HRCDC
Health Research Consent Declaration Committee

Date: 16th November 2021
Location: Videoconference by Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Claire Collins
Sheelah Connolly
Simon Furney
Aideen Hartney
Barry O' Sullivan
Dan Rea
Cornelius Cooney
Mary Tumelty
John Woods
Barry Lyons
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions ☒YES

New Amendments - For Consideration

Applicant	Ref No.	Title
Alistair Nichol	20-036-AF1/AMD1	EPO-TRAUMA

New Applications - For Consideration

Applicant	Ref No.	Title
Richard Flavin	19-005-AF2	St. James's Hospital Cancer Biobank
Andrew McCarren (lead/DCU); Grace Mulcahy (UCD)	21-015-AF1/CSO	UPCOM Study
Alberto Alvarez-Iglesias	21-018-AF1/CSO	Quantifying the Effects of Public Health Interventions in Ireland

Meeting Items

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

2. **Apologies**
   Zubair Kabir, Kevin Clarke and John Ferguson.

3. **Disclosure of Interest**

- Kathy Brickell (KB) declared her interest in amendment request 20-036-AF1/AMD1 (EPO-TRAUMA). KB was absent during the meeting when this amendment request was considered.
- Barry O'Sullivan (BO'S) declared his interest in application 21-015-AF1/CSO (UPCOM Study). BO'S was absent during the meeting when this application was considered.

4. Minutes of the last meeting

Draft minutes of 12th October 2021 were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

Reference ID:	21-016-AF1
Lead Applicant:	Elaine Walsh
Lead Data Controller:	University College Cork
Title:	STOPPFrail
Previous minutes	See minutes of 12th October 2021
Matter arising for consideration	• The Applicant provided a response in relation to the implementation of Condition 1 that was attached to the conditional declaration made by the HRCDC. • The Applicant outlined the challenges that would be faced in requiring the General Practice (GP) or nursing home staff, to review and collect the required data for the research study, rather than the UCC researcher. These included the staff's clinical workload and the extensive time that is required to review and collect the necessary data. • The Applicant highlighted that the GP or nursing staff may not capture all necessary data, which would be considered pertinent by researcher with pharmacy expertise. • The Applicant put forward the point that from a patient safety perspective, the researcher being a clinical pharmacist performing the reviews in the study ideally should have access to the full clinical record of the patient to ensure all medical conditions and medications are extracted accurately. • The Applicant was also of the view that restricting UCC researcher access to the medical records for the retrospective chart review elements of the study, once the pre-screening for participant eligibility is carried out, is not proportionate given the extent of data that will already be accessed and viewable during the pre-screening stage, including the data protection risks being no greater. • An additional proposed safeguard was also proposed by the Applicant, whereby the UCC researcher could liaise with staff at each site to discuss how best to collect the data required and minimise access to non-relevant personal data within the medical record.
HRCDC Comments:	• It was noted from the previous meeting, that the consensus of the HRCDC was that there was a public interest case in the study. • The HRCDC considered the response provided by the Applicant to have merit given the specific circumstances of this

	application. From the response provided, it was noted that the researcher would already have access to personal data from the medical records at the pre-screening stage of the study. The HRCDC further noted from the Applicants response, that no additional data protection risks should arise and that additional mitigating safeguards could be implemented. It was also noted the other practical difficulties in accessing the necessary data for the study. The HRCDC was of the view that it would be appropriate to amend Condition 1 to (i) enable the UCC researcher to access and review the participant's medical records and collect the necessary personal data for this study and, (ii) to include the additional safeguard proposed by the Applicant. • It was also commented that it was important that the extent of data accessed by the UCC researcher, during both the pre-screening stage and retrospective chart review stage, should be discussed as part of the public and patient involvement (PPI) activities and highlighted through the transparency measures being undertaken. • It was noted that conditions on PPI activity and the study information leaflets have already been attached to the consent declaration. • More generally, the HRCDC discussed that pre-screening of medical records, and retrospective review and collection of data from the same medical records are very similar in terms of personal data is being accessed. It was further commented that the amendments to the Health Research Regulations (and associated guidance) where pre-screening and retrospective chart review activities do not require participant consent, or a consent declaration, is very nuanced and should be carefully interpreted on a case-by-case basis. Some members queried whether the guidance was clear for researchers. Some members discussed the extent of data processing that could be covered by a consent declaration, if such data processing which would not fall under an amendment. The Secretariat would discuss any queries raised with members separately in case clarification is needed and if necessary, discuss with the the Department of Health.
HRCDC Decision:	It was the consensus of the HRCDC was that Condition #1 attached to the declaration could be amended. The scope of the declaration will be revised to reflect this amendment.
Conditions amended:	Condition 1 is amended as follows: (i) Prior to the retrospective chart review element of the study and subsequent access to and collection of the personal data, the researcher must liaise with staff at each site to discuss the most appropriate way to collect the data required, to minimise access to non-relevant personal data within the medical records. (i) The extent of data being accessed by the UCC researcher, during both the pre-screening stage and retrospective chart review stage, should be discussed as part of the public and

	patient involvement (PPI) activities and highlighted through the transparency measures being undertaken (linked to Condition 5 and 7).
Scope of declaration amended:	The declaration is amended to cover the following additional processing activities: access to, review of, collection of, transfer and receipt of personal data from General Practitioner (GP) practice or nursing home medical records and further data processing of pseudonymisation, analysis, storage and retention for the purpose of the STOPPFrail study where participants lack the decision-making capacity to provide consent.

6. Update on previous applications

Ref No. 21-013-AF1: Mammographic breast density and breast cancer outcomes in a population-based breast screening programme' (Maeve Mullooly - National Screening Service & Royal College of Surgeons in Ireland):

- The Applicant requested an extension to the timeline set to meet Condition 1 of the consent declaration made by the HRCDC at the meeting of 7th September 2021. The condition relates to the commencement of Patient and Public Involvement (PPI) activities and the Applicant confirmed that the study will not commence prior to meeting this condition.
- The HRCDC was of the view that the timeline for meeting Condition 1 can be extended to 30th March 2022, as requested by the Applicant.

7. Amendments

Reference ID:	20-036-AF1/AMD1
Lead Applicant:	Alistair Nichol
Lead Data Controller:	Monash University University College Dublin
Title:	EPO-TRAUMA
Research Objective:	See minutes of 11th December 2020
Purpose of Amendment:	The amendment request is for the following changes to the study: (i) the addition of a new hospital site and data processor, Cork University Hospital, (ii) the extension of the consent declaration by 1 year, (iii) a change to the 6-month follow-up assessment whereby it will be conducted by a central assessor from the Irish Critical Care - Clinical Trials Network at UCD - St. Vincent's University Hospital, instead of each hospital site.
HRCDC Comments:	The Chair provided an overview of the amendment request and requested members to indicate their approval to amend the conditional consent declaration and invited members to comment. It was the consensus of the HRCDC that the amendment to the consent declaration could be made.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Amendment Duration:	The Amendment is made commencing 16th November 2021. The consent declaration shall be valid until consent can be obtained from the participant's once decision-making capacity is

	regained. Where participant's decision-making capacity is not regained, the consent declaration shall cover the duration of the study until 31st Dec 2025 and for 15 years after the study concludes i.e., until 31st December 2040. This timeline reflects the extension of the consent declaration by 1 year as per the amendment request
HRCDC Comments:	The HRCDC commented that, in accordance with the standard conditions of the consent declaration, the appropriate legal agreements should also be in place between the data controllers of the study and the new clinical site, Cork University Hospital.

8. New Applications

Reference ID:	19-005-AF2
Lead Applicant:	Richard Flavin
Lead Data Controller:	St. James's Hospital Dublin
Title:	St. James's Hospital Cancer Biobank (SJHCB)
Research Objective:	The SJHCB commenced in 2008 and collects samples and personal data that can be used in research. The samples and data relate to colorectal and breast cancer patients. This biobank aims to facilitate research that will contribute to the development of new tests, treatments and ultimately an improvement in the clinical outcome of patients.
Reason for Declaration:	A consent declaration is required for the following limited data processing activities only, where consent originally obtained from a cohort of participants was not compliant under data protection legislation: (i) The storage only of this personal data for future, unspecified research studies but does not extend to the use or further processing of the personal data in other studies. (ii) Pseudonymisation of this personal data for the storage in the biobank, for security purposes.
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 HRCDC where reminded that the 'AF2' applications sought a declaration for studies that commenced prior to the Health Research Regulations (HRR). AF2 Applicants considered that the consent obtained was compliant with the previous data protection legislation. However, further to the amendments of HRR being made, some Applicants have now reviewed the consent obtained, and considered it not in line with the previous data protection legislation and still require a consent declaration. Therefore, the HRCDC must consider these studies as if no consent was obtained and balance the public interest case for the study. **Secretariat overview**

	• The Secretariat provided an overview of the application and scope of the declaration requested. It was highlighted that the Applicant has confirmed that a much narrower consent declaration is required following the introduction of the HRR amendments. • It was highlighted that the scope of the consent declaration is strictly limited to the ongoing storage and pseudonymisation of the personal data only and that no additional processing, including collection of follow-up data for the biobank, data linkage or processing the personal data in ongoing research studies are underway. • It was discussed that any further data processing beyond continued storage and pseudonymisation, will require the submission of an amendment request or a new HRCDC application, whichever is most appropriate. 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 conditional declaration should be made. **Public Interest** • The HRCDC discussed the public interest case in the SJHCB and considered the personal data and associated biological samples are valuable for future research. It was the view of the HRCDC that there is a strong public interest case for continuing to retain this personal data for future research studies. • However, while it was determined that there is a public interest case for the continued storage of this valuable data, it was also discussed that any future requests to further process this personal data for specific research studies, a separate public interest case will need to be made when submitting an amendment request or new application to the HRCDC. **Participant numbers and reconsenting** • The HRCDC noted that the reconsent process previously undertaken and outlined by the Applicant related to the Breast Predict Study, where participants were asked to consent or reconsent to their participation in the SJHCB and the Breast Predict study. • The Secretariat highlighted that the declaration would cover the processing of personal data of 316 participants whose consent was obtained using versions 1-3 of the consent forms, which were not compliant. The Applicant confirmed it was not possible to obtain reconsent for these participants. • The HRCDC discussed the Applicant's response, that this previous reconsenting process caused some distress to participants and that it required significant time and resources. It was noted from the information provided, that challenges also

existed in determining the status of the participant, as to whether they have passed away or if they are currently unwell.

- On balance with the information provided and acknowledging that the 316 participants previously provided consent, although not compliant, the HRCDC was of the view that reconsent was not required for the continued storage of this personal data for future research.
- The HRCDC discussed that any future requests to further process this personal data for future research studies, would need to outline why reconsent could not be obtained in the context of that additional processing.
- HRCDC acknowledged that there may be a risk of causing distress when attempting to reconsent participants, however, it should not be assumed that all participants would find reconsent distressing and therefore may not be a sufficient reason on its own for not seeking reconsent.

Public & patient involvement (PPI) and transparency

- The HRCDC noted that PPI activity has been undertaken in the past, but it was unclear how recent this engagement was. It was discussed that where the personal data of the 316 participants is further processed in future research studies, enhanced PPI activities should be undertaken, which could include continued engagement with the advocacy organisation and other participant representatives that have been referenced by the Applicant.
- HRCDC commented that enhanced transparency measures should be implemented by the SJHCB so that participants and the public may be informed about the ongoing work of the biobank as well as the use of their personal data in research studies. In addition, it was discussed that transparency measures should include providing appropriate contact information should a participant have any queries regarding the processing of their personal data or if they wish to exercise their data protection rights. It was commented that enhanced transparency measures could include hospital notices, information provided on relevant websites and other public communication channels.
- The HRCDC discussed that any future declaration amendment requests or new HRCDC application must highlight what enhanced transparency measures and PPI activity has been undertaken with regards the use of personal data in further research studies.

Duration of the declaration

- It was noted that an indefinite consent declaration was requested. The HRCDC was of the view that it would be appropriate to make a time-limited declaration of 10-years, with an option to extend, subject to HRCDC consideration.

Data transfer outside the EEA

	• The HRCDC noted that pseudonymised data and associated biological samples from the SJHCB may be transferred and processed outside the EEA for example, a future collaborative research studies with an academic partner. • It was discussed that any future use of the personal data beyond storage in the SJHCB, including data transfer, will require an amendment request or new consent declaration application. • With regards to the storage of the data, the HRCDC noted the use of a Biobank Information Management System. It was commented that the data controller should ensure that personal data stored within this system is held within the EEA, or that the required safeguards are in place if held outside the EEA. **Other** • The HRCDC queried what information such as an accompanying information leaflet, was provided to the 316 participants at the time of obtaining their consent. The HRCDC noted that versions 2 & 3 provided some additional information compared to version 1. The Secretariat highlighted that the Applicant has determined that participant consent obtained using these 3 versions of the consent form is not compliant under the HRR amendments. • The HRCDC noted and agreed with the observations of the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The declaration is made commencing 8th August 2018 and shall be valid until 16th November 2031 or upon confirmation that that personal data has been rendered anonymised or destroyed, whichever occurs sooner. The Applicant, on behalf of the data controller may seek an extension to the consent declaration by way of submitting an amendment request to the HRCDC for consideration.
Conditions Attached:	**Condition 1.** It is a condition of the consent declaration made that: (i) no further processing of the personal data for specific research studies can be carried out by the data controller without seeking an amendment to the consent declaration. An amendment must be requested by way of submitting an application[1] for HRCDC consideration, (ii) any subsequent amendment application submitted to the HRCDC must: - set out the public interest case for the processing of the data further for specific research studies, - outline what additional PPI engagement activities and transparency measures have been undertaken in relation to that additional data processing for the research study.

[1] https://hrcdc.ie/apply/#b-3

	- outline the feasibility and appropriateness for seeking or not seeking reconsent from participants. *NOTE:* Any third-party data controller seeking to process the personal data covered by this consent declaration, for the purposes of an independent research study, must apply for a separate consent declaration. **Condition 2.** Public and patient involvement (PPI) is considered an important activity by the HRCDC and is viewed as a key data protection safeguard in situations where the participant cannot provide consent. PPI also provides a valuable way of enhancing the level of transparency, which itself is an important data protection principle. It is a condition of this declaration that PPI activities are updated and enhanced through engagement with relevant individuals and/or representative groups of the study participants. Areas of consideration for PPI activity could include seeking views and perspectives on the development of specific research studies that will be undertaken, wider public transparency measures and the dissemination of research findings. Progress on meeting this condition is a reporting requirement as part of the Annual Review. **Condition 3.** The data controller is requested to enhance transparency measures to inform participants and the public about the ongoing work of the St. James's Hospital Cancer biobank, including, where relevant, the research undertaken using the personal data and associated biological samples that are stored as part of the biobank. Enhanced transparency measures must also provide appropriate contact information should participants have any queries or wish to request information regarding the processing of their personal data and associated biological samples or if they wish to exercise their data protection rights. Consideration should be given to enhancing transparency measures by way of hospital notices, relevant websites, and other public communication channels. Progress on meeting this condition is a reporting requirement as part of the Annual Review.
HRCDC Recommendations:	**Recommendation 1.** The data controller is recommended to ensure it is satisfied that the IT systems used by the SJHCB to host/store the personal data are hosted within the European Economic Area (EEA) or, if hosted outside the EEA, that it is done so in compliance with data protection legislation, and that the requisite standard contractual clauses are in place. The Applicant is recommended to discuss this matter with the data controller's Data Protection Officer.

Reference ID:	21-015-AF1/CSO
Lead Applicant:	Dr Andrew McCarren (DCU) Prof. Grace Mulcahy (UCD)
Lead Data Controller:	Dublin City University (DCU) University College Dublin (UCD)

Title:	UPCOM (Understanding and Preventing Covid-19 Outbreaks in Meat Processing Plants-Prepared for the Future)
Research Objective:	Rapid response to the COVID-19 pandemic requires infection prevention and control measures that can anticipate the eruption of hot-spots throughout society and act effectively to exclude infection from such environments, while also building a series of urgent measures should initial defences fail. Meat processing plants in Ireland and abroad have proved to be flashpoints for super-spreader and rapid-fire events that threaten spill-over into broader society. This study proposal will enhance knowledge of the dynamics and underlying physics, chemistry and biology of such events, hereby safeguarding and enhancing the sustainability of Ireland's food production and processing sectors. In addition to internal plant datasets the use of external data feeds such as the aggregated movements from datasets such as the COVID-19 contract tracing datasets will be invaluable to understand the movements between areas of infection and those that are less affected, and therefore understand the potential exposure a meat plant may face.
Reason for Declaration:	The Applicant is seeking to access and obtained pseudonymised data (research microdata files) from the COVID-19 Data Research Hub, hosted by the Central Statistics Office. As the data being accessed is pseudonymised data and that it is not feasible to seek consent from individuals whose data is held by the CSO within the COVID-19 data hub, a consent declaration is required.
HRCDC Comments:	***The minutes of the discussion for this application will be updated and published once the HRCDC have completed their deliberations.***
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information should be made.

Reference ID:	21-018-AF1/CSO
Lead Applicant:	Alberto Alvarez-Iglesias
Lead Data Controller:	National University of Ireland Galway
Title:	Quantifying the Effects of Public Health Interventions in Ireland
Research Objective:	One of the most powerful ways to slow the COVID-19 pandemic is to limit the spread of the virus between people. In practice, this can mean communities going into ‘lockdown’, individuals keeping physically distant from each other and people wearing masks when in shops and on public transport. This study has developed software to help forecast the outcome of applying such public health measures in Ireland during the COVID-19 pandemic. The interactive web-based application will help decision makers to assess the likely impact of a public health measure on how quickly the virus spreads, the costs and effects on the health system and the likely outcome for people in Ireland. The app will also map out potential alternative interventions and assess their likely outcomes for comparison. This study will enable predictions

	that are timely and are based on the most accurate and representative data on COVID-19 patients in Ireland.
Reason for Declaration:	The Applicant is seeking to access and obtained pseudonymised data (research microdata files) from the COVID-19 Data Research Hub, hosted by the Central Statistics Office. As the data being accessed is pseudonymised data and that it is not feasible to seek consent from individuals whose data is held by the CSO within the COVID-19 data hub, a consent declaration is required.
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 the HRCDC 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 conditional declaration should be made: **Public interest** • The HRCDC discussed the purpose of the study and the use of the CSO data. It was the view of the HRCDC that, on balance, there is a strong public interest in this study. **Data processing** • It was commented that more information could have been provided on the specific data fields that will be accessed within the CSO COVID-19 Research Data Hub. The HRCDC was of the view that the Applicant should report on the data fields that will be accessed as part of the Annual Review. **Other** • It was noted that access to the CSO Hub will be via an NUIG desktop or a personal laptop if working from home. • The HRCDC noted and agreed with the observations of the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee, including enhanced transparency measures and data protection training. • It was also discussed that the consent declaration will not be effective until final approval to access the COVID-19 Data Research Hub has been granted by the CSO.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The consent declaration is made on 16th November 2021 and is valid for one year until 16th November 2022, in line with the duration of the Officer of Statistics appointment made to the Applicant by the Central Statistic's Office (CSO). *NOTE 1:* The consent declaration will not come into effect until Condition 1 is met.

	NOTE 2: The Applicant may submit an amendment request to the consent declaration if an extension to the duration of the consent declaration is required, subject to the Applicant's reappointment as an Officer of Statistics and approval by the CSO.
Conditions Attached:	**Condition 1.** It is a condition that this consent declaration is not effective until final approval to access the COVID-19 Data Research Hub has been granted by the CSO. Confirmation of final CSO approval must be provided to the HRCDC as soon as possible. **Condition 2**. The Applicant is requested to implement transparency measures so that participants, the public and other relevant stakeholders, can be made aware of this research study, the study findings and the use of the COVID-19 Data Research Hub. Consideration should be given to providing information about the study, beyond the publication of the findings in a research paper, on platforms such as the data controller's website and other relevant platforms. The Applicant is required to report on the efforts made to implement transparency measures as part of the Annual Review. **Condition 3**. Aligned with the feedback from the Data Protection Officer, all relevant staff members involved in study must complete data protection training. **Condition 4.** As part of the Annual Review the Applicant is requested to provide additional information on the data fields that have accessed for this study from the CSO COVID-19 Research Data Hub.

9. Annual reviews

The Secretariat has received 8 Annual Reviews in advance of the meeting which were deemed satisfactory:

- Ref ID: 19-007-AF2 (Alistair Nichol - TAME Study)
- Ref ID: 19-010-AF3 (Karen Doyle - Stroke Thrombectomy)
- Ref ID: 19-016-AF2 (Cara Martin - CERVIVA HPV)
- Ref ID: 19-060-AF3 (Austin Stack - National Kidney Disease Surveillance System and Quality Assurance Programme)
- Ref ID: 20-004-AF1 (Sean Kennelly - Outcomes for Older People with Cognitive Impairment Attending the Emergency Department)
- Ref ID: 20-025-AF1 (Conor McAloon - Contact tracing & COVID Epidemiology)
- Ref ID: 20-026-AF1/COV (John Laffey - CHARTER-Irl Trial)
- Ref ID: 20-027-AF1 (Ger Curley - Immune Dysfunction in Acute Brain Injury)

10. Activities report & Upcoming events

The Secretariat provided a report on their activities to the HRCDC in advance of the meeting. In addition, past and upcoming events, as well as articles and reports of interest, were highlighted to the HRCDC.

11. Any Other Business

- The Chair reminded HRCDC members to review and complete the updated Conflict of Interest policy and log as well as the updated Decision Time use policy.

- The Chair updated the HRCDC members on the proposed dates for meetings in 2022. It was discussed whether members were happy with the current meeting arrangements with regards to the time and day of the week of Tuesdays at 10am. The HRCDC were informed that the Secretariat will forward a calendar of dates to the members. It was discussed that meetings will continue by videoconference but that the HRCDC will aim to meet in person in Spring 2022, subject to COVID-19 restrictions.
- The HRCDC noted the academic papers on the topic of the public interest and use of health data for research. It was agreed that it would be beneficial to have an expert speaker discuss this topic with the HRCDC.
- The HRCDC were informed that all completed Annual Reviews to date have been made available to access in Decision Time.

*** The Chair closed the meeting***