HRCDC
Health Research Consent Declaration Committee

Date: 14th November 2023
Location: Offices of the Health Research Board

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Simon Furney
Aideen Hartney
Zubair Kabir
Dan Rea
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
Dr Michael Farrell	19-006-AF3/AMD1	Contribution of Whole Genome Sequencing to Brain Tumour Biology

New Applications – For consideration

Applicant	Ref No.	Title
Dr Seán Millar	23-020-AF1	A Capture-Recapture Study to Estimate the Prevalence of Problem-Opioid Use in Ireland (2020 – 2022)
James Cashman	23-021-AF1	Patient-Reported Outcomes in Cemented and Uncemented Total Hip Replacements

Meeting Items

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

2. **Apologies**
   Mary Tumelty (Maternity leave), Sheelah Connolly, John Woods, Con Cooney, Barry Lyons

3. **Disclosure of Interest**
   Zubair Kabir declared his interest in application 23-020-AF1 and was absent during the meeting when this application was considered.

4. Minutes of the last meeting

Draft minutes of 17th October 2023 were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

The HRCDC were informed that a letter from the Chairperson has been issued to the Applicant/data controller of 19-086-AF1 (Sepsis Immunosuppression in Critical Ill Patients) with regards their progress on Condition 3 (PPI engagement).

6. Amendments

Reference ID:	19-006-AF3/AMD1
Lead Applicant:	Dr Michael Farrell
Lead Data Controller:	Beaumont Hospital Genuity Science (Ireland) Limited ("Genuity Science", formally GMI).
Title:	Contribution of Whole Genome Sequencing to Brain Tumour Biology
Research Objective:	See HRCDC Meeting minutes of 13th June 2019 and Appeal Panel minutes of 3rd September 2019.
Purpose of Amendment:	Genuity Science is withdrawing from its collaboration in this study; accordingly, the amendment is requested to remove Genuity Science as a joint data controller. Genuity Science confirms that all data and bio-samples it has received will no longer be held by them and will be repatriated to Beaumont Hospital. The amendment is also requested to extend the duration of the consent declaration by 1 year to enable Beaumont Hospital to complete the anonymisation process.
HRCDC Comments:	The Chairperson introduced the amendment request. The HRCDC were also reminded that the consent declaration in place was not made by the HRCDC; it was made by an independent and separate appeal panel. In addition to the change of data controllership and the extension of the consent declaration by one year, it was noted and discussed that, due to delays and other factors, the study progressed with the processing of data and bio-samples relating to a smaller number of brain tumours; specifically, it has progressed with the meningioma branch of this study consisting of approximately 230 samples. The Applicant confirmed that no other brain tumour types had been transferred to or processed by Genuity Science. It was also confirmed by the Applicant that the aims, objectives and purpose of the research to be conducted by Beaumont Hospital in this study is unchanged. The processing of the other available brain tumour samples and accompanying data will not occur. The Chairperson asked each member if they approved the amendment. It was the consensus of the HRCDC that the amendment request should be approved. **Confirmation of data deletion** • Given that Genuity Science will no longer be involved in this study, it was the view of the HRCDC that it should receive confirmation when the re-patriation of the bio-samples and

	associated personal data (including brain tumour sequencing data and other patient data) to Beaumont Hospital has occur and that any data held by Genuity Science has been fully deleted. **Data Security** • It was noted that a large of volume of data is to be returned to and stored by Beaumont Hospital. It was further noted that the provisional approval made by the Research Ethics Committee required them to confirm when the cloud storage for the repatriated data has been finalised. • It was noted that he sequencing data relates to tumour somatic DNA. The HRCDC discussed that it should still be treated as genetic data and accordingly the mechanisms for the transfer to and subsequent storage of this data by Beaumont Hospital must be satisfactorily secure. It was commented that it will be important for Genuity Science and Beaumont Hospital to ensure this. It was also discussed that full research ethics approval must also be obtained and confirmation of this provided to the HRCDC. **Other** • It was commented that the DPIA notes that data anonymisaiton has already occurred, however an extension is requested to enable anonymisation to be completed. In this context and given the volume of data to be returned and stored by Beaumont Hospital, it was discussed that the DPIA should be reviewed and updated to reflect this change. • In line with Condition 1 attached to the original declaration, it was commented that Beaumont Hospital should explore and consider making the genomic data from the meningioma tumours available to other researchers while ensuring compliance with data protection laws (e.g., the data made available is not personal data/is anonymised). • 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, including updating the study website in line with Condition 3 attached by the Appeal Panel.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved.
Conditions Attached:	**Condition 1.** The volume of data to be transferred/repatriated from Genuity Science to Beaumont Hospital, including the tumour sequencing data, is noted. The Applicant must ensure that (i) the mechanism for the transfer of this data and (ii) the system/solution to be implemented for the ongoing storage/analysis of this data must be sufficiently secure to protect the data. In this context, it is noted that provisional approval has been provided from the Beaumont Hospital Research Ethics Committee; full research ethics approval must therefore be obtained and confirmation of this provided to the HRCDC, including confirmation that it covers the finalised data security solutions for storage/analysis before any transfer of data occurs.

	Condition 2. Confirmation should be provided to the HRCDC once (i) the re-patriation of the bio-samples and any associated personal data to Beaumont Hospital has been completed and (ii) Genuity Science has fully deleted all the data it has received and/or generated with regards this study. Data includes tumour sequencing data and other patient data such as clinical data etc. **Condition 3.** The removal of Genuity Science and their deletion of the data, the repatriation of the bio-samples and data to Beaumont Hospital and information on the tumour type that is the focus of this study going forward (i.e., meningioma tumours), should be clearly described on the study's website. This condition is linked with Condition 3 attached by the appeal panel.

7. New Applications

Reference ID:	23-020-AF1
Lead Applicant:	Dr Seán Millar
Data Controllers:	University College Cork
Title:	A Capture-Recapture Study to Estimate the Prevalence of Problem-Opioid Use in Ireland (2020 – 2022)
Research Objective:	This research project aims to estimate the number of problem-opioid drug users in the Republic of Ireland from 2020 – 2022. Problematic opioid use is a significant problem in Ireland and across the globe. Opioids include drugs such as heroin, morphine, methadone, codeine, hydrocodone, fentanyl and tramadol. While some of these have valid medical purposes, their misuse as "street drugs" can lead to many health and social issues for users and society. This data will be used to compare trends in opioid use over time and inform government and policy makers regarding the scale of the problem. As measuring the prevalence of drug users is difficult, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) recommend the use of indirect methods such as the capture-recapture method to estimate the prevalence of high-risk drug users.
Reason for Declaration:	This is a retrospective observational study, using data previously collected by other agencies to perform statistical analysis and estimate the number of problematic opiate users in Ireland. The data collected includes demographic data such as participant name and date-of-birth which is required to match cases between the different registries and databases. A declaration is requested for UCC to obtain, match, consolidate the personal data. The personal data is subsequently fully anonymised before it is analysed. The consent declaration is requested as it is not considered feasible/practicable to obtain the explicit consent of participants for several reasons. The Applicant also stated that the nature of the capture-recapture method requires all individuals to be included.
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 Secretariat highlighted that a consent declaration was previously made for this study in December 2020 to cover the 2015-2019 cohort (HRCDC Ref: 20-034-AF1). It was highlighted that the consent declaration that was made expired in December 2021 and that the Applicant/data controller now wishes to repeat this study for the 2020-2022 cohort. It was further noted that methodology and data sources to be utilised remain unchanged. 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 with conditions attached should be made. **Public interest case** • The HRCDC discussed the aims and objectives of this study. The matter of consenting participants to this study was also discussed. • Based on the information provided, the HRCDC agreed with the rationale outlined by the Applicant for not seeking participant consent, including why the methodology required all participants to be included and to ensure consistency with the methods used in the previous study. On balance the HRCDC was of the view that there is a strong public interest case in this research. **Transparency and PPI** • The HRCDC noted and discussed the proposed transparency measures and PPI engagement activities that will be undertaken for the 2020-2022 cohort study. The HRCDC commented on the positive actions that had been taken and the measures that are to be implemented but also commented that other additional measures could be made to further strengthen transparency. • It was the view of the HRCDC that that proposed activities should be implemented as soon as practicable and prior to the study commencing. **Data Security** • The HRCDC noted that the data will be stored on a designated computer and would be encrypted. It was queried whether the security of the data could be further strengthened by utilising server or cloud storage of the data. • It was also noted that the DPO highlighted that advice should be sought from UCC IT Security on the secure methods of transfer. • The HRCDC was of the view that the Applicant/data controller should review the security of the data transfer and storage methods to ensure they are secure. **Other:** • The HRCDC noted that provisional research ethics approval is in place and that full approval will be granted when the data sharing agreements are finalised.

	• The HRCDC queried if the study maybe repeated again for future cohorts. If this will occur, it was discussed that the Applicant could submit an amendment prior to the consent declaration expiring. • 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. These observations included that the required data agreements are to be in place and that the transparency measures should more clearly outline the rights of participants, including that their right to withdraw from this study is limited and why it is limited. The HRCDC also agreed that additional transparency measures should be explored such as the use of social media, both to inform participants and the public about this study and to enhance signposting to the study webpages.
HRCDC Decision:	The consensus of the HRCDC was that a consent declaration with conditions attached should be made.
Duration of Declaration:	The consent declaration is made on 14th November 2023 and is valid for 6 months (until 31st May 2024) when the personal data is to be fully anonymised.
Conditions Attached:	**Condition 1.** The transparency measures and PPI activities for this latest cohort study (i.e., 2020-2022 cohort) that have been outlined in the HRCDC application form, should be implemented/undertaken as soon as practicable and prior to the study commencing. With regards to the transparency measures to be implemented, they should clearly outline the rights of participants, including that their right to withdraw from this study is limited and why it is limited. **Condition 2.** It is a condition that this declaration is not in effect until confirmation has been received by the HRCDC that the required data transfer agreements are in place between UCC (the data controller of the study) and the providers of the personal data. Linked to this full approval from the research ethics committee must also be in place and confirmation of this provided to the HRCDC. For the avoidance of doubt, no transfer of personal data can occur until the appropriate agreements and full REC approval are in place.
HRCDC Recommendations:	**Recommendation 1.** The Applicant/data controller is requested to review the security of the data transfer and storage methods to ensure they are sufficiently secure. **Recommendation 2.** The HRCDC positively notes the transparency measures that have been undertaken to date and the proposed measures that are to be undertaken. To further strengthen transparency for this study, the HRCDC recommends that the Applicant should explore the use of additional suitable transparency measures to inform participants and the public about this study and to enhance signposting to the study's web pages on the UCC and drugsandalcohol.ie websites. For example, consideration should be given to utilising the social media platforms/websites of the data controller (UCC) as well as the Probation Service and the HSE. The Applicant is requested to report on this at the Annual Review.

Reference ID:	23-021-AF1
Lead Applicant:	James Cashman
Data Controllers:	National Orthopaedic Hospital Cappagh (NOHC) National Office for Clinical Audit (NOCA) @ RCSI
Title:	Patient-Reported Outcomes in Cemented and Uncemented Total Hip Replacements
Research Objective:	The researchers aim to do a retrospective study looking at the Patient Related Outcome Measures (PROMs) in those that have undergone a hip replacement and compare the results between those who had a cemented implant vs those with a cement less implant. It seeks to use data that has been uploaded to the Irish National Orthopaedic Register (INOR). INOR uses two internationally recognised PROMs scoring tools. The Oxford Hip, which measures the pain and physical functioning, associated with the joint and the EQ5DL, which is a quality of life measurement-scoring tool.
Reason for Declaration:	The data processing activities for this study is limited to extracting and fully anonymising the pre-existing register data for this study as follows: • NOCA, as the owners of the Irish National Orthopaedic Register (INOR) will extract the data required for this study from this register i.e., data of NOHC patients included in the register from whom their register consent is already provided. • NOCA will fully, irrevocably anonymise the extracted dataset. The extracted, fully anonymised dataset will then be transferred to NOHC for study analysis. The timeline of patient data to be extracted is from June 2019 to 31st December 2023. Data on implants/patients from the National Orthopaedic Hospital Cappagh has been included on the register (INOR) since June 2019; patients have provided explicit consent with regards their personal data on the register. However, this register consent did not cover consent for research, including anonymising the data for research. Since 2022 all new implant patients have been asked for their separate consent to use their register data for research purposes. A process is also underway to seek retrospective research consent from those pre-existing patients who provided register consent between June 2019 to 2022. The declaration is requested to cover patients from Cappagh Hospital who provided register consent between June 2019 to 2022, but where their research consent is not yet obtained (n= 3170). The Applicant outlines that it will not be possible or practicable to obtain the research consent of all these pre-existing patients prior to commencing this specific research study. In addition, the Applicant notes that there may be rare cases where it is not possible to obtain research consent from a very small number of newly treated patients in Nov – Dec 2023 who are admitted outside the normal treatment pathway and therefore who may not yet provide their research consent prior to the study

	commencing (i.e., their research consent would be collected at the post-opt stage). The declaration is therefore also requested to cover these rare cases in November-December 2023.
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 introduced the study, and the Secretariat provided an overview of the data source to be utilised, the reasons for seeking a consent declaration and the cohort of participants that are requested to be covered. The Secretariat also confirmed that the scope of the consent declaration is limited to this research study only; the data processing for the purpose of the register does not fall under the remit of the HRCDC. It was also confirmed by the Applicant that the initial request for the consent declaration to extend to the processing of data of those who lack decision-making capacity is no longer applicable. 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 with conditions attached should be made. **Public interest case** • The HRCDC discussed the aims and objectives of this study and noted that the data processing was limited to anonymisation of the register data. It was commented that more specific information could have been provided on the data analysis component, however it was noted that the data would be fully anonymised at this stage. • On balance, it was the view of the HRCDC that there is a strong public interest case in this research. **Scope of the consent declaration** • The HRCDC discussed whether the scope of the consent declaration should extend to the small cohort of new patients to be treated in November – December 2023, who are admitted outside the normal treatment pathway and whose research consent may not be obtained in advance of this research study. • On balance the HRCDC was of the view that this small cohort could be included within the scope of the consent declaration. It was noted that the Applicant/data controller should be requested to report on the numbers within this cohort as part of the Annual Review. **Transparency and PPI** • The HRCDC noted the PPI activities outlined by the Applicant. In addition, the HRCDC discussed the transparency measures that will be implemented. It was discussed that the data will be extracted and anonymised in early January 2024 and that it was

	important that transparency measures are implemented to inform participants about this study and to provide them with adequate opportunity to withdraw/opt-out if they wish. • The HRCDC commented that the transparency measures should be implemented as soon as practicable and should outline clear information on how an individual can withdraw/opt-out before the data is fully anonymised. **Other:** • It was queried whether participants who have been asked to provide consent for processing their data for research but who refuse are included in this study. It was confirmed that the scope of the consent declaration will not extend to such individuals as it cannot override a participant's wish not to provide their consent for research. • 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, including providing clear information on the scope of the declaration and continuing to make efforts to obtain participant consent up until the point the data is extracted and anonymised.
HRCDC Decision:	The consensus of the HRCDC was that a consent declaration with conditions attached should be made.
Duration of Declaration:	The consent declaration is made on 14th November 2023 and is valid until 29th February 2024, when the data anonymisaiton is to be fully completed.
Conditions Attached:	**Condition 1.** The transparency measures outlined to the HRCDC should be implemented as soon as practicable and prior to the data being extracted and fully anonymised. It is important to ensure that the transparency measures provide clear information on the purpose of the study, data protection rights and how a participant can request to withdraw/opt-out from the study. It is also important to ensure that participants are given sufficient opportunity to withdraw/opt-out. **Condition 2.** Up until the point where the extraction and anonymisation of the data occurs in early 2024, the Applicant/data controllers should ensure (i) that research consent of the 2019-2022 patients who may be attending clinical follow-up during this period should still be sought and (ii) strong efforts should be made to obtain the post-opt research consent of the Nov-Dec 2023 patient cohort. On point (ii) the Applicant/data controller is also requested to report on the numbers within this November – December 2023 cohort whose consent for research was and was not obtained at the annual review.

8. Annual Reviews

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

- **Ref ID:** 19-020-AF2; Deirdre Murray, '*BASELINE study'* [*Declaration no longer required]*
- **Ref ID:** 21-016-AF1; Elaine Walsh, '*STOPPFrail study' [Declaration no longer required]*

- **Ref ID:** 19-060-AF3; Austin Stack, '*NKDSS QA'*
- **Ref ID:** 19-031-AF2; Jochen Prehn, *'Bowel Disease Bio-Resource Development'*
- **Ref ID:** 22-002-AF1; Michelle O'Brien, '*Understanding the wishes and support needs of people with intellectual disability as they grow older'.*
- **Ref ID:** 19-007-AF2; Alistair Nichol, '*TAME Trial'.*

9. Activities report and events of interest.

The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting. The following events were attended by the secretariat and a summary review of the events provided to the HRCDC. Presentation on UK amendments to data protection laws to be concluded at the December 2023 meeting.

- Enabling a trusted health data research environment – HRB event.
- GCP in regulated studies – presentation by HPRA.
- HSE Data collaborathon.
- Artificial Intelligence and GDPR – online seminar.
- HSE event - Evidence for policy making.
- Dementia Trials Ireland - Overview of clinical trials webinar.
- PDP - Data protection conference.

10. Any Other Business

- The Chairperson informed the Committee that Barry O'Sullivan (BOS) has stepped down from the HRCDC. The Chairperson acknowledged and thanked BOS for his contributions to the HRCDC and wished him well.
- The HRCDC was reminded that the next meeting is scheduled for 12th December 2023.

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

Before the formal commencement of the meeting the HRCDC attended a talk from Prof Alistair Nichol (Chair of the National Research Ethics Committee for Clinical Trials) on the operation of International Clinical Trials in Ireland.