HRCDC
Health Research Consent Declaration Committee

Date: 22nd August 2023
Location: Zoom videoconferencing

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Aideen Hartney
Zubair Kabir
Dan Rea
Cornelius Cooney
John Woods
Barry Lyons
Patricia O'Beirne
Susan Smith
Brid Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES

Returning Applications - For Consideration

Applicant	Ref No.	Title
Sam Manna	22-003-AF1/AMD1	A Phase 3, multicenter, randomized, double-blind, placebo- controlled study to assess the efficacy, safety, and tolerability of AVP-786 for the treatment of agitation in patients with dementia of the Alzheimer's type

New Amendments - For Consideration

Applicant	Ref No.	Title
Seamus McGuinness	21-011-AF1/CSO/AMD2	Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland
Gianpiero Cavalleri	22-006-AF1/AMD2	A description of the evolution of phenotype in epilepsy from paediatrics through adulthood and old age (HPO Study)
Norman Delanty	23-002-AF1/AMD1	Development and Establishment of the Epilepsy-Associated Ready Register (EAGER) – A Register of Patients with Epilepsy caused by Pathogenic Mutations
Bairbre McNicholas	20-039-AF1/AMD2	A pilot multicentre randomized controlled trial comparing an approach of individualized blood pressure targets to standard care among critically ill patients with shock

HRCDC
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New Applications – For consideration

Applicant	Ref No.	Title
Bairbre McNicholas	23-004-AF1	Individualised Blood Pressure Targets versus Standard Care among Critically Ill patients with Shock - A Multicentre Randomised Controlled Trial (REACT Shock RCT)
Iris Bobenhausen	23-010-AF1	EsSCAPE trial
Mary Mc Carron	23-011-AF1	Building Circles of Support for People with Intellectual Disabilities
Caroline O'Nolan	23-005-AF1	The journey from wardship to supported decision-making: An examination of the process and the experiences of people leaving wardship
Alistair Nichols	23-008-AF1	ARISE FLUIDS

Meeting Items

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

2. **Apologies**
   Sheelah Connolly, Mary Tumelty (Maternity Leave), Kathy Brickell, Simon Furney, Barry O' Sullivan.

3. **Disclosure of Interest**
   Evelyn Mahon (EM) and Aideen Hartney (AH) declared their interest in application 23-005-AF1. Both EM and AH were absent during the meeting when this application was considered.

4. **Minutes of the last meeting**
   Draft minutes of 13th June 2023 were circulated in advance of the meeting. The HRCDC queried if amended information leaflets were to be provided with regards application 21-002-AF1/AMD1, that was considered on 13th June meeting. The Secretariat provided an update on the responses that had been submitted by the Applicant since the HRCDC's decision, which were also discussed with the Chairperson. The HRCDC were informed of the discussions with the Applicant and changes that will be made to the PILs for 21-002-AF1/AMD1. The HRCDC approved the minutes without changes.

5. **For information**
   - *Update on NREC approval process for Clinical Trials*
     The Secretariat circulated an information paper to the HRCDC on the ethical and regulatory approval process arising from the new Clinical Trial Regulations and Clinical Trial Information System, specifically the process for approving applicable clinical trials by the National Office for Research Ethics Committee (NREC) and the Health Products Regulatory Authority (HPRA). The HRCDC were also informed of the proof of approval documentation that will now be issued by NREC/HPRA. These new approval documents may be submitted as part of applications to the HRCDC.

   - *Assisted Decision Making Act (AMDA):*

The Secretariat circulated an information paper to the HRCDC on the interplay between the ADMA, the Health Research Regulations and the consent declaration process; this paper was developed following discussions with the Department of Health and the Decision Support Service. The paper outlines whether and when a consent declaration may be required where research participant who may lack decision-making capacity has in place entered into the different support structures provided for in the ADMA and subject to what the agreements governing such structures allow for. The HRCDC were informed that the HRCDC website and application forms would be updated to provide information to researchers on this matter and to consider the ADMA support structures.

- *Deferred consent amendment*
  The Secretariat informed the HRCDC that it has received queries on the application of the Health Research Regulation amendment that, provides for deferred consent for the processing of personal data for health research in exceptional and specified circumstances where an individual is unable to give consent by reason of physical or mental incapacity and his or her vital (health) interests are engaged. It was noted that discussions had occurred and were ongoing with the Department of Health and Data Protection Commission on this matter to understand the extent to which this amendment may apply. Further updates will be provided as discussions progress.

- *Transfer Impact Assessments*
  HRCDC member John Woods (JW), who is the Data Protection Officer (DPO) at St Patrick's Mental Health Services, provided an overview of the purpose of Transfer Impact Assessments (TIA). It was noted that TIAs are a required process that data controllers should undertake when transferring personal data to 'third countries' that do not have an adequacy agreement; TIAs are in addition to other required safeguards such as Standard Contractual Clauses. The requirement to undertake a TIA follows the June 2021 Schrems II decision by the Court Justice of the European Union. A TIA is a risk assessment to help determine if the personal data transferred to a third country will be adequately protected and where necessary help to determine if other supplementary measures should be put in place. It was discussed that data controllers seeking a consent declaration who wish to transfer data to a third country should also consider the need for a TIA and that this will be reflected in the Secretariat's pre-review process and HRCDC's decisions.

6. Returning Applications:

Reference ID:	22-003-AF1/AMD1
Lead Applicant:	Sam Manna
Lead Data Controller:	Otsuka Pharmaceutical Development & Commercialization, Inc
Title:	A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of AVP-786 for the treatment of agitation in patients with dementia of the Alzheimer's type"
Research Objective:	See HRCDC Meeting minutes of 10th May 2022

Points to Discuss:	The Applicant provided additional information on the role and activities the laboratory data processor (Invitae Corporation) and on two data processors involved in recruitment and pre-screening activities (Clinical Trial Media and WCG ThreeWire).
HRCDC Comments:	The Chair requested the HRCDC to indicate whether the amendment request should be approved. After discussing the responses provided by the Applicant, it was the consensus of the HRCDC that the amendment request could be approved covering (i) the change in data controllership and (ii) the data processors named by the Applicant, with the exception of Clinical Trial Media and WCG ThreeWire who would not be covered by the consent declaration. The HRCDC discussed that this decision does not exclude the Applicant/data controller from submitting future amendment requests for consideration regarding data processing by Clinical Trial Media and/or WCG ThreeWire. **Additional Laboratories.** • Based on the information provided, including the additional information on Invitae Corporation, the HRCDC approved the inclusion of the additional laboratory data processors that were specifically named by Applicant in their amendment request form. • It was commented that the scope of the amendment will be clear that processing by the laboratories is for this specific study only and that a condition should be attached requiring the destruction or return of the samples and data by the laboratories. **Recruitment and pre-screening** • The HRCDC discussed the additional informaiton provided by the Applicant on the roles of Clinical Trial Media and WCG ThreeWire within this study, including on what data they will be processing and the supervision of their roles. It was noted that Clinical Trial Media would be involved in supporting the recruitment/enrolment process of participants identified from outside the hospital clinics, namely persons who reply online to the public campaign. WCG ThreeWire would be involved in supporting the hospital research team at the local site with identification, pre-screening and enrolment of participants; they may also be involved in reaching out to external sources to identify patients. It was also noted that both services are not mandatory with sites deciding if they wish to utilise the service of these parties. • In response to the HRCDC's question, the Applicant/data controller stated that information on these two parties is not outlined in the study protocol. With regards WCG ThreeWire it was noted that the Clinical Research Co-ordinator they employ at the local site would review the local sites records and may process identifiable patient data. On Clinical Trial Media, it was noted that they will process data including name, contact information and health data; on the health data to be collected, the response provided did not provide sufficient detail on what specific data will be processed, only that it includes information in relation to any aspect of your health and/or consequences of

	taking part in a clinical trial. Reference was also made to Clinical Trail Media collecting data that appeared to be related to activities beyond this research study such as data collected when visitors browse their website and other marketing and communication purposes. It was discussed that the consent declaration does not cover data processing that is beyond health research, such as for marketing or websites. • On balance the HRCDC was of the view that there remained a lack of clarity and specifics on the personal data to be processed by these two external companies. The HRCDC agreed that separate future amendment requests can be submitted for consideration should the local Irish sites wish to use the services of these two processors. It was commented that any amendment request should be clear on what data will be processed, taking into account the principle of data minimisation and the concerns above in relation to collecting data that appeared to be beyond this research study.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved, with the exception of Clinical Trial Media and WCG ThreeWire.
Conditions Attached:	**Condition 1.** Where samples and associated data are transferred/shared with the data processor laboratories named in your amendment request form, they must be either returned or deleted after the data processors have concluded their activities for this study. The data processor laboratories should not continue to process and retain samples and associated data for longer than is required for the purpose of this specific study. Linked to this, the data controller must ensure that the principle of data minimisation is adhered to i.e., only the minimum level of data should be transferred to these data processor laboratories. This condition is a reporting requirement of the Annual Review. **Condition 2**. The requisite research ethics committee approval for Ireland must be in place for the change in data controllership and it must be ensured that ethical approval covers the new data processors covered by this amendment. Confirmation that the required ethical approval is in place should be submitted to the HRCDC. **Condition 3**. The required data agreements/arrangements must in place between all the parties that are sharing and receiving data and associated samples; this includes required agreements or arrangements when sharing data of Irish based participants to the named parties outside the EEA to 'third countries' not covered by an adequacy decision, as defined in the GDPR, for example putting in place Standard Contractual Clauses. In this context the Applicant must also have regards to the requirement to undertake a Transfer Impact Assessment when transferring data to such parties in third countries as per the 2021 decision of the Court of Justice of the European Union.

7. Amendments:

Reference ID:	21-011-AF1/CSO/AMD2
Lead Applicant:	Seamus McGuinness
Lead Data Controller:	Economic and Social Research Institute
Title:	Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland
Research Objective:	See HRCDC Meeting minutes of 17th August 2021
Purpose of Amendment:	The amendment requests an extension of the consent declaration by 1 year to August 2024. The extension is due to delays that have occurred in accessing the data.
HRCDC Comments:	The Chair highlighted that this was a technical amendment to extend the duration of the declaration. The HRCDC were asked if they approved the amendment. It was the consensus of the HRCDC that the amendment request should be approved. **CSO and REC approvals** • It was queried whether the approvals from the CSO and applicable REC to access this data remained in place. The Secretariat highlighted that they are currently valid, however they expire in early 2024 and would need to be extended.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved.
Conditions Attached:	**Condition 1.** The Applicant must ensure that extended approvals from the CSO and REC are obtained and last for the duration of the consent declaration.

Reference ID:	22-006-AF1/AMD2
Lead Applicant:	Gianpiero Cavalleri
Lead Data Controller:	Royal College of Surgeons in Ireland, St James's Hospital, Beaumont Hospital
Title:	A description of the evolution of phenotype in epilepsy from paediatrics through adulthood and old age (HPO Study)
Research Objective:	See HRCDC Meeting minutes of 14th June 2022
Purpose of Amendment:	The amendment requests an extension to the duration the consent declaration to July 2024.
HRCDC Comments:	The Chair highlighted that this was a technical amendment to extend the duration of the declaration. The HRCDC were asked if they approved the amendment. It was the consensus of the HRCDC that the amendment request should be approved.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved.

Reference ID:	23-002-AF1/AMD1
Lead Applicant:	Norman Delanty
Lead Data Controller:	Royal College of Surgeons Ireland

	NEW: Beaumont Hospital
Title:	Development and Establishment of the Epilepsy-Associated Ready Register (EAGER) – A Register of Patients with Epilepsy caused by Pathogenic Mutations
Research Objective:	See HRCDC Meeting minutes of 29th March 2023
Purpose of Amendment:	RCSI and Beaumont Hospital recently reached an inter-institutional agreement concerning circumstances where PIs hold joint affiliation in both institutions. The agreement is that RCSI and Beaumont Hospital will act as joint data controllers in such circumstances. Since the Principal Investigator holds positions in both institutions, the request is to amend the Eager Register to joint controllership between RCSI and Beaumont. There is no further change to roles involving this register.
HRCDC Comments:	The Chair highlighted that this was a technical amendment to change the data controllership of the study to a joint controllership. The HRCDC were asked if they approved the amendment. It was the consensus of the HRCDC that the amendment request should be approved. It was commented that the parties need to ensure that appropriate joint data controller arrangements are in place and that such arrangements cover this study, including roles and responsibilities.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved.
Conditions Attached:	**Condition 1.** It must be ensured that there is an appropriate joint data controller arrangement between RCSI and Beaumont Hospital and that such arrangement covers this study, including roles and responsibilities. **Condition 2.** Signature on the amendment request form on behalf of Beaumont Hospital is outstanding and should be submitted as soon as practicable, and within 1 month of the date of the HRCDC's decision letter.

Reference ID:	20-039-AF1/AMD2
Lead Applicant:	Bairbre McNicholas
Lead Data Controller:	**Previous data controller:** Galway University Hospital - Saolta Hospital group. **Proposed new data controller:** Hunter New England Local Health District
Title:	A pilot multicentre randomized controlled trial comparing an approach of individualized blood pressure targets to standard care among critically ill patients with shock
Research Objective:	See HRCDC Meeting minutes of 2nd March 2021
Purpose of Amendment:	The amendment is requested to reflect a change in data controllership from Galway University Hospital to Hunter New England Health Local Health District as the sole data controller of the study. GUH is now a data processor. In addition, the original consent declaration application outlined that the sharing/transfer of data would be with the George Institute Australia; this has changed to the Hunter Medical Research

	Institute in Newcastle, Australia which is the research institute co-located/affiliated with the data controller, i.e., the Hunter New England Local Health District
HRCDC Comments:	It was highlighted to the HRCDC that the pilot trial is finished, and the Applicant had submitted a new application for a full version of this trial that follows on from this pilot; this new application is tabled for consideration at today's meeting (Ref: 23-004-AF1). It was noted that the changes requested in the amendment form for the pilot were incorporated into the main trial. In this context the HRCDC considered this amendment in conjunction with 23-004-AF1 and approved the amendment.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved.
Conditions Attached:	**Condition.** The Irish hospital sites must, alongside the data controller Hunter New England Health Local Health District, be responsible for the implementation of and compliance with the consent declaration and data protection requirements; there should also be a point of contact in Ireland for participant if a participant has queries or otherwise wishes to exercise their rights.

8. New Applications

Reference ID:	23-004-AF1
Lead Applicant:	Bairbre McNicholas
Data Controllers:	Hunter New England Health Local Health District (Australia)
Title:	Individualised Blood Pressure Targets versus Standard Care among Critically Ill patients with Shock - A Multicentre Randomised Controlled Trial (REACT Shock RCT)
Research Objective:	Blood pressure (BP) is a vital parameter and maintaining an adequate BP is one of the most fundamental tenets of management of shock. It is a decision that ICU clinicians make every time they assess such patients, and it is plausible that their decisions regarding BP targets may directly impact on outcomes of those patients. Conventional practice often results in a varying degree of untreated relative hypotension that is inadvertently accepted in real world setting. Minimising such variation by targeting a patient's own basal BP can be a simple strategy or a management approach that can potentially improve outcomes. Although it has been suggested by the guidelines, this approach has never been tested in an RCT among ICU patients with shock. Therefore, high-quality evidence from a well-designed RCT is needed to influence strength of recommendations regarding choice of BP targets for vasopressor support. This study will compare standard care to a strategy of targeting patients' usual pre-illness blood pressure (BP) during management of shock in ICU. 1260 eligible patients from sites around the world will be randomly assigned to either standard care (control) or a strategy of individualised BP target (intervention).
Reason for Declaration:	Patients with shock frequently present emergently and obtaining informed consent is not possible or practical.

	The consent declaration is requested to process the personal data of participants who lack decision-making capacity to provide explicit consent due to the nature of their medical condition. Data processing includes access, collection, analysis, and storage of the personal data of participants in Ireland for the purpose of the REACT-SHOCK RCT only, which includes follow-up data. Data sources include the local hospital records and GPs as well as data generated from the study intervention. Where a participant lacks decision-making capacity proxy assent will be requested followed by a consent to continue once the patient has capacity.
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** • Based on the information provided the HRCDC was of the view that there is a relatively strong public interest case. **Contacting GPs** • The HRCDC queried whether the participant's GP would be contacted to request data on blood pressure measurements as part of pre-screening to determine eligibility, prior to obtaining consent or proxy assent. It was highlighted that the Applicant had confirmed that proxy assent would always be obtained prior to study enrolment and that blood pressure measures for pre-screening from GPs will not occur prior to obtaining proxy assent or participant consent. The HRCDC agreed that no data should be obtained from GPs prior to obtaining proxy assent. **Decision making capacity.** • It was commented that decision making capacity is assessed on medical-based grounds, with the Applicant/data controller outlining that functional decision-making capacity has not been incorporated. • Reference is also made to contacting GPs to '*obtain informed consent where capacity was not reached within the hospital'.* The HRCDC stated that it was unclear if GPs would be undertaking the assessment of participant capacity post-hospital discharge or providing information on capacity to the research team for the capacity assessment. If the former it was queried what training or guidance would be provided to the GPs to determine decision-making capacity for this study and if assessing capacity after hospital discharge would be consistent, whether across different

	GPs or consistent with the assessment that would have been undertaken in the hospital. • The HRCDC discussed that the study should have regards to functional decision-making capacity, where appropriate. It was further discussed that the methods of assessing capacity should be consistent whether undertaken within the hospital or post hospital discharge, with training and guidance provided. **Public and patient involvement (PPI)** • The Applicant's response on the PPI activities undertaken were noted. The HRCDC commented that consideration should be given to further PPI engagement for the benefit of the study, including on the study informaiton leaflets. **Transfer to Australia** • It was queried how the data and the rights of participants in Ireland will be protected in the context that the data controller of the study is in Australia and that data from Ireland will be transferred to parties in Australia. • It was commented that the required agreements and arrangements governing the transfer and use of data, and roles and responsibilities will need to be in place; Standard Contractual Clauses used to transfer data outside the EEA set out requirements on data rights. It was also highlighted that a Transfer Impact Assessment would need to be undertaken which would highlight any supplemental safeguards that should be put in place. **Study and data withdrawal** • It was noted that where an individual wishes to withdraw from the study that permission to process the personal data already collected will be requested; where this is not permitted then '*all efforts'* to remove personal data will be made. • It was commented that data should be deleted if an individual withdraws from the study and wants the data deleted, having due regards that it this may not be possible following publication or other appliable GDPR derogations. **Study Informaiton Leaflets** • The HRCDC noted that the information leaflets include different sections on sharing/disclosing data to third parties. While specific reference is made to the HSE, reference was also made that third parties may include but are not limited to 'relevant industry bodies', 'external professional advisors' and 'others where it is permitted by law or where we have your consent/assent'. It was discussed that the information sections on sharing/disclosing data with third parties are very broad and didn't provide adequate clarity or information on who or what is meant by 'relevant industry bodies' 'external professional advisers' or 'others where permitted by law'. It was also not

	clear why or for purpose personal data would be shared with such third parties. • It was confirmed that the consent declaration made only covers data processing for this specific study and in this context the transfer and processing of personal data by the parties specifically named in the application form only, including the two Australian parties. The consent declaration/proxy assent does not cover processing for other purposes, including to other third parties or for future unknown research; it was discussed that any further processing beyond the scope of this specific study and/or to other third parties would require an amendment request form or new application to be submitted for consideration. • Given the scope of the consent declaration that can be made, the importance of providing clear and precise information and that proxy assent is not valid consent for future research, it was the view of the HRCDC that the references to sharing/disclosing data to third parties and for future research purposes should be amended. In addition, as the consent declaration and proxy assent is not valid consent for future research, any references to processing/using data in future research studies should also be amended in the documentation for the proxy; it should be highlighted that proxy assent is limited to storage of the data only for use in potential future studies. • In addition, it was noted that not all versions of the proxy information leaflet refer to monitoring by the Hunter Research Institute and that the current statements that data rights are limited (e.g., 'Your rights to access, change or move your information are limited, as we need to manage your information in specific ways…. ') should be refined to provide further context on why rights may be limited. • It was also not clear to the HRCDC whether the full study information leaflet will be read out when seeking verbal proxy assent or participant consent. The HRCDC commented that it should be read out and a copy provided to the individual. **Duration of the declaration** • The HRCDC discussed the request for a declaration of 19 years, consisting of 4 years for the study and 15 years of data archiving. It was commented that it may be appropriate to make a declaration of a shorter period and that the Applicant can request an extension by submitting an amendment request form (if required). **Other** • It was commented that the data, when transferred, will be held on the servers of the Australian data processor and that back-up data will be stored off-site. It was unclear if off-site meant back-ups were held by another third-party provider. The HRCDC stated that appropriate data agreements should be in place if back-ups of the data are held by another processor.

	• 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 on data agreements/arrangements, joint responsibility for complying with the declaration, REC approvals, permission to continue to process data after withdrawal and other amendments to the PILs.
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 22nd August 2023 and is valid until 30th September 2027 and for 10 years of data archiving thereafter.
Conditions Attached:	**Condition 1** The Irish hospital sites must, alongside the data controller Hunter New England Health Local Health District, be responsible for the implementation of and compliance with the consent declaration and data protection requirements; there should also be a point of contact in Ireland for participant if a participant has queries or otherwise wishes to exercise their rights. **Condition 2.** It is a condition that the protocol for assessing or re-assessing participant decision-making capacity is consistent throughout the course of this study, whether this assessment occurs within the hospital or post-hospital discharge and whether it is undertaken by the hospital staff and/or by or with the support of GPs; this should include the provision of necessary information and guidelines for those involved in this process. Please provide an update on this condition within 3 months. (Please also see Recommendation 1). **Condition 3.** The required data agreements and arrangements must be in place for this study, including agreements between the data controller of the study, the Irish sites, and the other named data processor in Australia. Data agreements/arrangements should also be in place if off-site back-up data is held by another third party. Further, the necessary agreements/arrangements must be implemented for transferring data outside the EEA (e.g., Standard Contractual Clauses) and a Transfer Impact Assessment must also be completed. Please also discuss these matters with the relevant data protection officer. The transfer of data between parties cannot occur prior to the necessary agreements being in place and required assessments being undertaken. **Condition 4.** Confirmation that research ethical approval was ratified by the full Galway REC should be submitted to the HRCDC as soon as possible. Feedback from the data controller of the study, Hunter New England Health Local Health District, must also be provided as soon as possible and within 1 month. The consent declaration will not cover data processing at the Galway site or data transfer to Australia prior to this condition being met. **Condition 5**. It is noted that where a proxy or participant wishes to withdraw from the study that either permission to continue to

	process the personal data already collected will be requested or, if this is not granted, *'all efforts'* to remove the personal data will be made. It is a condition of this declaration that if a proxy or participant wishes to withdraw and have the data removed then the personal data must be deleted up until the point where this cannot be done (i.e., publication of the findings or if other GDPR derogations may apply). If the study wishes to continue to process data after withdrawal, then specific, clear and separate proxy assent/participant consent should be obtained and recorded for this continued post-withdrawal processing. Where the proxy withdraws and provides assent for the data to continue to be processed then it remains that consent to continue for this processing must still be obtained from the participant if they regain capacity. **Condition 6.** There are references in the study information leaflets on sharing/disclosing data with the HSE and other third parties that may include but are not limited to '*industry bodies', 'external professional advisors' and 'others where it is permitted by law or where we have your consent/assent'*. It is not clear who or what is meant by '*these parties and* for what purpose personal data may be shared with the HSE and other such third parties. Therefore, the study information leaflets must provide more precise and granular informaiton on what is meant by '*industry bodies', 'external professional advisors' and 'others where it is permitted by law or where we have your consent/assent'* and outline what personal data may be shared with such third parties and the reasons for this sharing in the context of this study. In addition to amending the information leaflets as described above, the accompanying proxy assent and participant consent forms should also include clear options on sharing/disclosing data to third parties that aligns with the amended information leaflets. References and options to processing/using data in future research studies beyond this specific study should also be amended or removed in the documentation for the proxy, given that the scope of the declaration cannot cover future research studies and is limited to storage only for future research. This condition is to be addressed for the documents across all the Irish sites and the amendments made prior to the recruitment of participants. Please provide an update on this condition within 3 months.
HRCDC Recommendations:	**Recommendation 1:** aligned with the Assisted Decision-Making Act, the study is requested to have regards to assessing decision-making capacity from a functional assessment, where appropriate. **Recommendation 2.** The Applicant is requested to undertake further PPI engagement for the benefit of this study, including engaging with PPI representatives on the study information leaflets. **Recommendation 3:** When seeking verbal proxy assent or participant consent, it should be ensured that the individual fully understands all elements of the study and data activities, for

	example by reading out the full study information leaflet and providing a copy of the leaflet provided to the individual. **Recommendation 4:** the Applicant is requested to address the following in the study information leaflets across all sites to ensure clarify and transparency of information: - Not all versions of the proxy study information leaflet clearly refer to monitoring by the Hunter Research Institute. Further the Hunter Research Institute is also not clearly noted as acting on behalf of the sponsor in the consent to continue information leaflets for the Galway site. - All versions of the site information leaflets should be consistent to state that 'pseudonymised data', not 'anonymised data' recorded up the point of withdrawal will be included in the study subject to the proxy/participant's permission being granted. A description of what is meant by the term 'pseudonymised' should also be provided. The Applicant may also wish to consider the use of the term 'coded data', instead of 'pseudonymised data'. - It must be clearly outlined in all versions of the study documentation on the data that will be collected from the GP (this was addressed in the information leaflets for the pilot but is outstanding in the leaflets for this main trial). - Statements that data protection rights are limited should be refined to provide further context of why rights may be limited.

Reference ID:	23-011-AF1
Lead Applicant:	Mary Mc Carron
Data Controllers:	Trinity College Dublin
Title:	Building Circles of Support for People with Intellectual Disabilities
Research Objective:	The overall aim of the project is research findings to develop resources to enhance the Circles of Support (COS) for adults with intellectual disabilities (ID) that can be used in person-centred planning processes. This project will translate published IDS-TILDA findings from four completed Waves into new resources: 1. A COS Blueprint with Guidelines for service providers to promote COS, with specific measures to identify, recruit, support and sustain these Circles. 2. A COS Workbook for people with intellectual disabilities and their carers to better understand how to integrate COS into plans. This will include an easy-read and plain language Handbook with accompanying video. Project outputs will include testimonial case studies of six individuals with intellectual disabilities and their COS, who will be recruited from project partner Stewarts Care.
Reason for Declaration:	Explicit consent will be sought from all project participants, in line with the assumption of capacity outlined in The Assisted Decision-Making (Capacity) (Amendment) Act 2022. However, given the aim to include perspectives of participants with mixed levels of

	intellectual disability, there are likely to be some participants who will lack the capacity to provide explicit consent. The consent declaration is requested to cover the processing of personal data for those participants with ID who are unable to provide explicit consent. The Applicant/data controller requests that the consent declaration cover (i) the interviews/focus groups and (ii) the recording and publication of the case study video content; the videos will identify the participants.
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 discussion, it was the consensus of the HRCDC that a conditional declaration should be made. **Public interest** • The HRCDC was of the view that there is a strong public interest case for this study and that the aims of the study and the involvement of participant voices is important. **Data deletion & declaration duration** • The HRCDC commented that the personal data obtained from participants via the expression of interest process, who are not then selected for this study, should be deleted as soon as practicable. • It was also discussed that while an indefinite declaration can be given to cover the published videos, it should be limited for the other study data with a one-year duration considered appropriate. **Study information leaflets** • Overall, the HRCDC commented that the study documentation was well developed. However, it was noted that the information leaflets stated there were no risks to being involved in this study. While the HRCDC acknowledged that the study is implementing safeguards for the videos, it was discussed that there was a risk that the recordings that are made public could be misused and that participants should be informed of this. • It was also noted that the consent forms outline the videos will almost be impossible to delete once uploaded online, but that this was not clearly mentioned in the information leaflets. • The HRCDC was of the view that the proxy who provides assent on behalf of a participant who lacks decision-making capacity should be asked to sign a separate assent form and not the same form that is also provided to the participant with an intellectual disability. **Other**

	• It was commented that agreements needed to be in place with the data processor involved in the video recordings. • The HRCDC discussed that the Data Protection Impact Assessment provided was of a high standard. • The HRCDC also noted the system of '*process consent'* that will be adopted to ensure continued consent from the participant including on the pre-release of video recordings. The applicant has outlined how they will obtain consent to the best extent possible, for use of the video recordings.
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 22nd August 2023. With regards the video recordings the declaration will remain valid indefinitely, For the other personal data (i.e., demographic data, audio recordings, transcripts etc.) the declaration is in place until 30th November 2024; after this point the non-video personal data collected for this study should be deleted or fully anonymised.
Conditions Attached:	**Condition 1.** The study information leaflets should inform the participants that there may be a risk that the video recordings may be misused by other people after they are uploaded online. In addition, while the consent forms state that the videos will almost be impossible to delete once they are uploaded, this is not clearly mentioned in the information leaflets; information that the videos are impossible to fully delete should be included in both the consent form and the information leaflets. **Condition 2.** It is noted that the same document is used when requesting either participant consent or proxy assent i.e., there is a section for the participant or their support person to sign. The HRCDC is of the view that the proxy should be asked to sign a form that is separate to the form provided to the participant with an intellectual disability i.e., a single combined assent/consent signature form for both the participant and the proxy should not be used. (Please note that this condition requests separate assent/consent signature forms – it does not apply to the study information leaflets that are used). **Condition 3.** The personal data obtained from the expression of interest process of participants who subsequently not selected for this study should be deleted as soon as practicable. In line with the principle of data minimisation, personal data should not be processed for longer than is necessary. **Condition 4.** Appropriate data agreements must be in place with the data processor involved in the video recordings.

Reference ID:	23-010-AF1
Lead Applicant:	Iris Bobenhausen
Data Controllers:	BioTest AG
Title:	EsSCAPE trial

Research Objective:	This ESsCAPE study is a randomised, double-blind, multi-centre, phase III trial that will evaluate the safety and efficacy of trimodulin compared to placebo as an additional therapy to standard of care treatments for adult patients with severe community acquired pneumonia (sCAP), who are hospitalised and require ventilation to breathe. sCAP is a life-threatening disease, as patients may suffer from complications such as sepsis and multiple organ failure. As this represents an unmet need for these patients the primary goal is to improve patient's outcomes and the quality of life with trimodulin. Trimodulin is an immunoglobulin preparation which contains antibodies directed against a wide range of infectious pathogens. The hope is that trimodulin will augment the standard of care therapies, strengthening the body's immune responses to prevent further worsening of the disease and ultimately reduce the symptoms of sCAP, allowing patients to recover from the disease. Trimodulin will be compared with a placebo and administered intravenously.
Reason for Declaration:	This study involves patients suffering with severe community acquired pneumonia and requiring the use of invasive mechanical ventilation for breathing. Consent may not be possible to obtain as these patients will either feel very unwell and weak or using the ventilator. The consent declaration is therefore requested to process the personal data of participants who lack decision-making capacity to provide explicit consent. Where they lack decision-making capacity, then proxy assent will be obtained from a legally appointed representative and deferred consent to continued obtained as soon as possible. The data processing activities includes collection, transfer, analysis, storage of personal/pseudonymised data (including data associated with samples) for the purpose of (i) the main ESsCAPE clinical trial and (ii) the optional PK sub-study. GP data may also be used for pre-screening/eligibility and therefore this may also need to be covered. Future research will require an amendment or new application to be submitted.
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**. • Based on the information provided the HRCDC was of the view that there is a public interest case in this study. **Mental health data**

	• The HRCDC noted the response provided by the Applicant on the mental health data that would be collected. It was highlighted that mental health data included confusion, as well as eye and verbal responses using standard scores and tools. It was discussed that the data referenced was not traditional mental health data but other related health data. • The HRCDC was of the view that the Applicant should ensure that only the minimum level of data, including mental health data, is processed for this study. **Public and patient engagement** • The HRCDC was of the view that the response on PPI engagement was inadequate and therefore PPI engagement activities should be undertaken with appropriate groups such as ICUSteps, for example on matters such as the assent/consent process and study documentation. **Proxy assent/consent process**. • The responses from the Applicant highlighted that proxy assent will be obtained from a legally authorised representative who may include a family member, friend or a medical practitioner who is not involved in the conduct of the trial. • The HRCDC was of the view that a medical practitioner should not provide proxy assent on behalf of a participant who lacks decision-making capacity. It was also commented that a clear and consistent protocol should be in place for obtaining proxy assent from a relative or friend who understands the participant's will and preferences. **Data agreements/arrangements** • The Applicant had outlined that the external laboratory service providers used in this study are not considered data processors under guidance issued by the German data protection authorities. However, it was noted data agreements will be in place with the external laboratories including on the transfer and use of personal data that accompanies the bio-samples. **Study information leaflets** • The HRCDC noted that the proxy assent and consent forms includes statements that '*data may also be transferred outside my country'* and that '*I cannot participate'* or *'data cannot be processed*….' if permission/consent is not provided for this transfer. It was the view of the HRCDC that this wording is technical and legalistic and may pressurise the participant or proxy who provides consent or proxy assent. It was commented that the only non-EEA country that will receive personal data is the USA, specifically the named data processor parties involved in data capture services/technology and the Food and Drug Administration. It was discussed that a consent declaration, if made, would not cover the processing of personal data for other future unknown studies beyond this specific trial and that the sharing/disclosure and processing of personal data beyond the parties specifically named in the application will also not be

	covered. The HRCDC discussed that the wording of this section of the consent/assent forms should be reviewed and amended, with clarification provided on why data is shared with parties outside of Ireland for this study. • It was further commented that the references in the assent/consent forms on transferring coded data were also very broad and that more information and granular options could be provided on what data might be shared, with whom and for what purposes, e.g., shared with external labs for the purpose of this study if required. • The HRCDC further discussed that the incorrect references to sharing coded data with health insurers. It was discussed that this should be updated before the commencement of the study in Ireland. It was also noted that document headings were not provided on the various study documentation e.g., consent for future research form. • In addition, while the study information leaflets refer to destroying leftover samples or storing them for up to 6 months after the end of the study, it was not clear if this also applied to the external laboratory service providers who will be contracted. It was discussed that participants should be clearly informed if their samples will be deleted, stored or returned by the external labs. • The HRCDC also commented that initials should not be requested in the assent/consent forms but rather clear 'yes/no' options. It was further discussed that the reference in the study information leaflets for the proxy/participant to check with the private medical insurance company about this study should be made more prominent within the document. • Given the scope of the consent declaration that can be made, it was further discussed that references to sharing data with third parties for future studies do not apply where proxy assent is obtained and therefore these references should be removed from the documentation provided to the proxy. • Where participant consent is obtained for future research, it was also discussed that more information should be provided on the third parties with whom data and samples maybe shared with. • It was the view of the HRCDC that the changes made to the study documentation should be submitted within 3 months **Study withdrawal** • The response provided on with withdrawal of proxy assent/participant consent was discussed. It was noted that if an individual withdraws that data that is no longer required will be deleted immediately following checks by the responsible authorities, unless there are legal or other reporting obligations to comply with. The Applicant states elsewhere that samples and data already collected will continue to be used, but no new personal dta will be collected. • The HRCDC was of the view that it was not fully clear what happens the data and samples if an individual is withdrawn. It was discussed that where the proxy or participant withdraws that

	the data and associated samples should be destroyed unless there is a legal obligation to retain it, or it is no longer possible to have it destroyed. If there is a legal obligation to retain the data and not delete it then the HRCDC commented that this must be made clear in the study informaiton leaflets; it was the view of the HRCDC that individuals are also not provided with clear informaiton on their rights to have their data and samples delete but that data may also continue to be processed after the participant is withdrawn and the reasons why, for example for regulatory reasons. The HRCDC commented that the study documentation should consider the Irish context with regards withdrawing, data rights and what will happen the data and samples. **Other** • Reference was made by the Applicant to sharing data outside the EEA based on a GDPR derogation; the HRCDC queried what derogation was being replied upon. It was highlighted that the Data Privacy Framework has come into effect for the transfer of data between the EU and the USA. • It was noted that the separate withdrawal of assent/consent form primarily requests a signature but provides no further information on what will happen with regards data processing, including data associated with the bio-samples. • The HRCDC discussed the response from the Applicant on what is meant by '*adaptive design'* in the context of this study; the Applicant outlined that the study sample size may substantially increase if deemed necessary. It was commented that this change may require an amendment request to be submitted and that this will be outlined to the Applicant. • 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 local sites are also responsible for complying with the declaration, that the required data agreements and arrangements are in place with external laboratories, GPs etc. and clarity on the scope of the consent declaration.
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 22nd August 2023 and is valid until 31st December 2024 and for 25 years of data archiving thereafter, or until the personal data has been destroyed or irrevocable anonymised.
Conditions Attached:	**Condition 1.** The Irish hospital sites must, alongside the data controller BioTest AG, be responsible for implementation of and compliance with the consent declaration and data protection requirements; there should also be a point of contact in Ireland for participant if a participant has queries or otherwise wishes to exercise their rights.

	Condition 2. It is a condition of this declaration that proxy assent on behalf of a participant should only be obtained from a relative or friend who understands the participant's will and preference. **Condition 3.** The Applicant must ensure that data agreements/arrangements are in place between all the parties involved in this study; this includes agreements with the named data processors, Irish sites, the named laboratory service providers and with GPs, if GP data is provided for this study. The transfer of data, including data associated with samples, cannot occur prior to appropriate data agreements being in place. **Condition 4.** The Applicant is requested to undertake PPI engagement activities with relevant individuals or representative groups, for example ICUSteps. Consideration should be given to discussing/exploring matters such as the assent/consent process and study documentation with the PPI representatives. At the time of the first Annual Review, the Applicant/data controller is expected to report on the PPI activities that have been undertaken. **Condition 5.** Where the proxy or participant withdraws from the study, the data and associated samples should be destroyed unless there is a legal or regulatory obligation to retain it, or it is no longer possible to have it destroyed (e.g., after the publication of findings or other applicable GDPR derogation). This applies to the main study, sub-study and samples/data for future studies. Individuals should be provided with clear informaiton that as to why this is the case, for example for regulatory reasons; if there is a legal obligation or other valid derogation to retain the data and not delete it, then this must be made clear in the study informaiton leaflets. Lastly, the separate withdrawal of assent/consent form only requests a signature but does not provide informaiton on what will now happen the data and samples for the main study, sub-study and future studies. Informaiton on what will happen the data and associated samples should also be included in this separate withdrawal document. **Condition 6.** The Applicant/data controller is requested to address the following in the study information leaflets and assent/consent forms with regards sharing of data: ○ The consent forms include a separate section outlining that data '*may be transferred outside my country'* and states '*I cannot participate*' or '*data cannot be processed….' if permission/consent is not provided for this transfer*, with the individual asked to tick a box to expressly consent to this. It is the view of the HRCDC that the wording of this separate section is quite technical and legalistic and may cause undue pressure on the participant or proxy to agree to transfer of their data outside of their country. The HRCDC requests that this section is reviewed and amended to provide clarification on what data might be shared, with whom and for what purpose in the context of this study.

	○ The table in the consent form includes the following request*: 'I give permission for my coded data to be: if required, transferred to any country where laws protecting my personal information may be different to those in my own country*'. The HRCDC is of the view that this is a relatively broad statement, and that more information and corresponding, granular/layered consent options should be provided on what coded data may be shared, with whom and for what purpose in the context of this specific trial i.e., sharing with external laboratories for the purpose of this specific trial. ○ References to sharing data with third parties for future research studies beyond this specific study (and sub-study) do not apply where proxy assent is obtained; proxy assent and a consent declaration cannot cover sharing or processing of data for future unknown research studies. Therefore, such references in the main study information leaflets provided to the proxy should be removed/amended; the declaration can only cover storage only of the personal data for future research. The specific consent documentation for future studies provided to the proxy should also be amended to reflect that assent for future studies is for storage of data only for future research. *Please also refer to Condition 5 on PPI.* **Condition 7:** the Applicant/data controller is requested to further review and amend the study informaiton leaflets and assent/consent forms as follows: ○ Incorrect references to sharing personal data with health insurers should be removed. ○ While the study information leaflets refer to destroying leftover samples or storing them for up to 6 months after the end of the study, it was not clear if this applies to all the laboratories including the specifically named external laboratory service providers that are covered by this declaration. Participants should be clearly informed if their samples will be deleted, stored or returned by the external labs. ○ There are no 'yes/no' boxes provided in the assent/consent form – please include 'yes/no' boxes for each of the options in the assent/consent forms. Initials alone should not be used in the assent/consent forms. Individuals should be asked for their permission via 'yes/no' boxes.
HRCDC Recommendations:	**Recommendation:** The Applicant is requested to amend the study information leaflets as follows: ○ It should be ensured that clear and correct document headings are provided on all the study documentation for proxies and participants; for example, a clear heading should be provided on the consent for future research form. ○ the reference in the study information leaflets for the proxy/participant to check with the private medical insurance company about this study should be made more prominent within the document.

HRCDC Comment	The HRCDC commented that study information leaflets and consent/assent forms should be consistent and compliant with Irish policies.

Reference ID:	23-005-AF1
Lead Applicant:	Caroline O'Nolan
Data Controllers:	National Disability Authority
Title:	The journey from wardship to supported decision-making: An examination of the process and the experiences of people leaving wardship
Research Objective:	The process of dismantling wardship and moving to a system of supported decision-making commenced on 26th April 2023. The new system of supported decision-making is aligned with Article 12 (Equal Recognition before the Law) of the United Nations Convention on the Rights of Persons with a Disability (UNCRPD). This research will critically assess the process of transition from wardship. A mixed methods approach will be adopted and will include interviews with a range of participants and observations of court hearings. The inclusion of people who are Wards of Court is a fundamental part of this research. Participants will include Wards of Court and the Committees that act on their behalf and key informants that have knowledge of or experience regarding wardship or the Decision Support Service.
Reason for Declaration:	It will be assumed that all participants (i.e., those who are or who were wards of court) will have decision-making capacity from the outset, however it is expected that an unknown proportion may not have decision-making capacity to provide consent for this specific study. The Court Service has also provided permission/consent for the participation of the wards of court in this study. While this means there are no legal barriers from the court, the Applicant/data controller is of the view that this permission from the Court does not meet the requirements of HRR explicit consent e.g., the court permission/consent does not note the names of the wards. The consent declaration is therefore requested to process the personal data of participants who are or who were wards of court but who lack decision-making capacity to provide explicit consent for this study. Data processing includes personal data processed for the expression for the interest phase and the main study phase.
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 introduced the study and outlined the reasons for seeking a consent declaration and which participant cohorts do and

	do not need to be covered. 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 aims of this study and commented that it was important research. It was therefore the view of the HRCDC that the study had a strong public interest case. **Withdrawal and deletion of data** • The response that data cannot be removed from the study 3 months after the completion of the interview was discussed. It was commented that the study should be fully transparent that data can be removed before 3 months but also on the reasons why it is not possible for data to be removed following this time limit. • It should also be detailed if this time limit is applicable to some or to all of the study data that is held e.g., does it apply to the transcribed quantitative interview responses only or is there is other personal data held by the researchers that could still be deleted after 3-months, if requested. While noting the 3-month timeline, the HRCDC also commented that a consent declaration does not override the rights of participants and therefore if data can be deleted/removed after 3 months, if requested, then it should be deleted, subject to derogations that may apply. **Other** • It was commented that the study should document who has assessed the decision-making capacity of the participant. The form for recording this informaiton also prompts for a signature. • It was discussed that the interview recordings should be transcribed as soon as possible. • The GDPR statement that will be provided to participants was considered less accessible than the study informaiton leaflets or consent forms. It was the view of the HRCDC that the GDPR statement should be revised so that it aligns more closely with the accessibility of the other documentation. • The HRCDC discussed that it was important that personal data of participants is not published in any study reports. • A minor discrepancy was noted in the DPIA, with the Applicant stating that criminal record data will not be collected, however it was also stated that information in this area maybe disclosed during the study interviews. It was discussed that this should be highlighted to and addressed by the Applicant. • 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 deleting data from the expression of interest process as soon as possible and removing all references to the external transcriber in the study information leaflets.

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 22nd August 2023 and is valid until 30th September 2036 (a period of 3 years for the study and 10 years of data archiving).
Conditions Attached:	**Condition 1.** It is important to ensure that the study and the study information leaflets clearly outline that data can be removed before the referenced 3-month time limit is reached, and also to outline the reasons why it is not possible for data to be removed after this time limit, for example if it will then not be possible to remove that participant's qualitative response from the analysis and why. It should also be detailed if this time limit is applicable to some or to all of the study data e.g., does it apply to the transcribed qualitative interview responses only or is there is other personal data held by the researchers that could still be deleted after 3-months, if requested. Further, please note that it remains that if data can still be deleted/removed after 3 months then it should be deleted if requested, subject to relevant derogations that may apply; a consent declaration does not override the data rights of participants. **Condition 2.** Personal data collected from the expression of interest process on participants who were not selected for inclusion in this study should be deleted as soon as practicable. In line with the principle of data minimisation, only the minimum amount of personal data required for the study should be processed.
HRCDC Recommendations:	**Recommendation 1.** It was noted that the DPIA responses did not tick yes to processing data on criminal records, however it is also stated in the DPIA that data on criminal records may be disclosed during the interviews. Accordingly, the Applicant is requested to amend this section of the DPIA. **Recommendation 2.** All references to the use of an external transcriber should be removed from the study information leaflets, given that it is not proposed to use one. **Recommendation 3.** The HRCDC was of the view that the GDPR statement document submitted was not as accessible when compared to the study information leaflets and consent forms. Therefore, the Applicant is requested to revise this GDPR statement so that its accessibility aligns more closely with the other study documentation.

Reference ID:	23-008-AF1
Lead Applicant:	Alistair Nichols
Data Controllers:	Monash University, Australia
Title:	ARISE FLUIDS

Research Objective:	This trial will investigate if giving a smaller amount of initial IV fluid with earlier commencement of a medication drip ("vasopressors") to improve blood pressure leads to better patient outcomes than the conventional approach of giving a larger amount of fluid and starting medication later ("fluids"). Patients eligible for the trial who have suspected septic shock in the ED will be randomly allocated to receive treatment according to one of these treatment regimens. It will follow patients up and assess their progress. The main outcome the study aims to measure is the number of days the patient has survived out of hospital at 90 days after entering the trial. This outcome measure has been chosen in consultation with consumers as being a patient-centred measure which captures survival as well as being associated with severity of illness and quality of life.
Reason for Declaration:	Due to the nature of the trial and severity of illness participants will lack capacity to give informed consent on enrolment in the trial due to infection, delirium and sedation. Due to the critical nature of septic shock, treatment needs to be commenced rapidly under emergency conditions and is part of life-saving care. The consent declaration is requested to process personal data of participants who lack decision-making capacity to provide explicit consent. In such circumstances deferred proxy assent followed by consent to continue will be obtained. Data processing activities includes collection, transfer, analysis and storage of personal/pseudonymised data – this includes transfer of such data to Monash University, Australia.
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** • The HRCDC discussed the objectives of the study. It was commented that there have been many research studies conducted in this area to try and address similar questions, however this has been challenging for researchers. While this is not a study seeking to address a new issue, it remains an important matter for medicine and therefore it was the view of the HRCDC that there is a public interest case in this study. **Pseudonymised and anonymised data** • The HRCDC noted that the terms '*pseudonymised*' and '*anonymised*' data were used interchangeably in various responses provided by the Applicant, and in some parts of the study information leaflets. For example, if a participant withdraws the study information leaflets state that '*anonymised data'* may

	continue to be processed, but elsewhere the leaflets state '*pseudonymised data'* will continue to be processed. It was also noted that the data to be analysed by the data controller Monash University was described as *'anonymous'* in the responses as it will contain '*no patient identifiers'*; however it is further noted that the data will remain pseudonymised by way of the master list held at the local hospital sites who are the data processors and that pseudonymised data will be held for 15 years after the study. • Based on the information provided, the HRCDC discussed that the data to be transferred and analysed by Monash University is not anonymised data but remains pseudonymised. It was therefore of the view that the Applicant should ensure this is made transparent in the study documentation and to ensure consistent and correct use of terms. **Study withdrawal** • The HRCDC discussed that the study treatment/intervention period is very short, lasting only up to 24 hours following randomisation, with follow-up data then being collected over an extended period of time, including obtaining measures and outcomes months after the intervention has finished. The information provided also outlined that if an individual wishes to withdraw from the study, that the researchers would like to continue to use the data already collected and, in addition, will seek permission to continue to collect data during the hospital admission and other follow-up data. • In the context of this study, it was discussed that the individuals withdrawing from the study should not be asked for permission to continue to collect and process follow-up data after withdrawal. • The HRCDC also discussed that a consent declaration does not override the rights of participants; therefore, if a request is made to delete the personal data then this should be undertaken where practicable and subject to GDPR derogations that may apply. **Meta-analysis** • The response provided by the Applicant on conducting a future meta-analysis that includes data from this study was discussed by the HRCDC. It was noted that the Applicant confirmed that the meta-analysis will be using anonymised data only and therefore no personal data will be processed in a future meta-analysis. • The HRCDC queried how the data from this study will be rendered fully anonymised such that the meta-analysis is not using personal data, and further commented that it was unclear what the aims of this analysis would be, and which parties may be involved. However, it was discussed that the consent declaration will not cover this meta-analysis as, based on the replies from the Applicant, it will use anonymised data only. It was commented that it is the responsibility of the Applicant to ensure that the data used in any meta-analysis is fully anonymised.

	Study information leaflets • It was noted that the information leaflet states that pseudonymised data will be kept indefinitely, which does not align with the Applicant's response that data will be deleted after 15 years. The term '*I know of no known objections'* should also be positively re-phrased to ask whether the participant would wish to be included in this study. • The information leaflets also outline that other hospitals, rehabilitation hospitals or nursing homes, may be contacted as part of the follow-up process to verify discharge dates provided by the participant. It was discussed that the assent/consent form should provide an option to agree to this. It was noted that the proxy assent documents request the proxy to state 'yes' or 'no' to questions that they may not know the answer to, for example *'has your relative written down his or her views in a "living will?"'*. The HRCDC commented that a '*don't know'* option should be included. • There were some inaccurate references noted in the study information leaflets and the proxy assent forms on patient samples/materials, for example withdrawing samples and storing material for future studies. It was noted that no samples are collected for this study, only the results of tests carried out as part of routine care and treatment are used. There was also a reference to making data available in anonymised repositories which the Applicant clarified will not occur. The HRCDC further commented that more layperson language could be used, for example amend the sentence *'within the spectrum of accepted usual care'.* • The HRCDC also noted that the information leaflets include sections on sharing/disclosing data to third parties; reference is made that third parties may include but are not limited to '*relevant industry bodies', 'external professional advisors'* and '*others where it is permitted by law or where we have your consent/assent'*. It was discussed that this section on sharing/disclosing data with third parties is very broad and didn't provide adequate clarity or information on who or what is meant by '*relevant industry bodies' 'external professional advisers'* or '*others where permitted by law'*. It was also not clear why or for purpose personal data would be shared with such third parties. • It was discussed that the consent declaration made only covers data processing for the specific ARISE FLUIDS study only, and in this context the transfer and processing of personal data by the parties specifically named in the application form only. It was discussed that any further processing beyond the scope of this specific study and/or to other third parties would require an amendment request form or new application to be submitted for consideration. • Given the scope of the consent declaration that can be made, the importance of providing clear and precise information and that

	proxy assent is not valid consent for future research, it was the view of the HRCDC that the references to sharing/disclosing data to third parties should be amended. In addition, as the consent declaration and proxy assent is not valid consent for future research, references to processing/using data in future research studies should also be amended in the documentation for the proxy; it should be highlighted that proxy assent is limited to storage of the data only for use in potential future studies. **Other** • It was discussed that proxy assent should be re-affirmed at an appropriate point in the study where the participant continues to lack capacity for a prolonged period time. • 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 agreements should be in place, including for transferring outside the EEA, responsibility for compliance, clarity on what the scope of the declaration covers, amend the reference to joint data controllership within the study informaiton leaflets, permission to continue to processing already obtained data, deleting the data if deferred proxy assent cannot be obtained within a reasonable timeframe, and obtaining DPO feedback from Monash.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The declaration is made on 22nd August 2023 and is valid until 31st August 2027 and for 15 years archiving thereafter (until 31st August 2042), after which the pseudonymised data will be deleted.
Conditions Attached:	**Condition 1.** The Irish hospital sites must, alongside the data controller Monash University, be responsible for implementation of and compliance with the consent declaration and data protection requirements; there should also be a point of contact in Ireland for the participants if they wishes to withdraw or exercise their rights. **Condition 2.** The required data agreements and arrangements must be in place for this study. Further, the necessary agreements/arrangements must be implemented for transferring data outside the EEA (e.g., Standard Contractual Clauses) and a Transfer Impact Assessment must also be completed. Please see Chapter V of the GDPR and the 2021 decision of CJEU on Transfer Impact Assessments. Please also discuss these matters with the relevant data protection officer. The transfer of data between parties cannot occur prior to the necessary agreements being in place and required assessments being undertaken. **Condition 3**. Feedback on the DPIA from Monash University's Data Protection Officer must be submitted as soon as practicable and within 1 month of receipt of this decision letter. No data can be transferred to Monash prior to the submission of this DPO feedback. **Condition 4.** Due to the nature of this study, proxy assent will be deferred, including telephone assent. It is a condition of this

	declaration that the personal data of the participant should be deleted if deferred proxy assent is not obtained after a reasonable timeframe. **Condition 5.** Individuals withdrawing from the study should not be asked for permission to continue to collect and process follow-up data after withdrawal. ***Please note***: a consent declaration does not override the data protection rights of participants; therefore, if a request is made to delete the personal data, then this should be undertaken where practicable and subject to GDPR derogations that may apply. **Condition 6.** The following points should also be addressed in the study information leaflets and assent/consent forms: ○ Amend the inaccurate reference to joint data controller. ○ There are references in the study information leaflets on sharing/disclosing data with the HSE and other third parties that may include but are not limited to 'industry bodies', 'external professional advisors' and 'others where it is permitted by law or where we have your consent/assent'. It is not clear who or what is meant by these parties and why data may be shared with them in the context of this study. The study information leaflets must provide more precise and granular informaiton on what is meant by 'industry bodies', 'external professional advisors' and 'others where it is permitted by law or where we have your consent/assent' and outline what personal data may be shared with such third parties and the reasons for this sharing in the context of this study. The accompanying proxy assent and participant consent forms should also include clear options on sharing/disclosing data to third parties that aligns with the amended information leaflets. ○ References to processing/using data in future research studies beyond ARISE FLUIDS should be amended or removed in the documentation for the proxy; proxy assent is limited to storage of the data only for use in potential future studies. *Note:* Clear informaiton should be provided on who and why data may be shared with third parties in the context of this specific study. In addition, the scope of the consent declaration does cover processing of personal data by other third parties beyond those noted in the HRCDC application (i.e., SVUH and the Australian Data). Proxy assent and the consent declaration also does not cover future unknown research purposes. For the participant informaiton leaflet, if seeking consent to process data for future studies beyond the ARISE FLUID study it is responsibility of the data controller to ensure that sufficient information is provided to the participants with capacity and that any such consent obtained is compliant. ○ The Applicant must ensure that is clear and transparent in the study information leaflets that the data to be processed, including shared and analysed by Monash, is pseudonymised data, not anonymised data, and that the statement that pseudonymised

	data will be kept indefinitely is corrected i.e., such data is retained for 15 years and then deleted. **Condition 7.** Furter to Condition 5, where an individual withdraws from the study and the researchers wish to continue to process the personal data already obtained (and follow-up data where applicable), then permission for this must be obtained from the proxy and recorded. In addition, consent to continue from the participant when they regain decision-making capacity should also be obtained for this continued processing.
HRCDC Recommendations:	**Recommendation 1**. The Applicant to requested to review and amend the study information leaflets and assent/consent forms to ensure transparency and consistency of information, with the following points to be addressed: ○ The term 'I know of no known objections' should also be positively re-phrased to ask whether the participant would wish to be included in this study. ○ The information leaflets outline that other hospitals, rehabilitation hospitals or nursing homes, may be contacted as part of the follow-up process to verify discharge dates provided by the participant. The assent/consent form should provide an option to agree to this. ○ The proxy assent documents request the proxy to state 'yes' or 'no' to questions that they may not know the answer to, for example 'has your relative written down his or her views in a "living will?"'. A 'don't know' option should be included as some proxies may not know the answer to each of these types of questions. ○ There are some inaccurate references noted in the study information leaflets and the proxy assent forms on patient samples/materials, for example withdrawing samples and storing material for future studies. As no samples are collected for this study these references should be amended. ○ The reference to making data available in anonymised repositories should be removed as the Applicant has clarified this will not occur. ○ Where appropriate, the Applicant is requested to utilise more lay-person language in the study documentation, for example amend the sentence 'within the spectrum of accepted usual care'. **Recommendation 2:** Where the participant continues to lack capacity for a prolonged period time, proxy assent should be re-affirmed at an appropriate point in the study.

9. Annual Reviews

The Secretariat has received 16 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID: 20-031-AF1;** Ignacio Martin-Loeches, The effect of fluid resuscitation with 20% albumin versus crystalloid on the microcirculation in septic shock
- **Ref ID: 19-021-AF3;** Paul Corcoran, National Self Harm Registry Ireland

- **Ref ID**: **20-036-AF1;** Alistair Nichol, EPO-TRAUMA
- **Ref ID**: **19-009-AF3;** Aideen Hartney, Moving In Study**
- **Ref ID**: **19-041-AF3/COV;** Bairbre McNicholas, 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)
- **Ref ID**: **20-020-AFI/COV;** Paul Cotter, Irish Coronavirus Sequencing Consortium**
- **Ref ID**: **19-005-AF2;** Blanaid Mee, St. James's Hospital Cancer Biobank' (SJHCB)
- **Ref ID**: **20-035-AF1;** Ignacio Martin-Loeches, IV Zanamivir Effectiveness Study
- **Ref ID**: **21-004-AF1;** Alistair Nichol, AP-recAP-AKI-03-01 (REVIVAL)**
- **Ref ID**: **19-025-AF2;** Gerry McElvaney, Irish National AATD Registry' (The Alpha-1 Registry)
- **Ref ID**: **20-013-AF1/COV;** Maeve McGovern, Public Health Emergency SOLIDARITY TRIAL**
- **Ref ID**: **21-011-AF1/CSO;** Seamus McGuinness, Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland
- **Ref ID**: **22-006-AF1;** Gianpiero Cavalleri, HPO study
- **Ref ID**: **22-008-AF1;** Frank Moriarty, Evaluation of policies and practices to support safe and appropriate controlled drug prescribing.
- **Ref ID: 19-070-AF2;** Fergus McCarthy, SCOPE study
- **Ref ID: 20-024-AF1/COV;** Alistair Nichol, Genetics of Mortality in Clinical Care (GenOMICC)

10. Activities report and events of interest

The Secretariat circulated a report of it's activities to the HRCDC in advance of the meeting. The following upcoming events of interest and other relevant updates where also noted:

- **News: EU-USA Data Privacy Framework:** Ireland Update - European Commission adopts new adequacy decision for safe and trusted EU-US data flows - Lexology (https://www.lexology.com/library/detail.aspx?g=562a84ac-6c36-449f-8730-8e1ed87ef528&utm_source=Lexology+Daily+Newsfeed&utm_medium=HTML+email+-+Body+-+General+section&utm_campaign=Lexology+subscriber+daily+feed&utm_content=Lexology+Daily+Newsfeed+2023-07-12&utm_term=)

- **Event**: Hosted by the BioBANC na Gaillimhe team at the College of Medicine, Nursing and Health Sciences, the BioBANC Symposium is a multidisciplinary event for anyone involved or interested in getting involved in biobanking BioBANC Symposium II Tickets, Fri 1 Sep 2023 at 09:00 | Eventbrite

11. Any Other Business

- The Secretariat informed the HRCDC that an internal HRB audit is scheduled for 2023. This internal audit will examine governance procedures, storage and retention of records mainly. The committee are reminded to ensure conflict of interest declarations are up to date and decision time use forms have been signed, if asked by the Secretariat. The Secretariat will update the committee as more details are available.
- The Chairperson informed the HRCDC that Mr Peter Lennon (Department of Health) has announced his retirement. The HRCDC acknowledged the great contribution made by Mr Lennon to the development of the Health Research Regulations, the

establishment of the HRCDC and the support that was subsequently provided. The HRCDC wished Mr Lennon well in his retirement.

- The HRCDC discussed potential dates for an external presentation on Clinical Trials. It was discussed that the likely date will be at the November HRCDC meeting. It was also noted that the November meeting will be in person and will start at the later time of 10.30am and would run on until 2pm. Members were asked to check their availability for these times.

****The Chairperson thanked the HRCDC and the Secretariat for the work involved in this extended meeting and closed the meeting****