used at the other three sites; it was discussed that the documents for Galway, the Mater and Wexford provide participants and proxies with more detail about the study, data processing activities and other matters.
- It was the consensus of the HRCDC that, for the benefit of participants and those providing proxy assent, the SVUH study documentation should be reviewed and updated so that it's content, detail and structure are more aligned with the PILs and the assent/consent forms used at the other three sites, including but not limited to the following areas: the SVUH proxy PILs do not outline that if a participant doesn't regain capacity that they will continue to be included in the study on the basis of the proxy assent obtained; the SVUH information leaflet does not refer to destroying the data and samples upon withdrawal.
- It was also noted that the documents reference that data may be shared with 'Relevant Industry bodies', or similar, for this specific study, however the Applicant has confirmed this will not happen.
- It was also highlighted that the UCD DPO had provided feedback on changes that should be made to the information leaflets and assent/consent forms, including on collecting follow-up data from GPs and the storage data/samples for future research.
- The HRCDC also discussed that the phrase 'If there is no known objection by your relative to being included' should be more positively rephrased.

Data Protection Training:

- The replies noted that all staff would have completed Good Clinical Practice (GCP) training, however it was noted that the UCD DPO has queried if GDPR training has also been completed. It was the consensus of the HRCDC that the study should ensure that the researchers have completed adequate GDPR training.

Other:

- It was discussed that researchers can seek broad participant consent for future research and that it is the responsibility of the researchers/data controllers to ensure that any broad consent from participants for future research, including that the details on potentially sharing data/samples with other third parties for future research, such as commercial companies, is compliant and valid. It was commented that it would be beneficial to provide additional detail within the PIL on the type of future research that may be undertaken in the future.
- It was commented that the Applicant should report, in the annual review, on the numbers of participants who lack decision-making capacity who are recruited to the study.
- The HRCDC also noted, that updated research ethics approval from Wexford to cover those who lack decision-making capacity is required and that the Applicant must ensure that the required data agreements and arrangements are in place.

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 30th September 2037, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. An amendment to the research ethics approval from Wexford must be obtained to cover participants who lack decision-making capacity. This consent declaration will not cover data processing at the Wexford since until the requisite REC approval has been obtained.

Condition 2. In addition to assessing decision-making capacity during the hospital admission to determine if consent to continue could be obtained from the participant, decision-making capacity should also be re-assessed at the 3 month and 1 year follow-up points, where practicable, and consent to continue sought if they have regained capacity.

Condition 3. The Applicant is asked to report on the numbers of participants recruited to the study who continue to lack decision-making capacity as part of the Annual Review.

Condition 4. The required data agreements and arrangements must be in place between the parties involved in this study; this includes joint data controller arrangements, data controller – data processor agreements and data transfer agreements with GPs where patient's GP data is transferred for the purpose of this study. In addition, the study should ensure that the transfer or sharing of data/information from the GP to the study team is secure.

Condition 5. The following points are to be addressed with regards the study information and assent/consent forms:

- The SVUH proxy PILs do not outline that if a participant doesn't regain capacity that they will continue to be included in the study based on the proxy assent obtained; this should be amended.

- The study documents across all sites should provide consistent information on the participants data rights, including that the personal/pseudonymised data and samples will be destroyed upon withdrawal; it was noted that the SVUH information leaflets do not refer to destroying the data and samples upon withdrawal.
- The feedback/comments provided by the UCD data protection officer on the study information leaflets should be addressed for all sites e.g., providing a 'no consent' option for participants/proxy on using GP data; the information provided on, and seeking assent/consent for, the biobank etc.
- The SVUH PILs references that data may be disclosed/shared with '*relevant industry bodies*', and the documentation for the other sites refer to sharing data and/or samples with other parties for the purpose of the Cirrhosis-Acute Kidney Injury Cohort Study e.g., *'I agree for my relative's biological samples to be shared with commercial/biopharmaceutical companies for this study'.* The references to sharing data/samples with industry bodies and other parties for this specific study should be amended/removed; the Applicant has confirmed that only UCD will be involved in processing the samples and data for the purpose of the Cirrhosis-Acute Kidney Injury Cohort Study. (Please note that this point does not apply to references made on sharing data/samples with other parties with regards other future studies – please see recommendation 4 below)

The HRCDC acknowledged that the SVUH documentation was developed and used in the years prior to extending the study to the other sites, however, the Committee noted that the study documents used at the Mater, Galway and Wexford seemed to provide clearer information on matters such as details about the study, data processing activities and other areas. In addition to the points noted above, consideration should be given to aligning the SVUH documents more with the documents from the three other hospital sites.

HRCDC Recommendations:

Recommendation 1. The Applicant is requested to consider storing the contact details of the participant's GP in a separate location from the participant's pseudonymised study data to help prevent the risk of disclosure of the participant's identity.

Recommendation 2. The phrase in the study information leaflets 'If there is no known objection by your relative to being included' should be more positively rephrased to ask whether the proxy believes the participant would wish to be included in this study.

Recommendation 3. PPI engagement should be further enhanced through engagement with appropriate patient organisations such as the Irish Kidney Association, the Irish Liver Foundation or other similar bodies. Enhanced PPI engagement could include disseminating study findings or outcomes to relevant organisations and also requesting PPI feedback on the study information leaflets and assent/consent forms (please see Condition 5).

Recommendation 4. It is noted the study information leaflets and assent/consent documentation used at the sites refer to processing the personal/pseudonymised data and samples in future research that may involve commercial or for-profit companies or others. The Applicant should ensure that any participant consent for future research is compliant, including that the details on potentially sharing data/samples with other third parties including commercial companies, is clear and sufficient. The HRCDC also recommends that it would

be beneficial to provide additional detail within the PILs on the type of future research that may be undertaken in the future.
(Note: Researchers can seek broad participant consent for future research, however it is the responsibility of the researchers/data controllers to ensure that any broad consent from participants for future research is compliant and valid).

Recommendation 5. The Applicant is requested to ensure that an appropriate 'transport security protocol' is in place with regards the transfer of health data from the hospital to the RedCap database.

Annual Reviews

The Secretariat has received 6 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 23-002-AF1 (EAGER Register)
- **Ref ID:** 19-086-AF1 (Sepsis Immunosuppression in Critically Ill Patients)
- **Ref ID:** 24-001-AF1 (MALDI-TOF)*
- **Ref ID:** 19-085-AF1 (Blood Biomarkers to Predict Recovery from Ischaemic Stroke)
- **Ref ID:** 19-075-AF1 (University of Galway-Saolta Cancer Biobank)
- **Ref ID:** 23-003-AF1 (The CADY Sub-study 1: Biomarker and Major Adverse Cardiovascular Events (MACE) data Analysis)

* Declaration no longer required

HRCDC Primary and Secondary Reviewer pilot

A document on the feedback provided by the HRCDC members on the pilot Primary and Secondary Reviewer process was circulated to the HRCDC and an overview provided by the Secretariat.
Following discussion, the HRCDC agreed that the primary and secondary reviewer process will be implemented going forward with the following proposals also agreed:

- One primary and two secondary reviewers will be assigned to new consent declaration applications.
- Given the strong data safeguards in place, new applications seeking a consent declaration to process data from the Central Statistics Health Research Data Centre will not be considered by the primary/secondary reviewer process. These will be discussed by the committee at each meeting.
- For amendment requests that go to a HRCDC meeting, one primary and one secondary reviewer will be assigned to the amendment application.
- A PPI member will not need to be assigned as a Primary or Secondary Reviewer for every application. It will still be a requirement to have at least one PPI member at the HRCDC meeting to ensure a quorum.

The Chairperson discussed that these procedures can be revisited again if requested by the HRCDC or if deemed necessary to do so.

Activities report and events of interest

The Secretariat circulated a report of it's activities to the HRCDC in advance of the meeting.

HRCDC
Health Research Consent Declaration Committee

Any Other Business

The HRCDC were informed that the next meeting is scheduled for Tuesday 27th May.

The Chair closed the meeting