HRCDC
Health Research Consent Declaration Committee

Date: 30th April 2024
Location: Zoom videoconferencing

Minutes of the Meeting

HRCDC Attendance

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

Quorum for Decisions
☒YES

Returning Applications - For Consideration

Applicant	Ref No.	Title
Prof Ger Curley	24-002-AF1	Brain Oxygen Neuromonitoring in Australia and New Zealand Assessment (The BONANZA Trial)

New Applications – For consideration

Applicant	Ref No.	Title
Prof Alistair Nichol	24-003-AF1	Early Sedation with Dexmedetomidine vs. Placebo in Older Ventilated Critically Ill Patients (SPICE IV)
Maeve Herlihy	24-004-AF1	Acral Melanoma: Incidence, clinical course and survival patterns in Ireland from 1994 – 2022
Jarushka Naidoo	24-005-AF1	The 'Lung Health Check' Pilot

Meeting Items

1. Opening

The Chair opened the meeting and welcomed the members.

2. Apologies

Cornelius Cooney, Mary Tumelty (Maternity leave)

3. Disclosure of Interest

- Kathy Brickell (KB) declared her interest in applications 24-002-AF1 (The BONANZA Trial) and 24-003-AF1 (SPICE IV). KB was absent during the meeting when these applications were considered.
- Susan Smith (SS) noted that she had previously worked with the researcher involved in 24-005-AF1, however she is not involved in this specific study. It was considered that there was no conflict of interest that required SS to be absent for this agenda item.

4. Minutes of the last meeting

Draft minutes of 26th March 2024 were circulated in advance of the meeting and were approved by the HRCDC.

5. Chairperson approvals:

- **23-002-AF1/AMD2 (EAGER Register).** The HRCDC were informed that amendment request 23-002-AF1/AMD2 was approved via the Chairperson approval process. This amendment covers an extension of the consent declaration previously made by 1-year. The HRCDC were provided with the amendment decision letter.
- **23-015-AF1/AMD1 (Investigation into the use of IL-1Beta, I-CAM1 and/or E-Selectin in identifying the effects of infection in placental tissue).** The HRCDC were informed that amendment request 23-015-AF1/AMD1 was approved via the Chairperson approval process. This amendment covers an extension of the consent declaration previously made by 3 months to 31st July 2024, the change in data controller of the study to the South/South-west Hospital Group under the HSE, and the subsequent removal on Condition 3 on joint controller arrangements that was attached to the original consent declaration. The HRCDC were provided with the amendment decision letter.

6. Returning Applications:

Reference ID:	24-002-AF1
Lead Applicant:	Prof Ger Curley
Lead Data Controller:	Monash University
Title:	Brain Oxygen Neuromonitoring in Australia and New Zealand Assessment (The BONANZA Trial)
Research Objective:	See HRCDC Meeting minutes of 26th March 2024.
Points to Discuss:	The Committee had discussed this proposal at its previous meeting in March 2024, and had sought additional information from the Applicant. The Applicant provided additional information on whether the use brain oxygen monitoring is part of normal patient care in Beaumont Hospital and further information on the public interest case for this study. The Applicant also provided further details on the assent/consent process and the transfer of data.
HRCDC Comments:	The Chair requested the HRCDC to indicate whether the amendment request should be approved. After discussing the

	responses provided by the Applicant, it was the consensus of the HRCDC that the amendment request could be approved. The HRCDC discussed that the responses from the Applicant to its queries provided important clarification, including that brain oxygen monitoring does not form part of normal patient care in Beaumont Hospital, with an estimated 20% of patients with traumatic brain injury receiving this intervention alongside brain pressure monitoring. On balance and based on the information provided by the Applicant, the HRCDC was of the view that there is a strong public interest in this study. It was also commented that normal clinical practice within the hospital may change over time, such that a higher proportion of patients may receive brain oxygen monitoring as part of normal care. It was discussed that the Applicant should therefore be requested to inform the HRCDC in the Annual Review on any such changes in normal clinical practice. The HRCDC also discussed that matters discussed and noted at the 26th March HRCDC meeting, including data agreements and matters relating to the study informaiton leaflets should be conditions and recommendations attached to this amendment.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration is made, subject to conditions attached.
Duration of Declaration:	The consent declaration is made until 30th April 2042 or until the personal data is deleted or fully anonymised, whichever occurs first.
Conditions Attached:	**Condition 1.** The Irish hospital sites, Beaumont Hospital, with the data controller Monash University, are 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 required data agreements and arrangements must be in place for this study. Further, the necessary agreements/arrangements must be implemented for transferring data outside the EEA (e.g., Standard Contractual Clauses) and a Transfer Impact Assessment must also be completed. Please also discuss these matters with the relevant data protection officer. The transfer of data between parties cannot occur prior to the necessary agreements being in place and required assessments being undertaken. **Condition 3.** If deferred proxy assent and/or participant consent to continue is refused or withdrawn, then permission must still be sought from the proxy or participant to continue to process the personal/pseudonymised data already collected. If such permission is provided by the proxy, then consent should still be sought form the participant if they regain decision-making capacity.

	Condition 4. The Applicant is requested to inform the HRCDC in the Annual Review on whether normal clinical practice within Beaumont Hospital changes i.e., the percentage of patients receiving brain oxygen monitoring as part of normal care changes.
HRCDC Recommendations:	**Recommendation:** The HRCDC requests that the study information leaflets, and assent/consent forms are reviewed and amended as follows: - It should be made clear to the participant whether their treatment has already been completed by the time they are asked to provide consent. - Consider whether further information on the personal data to be processed for this study can be outlined. - The legal basis outlined for processing personal data is confusing and appears to combine two separate legal bases: the PILs currently state 'Legitimate public interest' which appears to combine the 'public interest' and 'legitimate interest' bases. - The phrase 'are you aware of any objections your relative had to being included…', should be more positively rephrased to ask the proxy if they believed the individual would wish to be included in this study. - The proxy information documents refer to seeking assent from the proxy to for their relative to be contacted by the researchers as part of this research study. Relative assent should not be required for the study to contact the participant and therefore such references should be removed. - The use of the terms 'optimisation; and 'standard' strategy in the study documentation to describe the two different intervention groups may cause confusion for the proxy and participant and should be amended to use more lay-person language. - References to brain oxygen monitoring being part of normal or standard patient care in Beaumont Hospital should be removed or amended considering the information provided to the HRCDC by the Applicant on this issue.

7. Assent for future research in proxy documentation.

- Following discussions at the January and February 2024 HRCDC meetings, a guidance document for researchers, of commonly occurring issues / omissions in study information leaflets was produced and is available on the HRCDC website. It was noted at that meeting that the HRCDC would later discuss and give further consideration to the matter of proxy assent for future research; specifically, whether such references should be included or removed from the proxy assent documentation, given that a consent declaration and proxy assent cannot cover future research purposes.
- A note on this matter was circulated to the HRCDC in advance of the April 2024 meeting which included suggested text for proxy assent and future research that the HRCDC were asked to consider. The rationale for the inclusion of this text provided by researchers/applicants was also included.
- The HRCDC discussed this note and the suggested text for proxy assent for future research purposes.
- The HRCDC further discussed matters such as whether capacity to consent for those who originally lacked decision-making capacity would be revisited or reassessed prior to processing their data for future research purposes. It was also noted that an

application would still need to be submitted to the HRCDC for consideration to further process the personal data in future research beyond the original study, even if proxy assent for future research was provided. It was commented that each application would be considered by the HRCDC on a case-by-case basis.

- The consensus of the HRCDC was that in the interest of transparency and given that a further application would need to be made to the HRCDC for future research, the proxy assent documentation could include references to seeking assent for future research. The HRCDC noted changes that should be made to the proposed text for the proxy assent documentation and the website guidance to provide further transparency as follows:
  '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'.

8. New Applications

Reference ID:	24-003-AF1
Lead Applicant:	Prof. Alistair Nichol
Data Controllers:	Monash University
Title:	Early Sedation with Dexmedetomidine vs. Placebo in Older Ventilated Critically Ill Patients (SPICE IV)
Research Objective:	Most ICU patients who need a breathing machine (ventilator) to help them breathe require sedation with one or more sedative (calming) drugs, given as continuous drip into a vein. Currently, there is no agreement amongst doctors around the world about the best choice of sedative drug or the best way to manage sedation. Many of the commonly used sedative drugs have side effects and are thought to be associated with longer time on the ventilator, longer stay in the ICU, leading to delirium (a confused state often including hallucinations) and decreased mental awareness after recovery from critical illness. Dexmedetomidine is a commonly used sedative drugs that can be used alone or in combination, to keep ICU patients comfortable while on a ventilator. The purpose of this study is to evaluate dexmedetomidine, which might improve survival and recovery for older patients who require sedation in ICU.
Reason for Declaration:	The patient population for SPICE IV are those who are experiencing critical illness and are unconscious, and as such will lack capacity to give informed consent on enrolment into the trial. All patients who will be eligible for participation will be unconscious and receiving ICU treatment and will be unable to participate in the informed consent process. The consent declaration is therefore requested to process the personal data (collection, transfer, analysis, storage etc.) of participants recruited to SPICE IV who lack capacity, for the purpose of this specific study.
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 a Consent Declaration is made, subject to conditions attached.

Public interest case

- The HRCDC discussed the aims and objectives of this study. Based on the information provided, the HRCDC was of the view that there is a very strong public interest case in this research.

Study information leaflets.

- The HRCDC noted the response from the Applicant on why changes to PILs that were requested in conditions attached to previous consent declarations made for similar ICU studies, had not been made for this study.
- The HRCDC discussed that such changes to the study documents should ideally have been made by the Applicant prior to submitting this new application. It was view of the HRCDC that the PIL changes requested in previous studies that are also applicable to this study should be made as soon as practicable.
- With regards the references to future research in the proxy assent documentation, the HRCDC noted that this could be amended as per the discussion earlier in this meeting under agenda item 7 of these minutes.
- The HRCDC also commented that section 11 of the study information leaflets on *'What if the participant withdraws from this research study'* did not align with the replies provided to the HRCDC. The text in the PILs states that personal data will be retained and used if a participant is withdrawn. It is not clear that participant data can/will be deleted prior to study analysis, with the study seeking to request to keep and use the data already collected, as per replies from applicant to the Secretariat's queries. It was also commented that the language used in this section of the PIL is legalistic and may be difficult to understand.
- It was noted that the participant study information leaflet refers to obtaining personal data from the patient's Fit Bit device, however no other references to this were made in the HRCDC application form or in the proxy information leaflet. It was discussed that the Applicant should review the study information leaflets to ensure they are aligned on whether Fit Bit data is used or not.

General point

- It was noted that new consent declaration applications from the same Applicant may not fully address common issues that were requested to be addressed by the HRCDC in study information leaflets. The HRCDC acknowledges that this can arise due to timing reasons, and it was agreed that the Secretariat will have

	the discretion on whether such outstanding issues should be addressed by the Applicant in their new application before it is considered by the HRCDC. **Other:** • The HRCDC queried when the interim analysis would be completed, noting that this timeline has implications for when participants can withdraw their personal data. • It was noted that as part of this study, data from this SPICE IV study will be included in a combined analysis with data from the earlier SPICE III study; the Applicant confirmed that this analysis is undertaken by Monash University. It was also confirmed that the scope of the consent declaration does not cover the processing of data from the SPICE III study as this study was undertaken prior to the Health Research Regulations. It was discussed that it is the responsibility of the data controller of SPICE III to ensure data protection compliance with regards the use of SPICE III data. • The HRCDC also noted that proxy assent is not deferred and that the required data agreements and arrangements are in place. Other observations included ensuring that the sites in Ireland will be jointly responsible for implementation and compliance with the declaration and seeking permission from the proxy/participant if the study wishes to continue to process personal data already collected post-withdrawal.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration is made, subject to conditions attached.
Duration of Declaration:	The consent declaration is made until 31st December 2025 and for 25 years thereafter (until 31st December 2050) or until the personal data is deleted or fully anonymised, whichever occurs first.
Conditions Attached:	**Condition 1.** The Irish hospital sites must, together with the data controller Monash University, 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 required data agreements and arrangements must be in place for this study. Further, the necessary agreements/arrangements must be implemented for transferring data outside the EEA (e.g., Standard Contractual Clauses) and a Transfer Impact Assessment must also be completed. The transfer of data between parties cannot occur prior to the necessary agreements being in place and required assessments being undertaken. **Condition 3.** • 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'. • The participant study information leaflet refers to obtaining personal data from the patient's Fit Bit device, however no other references to this are made in the HRCDC application form or in the proxy information leaflet. The Applicant should review the study information leaflets to ensure they are aligned on whether Fit Bit data is used or not. If it is not used, then this reference should be deleted. • The Applicant should re-visit the relevant conditions attached to consent declarations made in the previous year for their other similar ICU studies to identify changes to PILs that are also applicable to the SPICE IV study. These changes include the following: ○ More positively rephase text such as '*if there is no known objection' or 'are you aware of any objections*…' to more positively to ask the proxy if they believed the individual would wish to be included in this study. ○ References in the study documentation on sharing/disclosing personal data (including pseudonymised data) to third parties such as relevant industry bodies should be reviewed and amended to provide clearer information on who or what is meant by these third-party categories, what personal data may be shared with them and the reasons why. Where personal data is shared with third parties such as industry bodies, the accompanying proxy assent and participant consent forms should also include clear options on sharing/disclosing personal/pseudonymised data to third parties. The changes to the study documentation should be made as soon as possible in advance of the study commencing. The applicant is requested to report on this condition within 3 months. **Condition 4**. Where an individual withdraws from the study and the researchers wish to continue to process the personal data already obtained, then permission for this must be obtained from the proxy and recorded. In addition, consent to continue from the participant when they regain decision-making capacity should also be obtained for this continued processing *(Please also see Recommendation 1).*
HRCDC Recommendations:	**Recommendation.** The text in section 11 of the study information leaflets on study withdrawal, does not fully align with the replies provided to the HRCDC on study withdrawal and the deletion of data i.e., it is not fully clear that where there is a request to withdraw, that the study will discuss options with the proxy/ participant and ask their will and preferences on what they wish to happen to the

	data already collected. It was also commented by the HRCDC that the language used in this section of the PIL is quite legalistic. It is important to ensure that the individual clearly understands that the personal data can still be deleted prior to analysis and that options on what will happen the data will be discussed with them at the point of withdrawal. The Applicant is therefore requested to review and amend the above text in the study information leaflet, to ensure that it is clear.

Reference ID:	24-004-AF1
Lead Applicant:	Maeve Herlihy
Data Controllers:	University Hospital Limerick
Title:	Acral Melanoma: Incidence, clinical course and survival patterns in Ireland from 1994 – 2022
Research Objective:	Acral melanoma including acral lentiginous melanoma (ALM) is an aggressive subtype of cutaneous melanoma arising on the palms, soles or around the nails. It is the least common subtype of melanoma diagnosed overall, accounting for 2–3% of melanoma diagnoses. Compared with other subtypes of melanoma, most studies suggest that acral melanoma has a poorer prognosis, with diagnosis often occurring at a more advanced clinical stage. Many factors contribute to this including the propensity of this subtype of melanoma to affect areas not commonly examined by the patient or doctor and lesions mis-diagnosed as another pathology such as trauma, fungal infection or vascular ulcer. Furthermore, ALM has a disproportionately higher incidence in non-white patients compared to other melanoma subtypes. Reduced awareness of melanoma risk in non-white populations contributes to delayed diagnosis. This study aims to examine patient characteristics, tumour features, disease course and survival patterns of patients diagnosed with this rare and aggressive subtype of melanoma.
Reason for Declaration:	To process personal data provided by the National Cancer Registry Ireland (NCRI) of patients from 1994-2022 for this specific study (i.e., obtaining, sharing, analysis etc.) Patients include those diagnosed with acral melanoma and those diagnosed with other subtypes of melanoma The Applicant states that given the significant time period being studied, it will not be possible or practical to obtain explicit consent from all data subjects. The dataset requested from NCRI is considered pseudonymised.
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 a consent Declaration should be made, subject to conditions attached.

Public interest case

- The HRCDC discussed the aims and objective of this research and the study methodology. It was commented that the study was relatively low risk given that the data is pseudonymised.
- On balance, it was the view of the HRCDC that there is a public interest case in this research.

Data Governance

- The HRCDC discussed the data governance arrangements in place for this study. It was noted that Applicant had stated that the individual researcher was the data controller of this study, but it was later clarified that the data controller is UHL and not the individual researcher. It was also discussed that personnel, such as the Principal Investigator may not be permanent staff and therefore the study team and data controller need to have responsibilities defined, should the PI not be available to destroy or return the personal data once the study ends.
- Reference was also made in the study protocol to data being accessed by a senior biostatistician as part of the statistical analysis, but this was not mentioned in the main HRCDC application form. The HRCDC commented that it is important that the study logs all the personnel who will be accessing the pseudonymised data for this study.
- It was also discussed that data sharing agreements need to be in place between UHL and NCRI. It was commented that such agreements should also set out the roles and responsibilities of each party with regards the process for withdrawing a participant from the study.

Public and patient involvement

- The response from the Applicant on the PPI engagement to date was noted. However, the HRCDC was of the view that PPI in this study could be strengthened through discussions and engagement with cancer patient and research groups. Topics for PPI include the study transparency measures.

Transparency

- It was discussed that the transparency measures outlined by the Applicant should be implemented prior to the study commencing. It was further commented that the transparency measures must make it fully clear on how participants can request to be withdrawn from the study and have their data removed, including contact details. It should also be outlined at what point in the study, withdrawal would not be possible.

Discussions with NCRI – General note

- Following discussions by the HRCDC, it was suggested that the Secretariat could engage with the National Cancer Registry

	Ireland on a more standardised approach for health research studies seeking to process NCRI data, including the safeguards in place, pseudonymisation and anonymisation of data and considering the consent declaration application process. **Other:** • The HRCDC was of the view that the Applicant should report in the Annual Review on the total number of participants included in this study from the time period covered by this study; this includes those with Acral Melanoma and the comparator/matching cohort of patients. • The HRCDC queried whether the pseudonymised data transferred to UHL from NCRI could be fully anonymised at an earlier stage in the study, for example prior to the study analysis. • In addition, the HRCDC should be informed if the data was returned or destroyed following the study.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration should be made, subject to conditions attached.
Duration of Declaration:	The consent declaration is made until 30th September 2024 or until the personal data is deleted or fully anonymised, whichever occurs first.
Conditions Attached:	**Condition 1.** The study must ensure that it logs all the personnel who will be accessing the pseudonymised data for this study. In addition, it was discussed that study personnel, such as the Principal Investigator may not be permanent staff at UHL; therefore, the study team and data controller need to have responsibilities defined, should the PI not be available to destroy or return the personal data once the study ends. **Condition 2.** The necessary data sharing agreements must be in place between UHL and NCRI; the agreement should also set out the roles and responsibilities of each party with regards the process for withdrawing a participant from the study. Data cannot be transferred prior to the agreement being in place. **Condition 3.** The Applicant/data controller is requested to strengthen the level of public and patient involvement for this study through discussions with relevant cancer patient and cancer research groups. PPI discussions should consider matters such as the study transparency measures. PPI engagement should occur prior to the study commencing. Please report on this condition within 2 months. **Condition 4.** The transparency measures outlined by the Applicant should be implemented prior to the study commencing. The transparency measures must also make it fully clear on how participants can request to be withdrawn from the study and have their data removed, including contact details. It should also be outlined at what point in the study participant withdrawal would no longer be possible. Please provide an update on this condition within 2 months.

	Condition 5. In the Annual Review, the Applicant is requested to report on the total number of participants included in this study from the time period covered by this study; this includes those with Acral Melanoma and the comparator/matching cohort of patients. It should also be reported whether the personal/pseudonymised data was destroyed or returned to NCRI after the end of this study.

Reference ID:	24-005-AF1
Lead Applicant:	Jarushka Naidoo
Data Controllers:	Royal College of Surgeons Ireland Beaumont Hospital Centric Health
Title:	The 'Lung Health Check' Pilot
Research Objective:	This clinical pilot aims to test the feasibility of lung cancer screening in Ireland. Current/former smokers aged 55-74 years old, are at greater risk of developing lung cancer (LC). In Ireland, ~2,690 people are diagnosed with LC every year, of which 2/3 will die of the disease. As 8/10 are diagnosed with advanced LC, the goal of this study is to identify lung cancer early, in people without symptoms. Participant selection is based on age, smoking history, and relevant medical history. Participants will have a 'lung health check' including: a breathing test, low-dose chest CT scan, and smoking cessation education. The purpose of the chest CT is to pick up lung cancer at an early stage. Earlier detection of lung cancer improves survival, and likelihood of treatment. The lung health check pilot will be delivered by community-based mobile unit in North Dublin/North East, in line with international recommendations.
Reason for Declaration:	To meet the target of 2138 participant lung checks in this pilot, 30,000 patients aged between 55-74 years from Centric Health Network GP practices will need to be contacted to determine their eligibility. Given this high number of potential participants who will need to be contacted, an external vendor with the requisite staffing and infrastructure will be employed to do this contact and pre-screening work; the sharing and processing of personal data (i.e., contact information) to and by this external vendor to contact patients will be undertaken without initial patient consent. The consent declaration is therefore requested to only cover obtaining and using personal data from the GP records to contact potential participants to assess their suitability for participation in this pilot
HRCDC Comments:	The Secretariat introduced the application and outlined the limited data processing that was requested to be covered by this consent declaration. It was highlighted that the study, when contacting the patient for the pre-screening phone call, will seek to obtain the patient's verbal consent for the pre-screening and associated data processing, and that written consent will also then be obtained when eligible patients attend the screening unit.

	The HRCDC noted that ethics approval had been granted for study concerning the provision of a lung cancer screening pilot, excluding the sharing of data from this pilot with the EU4Health - SOLACE consortium. 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 a Consent Declaration, subject to conditions attached, should be made. **Public interest case** • The HRCDC discussed that there is a very strong public interest with regards a lung screening pilot study in Ireland. On balance, it was also the consensus of the HRCDC that sharing the patients contact details with a specialist third-party contractor who will contact the patients to organise and undertake the pre-screening calls was reasonable, given the very large number of individuals who will need to be contacted and the practical challenges this involves. • However, the HRCDC also noted that the study consent documents to be provided to the patient when they attend the screening unit, notes the optional collection of blood and breath biosamples that will be stored in a biorepository/biobank for future research. It was commented that there is a lack of clarity provided on this optional biorepository. In addition to the optional biorepository, reference was also made by the Applicant to sharing patient data with the SOLACE consortium, an EU consortium of clinical pilots of which this study is a member of. It was noted that there is not REC approval, as of yet, for sharing data from the screening pilot study with SOLACE. • It was discussed that the public interest case considered by the HRCDC, and the scope of the consent declaration, is for the Lung Health Check pilot only, in the context for the sharing and use of patient contact details, to enable the third-party contractor to contact patients for pre-screening purposes for the screening pilot. It was highlighted and confirmed that (i) the biorepository and (ii) other activities involved in the pilot lung screening from the pre-screening phase onwards, including data sharing with SOLACE, is not within the scope of this consent declaration and accordingly the HRCDC only looked at the public interest case of the Lung Health Check pilot in the context for the sharing and use of patient contact details. The public interest case for an optional biorepository was not part of the HRCDC application and was not considered by the HRCDC as part of its deliberations and it was commented that the optional biorepository appeared to be a separate research activity from the pilot lung screening study. **Invitation letter**

	• It was commented that the pilot screening invitation letter, as currently drafted, reads as if it was issued directly from or by the patient's own GP practice. The HRCDC was of the view that in the interests of transparency and for the benefit of the study and patients, the invitation letter should make it clear that it is being issued by the 3rd party contractor on behalf of or in collaboration with their GP; accordingly, the details of the 3rd party should also be clearly noted in the letter. • It was further commented that the letter could also provide patients with the phone number that will be contacting them to conduct the pre-screening calls, in order to help potentially improve the take-up of the calls by patients. • It was commented that the letterhead should be amended to include the third-party contractor and, if useful, the research team and Centric Health. **Written consent documentation.** • The HRCDC was of the view that the documentation used to obtain written consent from the patient for the lung screening when they attend the screening unit, should remove the references to providing optional samples for a separate biorepository for future research. It was commented that consent for the biorepository should not be bundled with the consent for the lung screening pilot study as they are both separate, distinct activities; such consent should be obtained separately from the participant. **Verbal consent** • It was discussed that when patients are contacted for pre-screening, that verbal consent will be sought on the phone for this activity. It was also noted that while a potentially eligible patient may invite a family member or friend to support them during the pre-screening phone call, the patient must have the capacity to provide their own verbal consent; the Applicant confirmed that capacity to consent is an inclusion criterion for this pilot lung screening. It was commented that if there is a question on patient decision-making capacity at the point of seeking verbal consent, then verbal consent should not be obtained from the patient. It was further commented that the study must ensure that verbal consent is obtained from the patient and that they have decision-making capacity; it should not be provided by a relative or friend on behalf of a patient who lacks decision-making capacity. • It was also commented that the study does not outline how they will record whether a patient is being supported by a relative or friend during the verbal consent process and pre-screening phone call. • It was also the view of the HRCDC that the script used, in part, to obtain verbal consent, should provide more information on what the potentially eligible patient is being asked to consent to with regards pre-screening and the processing of their personal data.

	Transparency • It was noted that in addition to the invitation letters, the trial will also be communicated within the GP practices; examples of measures that may be used include leaflets, information boards, information evenings and the use of GP apps. It was further noted that there will also be a dedicated website for the pilot study. The HRCDC welcomed this approach to transparency measures. **Data agreements** • It was commented that the patient contact information that is the subject of this declaration, should not be retained by the 3rd party contractor beyond the period needed to contact patients to determine their eligibility for the pilot screening. It was discussed that the data agreement/arrangements between the data controllers of the study and the 3rd party contractor should cover the return of or destruction of this data. The Applicant confirmed that the process for contacting patients should be completed by the end of 2025. **Other:** • The HRCDC commented that the consent declaration only covers patient contact details obtained from GP practices within Centric Health who agree to provide such details. • The HRCDC also noted other points that may need to be considered by the Committee, including the submission of the outstanding signature and data protection officer feedback from RCSI.
HRCDC Decision:	The consensus of the HRCDC was that a Consent Declaration should be made, subject to conditions attached.
Duration of Declaration:	The consent declaration is made until 31st December 2025 or until the personal data is deleted or fully anonymised, whichever occurs first.
Conditions Attached:	**Condition 1.** In the interest of transparency, the invitation letter should be amended to make it fully clear that this invite is being issued by the named 3rd party contractor on behalf of (or in collaboration with) the patient's GP; accordingly, the details and role of the 3rd party contractor should be clearly noted in the letter. The invitation letterhead must be amended to include the third-party contractor and, if also useful, consider including the research team and Centric Health. **Condition 2.** It is noted that while a potentially eligible patient may invite a family member or friend to support them during the pre-screening and verbal consent call, the study must ensure that the patient has decision making capacity and that verbal consent is provided by them at the point of the pre-screening call. Verbal consent should not be provided by a relative or friend on behalf of a patient who lacks decision-making capacity. If there is a question on the patient's capacity at the point of seeking verbal consent, then verbal consent should not be obtained from the patient. It should be

	ensured there are processes in place to ensure that verbal consent is obtained from the patient. **Condition 3.** The documentation used to obtain written consent from the patient for the lung health screening when they attend the screening unit, should remove the references to providing optional samples/data for a separate biorepository for future research. This must be implemented prior to the start of the lung health check screening and confirmation of this provided to the HRCDC. **Condition 4.** The Lung Health Check script notes the following under 'verbal consent': '*Can I check you are happy to proceed and give your consent for me to collect the answers to the questions and record them as part of the study'*. The Applicant is requested to review and amend the verbal consent script so that it provides much more detailed information on what the patient is being asked to consent to, and to ensure informed verbal consent is being obtained for the applicable study activities; i.e., the participant is being asked to provide verbal consent for the pre-screening/eligibility assessment and the associated processing of their personal data for this activity. Linked to this, it is noted that the verbal consent script does not provide any information on data sharing with SOLACE and therefore this must also be addressed as part of this condition when amending the verbal consent script, so that informed verbal consent for this activity is also obtained. The verbal consent script must be amended as above prior to the pre-screening phone calls commencing. **Condition 5.** The required data agreements and arrangements must be in place between the parties involved in this pilot screening study; this includes agreements with the 3rd party contractor. The patient contact information that is the subject of this declaration, should also not be retained by the 3rd party contractor beyond the period needed to contact patients to determine their eligibility for the pilot screening; the data agreement/arrangements between the data controllers of the study and the 3rd party contractor should therefore cover the return of or destruction of this data. **Condition 6**. An authorised signature on the HRCDC application and data protection officer feedback on the DPIA from RCSI must be submitted before the study commences, or at minimum within 2 months. A signature and DPO feedback are required from each joint data controller of the study
HRCDC Recommendations:	**Recommendation 1.** To help potentially improve the take-up of the calls by patients, the letter could provide patients with the phone number that will be contacting them to conduct the pre-screening call. **Recommendation 2.** The study should record whether a patient is being supported by a relative or friend during the verbal consent process and pre-screening phone call.

9. Annual Reviews

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

- **Ref ID**: 19-005-AF2 [St. James's Hospital Cancer Biobank]
- **Ref ID**: 19-022-AF2 [TILDA]
- **Ref ID:** 19-085-AF1 [Blood Biomarkers to Predict Recovery from Ischaemic Stroke]
- **Ref ID:** 19-086-AF1 [Sepsis Immunosuppression in Critically Ill Patients]
- **Ref ID:** 20-022-AF1 [PHIND study]
- **Ref ID:** 21-003-AF1 [Investigating the Epidemiology of Mycobacterium bovis infection in humans]
- **Ref ID:** 23-001-AF1 [EUROPA T-DXd]**
- **Ref ID:** 23-002-AF1 [EAGER Register]

***Declaration no longer required.*

10. Any Other Business

Next HRCDC meeting on 28th May is in-person at the offices of HRB.

Note: Due to time constraints, items tabled for this meeting will be tabled for the next HRCDC meeting on 28th May. These include (i) discussion on Annual Report for 23-003-AF1 (CADY study), (ii) overview of the Annual Review Process and (iii) April Activities Report.

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