HRCDC
Health Research Consent Declaration Committee

Minutes of the Meeting – APPROVED

Date: 13th August 2024
Location: Zoom videoconferencing

HRCDC Attendance:

Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Aideen Hartney
Zubair Kabir
Dan Rea
Barry Lyons
Patricia O'Beirne
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions

YES

New Applications – For consideration

Applicant: Prof. Fionnuala Ní Áinle
Ref No: 24-006-AF1
Title: Determining the Impact of the "Thrombocalc" VTE Risk Assessment on the Incidence of postpartum VTE in the Rotunda Hospital, and derivation of a novel postpartum VTE risk prediction model.

Applicant: Professor David Williams
Ref No: 24-008-AF1
Title: Development and Validation of a Risk Prediction Model of Adverse Drug Events in Older Adults Presenting to an Acute Tertiary Hospital

Opening

The Chair opened the meeting and welcomed the members.

Apologies

Sheelah Connolly, Simon Furney, Cornelius Cooney, Mary Tumelty (Maternity leave), Susan Smith, Paul Stynes, Aisling McMahon, John Woods.

Disclosure of Interest

Zubair Kabir (ZK) informed the HRCDC that he has previously worked with researchers noted in applications 24-006-AF1 and 24-008-AF1, however ZK is not involved in these two studies. It was determined that ZK did not have a potential conflict that would require him to be absent from the meeting when these applications were considered.

Minutes of the last meeting

Draft minutes of 25th June 2024 were circulated in advance of the meeting and were approved by the HRCDC.

Chairperson Approvals

- **Ref ID: 22-005-AF1/AMD3.** The HRCDC were informed that amendment request 22-005-AF1/AMD3 was approved via the Chairperson approval process. The amendment covers the extension of the consent declaration until 31st July 2026.
- **Ref ID: 22-006-AF1/AMD3.** The HRCDC were informed that amendment request 22-006-AF1/AMD3 was approved via the Chairperson approval process. The amendment covers the extension of the consent declaration until 31st July 2025.
- **Ref ID: 24-001-AF1/AMD1.** The HRCDC were informed that amendment request 24-001-AF1/AMD1 was approved via the Chairperson approval process. The amendment covers the extension of the consent declaration by 2 months to 31st August 2024.
- **Ref ID: 22-001-AF1/CSO/AMD3.** The HRCDC were informed that amendment request 22-001-AF1/CSO/AMD3 was approved via the Chairperson approval process. The amendment covers the extension of the consent declaration until 31st March 2025.

The Chairperson also informed the HRCDC that, in addition to extending the duration of the consent declarations, the amendment decision letters for 22-005-AF1/AMD3 and 22-006-AF1/AMD3 also noted a technical change to the scope declaration that related to the data flow, specifically, the pseudonymised data for these studies is no longer extracted from the 'epilepsy warehouse reporting system' and is now extracted by hospital technical personnel.

Updates on previous applications

24-007-AF1 (STARGATE study): The Chair updated the committee that the Applicant had informed the Secretariat that they have withdrawn the consent declaration.

New Applications

Reference ID:

24-006-AF1

Lead Applicant:

Prof. Fionnuala Ní Áinle

Lead Data Controller:

Rotunda Hospital

HRCDC
Health Research Consent
Declaration Committee

Title:

Determining the Impact of the 'Thrombocalc' VTE Risk Assessment on the Incidence of postpartum VTE in the Rotunda Hospital, and derivation of a novel postpartum VTE risk prediction model.

Research Objective:

Pregnancy-associated blood clots, also called venous thromboembolism (VTE), are the leading cause of direct maternal death in Ireland and the UK. Current clinical guidelines recommend that women who have an elevated risk of VTE during pregnancy or after childbirth should receive anticoagulant medication.

Achieving universal VTE risk assessment is a challenge in busy postnatal environments. Despite the terrible impact of VTE, compliance with VTE prevention strategies in Irish maternity units was shown to be sub-optimal. There was a clear demand for a more streamlined approach to VTE prevention at a national level.

In 2014, a multidisciplinary team in the Rotunda Hospital developed an electronic risk assessment tool called 'Thrombocalc' which calculates a simple risk score and makes recommendations on thromboprophylaxis based on each woman's individual VTE risk factors. Thrombocalc is a tangible solution to a common problem. Through collaborative research and quality improvement, Thrombocalc was embedded in routine care.

Through this research the Applicant wants to find out exactly how much the electronic tool, Thrombocalc, reduces the number of people who develop a blood clot after pregnancy. They also want to refine the current tool to ensure they are using the best way to estimate a person's risk of developing a blood clot in the 6 weeks after pregnancy. This information will help show how best to prevent blood clots after a baby is born.

To do this the study needs to compare how many women had a blood clot before Thrombocalc was introduced into the Rotunda Hospital and how many women had a blood clot after Thrombocalc was introduced. To do the second, the study needs to look at all of the risk factors that each woman had, and to use this data to build a good "model" using statistical techniques that will allow them to predict her risk of a blood clot. This will be the first time that this will have been done with such high-quality data.

It is often difficult to find out exactly how many women get blood clots after they leave the hospital with their baby. This research will use 3 ways of finding out this information; (1) Using scan results which were used to diagnose the blood clot, (2) Using records collected by the hospital called Hospital In-patient Enquiry (HIPE) records, which are reported to the Health Service Executive (HSE) and (3) Using the patient's individual medical chart.

The findings from this research will be used to deliver the right treatment to the right patient, preventing dangerous blood clots in those who are at risk and avoiding unnecessary blood thinner injections in those who don't need it.

Reason for Declaration:

A consent declaration is requested due to the large number of patients involved in this study, estimated at >70,000 and the time period that is covered; the Applicant outlined that it is not practicable or feasible to obtain the explicit consent of the participants for these reasons.

HRCDC Comments:

The Chair introduced the study and 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 study activities, aims and objectives. It was discussed that the Thrombocalc tool aims to reduce the risk of VTE in pregnant women and therefore reduce mortality. It was commented that the study sample size of women with VTE was relatively small. While the number of women who die each year from VTE is low, it was also highlighted that the study may help avoid unnecessary blood thinner injections for women who don't need it. It was also commented that the study is relatively low risk, involving the processing of retrospective data.
- On balance it was the view of the HRCDC that there is a public interest case in this study.

Transparency measures

- The Applicant outlined that they would provide posters and notices within the Rotunda to explain the study and data processing; the posters will also be advertised on advocacy group websites. It was commented that the poster content should be provided in lay-person's language, for example the heading of the poster could be simplified. It was also discussed that the poster should include more details on how to withdraw and provide a phone number as well as the email address.
- Further to sharing the posters, it was commented that there should also be a webpage for this study that includes details on the participants data rights and that the link to this website should be shared with the advocacy groups to provide on their own websites.

Data Processing

- The responses from the Applicant outlined that data on all women who attended the Rotunda who were investigated for suspected VTE during the study period would be included in this study; it was further outlined data would be collected from the Rotunda medical records as well as records from other hospitals the patient may have attended. The Applicant confirmed that this will include the Mater Hospital and other hospitals in the Leinster region.
- The HRCDC was of the view that the Applicant should report in the Annual Review on the hospitals where data is collected from, if beyond the Rotunda and the Mater, and confirm that the required data agreements are in place.

Other:

- The HRCDC commented that there was a good level of public and patient involvement in this study.
- Reference was made to the declaration being required for 4 or 5 years; the Secretariat highlighted that the Applicant had confirmed it is required for 5 years.
- It was queried whether the data to be shared with RCSI, a named data processor was pseudonymised or fully anonymised. It was highlighted that the Applicant had confirmed it was fully anonymised, following clarifications from the Secretariat.
- It was discussed that this study involves an internal validation of this tool. Reference was made by the Applicant to potentially externally validating the tool; following clarifications to the Secretariat, an external validation of this tool using personal/pseudonymised data would not occur and therefore is not within the scope of this consent declaration. The

Applicant outlined that an external validation may occur in the future but would likely involve anonymised data only. It was also noted by the Applicant that the anonymised data produced at the end of this study may be used in the future for other model or tool validations.

- 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 making the scope of the consent declaration clear in the decision letter, ensuring that the required data agreements and arrangements are in place, implement the transparency measures before the study commences and matters relating to data withdrawal.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration, subject to conditions attached, should be made.

Duration of Declaration:

The consent declaration is made on 13th August 2024 and is valid for 5 years until 31st July 2029, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. The required data agreements and arrangements for the transfer and processing of personal/pseudonymised data must be in place; data cannot be transferred until such agreements/arrangements are in place.

Condition 2. The transparency measures should be in place prior to the study commencing.

Condition 3. The Applicant must report in the Annual Review if data is obtained from medical records from other hospitals in Leinster, beyond the Rotunda and the Mater, and confirm that the required data agreements with those hospitals are in place.

HRCDC Recommendations:

Recommendation 1. The information posters/notices on this study should be reviewed and amended to ensure that it provides details in lay-person language; for example, the title of the study poster should be revisited. The poster should also provide further details on withdrawing from the study and the deletion of the data, including providing a phone number as well as the email address. As part of this process to improve readability, it is also recommended to have the revised study information poster reviewed by suitable public and patient representatives.

Recommendation 2: There should be a webpage for this study that includes details on the participants data rights, including right to withdraw, and that the link to this website should be shared with the advocacy groups to provide on their own websites, along with the poster.

Reference ID:

24-008-AF1

Lead Applicant:
Professor David Williams

Lead Data Controller:
Beaumont Hospital
Royal College of Surgeons in Ireland

Title:
Development and Validation of a Risk Prediction Model of Adverse Drug Events in Older Adults Presenting to an Acute Tertiary Hospital

Research Objective:
The Irish population is ageing, and this is leading to an increase in the use of medications. Older adults are at significant risk of experiencing an adverse drug event/reaction (ADE/ADR) - an event/reaction that is harmful or unpleasant and unintended and which occurs at normal doses. Approximately 10% of hospital admissions in those aged over 65 years are ADR-related and 70% of all these admissions are preventable or avoidable. However, there is a lack of valid and reliable methods or tools for physicians to detect and predict ADRs and this study is being performed to ensure a newly developed risk prediction tool is valid and reliable. The tool will use participant information such as age, gender, medications, medical conditions, use of walking aids, help with daily activities among others. The study will be conducted to test the tool in real world settings to ensure it is reliable and valid and user-friendly.

Reason for Declaration:
The consent declaration is requested to process the personal data of participants who lack decision-making capacity. Within the study there is a sub-group of people with dementia resulting in loss of decision-making capacity and people who may have intellectual disability that separately or in combination has resulted in lack of decision-making capacity. Additionally, older adults presenting acutely to the hospital may have a delirium which can impact on the participants' ability to consent, but these patients may regain capacity to consent, and they will be given the time to recover in order to optimise their capacity.

HRCDC Comments:
The Chairperson introduced the study and 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 research. Based on the information provided it was the consensus of the HRCDC that there is a strong public interest case in this study.

Data collection:
- The Applicant had outlined the type of data to be collected in this study including the participant's name, contact information and the types of clinical data to be collected including details of hospital admission, medical conditions, medications, hospital results etc. It was noted that the study would request personal data from the participant's GP or

community pharmacist if it was found that the data required was missing from the hospital's records.

- Where data is requested from the GP or pharmacist, it was highlighted that the first point of contact with them would be by a phone call while the data would be transferred by secure email facility. It was also highlighted that agreements would be in place for such data transfers and that proxy assent/participant consent is sought for this activity.
- The HRCDC also commented on the collection of data relating to whether the participant has private health insurance and/or a medical card. The reply from the Applicant noted that this is limited to a yes or no response on whether they have insurance or a medical card; data on the details of the medical card or private insurance would not be collected. The Applicant noted that this data was being collected to act as a proxy or indicator on socio-economic background; the HRCDC queried as to how good an indicator this data may be.
- It was noted that the Applicant aims to complete the assenting/consenting of participants and data collection within 6 months. The HRCDC commented that this seemed a relatively short time period given the number of participants involved which is expected to be up to 3000. The HRCDC was of the view that the decision letter should highlight that the study can request an extension to the consent declaration.

Data deletion and anonymisation

- The Applicant outlined that the personal data covered by the consent declaration for those who lack decision making capacity will be deleted once the research is completed by July 2025. For those participants who provide consent their data will be fully anonymised and then retained for up to seven years. The Applicant outlined that their anonymised data may be used in future studies.
- The HRCDC queried why the data of those covered by the consent declaration would be deleted at the end of the study and not fully anonymised and used in the future given that this would impact the completeness and representation of the anonymised data that could be used for other future purposes. It was commented that the Applicant may not have known that personal data processed under a consent declaration could be fully anonymised, rather than deleted, at the end of the study after which the fully anonymised data falls outside the remit of the consent declaration process and HRCDC. It was discussed that this will be highlighted to the Applicant in the HRCDC decision letter.

Study information leaflets

- It was the view of the HRCDC that the study information leaflets and proxy assent and participant consent forms where quite technical in nature and should be written from a more lay-persons perspective to help the readers better understand the study, what is involved and the processing of data. It was commented that the language used was not reader friendly, in particular when considering the cohort of participants who are the focus of this study.
- In addition, the HRCDC also noted other inconsistencies and errors in the study documentation. For example, it was noted that the proxy study documentation was worded in places as if the proxy, not the participant, was the individual enrolled into the study and having their data processed, for example by referring to 'my participation' and

'my name and address'. Also, the terms 'consent' and 'assent' where incorrectly used. The proxy assent documentation further included assent options to linking the participant's medical card number with data from the Primary Care Reimbursement Services as well as a questionnaire, which the Applicant confirmed is an error. The proxy assent documents also include references to anonymisation of the data and processing data in future studies, which does not align with the Applicant's reply on what will happen the data at the end of the study; more generally, there were other inconsistences noted around the retention period of data. The HRCDC was also of the view that the proxy documentation should ask the proxy to consider the participant's will and preferences on whether they would wish to be included in this study and that references to the HRCDC providing consent for this study should be removed.

- Overall, it was the view of the HRCDC that the study information leaflets, and assent/consent forms need to be revised and amended to improve readably and address errors and inconsistences prior to the study commencing. For the benefit of the study and participants, it was also discussed that the updated documents should be reviewed by appropriate public and patient representatives, before commencement of the study.

Other:

- It was commented that the scope of the consent declaration should be clearly outlined in the decision letter.
- The HRCDC noted that there was strong public and patient involvement in this study, however no specific details were provided on which groups were consulted and if these were formal PPI groups.
- It was commented that study findings should be disseminated beyond medical journals to include patient groups.
- The Secretariat highlighted the Applicant's response that data from a previous related study, ADAPT, is not being processed in this study.
- 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 that the required data agreements and arrangements and full research ethics approvals need to be in place for each site prior to study commencing.

HRCDC Decision:

The consensus of the HRCDC was that a Consent Declaration is made, subject to conditions.

Duration of Declaration:

The consent declaration is made until 31st July 2025, or until the personal data is deleted or fully anonymised, whichever occurs first.

Conditions Attached:

Condition 1. Full research ethics committee approval must be obtained for each site. The consent declaration is not in effect where REC approval is not in place. Confirmation of REC approval should be submitted, when available.

Condition 2. The required data agreements and arrangements must be in place prior to the transfer and processing of data for this study**.**

Condition 3.

(a) The versions of the study information leaflets, and the family member proxy assent/participant consent forms are quite technical in nature, with language such as 'risk prediction algorithm' impacting the readability of these documents. Accordingly, the Applicant/data controller should review and amend these documents, ensuring that they use more lay-person language to help improve their overall readability to help participants and/or their family member better understand the study and the processing of data. Once amended, the updated documents should be reviewed by appropriate public and patient representative(s) to help ensure readability. (See websites such as NALA.ie as an example when working to improved document readability).

(b) The family member documentation should ask them to consider the participant's will and preferences on whether they would wish to be included in this study.

(c) the HRCDC notes that there are inconsistencies and errors within study documentation that should be addressed. Examples include:

- The family member proxy study documentation is worded in various places as if the proxy providing assent on behalf of the participant who lacks capacity, is the individual who is enrolled into the study and having their data processed, for example by referring to 'my participation' and 'my name and address' as well as 'my data'.
- The term 'assent', not 'consent', should be used when referring to seeking permission from the family member to process personal data on behalf of the participant who lacks decision-making capacity
- The family member proxy assent form submitted, provides an option to assent to linking the participants GMS medical card to the prescription dispensing information collected by the PCRS as well as reference to a questionnaire. The Applicant has already confirmed to the HRCDC that this is an error and so this should be deleted.
- The patient re-consent form includes a section with wording that refers to the HRCDC previously providing 'consent' for the study; this wording should be removed as the HRCDC does not provide consent on behalf of the participant.
- On what will happen the data at the end of the study, the replies to the HRCDC state that the data processed under the consent declaration for those who lack decision-making capacity will be deleted after the study ends in July 2025, while it will be anonymised and used in the future for those who provide consent. For informaiton, please note that the Applicant/data controller can choose to fully anonymise the personal/pseudonymised data of those covered by the consent declaration at the end of the study as the exit strategy, instead of deleting it.
  Given the replies to the HRCDC, the following inconsistences were noted in the study documents on what will happen the data and need to be addressed:
  - All three versions of the documents submitted to the HRCDC also separately refer to storing and using coded electronic data for future further research for 7 years,

which is inconsistent with the replies to the HRCDC that data will be deleted or anonymised.

The informaiton and options on data archiving, future use and anonymisaiton/deletion outlined in all the versions of the study documents need to be reviewed and amended to provide clear and consistent information.
As proxy assent and a consent declaration cannot cover the processing of personal/pseudonymised data in other future studies, there should be no references to the further future use of personal/pseudonymised data in the family member proxy documentation.
With regards participant consent to store and further use personal data in future research, it is the responsibility of the Applicant to ensure they have obtained valid consent for this.

Note: In summary, the study information leaflets, and assent/consent forms should be amended to address the above points prior to the study commencing and confirmation that that changes have been made should be provided to the Secretariat. Please note that submitting the revised documents to the Secretariat/HRCDC is not required.

HRCDC Recommendations:

Recommendation. The study findings should be disseminated beyond medical journals to include patient groups.

Annual Reviews

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

- **Ref ID:** 19-077-AF3 (IPCOR)
- **Ref ID:** 22-009-AF1 (Linking and harnessing health and population data to improve outcomes in Out-of-Hospital Cardiac Arrest)
- **Ref ID:** 22-006-AF1 (HPO study)
- **Ref ID:** 22-005-AF1 (EPIDIVE Phase 2)
- **Ref ID:** 23-004-AF1 (REACT SHOCK)
- **Ref ID:** 19-041-AF3/COV (The role of T-Regulatory and Mononuclear Phagocyte Cells causing Immune Dysfunction in Sepsis - A study on the role of immune dysfunction in sepsis and COVID-19)

Activities report and events of interest

- The Secretariat circulated a report of its activities to the HRCDC in advance of the meeting and it was discussed with the HRCDC.
- There was a discussion on the report of the meeting with the Health Research Authority (UK) and the Confidentiality Advisory Group, in relation to aspects of their operations that could be adopted by the HRCDC.
- The summary of the meeting with the EU4Health Steering group meeting was also discussed including the recently published Health Information Bill.

Any Other Business

- The Secretariat circulated an informaiton note with regards the controllership of research studies involving HSE hospitals as the data controller of the study and this was discussed by the HRCDC.
- The Secretariat provided a brief update on the HRCDC website.

The Chair closed the meeting