HRCDC
Health Research Consent Declaration Committee

Date: 19th September 2023
Location: Zoom Videoconferencing

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus (Chairperson)
Kathy Brickell
Alyson Bailey
Sheelah Connolly
Aideen Hartney
Dan Rea
Cornelius Cooney
John Woods
Susan Smith
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES

New Amendments - For Consideration

Applicant	Ref No.	Title
Sean Kennelly	20-004-AF1/AMD1	Outcomes for Older People with Cognitive Impairment Attending the Emergency Department (ED)
Norman Delanty	22-005-AF1/AMD2	Longitudinal analysis of clinical markers of response to treatment in people with epilepsy (EPIDIVE Phase 2)
Alistair Nichol	20-036-AF1/AMD2	EPO-Trauma

New Applications – For consideration

Applicant	Ref No.	Title
Alistair Nichol	23-009-AF1	Anaemia management with red Blood Cell transfusion to improve post intensive care disability- a randomised controlled trial – (The ABC post-intensive care trial)
Brendan Fitzgerald	23-015-AF1	Investigation into the use of IL-1, I-CAM1 and/or E-Selectin in identifying the effects of infection in placental tissue.
Owen Smith	23-014-AF1	Adolescent and Young Adult (AYA) Cancer Epidemiology in Ireland – a retrospective review of National Cancer Registry Ireland (NCRI) data from 2002 to 2018

Meeting Items

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Health Research Consent Declaration Committee

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

2. **Apologies**
   Evelyn Mahon, Simon Furney, Patricia O'Beirne, Barry Lyons, Zubair Kabir, Barry O' Sullivan, Mary Tumelty (Maternity leave).

3. **Disclosure of Interest**
   - Kathy Brickell (KB) declared her interest in application 20-036-AF1/AMD2 (EPO-Trauma) and application 23-009-AF1 (the ABC post-intensive care trial). KB was absent during the meeting when these applications were considered.
   - Susan Smith (SS) declared her interest in application 20-004-AF1/AMD1 (Outcomes for Older People with Cognitive Impairment Attending the Emergency Department (ED)). SS was absent during the meeting when this application was considered.
   - The Chairperson (Brigid McManus) noted that she is on the board of Children's Health Ireland (CHI) where Prof Owen Smith – Principal Investigator for application 23-014-AF1 - is employed. However, it was noted that application 23-014-AF1 is not from CHI but is a Trinity College Dublin study. It was agreed by the HRCDC that this was not an interest that would require the Chairperson to be absent during the meeting when this application was considered.

4. **Minutes of the last meeting**
   Draft minutes of 22nd August 2023 were circulated in advance of the meeting and were approved by the HRCDC, subject to the correction of minor typos.

5. **Amendments:**

Reference ID:	20-004-AF1/AMD1
Lead Applicant:	Sean Kennelly
Data Controller:	Tallaght University Hospital
Title:	Outcomes for Older People with Cognitive Impairment Attending the Emergency Department (ED)
Research Objective:	See HRCDC meeting minutes of 25th May 2020.
Purpose of Amendment:	Due to delays because of COVID-19, the study requests an extension of the duration of the declaration until August 2025. Participants have yet to be recruited to this study.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair requested each HRCDC member to indicate whether the amendment should be approved. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the Amendment should be approved. The HRCDC noted that Recommendation 4 attached to the original consent declaration requested the Applicant/data controller to first determine if the participant who lacks decision-making capacity to

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	provide consent has a legally appointed representative. Given the recent enactment of the Assisted Decision-Making Act (ADMA) 2015, the HRCDC further commented that the Applicant/data controller should consider the ADMA when undertaking this study.
HRCDC Decision:	The consensus of the HRCDC was that the Amendment should be approved.

Reference ID:	22-005-AF1/AMD2
Lead Applicant:	Norman Delanty
Data Controller:	Royal College of Surgeons in Ireland Beaumont Hospital St James's Hospital
Title:	Longitudinal analysis of clinical markers of response to treatment in people with epilepsy (EPIDIVE Phase 2)
Research Objective:	Please see HRCDC minutes of 14th June 2022 and 13th December 2022.
Purpose of Amendment:	Due to delays the study only commenced during summer 2023 and therefore the data controller requests an extension of the duration of the consent declaration until 31st July 2024.
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 the amendment request should be approved. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the Amendment should be approved.
HRCDC Decision:	The consensus of the HRCDC was that the Amendment should be approved.

Reference ID:	20-036-AF1/AMD2
Lead Applicant:	Alistair Nichol
Data Controller:	Monash University University College Dublin
Title:	EPO-Trauma
Research Objective:	Please see HRCDC meeting minutes of 11th December 2020 and 16th November 2021.
Purpose of Amendment:	The amendment is requested to add Tallaght University Hospital (TUH) and the Mater Misericordiae University Hospital (MMUH) as participating sites and data processors to this study. (Note: the MMUH was outlined as a site in the original HRCDC application form).
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

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	considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair requested each HRCDC member to indicate whether the amendment request should be approved. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the Amendment should be approved. **Patient information leaflets and Consent forms** • The HRCDC discussed Recommendation 1 that was attached the original application (i.e., review of the study information leaflets) and queried the extent to which it was considered by the Applicant/data controller; the Secretariat outlined the responses provided by the Applicant in relation to this Recommendation. It was noted by the HRCDC that the documents continue to include the statement '*you may have data protection rights'*. • The Secretariat highlighted that the study has developed a separate 'patient information brochure' to provide participants and families with a useful information tool, and that this brochure was reviewed by a panel of PPI representatives. • The HRCDC was of the view that the Applicant/data controller should be requested to further consider Recommendation 1 where possible. The Applicant is also asked to submit the new patient brochure.
HRCDC Decision:	The consensus of the HRCDC was that the Amendment should be approved.
HRCDC Recommendations:	**Recommendation 1.**The HRCDC is of the view that the points outlined in Recommendation 1 should be further considered by the Applicant where possible, including the use technical language and the readability of the documents (e.g., reviewing/amending the use of non-defined acronyms) as well as the use of statements such as 'you may have data protection rights' (this statement should be amended to note that participants do have such rights). It was noted also that the researchers have engaged with a PPI group, and they have produced an additional patient information brochure. The Applicant is asked to submit this new patient brochure at the next annual review due for the study.

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6. New Applications

Reference ID:	23-009-AF1
Lead Applicant:	Alistair Nichol
Data Controllers:	University of Edinburgh
Title:	Anaemia management with red Blood Cell transfusion to improve post intensive care disability- a randomised controlled trial – (The ABC post-intensive care trial)
Research Objective:	People who are discharged from intensive care (ICU) are often anaemic, due to their severe illness impacting their body's ability to produce new blood cells. This usually does not cause issues for the patient, and therefore is generally not treated when they are in ICU,

	or after. However, it can sometimes take months for the body to recover from this anaemia. People typically feel tired in the weeks and months after ICU discharge, which is a symptom of anaemia. It is not yet known if treating post intensive care anaemia will help with this tiredness. This trial will aim to find out if treating the anaemia while patients are in ICU with a blood transfusion helps with these symptoms. A consent declaration is being sought for this research as patients may not be able to consent upon their ICU discharge, due to delirium, severe tiredness, and impaired short-term memory.
Reason for Declaration:	Due to the nature of the trial and severity of illness participants, some will lack capacity to give informed consent on enrolment in the trial due to delirium, severe fatigue, and cognitive impairment impacting short-term memory common in those being discharged from ICU. The consent declaration is therefore requested to process the personal data for those who lack decision-making capacity to provide explicit consent. **Note:** participants under 18-years of age will not be recruited at SVUH. In addition, the Irish sites will not be involved in the sub-study, only the main ABC trial and the scope of the declaration only includes data on SVUH participants (other sites and/or data sources e.g., HIPE) are not covered.
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 provided an overview of the application and highlighted that the study in Ireland will not involve participants under 18-years of age and that the consent declaration, if made, will not cover data processing for the sub-study, only the main ABC Trail. Correspondingly it was confirmed that data and associated samples from participants in Ireland would not be transferred to Oxford University. In addition, it was noted that reference to sharing data with Monash University was an error and that data linkage for follow-up data at 5-years will not occur. It was also highlighted that follow-up questionnaires will not be conducted if the participant continues to lack decision-making capacity after hospital discharge. 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 case** • The HRCDC discussed the study activities, including the follow-up data collection, primary and secondary outcomes, and how the researchers are monitoring the impact of the intervention on the patient.

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	• It was the view of the HRCDC that there is a strong public interest case in this research. **Transparency and study withdrawal** • The HRCDC discussed the study information leaflets and assent/consent forms. It was commented that the statement '*you may have data rights'* should be rephrased and that the data protection rights should be clearly outlined. • The HRCDC also commented that the information provided on the right to withdraw from the study and options on what will happen the personal data were not fully clear and consistent through all the documents submitted. The responses in the HRCDC application form outlined that all data will be deleted but also that a request will be made to keep the data. It was also noted that the study information leaflets include different options on what will happen the data if proxy assent or participant consent is withdrawn, including options relating to the continued use of data already collected and the continued collection of follow-up data. It was further noted that a request can be made to remove data from the study analysis but that the data will be retain by the controller for reasons of study validity and safety details. • It was discussed that clear and consistent information should be provided to participants on study withdrawal and what will happen the personal data in such circumstances, including any options that may be provided. While information was provided to the HRCDC on why data would still be retained but not included in the study analysis, it was discussed that clear information on this should also be provided in the documents given to the proxy and the participant. **Follow-up data** • It was noted that if the participant is discharged to another acute hospital during the study, then their treatment randomisation will be maintained where possible, and the original site study team will '*attempt to provide advice'* to the hospital and obtain the relevant study data. The HRCDC queried how this will be undertaken including what agreements would be in place with the other hospital. • It was discussed that data agreements would need to be in place where data is being provided from another acute hospital where participant is discharged to. **Other** • It was the view of the HRCDC that the Applicant should be requested to provide an update on the numbers of participants recruited to the study in Ireland, and the numbers who have provided consent to continue, as part of the Annual Reviews.

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	• It was discussed that the study should abide by the principle of data minimisation, for example the information provided in the HRCDC application form referred to collecting date of birth while the DPIA referred to collecting age only. • 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 clear communication on the scope of the consent declaration, amendments and clarifications to the study information documents, extended research ethics approval, data agreements, responsibility for compliance with the consent declaration and providing anonymised data in a research archive.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The consent declaration is made until 31st August 2025 and for 5 years thereafter, or until the personal data is deleted or fully anonymised, whichever occurs first.
Conditions Attached:	**Condition 1.** Research ethics committee approval for an extension to the study must be obtained and a copy of this approval submitted to the Secretariat. The consent declaration does not cover this study if valid REC approval is not in place or has expired. **Condition 2.** The study should comply with the principle of data minimisation, for example can age, rather than date of birth, be collected and processed. **Condition 3.** The necessary data agreements and arrangements must be in place between the study parties, including a data controller to data processor agreement between University of Edinburgh and St Vincent's University Hospital, prior to the transfer of data occurring. Further to this, it is noted that the study protocol states the following: *'If a participant is discharged to another acute care hospital from the enrolling hospital as part of the same hospitalization, the randomization allocation will be maintained wherever possible until discharge from that acute hospital. The site study team will attempt to provide advice to the hospital to which the patient is discharged and obtain relevant study assessment data'*. Where this occurs then data agreements must also be in place with the other acute hospital. **Condition 4**. The Applicant/data controller is requested to review and amend the study information leaflets and assent/consent documentation to ensure clarity and consistency of information. Specifically, the following points must be addressed prior to the study commencing: • the study information leaflets should clearly outline what samples and data will be collected and processed from Irish participants, including following-up data and samples. In addition, references to the sub-study, sharing data/samples with Oxford University and 5-year follow-up and data linkage should be removed from the documents used in Ireland, as it has been confirmed that these activities are not applicable to Ireland.

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	• References to requesting permission to use personal data in other future research studies should not be included in the documentation provided to the proxy; proxy assent and the consent declaration cannot cover data processing for future research studies. The consent declaration can only cover storage only for future studies. • The statement in the information leaflet that '*you may have rights'* should be amended to confirm that individuals do have rights. Linked to this, the data protection rights should also be clearly listed i.e., right of access, right to erasure etc. • It must be ensured that the study documentation, and the request to withdraw form, provide clear and concise information on withdrawing from the study and what will happen the personal data if a request is made to withdraw, including clear information on the options that will be provided. • Aligned with the information provided to the HRCDC, it must be clearly outlined to individuals why data that is removed from the study analysis is still retained by the data controller for reasons of data validity, study safety etc. In this context the statement 'If *you do decide to stop being part of the study at any time, the University of Edinburgh and NHS Lothian, as co--sponsors, will keep information about you that we already have. The University of Edinburgh and NHS Lothian need to manage your records in specific ways for the research to be reliable….*' should be amended to clarify and reassure individuals why data will still be retained. **Condition 5.** Where proxy assent/participant consent is withdrawn and the study wishes to continue to process the data already collected and/or continue to collect and process follow-up data, then permission for this must be obtained and recorded from the proxy or participant, whichever is relevant. Please note: if such permission is obtained from the proxy on behalf of a participant who lacks decision-making capacity, then participant consent to continue must also be obtained for this continued data processing when they regain decision-making capacity. **Condition 6.** As part of the Annual Review the Applicant/data controller is requested to report on the number of participants recruited to this study from the Irish site and to also report on the numbers who have provided consent to continue.
Recommendations	**Recommendation:** Consideration should be given to including '*Don't know'* options in the assent form for relevant questions. For example, the point in the assent form asking about a participant's living will.

Reference ID:	23-015-AF1
Lead Applicant:	Dr Brendan Fitzgerald
Data Controllers:	Cork University Hospital & Cork University Maternity Hospital

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Title:	Investigation into the use of IL-1β, I-CAM1 and/or E-Selectin in identifying the effects of infection in placental tissue.
Research Objective:	Chorioamnionitis is a bacterial infection unique to pregnancy, associated with complications in preterm babies such as infection (e.g., meningitis or pneumonia), severe neonatal brain injuries, and in some cases, death. Testing will be carried out on chorioamnionitis affected placental tissue, previously submitted for histological analysis immediately following birth. Immunohistochemical staining with IL-1β, I-CAM1 and E-Selectin antibodies is hypothesised to identify endothelial cell activation as part of an inflammatory response to infection, the severity of which may be determined by the level of antibody expression present once stained. Correlation may be identified between the grade of infection assigned to the patient cases upon H&E analysis, and the level of antibody expression observed. This may hold diagnostic value for the identification of neonatal sepsis through placental tissue evaluation and expanded in the future to other tissue types for the purpose of identifying sepsis related deaths in both adults and infants.
Reason for Declaration:	The study will undertake pre-screening activities (i.e., identifying the suitable tissue samples) in line with the pre-screening amendment to the Health Research Regulations. Following the identification of the participant samples after pre-screening, the samples and the relevant Lab Accession Numbers will be extracted and the samples then pseudonymised using another number and linked to the master list; this limited pseudonymised data will be retained while the samples are prepared for staining (i.e., cutting and slicing) and to return them to the patient's file. Once the selected samples are prepared and returned, they will be anonymised i.e., the master list will be deleted and therefore no pseudonymised data will continue to be processed. The consent declaration is therefore requested for the processing of the limited pseudonymised data (i.e., Lab accession number and study sample code and master list) during the preparation of the samples for staining.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a conditional declaration should be made. **Consent and public interest**

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	• The HRCDC discussed this study including the reasons outlined for not seeking explicit consent and the strength of the public interest case. • Based on the information provided, the HRCDC was of the view that there is a public interest case in this study and that the study would not be required to seek explicit consent. **PPI and Transparency** • The HRCDC noted that the information poster submitted was informative and will be placed in hospital waiting rooms, however it commented that participants in the research study may not have the opportunity to see these posters and that it does not include specific information on withdrawing from the study, including how to withdraw and when withdrawal may no longer be possible. It was also commented that the phrase in the poster on informing if you have been selected as a participant should be rephrased. • It was further discussed that the separate study information leaflets contained language that was quite technical and not patient friendly, for example using technical terms such as 'Histopathology', 'Pathology', the scientific description of the study and not explaining what is meant by anonymisation, etc. It was also noted that these study information leaflets refer to 30 participants, however the Applicant/data controller requests that the consent declaration be made to cover up to 40 participants. • The HRCDC also discussed it's concerns that no public and participant (PPI) engagement activities have been carried out in relation to this study. While it was noted that this study has a relatively short duration, it was also discussed that it is being carried out in a particularly sensitive area and therefore the HRCDC was of the view that it would be appropriate and suitable to undertake PPI engagement. While the Applicant noted that there are no known specific PPI representative groups on this disease area, the HRCDC commented that there are other suitable groups who could be engaged with in the area of maternal and infant health, for example PPI groups from the study sponsor i.e., the INFANT centre. The HRCDC discussed that it would be a benefit for the applicants to consult with a PPI group on matters such as the study information leaflet. **Other:** • It is noted that an inter-institutional agreement is in place between CUMH and CUH. It was commented that the applicant must ensure that the agreement in place between CUH and CUMH meets the requirement of a joint controller arrangement and covers 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 implementing transparency measures and clear communication on the scope of the consent declaration made.

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HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The consent declaration is made until 30th April 2024, or once the personal data has been fully anonymised or deleted, whichever occurs first.
Conditions Attached:	**Condition 1.** The Applicant/data controller must implement the transparency measures prior to the study commencing i.e., the study information posters and study information leaflets). With regards the transparency measures the Applicant/data controller is also required to review and amend these documents as follows: - The information poster to be provided in the hospital waiting rooms should include specific information on withdrawing from the study, including how to withdraw and the point at which it may no longer be possible to withdraw. Linked to this, the phrase in the poster '*We will be able to inform you if you have been selected as a participant while this information is available*' should be amended to outline that an individual can contact the study if they any questions on their potential inclusion in the study and would wish to withdraw. - It was the view of the HRCDC that language used in the separate study information leaflet was overly technical (e.g., use of scientific terms such as 'Histopathology' and the description of the study) and that it could be made more reader friendly. In addition, it should be outlined that 40 participants, not 30, will be included in this study. **Condition 2.** The Applicant/data controller should undertake some public and patient engagement with regards to this study before study commencement, including on the study transparency measures i.e., posters and information leaflets. While it is noted that there may not be a PPI group in this specific area, and while the HRCDC is not requesting the Applicant to set up a specific PPI group, it is considered that there are other groups in the broader areas of maternal and infant health who may be able to provide input into the study and who could be contacted for some engagement. Such groups that could be considered to provide input may include PPI groups from the UCC INFANT centre (the study sponsor) and/or other patient Advocacy groups. The Applicant is requested to provide an update on this condition prior to the study commencing. **Condition 3.** It must be ensured that the data agreements/ arrangements to be put in place between CUH and CUMH also meet the requirement of a joint data controller arrangement and cover this specific study.

Reference ID:	23-014-AF1
Lead Applicant:	Professor Owen Smith
Data Controllers:	Trinity College Dublin

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Title:	Adolescent and Young Adult (AYA) Cancer Epidemiology in Ireland – a retrospective review of National Cancer Registry Ireland (NCRI) data from 2002 to 2018
Research Objective:	This study involves the collection and analysis of retrospective data to advance our knowledge of the epidemiology of adolescent and young adult cancer in Ireland. Data collected will include incidence rates, age at diagnosis, geographical location, disease type and survival of all patients aged 16-24 +364 days diagnosed with cancer between the years of 2002 to 2018 in the Republic of Ireland. Existing pseudonymised data collected by the NCRI will be used for the study.
Reason for Declaration:	The consent declaration is requested to process the personal data (which is considered pseudonymised data) provided by the National Cancer Registry of Ireland for the purpose of this study. The Applicant outlines the reasons for not seeking consent, including the number of participants involved (approx. 2500).
HRCDC Comments:	The HRCDC noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a conditional declaration should be made. **Public interest case** • The HRCDC discussed the aims and objectives of the study and noted the reasons why consent could not be obtained, including the number of participants involved. • It was the view of the HRCDC that research in this area is very important and therefore there is a strong public interest case in this study. **PPI and Transparency** • The Applicant outlined the transparency measures that will be undertaken with regard to this project, specifically providing study information on NCRI and Trinity College (TCD) websites etc). The HRCDC was of the view that transparency measures should be in place before the start of the study to help ensure public awareness and that they should include information on participants' data protection rights, including the right to withdraw from the study and how to exercise their rights. • While the response from the Applicant on PPI engagement was noted, the HRCDC also discussed that the study should engage with PPI representatives on this particular study. **Study withdrawal** • It was discussed that there should be a clear process in place between TCD and NCRI to enable the withdrawal of a participant

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	from this study, if such a request is made, and that the responsibility for this process is clearly documented. Information on withdrawing from this study should also be included in the study's transparency measures. **Data sharing agreements** • The HRCDC noted that TCD is the data controller of the study, as outlined by the applicant in its communications with the Secretariat. It was further noted that data sharing agreements are not in place yet and it would be a requirement of the declaration that these are in place before the study commences and before any data is shared. **Data Minimisation** • The HRCDC noted that one of the data points being collected is geographical location. The Applicant is asked to inform the HRCDC as to what specific geographical data is being collected (i.e., region, county, town, etc). • It was also discussed that geographical location combined with the nature of this study, could increase the risk of participant re-identification. The HRCDC commented that the study should ensure steps are taken to prevent such re-identification and that the study should take on board and comply with the principle of data minimisation. **IT systems.** • The committee discussed the IT systems to be used throughout the study. It was queried the extent to which the data would be protected by measures such as encryption and where the data would be stored and backed-up. Based on the information provided the HRCDC was of the view that adequate security measures appeared to be in place.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The consent declaration is made until 31st December 2027, or until the data is deleted or fully anonymised, whichever occurs first.
Conditions Attached:	**Condition 1.** The Applicant/data controller is requested to strengthen the level of public and patient involvement (PPI) with regards this specific research study. Accordingly, the study should engage with representative groups from the area of adolescent and young people's cancer. Consideration should be given to engaging with PPI representatives on matters such as transparency measures. The Applicant is requested to report on PPI engagement within 3 months. **Condition 2**. Measures to inform participants and the public about this study must be in place prior to the commencement of this research i.e., providing information on the NCRI and TCD websites; data processing cannot commence until adequate transparency measures are in place. Transparency measures should also include clear information on the participant's data protection rights, including how to exercise such rights and provide a point of contact.

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	The right of the participants to withdraw from the study and have their data removed should be clearly outlined in the transparency measures. The point at which data can no longer to deleted/removed should also be clearly highlighted. Further to providing such information on the NCRI and TCD websites, the Applicant/data controller is also requested to consider other methods of enhancing transparency such as links with relevant groups or networks. The Applicant is requested to report on this condition within 3 months. **Condition 3.** A clear process to enable participants to request to withdraw from the study and have their data removed should be in place between NCRI and TCD, with responsibilities for this process clearly documented. **Condition 4.** The appropriate data sharing agreements must be in place between the parties. Data cannot be transferred prior to the data agreements being in place. **Condition 5.** It is noted that 'geographical location' will be collected, however it is not clear what this is specifically referring to e.g., a county, town, electoral district etc. Given that geographical data will be collected and in the context of the nature of this study, the Applicant/data controller should ensure steps are taken to prevent participant re-identification using geographical and the other data variables that will be collected. More generally, the study should take on board and comply with the principle of data minimisation. Lastly, the Applicant is requested to report on what is specifically meant by geographical data within 3 months.

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7. Annual Reviews

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

- **Ref ID: 22-005-AF1;** Norman Delanty, EPIDIVE Phase 2
- **Ref ID: 20-004-AF1;** Sean Kennelly, Outcomes for Older People with Cognitive Impairment Attending the Emergency Department (ED) (Deemed completed subject to submitting their amendment 20-004-AF1/AMD1)
- **Ref ID: 22-007-AF1;** Denis O'Mahony, OPTIMATE Trial
- **Ref ID: 21-009-AF1;** Mary McCarron, Including best practices and the voices of experience in developing post-diagnostic dementia support guidelines for people with an intellectual disability. *[The HRCDC were informed that a consent declaration is no longer required for this study]*
- **Ref ID 19-023-AF1;** Ger Curley, Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis
- **Ref ID: 19-062-AF1;** Zena Moore, The relationship between Sub Epidermal Moisture (SEM) measurement and Inflammatory markers in the early identification of Pressure Ulcers
- **Ref ID: 19-085-AF1:** Shona Pfeiffer, Blood Biomarkers to Predict Recovery from Ischaemic Stroke.
- **Ref ID: 20-039-AF1:** Bairbre McNicholas, REACT-SHOCK Pilot

8. Activities report and events of interest

In advance of the meeting, the Secretariat circulated a report detailing the events and other relevant activities attended by the Secretariat since the previous HRCDC meeting. The Secretariat provided the HRCDC with an overview of this report.

9. Any Other Business

- In advance of the meeting, the Secretariat circulated a draft of proposed updates to the HRCDC application form to encompass relevant questions regarding the Assisted Decision-Making Act. The HRCDC were asked to provide any feedback or comments within the next 2 weeks.
- The HRCDC were reminded that the next meeting is scheduled for 17th October 2023.

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

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