HRCDC
Health Research Consent Declaration Committee

Date: 6th September 2022
Location: Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Claire Collins
Simon Furney
Aideen Hartney
Dan Rea
Cornelius Cooney
Mary Tumelty
Jonny Barrett (Secretariat)
Noreen O'Brien (Secretariat)

Quorum for Decisions
☒**YES**

Returning Applications - For Consideration

Applicant	Ref No.	Title
Michelle O'Brien	22-002-AF1	Understanding the wishes and support needs of people with intellectual disability as they grow older (Old title – Positively supporting changing needs in a community residential setting – A service perspective)

New Amendments - For Consideration

Applicant	Ref No.	Title
Alistair Nichol	20-024-AF1/COV/AMD1	Genetics of Mortality in Critical Care (GenOMICC)

New Applications – For consideration

Applicant	Ref No.	Title
Gianpiero Cavalleri	22-010-AF1	Blockchain and AI Enabled Stratified Trials System (BESTS): A pilot study
Iracema Leroi	22-011-AF1	SENSE-Cog Residential Care: A feasibility study of hearing and vision support to improve quality of life in care home residents with dementia

Meeting Items

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

2. Apologies
Zubair Kabir, Sheelah Connolly, Barry O' Sullivan, John Woods, Kathy Brickell, Barry Lyons, Caroline Byrne (Secretariat), Marta Pisarska (Secretariat)

3. Disclosure of Interest
20-011-AF1 (SENSE-Cog study): Alyson Bailey (AB) disclosed an interest in this application and was absent for this part of the meeting.

4. Minutes of previous meeting
Draft minutes of 12th July 2022 were circulated in advance of the meeting and were approved by the HRCDC.

5. Written Procedure: Ref ID: 21-011-AF1/CSO/AMD1
Applicant: Seamus McGuinness, '*Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland'.*
The HRCDC noted the decision to approve this amendment request to the existing consent declaration. The amendment related to extending the duration of the consent declaration to 17th August 2023. The HRCDC reviewed the submitted documents by written procedure and approved the amendment. A decision letter was issued to the Applicant on 18th August 2022 and the following conditions were attached to the approved amendment:

- Condition 1. The Applicant must continue to be appointed as an Officer of Statistics and have the continued approval of the CSO to access the COVID-19 Data Research Hub for a further year. Confirmation of this must be provided to the HRCDC as soon as possible.
- Condition 2. The Applicant is requested to provide confirmation from the ESRI research ethics committee (REC) that the current ethical approval for this study covers the 1-year study extension. If updated REC approval is required, then this must be sought, and confirmation of the updated approval submitted to the HRCDC. The Applicant is requested to provide confirmation of REC approval as soon as is practicable and no later than 3 months from receipt of the HRCDC's decision letter.

6. Returning Applications:

Reference ID:	22-002-AF1
Lead Applicant:	Michelle O'Brien
Lead Data Controller:	Avista – St Anne's
Title:	Understanding the wishes and support needs of people with intellectual disability as they grow older (Old title – Positively supporting changing needs in a community residential setting – A service perspective)
Research Objective:	See HRCDC Meeting minutes of 14th June 2022
Reason for Declaration:	See HRCDC Meeting minutes of 14th June 2022
HRCDC Comments:	The Chairperson introduced the agenda item and reminded the members of the additional information that was requested from the Applicant, in particular information as to whether and how family members of participants with an intellectual disability can be informed about this study. It was noted that the Applicant had appeared to address this matter and the Chair requested the HRCDC to confirm whether the

	consent declaration should be made, taking into account the previous discussion at the June meeting and the additional information that has been provided by the Applicant. The consensus of the HRCDC was that a conditional consent declaration should be made. The decision was based on the following discussion points: **Public Interest** • Based on the information provided by the Applicant, the HRCDC was of the view that there is a public interest in this study. • It was the view of the HRCDC that the findings and outputs from this study should be published and disseminated. It was commented that this would enhance further the public interest case and would be beneficial given that importance of research in this area. **Informing and Involving Family** • The Applicant outlined that the family will be informed about the study via a study letter. It was further noted that the letter invites the family member to input into determining the will and preferences of the service user participant, and that their input will be reviewed by the study team as part of the overall process for determining the participant's will and preference. • The HRCDC discussed that it is important to consider the input of the family member where they are articulating the will and preferences of their relative who lacks decision making capacity. It was discussed as to whether seeking family member assent would be appropriate in cases where the family member is closely involved in care of their relative. However, it was commented that the personal views of the family member should not override that of the proposed participant. It was further commented that in many cases it is likely that the participant with an intellectual disability would be able to express a view on whether they wish to take part in this study. • The HRCDC discussed that it was not clear from the documentation how a potential difference of views with the relative about participation in the study would be resolved. If a family member, when informed, does not wish for their relative to participate, and the participant is to be included in the study, it was the view of the HRCDC that it would be beneficial to document how the will and preference of the participant was determined and how the family member's view was considered as part of this. **Study information leaflets** • It was highlighted that the Applicant has confirmed that the easy-to-read version of the study documentation only, is to be used with service user participants with an intellectual disability. It was noted that the standard version would not be used with this cohort. The standard version will only be used to recruit family members for their own participation in the study.

	• In response to the HRCDC's request for further information, an updated easy-to-read version of the study documentation was submitted by the Applicant. It was noted that changes were made to this updated version, and these were highlighted to the HRCDC. It was discussed that further amendments should be made to this updated easy-to-read documentation, such as the re-inclusion of a data protection notice, information on the data sources to be used and clarity on withdrawing from the study which still remained unclear. • Further to the easy-to-read documents, an updated standard version of the study documentation for family members was also submitted. It was commented that amendments should also be made to this version of the information leaflet for the benefit of the study and the family members. **Data Processor and audio recordings** • From the responses provided by the Applicant it was identified that audio recordings are to be transferred to the data processor, Trinity College Dublin (TCD). • The Applicant stated that personal data of participants who lack decision-making capacity would not be recorded due to the nature of the interviews. The HRCDC discussed that safeguards should be in place to prevent inadvertently recording personally identifiable information. Should identifiable information be incidentally recorded in the material transferred to TCD, it was commented that steps should be taken to protect this data. For example, beyond the audio file TCD should not transcribe or otherwise record the identifiable data. It was also commented that the audio file should be deleted by TCD as soon as practicable. • The HRCDC also discussed that the required data processing agreements must be in place between Avista and TCD and that, as is normal in these agreements, TCD would undertake not to attempt to re-identify the participants. **Study questionnaire** • Given the nature of some of the questions outlined in the study questionnaire, it was the view of the HRCDC that the questionnaire should be completed in the presence of the participant and with their involvement in relevant questions. **Other** • The HRCDC noted and agreed with the observations of the Secretariat, highlighted at the 14th June HRCDC meeting, regarding technical and more standard safeguards that may need to be considered by the Committee, including observations on the study information leaflets and data minimisation. • It was noted that confirmation of full research ethics committee review has been provided by the Applicant.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.

Duration of Declaration:	The Declaration is made on 6th September 2022 and is valid until 30th September 2029, or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner.
Conditions Attached:	**Condition 1.** The family of service user participants with an intellectual disability should be informed about this study, the proposed inclusion of their relative within this study and be invited to provide input to help determine their relative's will and preferences. Importantly, family member input should be sought to help understand what the will and preference of the participant is; if the family member, when informed, does not wish for their relative to participate, and the participant is enrolled in the study, the Applicant should document how the will and preference of the participant was determined and how the family members' view was considered as part of this. **Condition 2.** It is a condition of this declaration that the study questionnaire should be completed in the presence of the service user participant with an intellectual disability, and with their involvement in relevant questions, in particular those questions that relate to friends, family and social interactions. Further, where possible, Avista staff with sufficient knowledge and understanding of the participant should be involved in and support the completion of the questionnaire. An appropriate family member with a close relationship with the service user participant should also support their relative during their focus groups, where possible. **Condition 3.** Appropriate safeguards should be implemented to prevent the audio recording of personally identifiable information. Further safeguarding steps should also be taken if it is found that identifiable information has been unintentionally recorded and transferred in the material sent to the data processor, Trinity College Dublin (TCD). For example, beyond the audio file, TCD should not transcribe or otherwise capture, record or hold any such identifiable information when processing the audio. In line with the principle of data minimisation the Applicant should ensure that the audio recordings are held for the shortest time possible. Consideration should also be given as to whether the audio files can be deleted before 12 months. **Condition 4.** The appropriate agreements/arrangements must be in place between the data controller, Avista and the data processor, TCD, governing the transfer and use of the data, including pseudonymised data. Such agreements/arrangements should also cover the transfer and use of the audio files. In addition, the agreements/arrangements should, as is normal in these agreements, outline that TCD would undertake not to attempt to re-identify the participants. For the avoidance of doubt the transfer of data between Avista and TCD cannot occur until this condition has been met.

	Condition 5. The Applicant is requested to publish/disseminate the findings of this study to relevant researchers, appropriate organisations and the wider public. **Condition 6.** The Applicant is requested to review and amend the easy-to-read (ETR) version of study documentation to ensure that clarity and consistency of information is provided to service users participants with an intellectual disability. The following specific observations are made by the HRCDC and should be addressed in the ETR documentation: • reference is made to undertaking focus groups. The ETR documentation should also note the use of medical records/care plans and the completion of questionnaires, and who will be collecting this data. Reference should also be made that other stakeholders (e.g., family members, staff) will be completing their own focus groups. • it is noted that the initial ETR version submitted to the HRCDC included a page on GDPR that outlined the participant's data protection rights, however this page has been removed. Information regarding GDPR and data protection rights should be re-incorporated in the latest version of the ETR study documentation. • it should be clearly outlined how long personal data and the audio recordings will be retained. • reference to an expression of interest form should be removed as the Applicant has confirmed it will not be used in this study • the initial ETR consent form submitted, included a number of yes/no options that have been removed from the updated version. Consideration should be given to re-incorporating these yes/no options in the updated version of the ETR consent form • Ensure that clear and concise information is outlined in the ETR form regarding withdrawing from the study and the deletion of the participant's data. This includes withdrawing and deleting data both before and after the publication of the study findings: ○ should they wish to withdraw prior to publication, it should be clearly outlined to what extent it is or isn't possible to remove the service user participant's data and contributions from the study analysis and findings. In addition, if there is a timeline after which data cannot be removed from analysis and publication then this should also be outlined. ○ It should be clearly outlined that if a participant withdraws after the publication of findings that they will not be identifiable from the published report. ○ Further to withdrawal and removing data prior to publication, the updated standard information leaflet for the family outlines that they can ask for their stored data to be destroyed up until has been anonymised. Similar information should be provided to service user participants within the ETR version of the consent form. It should also be clear that if they don't wish for their data to be deleted then it will continue to be held and processed as the default situation. If a participant withdraws,

	clear options on what will happen their data should be provided. A consent declaration cannot override a participant's decision to withdraw from the study. Where a participant withdraws it is the responsibility of the data controller to ensure data protection compliance.
HRCDC Recommendations:	**Recommendation 1.** In line with the principle of data minimisation, the Applicant is requested to consider deleting or irrevocably anonymising the personal data prior to September 2029. **Recommendation 2.** The Applicant is requested to review the standard family information leaflet and consent form to ensure it is tailored specifically for the recruitment of the family member to this study and that it provides clear and accurate information on the study and the data processing. The following observations have been made by the HRCDC and should be considered by the Applicant: • Aligned with the details in Condition 6, clear information should be provided in the family information leaflet regarding withdrawing from the study and the deletion of data. This includes clearly outlining to what extent it is or isn't possible to remove the participant's data and contributions from the study analysis and findings, should they wish to withdraw prior to publication, and if there is a timeline after which data cannot be removed from the analysis and publication. It should also be clearly outlined that if a participant withdraws after the publication of findings that they will not be identifiable from the published report • The family information leaflet states: '*By law we can use your personal information for scientific research (in the public interest)'* with footnotes referring to the Art 6 and Art 9 legal basis for processing personal data. The HRCDC discussed that this statement as currently worded may be misinterpreted by the family member. For example, it could be interpreted that the family member has limited say on the use of their data. The Applicant is therefore requested to amend this statement and just outline what the Art 6 and Art 9 legal basis is for the processing of personal data. • The standard family information leaflets refer to storing data for 7 years but also to deleting names and pseudonyms 1 year after submission of the final report. Aligned with the information submitted to the HRCDC, it should be clear that the duration of data storage is 7 years. • Remove reference to AudioTrans • As the standard version of the study document is for family members only, it should be ensured that the document is written for the perspective and purpose of consenting the family member for their own participation in the study, and not a document that is seeking proxy assent from the family member on behalf of the service user participant with an intellectual disability. For example, references such as '*You/ your family member who is supported in Avista*' should be amended given that it is the family

	member who receives support from Avista. In addition, requesting access to '*your medical records'* should be removed from the family study documentation as they will not be accessed. Other sections that read as if the family member is being asked to provide proxy assent on behalf of their relative should also be amended.

7. Amendments:

Reference ID:	20-024-AF1/COV/AMD1
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St Vincent's University Hospital University of Edinburgh NHS Lothian Health Board.
Title:	Genetics of Mortality in Critical Care (GenOMICC)
Research Objective:	See minutes of 4th September 2020
Purpose of Amendment:	The amendment is requested to add a number of additional disease cohorts to this study i.e., disease cohorts beyond COVID-19 which was the subject of the original HRCDC application. There are no further changes to the study (e.g., data processing activities, assent/consent process etc.)
HRCDC Comments:	The Chair introduced the amendment request and requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, it was the consensus of the HRCDC that a formal decision should be deferred pending receipt of further information from the Applicant through the submission of a new HRCDC application form. This decision was based on the following discussion: **Scale of the amendment** • The HRCDC discussed that the consent declaration made for the GenOMICC study focused on COVID-19 only and that the amendment was requesting an expansion of the study to include several new disease areas including pancreatitis, emerging infection and critical illness syndrome. It was commented that some of the new disease areas were related to COVID-19, others however were not related and appeared quite broad and open-ended in nature. • While the HRCDC discussed that there is a level of public interest in expanding the study, given that the purpose of the research has expanded considerably beyond COVID-19, the HRCDC was of the view that it would be more appropriate for the Applicant to submit a new HRCDC application for consideration. It was also commented that the submission of a new application would enable the Applicant to provide a further level of detail and information on this expanded study, including on areas such as PPI engagement and transparency with individuals or groups who represent or have experience regarding the new disease areas that are to be added to this study. **Research Ethics Committee Approval**

	• It was discussed that the study received initial ethical approval from the National Research Ethics Committee for COVID-19 (NREC-COVID-19) that was established in 2020. The HRCDC were also reminded that this study was submitted and processed via the integrated NREC-HRCDC application for COVID-19 specific research. • It was noted and discussed that the addition of these new disease cohorts received amended approval from the NREC for COVID-19.
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information. Specifically, it was determined that the Applicant should submit a new HRCDC application for consideration.

8. New Applications

Reference ID:	22-010-AF1
Lead Applicant:	Gianpiero Cavalleri
Data Controllers:	Royal College of Surgeons in Ireland (RCSI) Beaumont Hospital St James's Hospital
Title:	Blockchain and AI Enabled Stratified Trials System (BESTS): A pilot study
Research Objective:	Blockchain and Artificial Intelligence (AI) Enabled Stratified Trials System (BESTS) is a newly developed technology that aims to match people to relevant clinical trials, using their health data. Health data is information about a person's medical condition and their genetics. Blockchain is a highly secure IT infrastructure that protects health data entered into the system from outside cyberattacks. Artificial intelligence (AI) uses a person's health data to match them to relevant clinical trials. This pilot research study is to test prototypes of BESTS with potential users including patients, care-partners, decision makers and healthcare providers. Understanding from a user perspective what they like, what they would change, how easy it is to use and how it can be improved, will allow researchers develop a system to empower patients and care-partners to seek out ongoing clinical trials in a safe, transparent, trustworthy manner. The overall objective is to test and validate the functionality, technical performance, standard operating procedures and user experience of a prototype version of the BESTS (Blockchain and AI-Enabled Stratified Trial System) platform. This study will examine the usability and utility of the BESTS platform, how it works in controlled practice and its effectiveness in enhancing the care pathway for patients, their families and healthcare professionals alike before approving for wider use.
Reason for Declaration:	In some cases, participants will lack decision-making capacity due to the impact of their intellectual disabilities. A consent declaration is requested for the processing of personal data of this cohort for the purpose of this specific trial/pilot of the BEST 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 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 formal decision should be deferred pending receipt of further information. **Public interest case** • The HRCDC discussed the public interest case in this study. It was noted and discussed that this study is a test of the BEST platform, involving the processing of genetic data, whole genome sequencing (WGS) and the collection and processing of a large volume of other types of personal data, including clinical data. • It was noted that the study aims to recruit a higher proportion of patient participants who lack decision-making capacity compared to those who have capacity. The HRCDC queried why the processing of this type and volume of sensitive personal data, including WGS, of patient participants who lacked decision-making capacity was necessary for the testing stage of the BEST platform, which includes assessing the platform's security. It was queried why the study could not test the platform using the personal data of those who have the decision-making capacity to consent only and whether any PPI engagement had been undertaken on this matter. It was further noted that undertaking WGS on participants who lack decision-making capacity was an area that was raised in the feedback from the research ethics committee. • The HRCDC discussed the use of AI within the BEST platform. It was commented that the use of AI could create biasness by disadvantaging certain cohorts of participants, in particular those with more serious or rarer health conditions. It was commented that it is therefore important to ensure a sufficient sample is tested. • Notwithstanding that the application was relatively detailed, including detailed technical information, based on the information provided, and in the context of the volume and type of personal data to be processed, the HRCDC commented that the Applicant had not provided a detailed or sufficient public interest case regarding the broader BEST platform itself. The HRCDC was also of the view that the Applicant had not sufficiently outlined the public interest case for processing the personal data of patient participants who lack decision-making capacity in the initial trial phase. The HRCDC discussed that more explicit information should be requested from the Applicant on these to determine whether the public interest outweighs the requirement to obtain

	explicit consent. It was also of the view that more information regarding PPI engagement should be requested. **Determining capacity** • Where a participant lacks decision-making capacity, it was noted that proxy assent will be obtained on their behalf from a trusted family member, decision-maker or healthcare professional. • However, from the information provided by the Applicant it was not fully clear how the decision-making capacity of participants is to be determined. It was commented that more information should be requested from the Applicant on this matter. **Review by healthcare professional** • It was noted that the data protection risks will be reduced by having a healthcare professional (HCP) review the clinical trial matches which are identified by the BEST platform. • Given that this study is focused on the testing and trialling of the BEST platform only, it was queried whether the HCP review forms part of this study or refers to the process that will occur should the platform be rolled out in the real world. **Blockchain** • It was noted that the use of blockchain in this study relates to the participant's consent decisions, specifically the management and storage of the pseudonymised consent. • The HRCDC discussed the security and privacy in using blockchain. It was commented that other appropriate alternatives to managing and storing consent could be available. The HRCDC was therefore of the view that more information regarding the use of the blockchain technology should be requested form the Applicant.
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information. As there were a number of queries noted it was discussed that the Secretariat would circulate the queries to the HRCDC in advance of forwarding them to the Applicant.
Further Information Requested:	**Query 1**. From the information provided in the submitted documents, the public interest case is not clear to the HRCDC and therefore more explicit information is requested on this matter. Specifically, the Applicant is requested to provide the following: (i) more information on the public interest case regarding the BEST platform more generally, (ii) more information on the public interest case for testing/piloting the BEST platform using this volume and type of personal data, including whole genome sequencing, of patient participants who lack decision making capacity. On point (ii) the Applicant's response should articulate why it is necessary to test the BEST platform, including assessing the platforms security, using personal data of those who lack capacity as opposed to testing using the personal data of participants who have the capacity to consent only. The response should also outline why a higher proportion of patient participants to be recruited for the

	testing of the platform lack decision-making capacity. The reply to this query on public interest should also be provided in the context of the large volume and sensitive nature of the personal data that is to be processed, including whole genome sequencing, of the cohort of participants who lack decision-making capacity. **Query 2.** Further to point 1, please comment whether any engagement or input was sought from relevant PPI representatives, regarding the inclusion of participants who lack decision-making capacity in this trial of the BEST platform. **Query 3.** The Beaumont Hospital DPIA references that a healthcare professional (HCP) will review the clinical trial matches that are identified by the BEST platform. Please confirm that the HCP review is not undertaken as part of this specific study to test the BEST platform, but refers to the protocol that will occur should the BEST platform be rolled out. **Query 4.** The use of blockchain for consent storage and management is noted. The Applicant is requested to provide further information as to why blockchain, and no other alternatives, is used within this study and the BEST platform. **Query 5.** The HRCDC requests further information on how a participant's decision-making capacity to provide explicit for this study is to be determined.

Application Ref ID: 22-011-AF1 *(SENSE-Cog Residential Care: A feasibility study of hearing and vision support to improve quality of life in care home residents with dementia)*

- This Application was tabled for consideration. However, information specifying the data processors within this study, namely the nursing home sites, were not provided as they are unknown at this time. The Health Research Regulations require the HRCDC to be furnished with specification of the data processors involved in the research study.
- The HRCDC discussed that the application could not be formally considered prior to the Applicant confirming which nursing home sites will be included in this study.
- While the application could not be formally considered, the members of the HRCDC did note areas where further information from the Applicant would be useful, namely public and patient involvement and how participants in the control group of nursing homes are to be identified and recruited.

9. Annual Reviews

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

- **Ref ID:** 19-009-AF3: Aideen Hartney, Moving in Study.
- **Ref ID:** 19-025-AF2; Tomas Carroll, Irish National AATD Registry' (The Alpha-1 Registry)
- **Ref ID:** 19-033-AF3; Gerard Bury, The Medical Emergencies Responder -Integration and Training (MERIT) programme study (Cardiac Arrest and Pre-Hospital Thrombolysis in Irish General Practice
- **Ref ID:** 20-020-AF1-COV; Paul Cotter, Irish Coronavirus Sequencing Consortium

- **Ref ID:** 21-001-AF1; Patrick Sheahan, Determination of HPV status of Oropharynx cancer using p16 immunohistochemistry, morphology, and RNAscope (RNA ISH)
- **Ref ID:** 21-004-AF1; Alistair Nichol, AP-recAP-AKI-03-01 (REVIVAL)
- **Ref ID:** 21-006-AF1: Carla Perrotta, SARS-CoV-2 clusters and superspreading events in workplaces in Ireland: a retrospective analysis
- **Ref ID:** 21-011-AF1-CSO; Seamus McGuinness, Examination of the relationship between the COVID-19 pandemic, unemployment, and social disadvantage in Ireland.

10. Activities report and events of interest

- **Paper/Article:** Health Research Data Protection Network (HRDPN) Practical Guide on Data Protection for Health Researchers: https://ncto.ie/wp-content/uploads/2022/07/HRDPN-Data-Protection-Guide-Document-for-Health-Researchers.July-2022.v1.pdf.
- **Paper/Article:** HRB Annual Report 2021 - Part 1; https://www.hrb.ie/search/publications/publication/health-research-board-annual-report-2021-part-one/returnPage/1/.
- **Paper/Article:** Fears over China's access to genetic data of UK citizens | Medical research | The Guardian: https://www.theguardian.com/science/2022/aug/20/fears-over-chinas-access-to-genetic-data-of-uk-citizens?CMP=Share_iOSApp_Othe
- **Event:** Association of Data Protection Officers -13th National Annual Data Protection Conference (12th October, Liberty Hall Dublin); https://www.dpo.ie/conference
- **Event:** HRB Conference: Personalised Medicine (30th November, Radisson Blu, Dublin); https://www.hrb.ie/news/events/upcoming-events/personalised-medicine/
- **Event:** Health Data Research UK Scientific Conference 2022: Data for global health and society (14th December 2022, Birmingham, 9:30-17:00 - Virtual Tickets available): https://www.hdruk.ac.uk/news-opinion-events/events/health-data-research-uk-scientific-conference-2022-data-for-global-health-and-society/?utm_source=email&utm_medium=email&utm_campaign=science+conference+launch

11. Any Other Business

- The HRCDC was informed that the Secretariat will be in touch shortly regarding updating the iPad software.
- It was discussed that there would be benefits to formally outline a more detailed procedure document with regards considering applications by written procedure. It was commented that considering applications by written procedure is at the discretion of the HRCDC and subject to the nature of the application. The HRCDC further discussed that a procedure document for consent declaration amendments would be beneficial, in particular a procedure to help determine if an amendment or new HRCDC application should be submitted, subject to the extent and nature of changes that have been made to a study and the change in the scope of the consent declaration that is requested. It was noted that the procedure documents, once developed, would be discussed at the October or subsequent HRCDC meeting.
- The HRCDC acknowledged the work of Secretariat in pre-reviewing applications and supporting Applicants. It was noted that while some submitted applications are of a good and reasonable standard, others that have been submitted are less so, despite

all the guidance and material available. It was discussed that this matter can be discussed further by the HRCDC as an agenda item at a future meeting.

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