HRCDC
Health Research Consent Declaration Committee

Date: 30th January 2024
Location: Zoom videoconferencing

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Sheelah Connolly
Aideen Hartney
Dan Rea
John Woods
Barry Lyons
Patricia O'Beirne
Susan Smith
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES

New Amendments - For Consideration

Applicant	Ref No.	Title
Sharon O'Toole (TCD) & Fiona Lyng (TUDublin)	19-045-AF2/AMD1	The Gynaecological Biobank - collaboration with Technological University of Dublin entitled 'Development of methods based on vibrational spectroscopy of minimally invasive biofluids for early detection of ovarian and endometrial cancer'
Prof Alistair Nichol	19-004-AF2/AMD4	Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community- Acquired Pneumonia (REMAP-CAP)

New Applications – For consideration

Applicant	Ref No.	Title
Prof Alistair Nichol	23-024-AF1	Platform of Randomized Adaptive Clinical Trials in Critical Illness (PRACTICAL) Randomized Controlled Trial - Invasive Mechanical Ventilation domain

Meeting Items

1. **Opening**
   The Chair opened the meeting and welcomed the members.

2. **Apologies**

Simon Furney, Zubair Kabir, Kathy Brickell, Cornelius Cooney, Mary Tumelty (Maternity Leave)

3. Disclosure of Interest

There were no disclosures of interest for this meeting.

4. Minutes of the last meeting

Draft minutes of 12th December 2023 were circulated in advance of the meeting. It was discussed that a recommendation attached to the consent declaration for 23-012-AF1 (Research Use of Diagnostic Genomic Testing Data Epilepsy) on providing options to notify individuals of incidental findings, could be confusing, specifically the option that is provided in the proxy assent form.

It was discussed that the Secretariat will contact the Applicant to provide clarity on this matter.

5. 19-086-AF1 (Sepsis Immunosuppression in Critically Ill Patients).

- The HRCDC were informed that there was no response from the study to the Chairperson letter of 6th November 2023, requesting the Applicant to respond to the HRCDC's concerns regarding compliance with Condition 3 (PPI engagement) by the requested January deadline. The HRCDC was provided with a summary of the communications on this matter between the main contact in the study, Prof Loeches and the HRCDC since 6th November 2023 Chairperson letter. –
- The HRCDC considered what actions should be taken following the expiry of the deadline, including whether the process to revoke the consent declaration should be initiated on the grounds that an attached condition is not being satisfactorily met, based on the information that has been submitted by the Applicant to date.
- With regards to conditions relating to public and patient involvement, it was discussed why PPI engagement is considered an important data protection safeguard when undertaking research in the absence of participant consent, including that it further helps to put the participants at the centre of the study. It was also discussed that although the Applicant had previously informed the HRCDC of their involvement in broader PPI activities, PPI engagement with regards this specific study is what is expected and that this had been clearly highlighted to the Applicant, alongside PPI resources that could be contacted. The importance of Applicant abiding by conditions attached to the consent declaration, that they had accepted, was noted.
- Following a discussion, the HRCDC agreed that this matter would be considered at the next HRCDC meeting. The HRCDC was of the view that correspondence would be sent to the Applicant/data controller informing them that the committee will consider revoking the consent declaration at the next meeting and to reemphasise the importance of an urgent response to condition 3. The Applicant will also be asked to consult with their DPO regarding potential implications that this would likely have on the research study. It was also agreed that the correspondence would detail a number of other important points including, the efforts that have made to engage with them on this matter.

6. Chairperson Approvals:

- **22-009-AF1/AMD1 (**Linking and harnessing health and population data to improve outcomes in Out-of-Hospital Cardiac Arrest)**.**
  The HRCDC were informed that amendment request 22-009-AF1/AMD1 was approved via the Chairperson approval process. This amendment covers a change in the time period of the personal data to processed in this study to now cover 2014-2022. The HRCDC were provided with the amendment decision letter**.**

7. Amendments

Reference ID:	19-045-AF2/AMD1
Lead Applicant:	Sharon O'Toole (TCD) & Fiona Lyng (TUDublin)
Lead Data Controller:	Trinity College Dublin (TCD) St James's Hospital Dublin (SJH) Technological University of Dublin (TUDublin)
Title:	The Gynaecological Biobank (formally the DISCOVARY Bioresource) – a collaboration with the Technological University of Dublin entitled *'Development of methods based on vibrational spectroscopy of minimally invasive biofluids for early detection of ovarian and endometrial cancer'*
Research Objective:	See HRCDC Meeting minutes of 14th December 2021
Purpose of Amendment:	Trinity College Dublin and St James's Hospital, the joint controllers of the bioresource/biobank, are aiming to undertake a new collaboration with TUDublin, using the personal data and associated samples that are held by the bioresource. This collaboration is titled: '*Development of methods based on vibrational spectroscopy of minimally invasive biofluids for early detection of ovarian and endometrial cancer'.* The amendment is therefore sought to cover the processing of personal data from the bioresource/biobank for this new research collaboration. TCD, SJH and TUDublin are confirmed joint controllers on this specific collaboration.
HRCDC Comments:	The Chairperson introduced the amendment and highlighted what is covered by the original consent declaration that was made. The Chairperson requested each HRCDC member to indicate whether the amendment should be approved. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment request should be approved. The HRCDC commented that the new collaborative study was of strong public interest. It was also discussed that the amendment relates to a new collaborative study in the area of gynaecological cancer and involves the same joint data controllers as the biobank. It was highlighted that the appropriate data agreements need to be place prior to the transfer of data and associated samples between the parties. The HRCDC noted that the duration of the amendment requested for this collaboration also approached the expiry date of the original declaration made for this bioresource. It was commented that the Applicant/data controller had also acknowledged this. The HRCDC commented that the duration of the original consent declaration and the amendment should be highlighted in the decision letter alongside information on the Chairperson approval process for administrative amendments, should they wish to seek an extension. The HRCDC also noted more standard safeguards that may need to be considered by the Committee, including that the required data

	agreements are put in place, updates to the study website and providing clarity on the scope of the amendment.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved.
Conditions Attached:	**Condition 1.** The required appropriate data and material agreements, including joint controller arrangements, must be put in place between the parties for this specific collaborative study. For the avoidance of doubt, personal data and associated biosamples cannot be transferred prior to the necessary agreements being implemented. **Condition 2.** The study website should be updated to inform and provide information on this new collaboration between St James's Hospital, Trinity College Dublin and the Technological University of Dublin. This aligns with Condition 6 of the original consent declaration.

Reference ID:	19-004-AF2/AMD4
Lead Applicant:	Prof Alistair Nichol
Lead Data Controller:	St. Vincent's University Hospital University Medical Centre Utrecht Monash University
Title:	Randomized, Embedded, Multifactorial, Adaptive Platform trial for Community- Acquired Pneumonia (REMAP-CAP)
Research Objective:	See HRCDC Meeting minutes of 25th July 2019, 2nd April 2020, 10th June 2020 and 23rd September 2020.

Purpose of Amendment:	The amendment request is for the following changes to the study:
	- The inclusion of two additional sites: Tallaght University Hospital and Wexford General Hospital.
	- The addition of new treatment domains to the trial:
	  ○ Mechanical Ventilation domain
	  ○ Statin/Simvastatin Domain. Note: this domain closed 9th Jan 2023.
	  ○ Endothelial domain (NREC approval 15th December 2023)
	  ○ Influenza Immune Modulation domain (NREC approval 15th December 2023)
	- Extension of the period of data storage to 25 years to align with the new Clinical Trials Regulation.

HRCDC Comments:	The Chairperson introduced the amendment and requested each HRCDC member to indicate whether the amendment should be approved. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment request should be approved. **Public interest** • The HRCDC noted that a number of amendments have previously been submitted and approved for the REMAP-CAP study, including to add new study domains. While the study had added new domains over time, it was discussed that the study

	remains focused on the same disease area and patient cohort; therefore, an amendment request form was appropriate to consider. • On balance the HRCDC was of the view that there is a public interest case for approving the amendment. **New domains** • From the information submitted, the HRCDC noted that two of the domains that are requested to be covered in this amendment have already commenced, with one of these domains having closed. The Applicant provided correspondence detailing the reason for this oversight. • The HRCDC commented that the amendment cannot retrospectively cover the processing of personal data that has already occurred with regards these two new domains; the amendment request will cover the processing of personal data of new, prospective participants only to the new domains. • It was also discussed that the amendment cannot cover data processing for the Statin/Simvastatin Domain as this has now closed. • Given that personal data was processed without a consent declaration, the HRCDC considered that it was important that the position of this data should be discussed with the relevant data protection officer (DPO) and their research ethics committee. **Data agreements** • It was commented that the appropriate data agreements and arrangements will need to be in place with each of the new hospital sites. **Consent/assent forms and Study Information Leaflets** • As part of the amendment request, the Applicant submitted the most up-to-date study information leaflets and assent/consent forms. These were the 'master' versions for both COVID-19 and non-COVID-19 participants that had received ethics approval. • It was noted that these 'master' versions were not fully updated to reflect the new domains in Ireland. The HRCDC commented that the study documents would need to be updated to accurately reflect all the domains that are active in Ireland, including the new domains covered by this amendment. • The HRCDC also discussed other elements of the study documentation, including whether it was apt and as readable as possible for participants. It was commented that matters raised by the HRCDC in previous applications from this Applicant with regards study information leaflets and assent/consent forms, have not been fully addressed in the master documents for this study. For example, it was noted that the term 'no known objection' rather than a positive rephrasing, continued to be included in the master documents. The inclusion of a 'don't know' option for relevant parts of the assent/consent process such as 'Does the participant have a living-will' has also not been considered.

	• In addition, it was noted that the master study documents refer to and request permission to use data in future studies. It was commented that the HSE consent policy for research provides guidance on seeking broad consent for future studies. including what should be included in the study documentation for future studies. The HRCDC commented that the Applicant should consult this HSE policy document. • The HRCDC also discussed the merits of providing a brief summary note and/or infographics to participants and their proxies as part of the assent/consent process, alongside the main study documents. The importance of discussing the study documents with the participant and proxies was also highlighted. • The HRCDC noted that as this is an amendment rather than a new application it was of the view that these matters would be highlighted to the Applicant/data controller for consideration as a request within the amendment approval letter.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved.
Conditions Attached:	**Condition 1.** The appropriate data agreements and arrangements must be in place with the two new additional sites. Data transfer cannot occur from these sites prior to the necessary data agreements being in place. **Condition 2.** The study information leaflets should be updated to accurately reflect all the domains that are active in Ireland, including the new domains covered by this amendment.

8. New Applications

Reference ID:	23-024-AF1
Lead Applicant:	Prof Alistair Nichol
Data Controllers:	University Health Network (Canada)
Title:	Platform of Randomized Adaptive Clinical Trials in Critical Illness (PRACTICAL) Randomized Controlled Trial - Invasive Mechanical Ventilation domain
Research Objective:	Acute hypoxemic respiratory failure (AHRF) is a type of lung failure, usually caused by problems with heart and lung conditions preventing the lungs from working as they should. AHRF is a common, life-threatening condition associated with significant risk of death and disability. Patients who develop AHRF usually need machines to support their lungs, including mechanical ventilation where a machine is breathing for the patient. Mechanical ventilation and intensive care treatment can itself cause lung problems and infections. Doctors are interested in more effective ways to treat AHRF. In this study, multiple different potential treatments will be tested, to investigate the best strategy to treat people with this disorder. This will include different mechanical ventilation settings, which may reduce the damage this process can have on the patient and

	help them recover quicker. The primary objective for the invasive mechanical ventilation domain, which is domain proposed to run in St Vincent's University Hospital, is to identify the invasive mechanical ventilation strategy that most effectively improves patient outcomes among conventional lung-protective ventilation and driving pressure-limited ventilation.
Reason for Declaration:	The consent declaration is requested for the processing of personal data of those who lack decision-making capacity. Data processing includes access, collection, transfer, analysis, storage. Data in Ireland will be transferred to parties outside the state, including the Sponsor and other named data processors.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that Consent Declaration should be made, subject to conditions attached. **Public interest case** • The HRCDC discussed the study activities, aims and objectives. It was the view of the HRCDC that there is a strong public interest case in this research. **Assent/consent process** • The timeline for seeking deferred proxy assent was discussed. It was noted that deferred proxy assent will be sought within 72 hours of the participant's enrolment; if deferred proxy assent cannot be obtained then the personal data will be kept but not uploaded, and consent to continue will then be sought from the participant when they regain capacity. The Applicant confirmed that the data would not be used if the participant doesn't regain capacity, in this case. **Study information leaflets** • It was highlighted that the proxy assent documents referred to both 'relative' and 'person responsible'. It was discussed that the document should be consistent in its language. • It was discussed that the study documents should clearly outline the named data processors from outside Ireland who will process personal/pseudonymised data in this study and for what purpose. The countries where data will be sent should also be clearly noted. • It was commented that matters raised by the HRCDC in previous applications with regards study information leaflets and assent/consent forms, have not been fully addressed in the study documents for this study. For example, the term 'no known objection' rather than a positive rephrasing, continued to be

	included in the master documents. Reference to the HSE consent policy for research for guidance on seeking broad consent for future studies was also highlighted in the context of this study. • The HRCDC also noted the reference in the study information leaflets to 'disclosure to third parties' such as the 'Health Products Regulatory Authority', 'relevant industry bodies', 'external professional advisors' and 'others, where it is permitted by law'. It was discussed that, whether the third party is involved in statutory oversight or regulation or another matter, the information sections on sharing/disclosing data to other third parties should be reviewed and amended to provide clearer information on who or what is meant by these very broad categories of different such as 'relevant industry bodies,' 'external professional advisers' or 'others were permitted by law' and why personal data would be shared with such third parties. The accompanying proxy assent and participant consent forms should also include clearer options on sharing/disclosing data with other such third parties that aligns with the amended information leaflets. **Data Transfers** • From the information provided, pseudonymised data will be transferred from Ireland to parties outside the EEA, this includes the sponsor/data controller in Canada as well as other named data processors in Canada, the United States and Argentina. • The responses from the Applicant confirmed that the legal basis for such transfer of data includes EU Adequacy Decisions. It was highlighted that the EU Adequacy Decisions covers Argentina and commercial organisations in Canada and the US. For the parties where such Adequacy Decisions do not apply, it was discussed that other legal basis, such as standard contractual clauses, including with Transfer Impact Assessments, where necessary, will need be put in place prior to the transfer of any personal data. • In addition to the legal basis for the transfer of data outside the EEA, other required data agreements/arrangements will also need to be put in place. **Destruction/Anonymisation of the personal data** • The responses from the Applicant stated that the data will be fully anonymised after 20 years but also then stated, 'where under sponsor's instructions the data will be destroyed'. • It was not clear if destroying the data under the sponsor's instructions meant (i) destroying personal identifiable data to fully anonymise the dataset (ii) destroying all the data such that no data is archived or (iii) destroying the anonymised data at a later point in time. It was discussed that this should be clarified by the Applicant. **DPIA**

	• It was noted that the DPIA submitted had identified data protection risks but did not include corresponding mitigating actions. The HRCDC was of the view mitigating actions should be included in the DPIA. **PPI engagement** • The HRCDC noted that PPI engagement is pending, with the study to be discussed with the ICC-CTN PPI group at the next meeting. The HRCDC commented that it would be preferable if studies would undertake PPI engagement prior to seeking a consent declaration. • It was the view of the HRCDC that the study should report on this PPI engagement as part of the Annual Review, including on the feedback that was received and how it was taken on board. **Other:** • The HRCDC also noted technical and more standard safeguards that may need to be considered by the Committee, including the submission of outstanding feedback from the data protection officer, clarity on the scope of the consent declaration made and responsibility for implementation of, and compliance with the consent declaration, amending the legal basis noted in the DPIA and withdrawing from the study and the use of personal data.
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 from 30th January 2024 until 31st January 2046 (i.e., for the duration of the study plus 20 years archiving), or until the personal data is fully anonymised or deleted, or explicit consent is obtained from all participants.
Conditions Attached:	**Condition 1.** St Vincent's Hospital must, alongside the data controller, the University Health Network, 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 participant if a participant has queries or otherwise wishes to exercise their rights. **Condition 2.** The necessary data agreements and arrangements must be in place between the parties involved in the study prior to the sharing/transfer/disclosure of personal data. This includes the necessary data controller/data processor agreements in addition to the necessary agreements that need to be in place to share personal data to parties outside the EEA. ***Note:*** the HRCDC application refers to the 'Adequacy Decisions' as the legal basis for transferring data outside the EEA. However, it is noted that the named parties (i.e., data processors) to whom personal data will be shared with are based in Canada, the USA and Argentina. Adequacy Decisions are in place for Argentia and cover commercial organisations in Canada only and in the United States covers commercial organisations participating in the EU-US Data Privacy Framework. Where Adequacy Decisions do not apply to the organisations outside the EEA, then the study must utilise an

	alternative legal basis such as Standard Contractual Clauses, and transfer impact assessments. **Condition 3.** The responses from the Applicant stated that the data will be fully anonymised after 20 years but also states 'where under sponsor's instructions the data will be destroyed'. It is not clear if this statement on destroying the data under the sponsor's instructions means (i) destroying personal identifiable data to fully anonymise the dataset (ii) destroying all the data such that no data is archived or (iii) destroying the anonymised data at a later point in time. The Applicant is requested to provide clarity on this matter when confirming acceptance or otherwise of this consent declaration. **Condition 4.** The feedback from the data controller's data protection officer on the DPIA is to be submitted as soon as practicable and **within 2 months.** The transfer of personal/pseudonymised data cannot commence until the DPO feedback has been provided. In addition, it is noted that the DPIA submitted identified data protection risks but did not include corresponding mitigating actions. This section of the DPIA should be addressed and an update also provided **within 2 months.** **Condition 5.** It is acknowledged that PPI engagement is pending, with the study to be discussed with the ICC-CTN PPI group at the next meeting. The study is requested to report on this PPI engagement as part of the Annual Review, including on the feedback that was received and how it was taken on board. **Condition 6.** Where proxy assent/participant consent is withdrawn or is refused and the study wishes to continue to process the data already collected, then permission for this must be obtained and recorded from the proxy or participant, whichever is relevant. If such permission is obtained from the proxy on behalf of a participant who lacks decision-making capacity, then participant consent to continue must also be obtained for this continued data processing when they regain decision-making capacity. It should also be outlined to individuals when it may no longer be possible to remove the data (i.e., not possible to remove it from interim analysis but can be removed from future analysis). **Condition 7.** The Applicant is requested to amend the study information leaflets and assent/consent forms as follows, at the earliest opportunity: ○ The study information leaflets should clearly outline the parties involved in this study who are involved in the processing of data and their role in this research, including those based outside of Ireland (i.e., the data controller/sponsor and the data processors who were named as part of the HRCDC application and named in the scope section of the decision letter)

	○ The section in the information leaflets on sharing/disclosing data with the HSE 'other third parties' should be reviewed and amended to provide clearer information on who or what is meant by these very broad categories of third parties (i.e., 'relevant industry bodies', 'external professional advisors', others were permitted by law' etc.) and why personal data may be shared with them, whether the third party is involved in statutory oversight or regulation of the study, or another separate matter. The accompanying proxy assent and participant consent forms should also include clearer options on sharing/disclosing data with other such third parties that aligns with the amended information leaflets.
HRCDC Recommendations:	**Recommendation 1.** The lawful basis for processing personal data that is referenced in the DPIA does not align with the basis noted to the HRCDC (i.e., 'public interest' and 'scientific research'). The Applicant is asked to address this inconsistency in the DPIA. **Recommendation 2**. The Applicant is requested to amend the study information leaflets and assent/consent forms as follows at the earliest opportunity: ○ The proxy assent documents use both 'relative' and 'person responsible' as interchangeable terms. The document should be consistent in the terms used and therefore use only one term. ○ The statement 'If there is no known objection by your relative to be included' should be more positively rephrased to ask if they thought the participant would wish to be included in this research study. ○ Permission to use the personal data in future research studies is requested (e.g., participant consent form). The study documents should provide the individual with sufficient information and options to understand how the personal data might be used for future research. Please refer to Section 2.3. of the HSE Consent Policy for Health and Social Care Research that provides information to researchers when seeking broad consent for future research. As a general point, researchers need to ensure that any consent obtained for the future use of data from is compliant with data protection legislation. ***(Note:*** the proxy assent form also refers to data processing for future research purposes. As has been noted previously, proxy assent and a consent declaration does not cover data processing in future research but can cover the storage only of the personal data for potential future research.

9. HRCDC Annual Report 2023

A draft of the HRCDC 2023 Annual Report was circulated to the HRCDC in advance of the meeting; an Annual Report is due to be submitted to the Minister for Health by 31st March each year.

The HRCDC were asked to submit any comments or feedback on the Annual Report by 9th February. A final draft of the report will be tabled at the February meeting.

10. HRCDC Standard Operating Procedures (SOP) and HRCDC website document

A revised version of the SOPs was circulated to the HRCDC in advance of the meeting; the main updates to the SOPs related to the Chairperson approval process for certain administrative/technical amendments.

The Secretariat also provided the Committee with a proposed document for the HRCDC website detailing commonly occurring issues that the HRCDC identifies in study information leaflets and assent/consent forms. The proposed document aims to provide some guidance to researchers before submitting a consent declaration application. It was commented that the Secretariat will aim to discuss the matter of issues with study information leaflets and assent/consent form issues with the National Research Ethics Committee, including the references to using data in future research that was raised in the applications considered during today's meeting.

The HRCDC were asked to review these documents and submit any feedback to the Secretariat.

11. Annual Reviews

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

- **Ref ID: 20-024-AF1;** Alistair Nichol, *GENOMMIC Study*
- **Ref ID: 20-031-AF1;** Ignacio Martin-Loeches, The effect of fluid resuscitation with 20% albumin versus crystalloid on the microcirculation in septic
- **Ref ID: 20-036-AF1**; Alistair Nichol, *EPO-TRAUMA.*
- **Ref ID: 21-012-AF1;** Norman Delanty, *Everolimus for drug-resistant seizures associated with GATOR1 complex epilepsies.*
- **Ref ID: 22-009-AF1;** Tomás Barry, *Linking and harnessing health and population data to improve outcomes in Out-of-Hospital Cardiac Arrest.*
- **Ref ID: 22-011-AF1;** Iracema Leroi*, SENSE-Cog Residential Care: A feasibility study of hearing and vision support to improve quality of life in care home residents with dementia.*

12. Activities report and events of interest

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

13. Any Other Business

- The HRCDC were informed that John Woods, Mary Tumelty, Con Cooney and Barry Lyons have been reappointed to the Committee for a second term. The Chairperson welcomed the reappointment of these members and looks forward to their continued membership of the Committee.
- The Chairperson also informed the Committee of the appointment of Prof Paul Stynes to the HRCDC. Prof Stynes is Dean of School of Computing at the National College of Ireland. The Chairperson welcomed the appointment of Prof Stynes to the HRCDC and looks forward to welcoming him at his first meeting.
- The HRCDC were reminded that the next meeting is scheduled for 27th February 2024.

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