HRCDC
Health Research Consent Declaration Committee

Date: 25th January 2023
Location: Zoom videoconferencing

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Claire Collins
Aideen Hartney
Dan Rea
Cornelius Cooney
Mary Tumelty
John Woods
Barry Lyons
Jonny Barrett (Secretariat)
Noreen O'Brien (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES

New Applications – For consideration

Applicant	Ref No.	Title
Prof. David Williams	22-013-AF1	Maximising equity and accessibility of acute stroke care pathways in Ireland (Part C): Patient outcome and experience

Meeting Items

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

2. **Apologies**
   Sheelah Connolly, Simon Furney, Kathy Brickell, Zubair Kabir, Barry O' Sullivan.

3. **Disclosure of Interest**
   There were no disclosures of interest for this meeting.

4. **Minutes of the last meeting**
   Draft minutes of 13th December 2022 were circulated in advance of the meeting and were approved by the HRCDC.

5. **Mid-term report on implementation of Conditions: 19-021-AF3/AMD1, National Self-Harm Registry Ireland.**
   - An amendment to the consent declaration made to the National Self-Harm Registry was approved by the HRCDC on 10th May 2022. The amendment extended the duration of the initial consent declaration by 1 year to May 2023. In approving the amendment,

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the HRCDC attached a condition that the Applicant was required to make satisfactory progress in enhancing PPI activities and transparency measures, conditions that were attached to the original consent declaration of 30th April 2020. The Applicant was required to submit a Mid-term report to the HRCDC by 31st December 2022, detailing the progress made to meet these conditions.

- The mid-term report for 19-021-AF3/AMD1 was submitted by the Applicant and circulated to the HRCDC in advance of the meeting.

PPI activities:

- The Applicant's mid-term report outlined the progress made to date to establish an advisory PPI panel, noting that introductory meetings have or are to be held with each individual member. The mid-term report also outlined the membership of the PPI panel which consists of different representative organisations.
- The HRCDC commented that the Registry is still in the process of operationalising the PPI panel and onboarding its members. It was discussed that the panel has not yet convened as a group to discuss matters relating to the Registry, including the feasibility of obtaining consent or proxy assent, and that such PPI activities with the panel remained planned.
- While it was acknowledged that the PPI panel is being established, it was the view of the HRCDC that the work to enhance PPI engagement needs to be expedited, and direct engagement needs to be undertaken with the panel as soon as practicable and without delays.

Transparency measures:

- The mid-term report outlined that the registry's hospital information poster and leaflet is currently being updated and will be distributed in early 2023. The response in the mid-term report described some of the challenges in disseminating the poster and leaflet within a hospital setting (i.e., within the emergency department) and outlined what alternative approaches could be taken, including providing information in certain hospital areas that are considered more targeted, as well as via screens displayed in the hospital. The mid-term report also noted that the Applicant will seek to establish what, if any, information is already provided to patients when discharged from hospital and whether information on the Registry can also be provided at this point.
- Beyond the hospital settings, the Applicant stated that a link to the registry website has been provided on the website of the HSE's National Office of Suicide Prevention (NOSP), while information has not been made available on other relevant third-party websites. The Applicant outlined that there are plans to explore with third parties on providing links on their organisation's own websites, including those involved in the PPI Advisory Panel.
- The HRCDC discussed that it should have been feasible and practicable for the Applicant to make much more progress to enhance transparency measures regarding the Registry. On the hospital-based transparency measures, notwithstanding the potential difficulties outlined in the mid-term report, it was commented that the latest version of the Registry poster and information leaflets are still in development and haven't been distributed to emergency departments. It was also discussed that nothing has been implemented in practice within the hospitals since the amendment was

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approved. The provision of information or a link to the Registry's website via third-party websites had also not progressed, while the Registry link available on the NOSP website was considered inadequate and not easy to find for patients and public. The HRCDC discussed that, for the most part, the transparency measures detailed by the Applicant, were still proposed or potential activities that had yet to be explored or discussed in detail with the relevant personnel such that they could be implemented.

- The HRCDC was also of the view that the Registry's own website and other social media channels did not provide adequate information for patients or the wider public. It did not provide important information to patients on where or how personal data for the Registry is collected, the data protection rights of participants including withdrawing from the registry and how to exercise their rights. The HRCDC commented that it was important that the information available on the website is updated immediately.

Conclusion:

- Based on the mid-term report, the HRCDC was of the view that the response to the Applicant should note the concerns raised on the limited progress that has been made to date on enhancing PPI and transparency measures. It was also discussed that the response should clearly outline the vital importance in ensuring that the attached conditions are progressed satisfactorily, in particular as the declaration is due to expire in May 2023. The HRCDC discussed that the progress made to meet the attached conditions will be very important considerations when an amendment be submitted to request a further extension of the consent declaration.

6. New Applications

Reference ID:	22-013-AF1
Lead Applicant:	Prof. David Williams
Data Controllers:	Royal College of Surgeons in Ireland (RCSI)
Title:	Maximising equity and accessibility of acute stroke care pathways in Ireland (Part C): Patient outcome and experience.
Research Objective:	This study aims to understand what happens to individual patients around the time of their stroke. By understanding the individual factors that help or hinder people from seeking or receiving care quickly this study hopes to understand how best to plan and organise stroke services in the future. Some strokes are relatively mild and some very severe and life-changing and so this study hopes to include patients with a variety of experiences to better learn from the experience of all. This is a prospective, single-site, observational study to identify clinical, behavioural, and sociodemographic factors that may influence outcomes following presentation of patients who have recently experienced acute stroke care in a Comprehensive Stroke Centre.
Reason for Declaration:	The consent declaration is sought to process the personal data of stroke patients who lack decision-making capacity (i.e., collection, transfer, analysis, storage etc.). The personal data will be obtained from in-patient survey, qualitative interviews and medical chart review. Where a patient lacks decision-making capacity, proxy

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	assent from a relative will be sought and deferred consent obtained where possible. The relative/proxy will complete the survey/interview on behalf of participant who lacks capacity. If deemed suitable and appropriate fully anonymised data will be made available in a public repository.
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. **Public interest case** • The HRCDC discussed the aims and objectives of the study. Based on the information provided the HRCDC was of the view that there is a strong public interest in this study. **Data Controller and ethics approval** • The HRCDC noted that the Applicant had confirmed that RCSI was the sole data controller and that Beaumont Hospital was a data processor in the study. It was also noted that research ethics committee (REC) approval was obtained from the Beaumont Hospital REC, with the Applicant stating the RCSI approval was not required. • The HRCDC queried whether the designation of Beaumont Hospital as a data processor i.e., processing personal data on behalf of RCSI, was correct, as personal data was obtained from medical records under the control of Beaumont Hospital and that the Beaumont Hospital REC, not the RCSI REC, had approved the study. It was commented that in many hospitals where these types of studies are undertaken and studies that use hospital data, the hospital would be considered as either a joint controller of the study, or an independent data controller with a data agreement in place with the controller of the study. It was discussed that it is the responsibility of the relevant parties to determine the roles and responsibilities within this study, including determining who is a data controller and data processor. It was commented that the Applicant should examine the roles and responsibilities of each party to ensure their designation is correct. **Data minimisation** • It was noted that the personal data to be collected and processed included granular information such as Eircode and date of birth. The HRCDC queried whether this type of personal data is required and whether age, instead of date of birth, could be collected instead. The HRCDC was therefore of the view that the Applicant should be requested to review the data to be collected in the context of the principle of data minimisation. **Assent/consent process and General Practitioners**

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	• The HRCDC noted that the initial assent/consent process involved determining decision-making capacity via a functional perspective and commended this approach. • Where a participant who lacked decision-making capacity at the time of the recruitment and the in-patient survey is subsequently selected for the 3-month interview, it was noted that their GP may be contacted for their opinion on the appropriateness of approaching the patient for recruitment to the interview and/or capacity reassessment where they have left the hospital. The Applicant stated that this contact with the GPs would involve verbally seeking their opinions. The HRCDC discussed this process and the purpose of contacting GPs. It was commented that the study should examine how it will ensure that GPs are appropriately informed about this study in advance, including that they may be approached for information. It was also discussed that the Applicant must ensure that any required agreements or arrangements are in place with GPs and to discuss this matter with their data protection officer. • More broadly, the HRCDC discussed when and how decision-making capacity should be re-assessed during the study to determine if the patient participant can provide deferred consent. The HRCDC was of the view that the Applicant could have provided more information on how, in practice, decision-making capacity was to be appropriately re-assessed during the study, including prior to the 3-month interview and where the patient was discharged from hospital. It was also discussed that more information could have been outlined on how a phone call with the GPs could help to determine if it was appropriate to approach the patient for the 3-month interview and would provide information on re-assessing decision-making capacity. It was commented that re-assessing capacity should always be undertaken from a functional perspective, and that a clear process for re-assessing functional capacity should be in place during the study and up until the 3-month follow-up, engaging the patient. In this context it was also commented that the role the GPs in the re-assessment process should be carefully considered. **Relative's Survey Replies** • The HRCDC discussed that more clarity could have been provided on the extent to which a patient who later regains capacity would be able to review, comment and/or edit or change the survey responses that were previously provided on their behalf by their relative. It was the view of the HRCDC that the survey responses provided by a relative should always be provided to the patient should they regain decision making capacity to seek their feedback and comments, and where possible and appropriate to take these comments on board. **Study Information Leaflets**

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	• With regards the study information leaflet and consent form for participants who regain decision-making capacity, whether regained at the point of the in-patient survey or interview, the HRCDC was of the view that the Applicant should ensure that the documentation specifically requests the patient to consent to the retention and continued processing of the personal data that was collected when they lacked-decision making capacity. • It was further commented that the assent/consent documentation should outline that anonymised data maybe made available in a public repository and to seek assent/consent for this potential activity. In addition, the HRCDC noted that the information provided on the legal basis for processing personal data and the data retention periods were inconsistent across the different versions of the study information leaflets and should be corrected where appropriate. It was also the view of the HRCDC that clear information should be provided on the secure storage and deletion of the audio and video files across all versions of the study information leaflets and that note that interviews will be transcribed by a third party. • The HRCDC further noted that the term 'consent' was used in the study documentation when referring to seeking proxy assent from a relative. It was commented that 'consent' should only be used when referring to seeking permission from the patient who has decision-making capacity; 'proxy assent' should be used in the documentation when seeking permission from the relative to process personal data. • The information leaflets also refer to the role of the HRCDC in the context of the assent/consent process. It was commented that the role and remit of the HRCDC should be clarified and simply reference that a consent declaration has been made. • The HRCDC also queried the use of QR codes in the study information leaflets. **Exit Strategy** • It was discussed that the study, when completed, will either delete the data or, if it is considered beneficial, fully anonymised data will be made available in a public repository. The HRCDC queried how and who will determine what will happen the data at the end of the study and commented that more information on this would have been beneficial. Should fully anonymised data be made available in a public repository, it was discussed that the data controller must ensure it has been fully anonymised. **Data Security and Confidentiality** • The HRCDC discussed that the video/audio recordings of the interviews must be stored in a secure environment and only held for the minimum period necessary. • It was also the view of the HRCDC that the study should ensure that all efforts are made to protect patient confidentiality and privacy. This includes ensuring that patient information obtained during the study is not inadvertently passed on to family

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	members, and that efforts are made to protect patient privacy if the study survey and interviews are not conducted in a wholly private setting, for example if they are conducted in a hospital ward. **Other** • It was noted that the study was implementing various PPI engagement activities. It was commented that PPI engagement included patients who had experience of a stroke. While the level of PPI engagement was noted and welcomed, it was commented that the study should always be mindful of the will and preferences of the patients recruited to this study. • The HRCDC commented positively on the patient centric design of the survey and interview questions and the plan to test the robustness of the pseudonymisation process. • It was noted that the study information leaflet for the relative outlined that the survey will be completed while the relative is in the hospital and that it will ideally be completed in the presence of the patient. The HRCDC noted the response in the application form that the patient will be present for the survey and interviews as far as is practicable, noting reasons why this may not occur. The HRCDC queried whether the survey may be undertaken outside the hospital setting. • The HRCDC also noted and agreed with the observations made by the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee, that were similar to conditions made in previous consent declarations. These observations included that the relative providing proxy assent is the person most suitable to understand the patient's will and preferences and that the patient is involved in the assent/consent process and study activities, protections in place when recording interviews, information on the anonymisation of the data if this occurs, confirmation of full REC approval, ensuring the required data agreements and arrangements are in place, and providing information to the relative and patient on the options on what will happen their data if they withdraw.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration, should be made.
Duration of Declaration:	The Declaration is made commencing 25th January 2023 and shall be valid until 30th April 2025 or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner.
Conditions Attached:	**Condition 1.** The Applicant is requested to revisit the designation of the roles and responsibilities within this study to ensure that the designation of RCSI as the data controller of the study, and Beaumont Hospital as a data processor, is correct. Please discuss this matter with the relevant data protection officers (DPOs) and respond to the HRCDC within 2 months of the date of this declaration. Should the data controllership arrangement

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	subsequently change you should consult the Secretariat on whether an amendment is required. **Condition 2.** Once obtained, the Applicant is requested to submit confirmation of full research ethics committee approval from the Beaumont Hospital REC. Confirmation should be provided as soon as practicable and within 2 months of receipt of this letter. **Condition 3.** The Applicant should ensure that the required data agreements/arrangements are in place with the relevant parties for the purpose of this study. **Condition 4.** The Applicant is requested to review the personal data to be collected and otherwise processed for the purpose of this study to ensure that only the minimum data required is processed. The HRCDC is of the view that serious consideration should be given as to whether Eircode and exact date of birth (as opposed to age only) should be used. **Condition 5.** Where the patient has been discharged from hospital, it is noted that the patient's general practitioner (GP) may be contacted by the study for their opinion on the appropriateness of approaching the patient for recruitment to the 3-month interview and as part of reassessing capacity. In advance of contacting GPs, the study should examine how it will ensure that the GPs are appropriately informed about this study and that they will be asked for information, including that the patient's relative has provided assent for this. Aligned with Condition 3, the Applicant must also ensure that any required agreements or arrangements are put in place with GPs should they be necessary to authorising the sharing of information on the patient. The Applicant should discuss this matter with their DPO. **Condition 6.** With regards the proxy assent and consent process and study activities the Applicant is requested to undertake the following: • Ensure that the relative who provides proxy assent on behalf of the patient who lacks decision-making capacity is the most appropriate to understand the patient's will and preferences. • Decision-making capacity of the patient should be determined from a functional assessment at the initial assessment and recruitment phase, and at subsequent appropriate points during the course of study • The Applicant must ensure that a clear process is in place on when and how decision-making capacity will be re-assessed from a functional perspective for all patients following their initial recruitment, and up until the 3-month follow-up interview for those invited to complete the interview. Strong consideration should be given as to whether capacity can be appropriately re-assessed, and patient consent obtained, at each point of study contact. On approaching the GP of patients who lacked decision-capacity at the survey stage and who are invited to participate in the 3-month interview, the role of and protocol for contacting the GP and how they will be involved in practice in the process of re-assessing

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	decision-making capacity from a functional perspective, should be clearly outlined in this process. • Further to the patient's relative, where they lack decision making capacity, the patient should be involved to the greatest extent possible in (i) the assent/consent process during the course of the study and (ii) the study activities. The Applicant is requested to report on this process as part of the Annual Review, including the number of participants recruited to the study who have not been able to provide explicit consent. **Condition 7.** Where a patient regains decision-making capacity during the study, the survey responses provided on their behalf by their relative should always be provided to the patient as a standard process. The study should also consider and take on board any comments or edits/changes that the patient may have to their relative's survey responses, where this is deemed suitable and appropriate. **Condition 8.** As part of the Annual Review, the Applicant must inform the HRCDC whether fully anonymised data is to be made available in a public repository at the end of the study or if the data will be deleted. The Applicant must also ensure that any data made available in a public repository is fully, irrevocably anonymised; in this context no audio or video recordings should be made available. **Condition 9.** With regards the surveys/interviews and the audio/video recordings, the HRCDC requests the following; • Any audio or video recordings must be stored in a secure environment and held for the minimum period that is necessary. • Steps should be taken to prevent directly identifiable data being recorded or otherwise provided to the transcription service provider. **Condition 10.** To ensure clarity and transparency for participants and/or their relatives, the HRCDC requests that the following observations are addressed regarding the study information leaflets and assent/consent forms for patients and their relative: (i) The term '*consen*t' should not be used when referring to seeking permission from a relative on behalf of a patient who lacks decision-making capacity to provide consent for data processing; the term '*proxy assent'* should instead be used when referring to permission from a relative. Accordingly, the inaccurate use of '*consent'* from a relative in both the relative and patient information leaflets and assent/consent forms should be amended. (ii) The study information leaflets and corresponding proxy assent an consent forms should outline that fully anonymised data may be made available in a public repository and to request specific permission for this from the relative and/or patient. (iii) Where a patient regains decision-making capacity and is requested to provide deferred consent, the study information leaflet and deferred consent form should request their deferred consent for the continued retention and processing of

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	their personal data that was collected for the study when they lacked decision-making capacity. (iv) All versions of the study information leaflets for the relative and the patient should be consistent on the Art 6 and Art 9 bases for processing personal data and on the duration of data retention. The versions submitted to the HRCDC refer to either Art 6(1)(e) or Art 6(1)(f) and state different data retention periods of either 5 years or until April 2025. Of note the responses to the HRCDC state that the legal basis is Art 6(1)(e) and that the data will be retained until April 2025. (v) The study information leaflets should provide clear information on the secure storage and retention of the interview recordings. (vi) All the study information leaflets should note that the recordings will be transcribed by a third party, (vii) The study information leaflets should provide more clear information on what will happen the personal data collected if proxy assent from the relative is withdrawn and/or if the patient wants to withdraw from the study or does not provide deferred consent i.e., information that aligns with the responses provided to the HRCDC. Details should be provided in the study information leaflets on the options that will be given to the individual on what will happen their data in such circumstances, including that data can be removed from the study and deleted, and at what point it would not be possible to withdraw their data from the study. (viii) To avoid potential confusion about the role of the HRCDC, the reference to the HRCDC in the study information leaflets should be removed or otherwise amended to simply outline that a consent declaration has been made for this study.
HRCDC Recommendations:	**Recommendation.** The study is recommended to ensure that all efforts are made to protect patient confidentiality and privacy. This includes ensuring that confidential patient information obtained during the study is not inadvertently passed on to or shared with family members, and that efforts are made to protect patient privacy if the study survey and/or interviews are not conducted in a wholly private setting, for example if they are conducted in a hospital ward.

7. HRCDC Standard Operating Procedures

The Secretariat circulated a copy of the updated Standard Operating Procedures (SOPs) to the HRCDC, that incorporated the feedback received from the Committee members since the December 2022 meeting. The Secretariat highlighted the changes that had been made to the document. The HRCDC discussed and approved the updated SOPs.

8. HRCDC 2022 Annual Report

An update was provided on the 2022 HRCDC Annual Report that is due to be submitted to Minister by 31st March 2023. It was noted that the Annual Report is currently being drafted and will be circulated in advance of the next HRCDC meeting on 28th February.

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The Secretariat provided an overview of the HRCDC and Secretariat's activities in 2022 that will also be incorporated in the 2022 Annual Report.

9. Annual Reviews

The Secretariat has received 7 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID: 19-007-AF2;** Alistair Nichol, Targeted Therapeutic Mild Hypercapnia After Resuscitated Cardiac Arrest: A Phase III Multi-Centre Randomised Controlled Trial (TAME Cardiac Arrest Study)
- **Ref ID: 19-012-AF2;** Leonie Young, Breast Cancer Proteomics and Molecular Heterogeneity
- **Ref ID: 19-024-AF2**; Geraldine Boylan, 'Development of a Real Time Seizure Detection Algorithm for Neonates'
- **Ref ID: 19-031-AF2;** Jochen Prehn-Deborah McNamara, Bowel Disease Bio-Resource Development Identification of Potential Biomarkers for Bowel Disease
- **Ref ID: 19-072-AF2**; Eugene Dempsey, Multimodal Assessment of New-borns at risk of Neonatal Hypoxic Ischaemic Encephalopathy - The MONITOR Study.
- **Ref ID: 20-037-AF1/COV;** Emer Doheny, Home monitoring of respiration in COVID-19 patients using smartphone technology: analysis of retrospective data.
- **Ref ID: 21-015-AF1/CSO**; Andrew McCarren, UPCOM - Understanding and Preventing Covid-19 Outbreaks in Meat Processing Plants Prepared for the Future.

The Secretariat provided the HRCDC with a update on the status and progress of conditions for 20-037-AF1/COV and 21-015-AF1/CSO. It was also noted that the consent declarations for these applications had expired and/or are no longer required.

10. Activities report and events of interest.

The following upcoming events of interest and other relevant updates where noted:

- **Previous event** - Launch of HSE Genomic Strategy (13th December 2022): https://www.hse.ie/eng/services/news/media/pressrel/hse-launches-first-national-genetics-and-genomics-strategy-for-ireland.html
- **Upcoming event -** Launch of HSE National Consent Policy for Health and Social Care Research (Tuesday 9th February, webinar): registration available at: https://zoom.us/webinar/register/WN_Em1i94kXQL6nHEcGzxhtug (Copy of the policy is also provided)
- **For Information** − Launch of the National REC for the COVID-19 Biobank announced: https://www.nrecoffice.ie/committees/nicb-rec/. https://www.nrecoffice.ie/national-office-establishes-new-research-ethics-committee-for-the-national-irish-covid-19-biobank/.

11. Any Other Business

- The Secretariat discussed housekeeping including Disclosures of Interest for 2023, Decision Time and iPad policies, for which the Secretariat will follow-up with members in due course.
- The HRCDC were provided with an update on the Secretariat Programme Manager vacancy.
- The Chairperson informed the HRCDC that this was Noreen O'Brien's last meeting. The Chairperson, HRCDC and Secretariat acknowledged and thanked Noreen for her work with the Secretariat and wished her the best in her next role.

The Chair closed the meeting

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