HRCDC
Health Research Consent Declaration Committee

Date: 14th December 2021
Location: Videoconference by Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Kevin Clarke
Sheelah Connolly
Aideen Hartney
Zubair Kabir
Dan Rea
Mary Tumelty
Barry Lyons
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒**YES**

Returning Applications - For consideration

Applicant	Ref No.	Title
Andrew McCarron	21-015-AF1/CSO	UPCOM (Understanding and Preventing Covid-19 Outbreaks in Meat Processing Plants Prepared for the Future)

New Amendments - For consideration

Applicant	Ref No.	Title
Ignacio Martin-Loeches	20-031-AF1/AMD1	The effect of fluid resuscitation with 20% albumin versus crystalloid on the microcirculation in septic shock
John Laffey	20-026-AF1/AMD1	'Charter Trial - Can Nebulised HepArin Reduce acuTE lung injury in Patients with SARS-CoV-2 Requiring Mechanical Ventilation in Ireland (CHARTER-Irl)

New Applications - For consideration

Applicant	Ref No.	Title
Sharon O'Toole	19-045-AF2	DISCOVARY Bioresource, including the current studies processing DISCOVARY Bioresource Data.

HRCDC
Health Research Consent
Declaration Committee

Meeting Items

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

2. **Apologies**
   Simon Furney, Claire Collins, John Ferguson, Barry O' Sullivan, Cornelius Cooney, John Woods.

3. **Disclosure of Interest**
   There were no disclosures of interest for this meeting.

4. **Minutes of the last meeting**
   Draft minutes of 16th November 2021 were circulated in advance of the meeting and were approved by the HRCDC, noting that a minor discussion point should be added.

5. **Matters arising**
   Following the HRCDC meeting of 16th November 2021, the Secretariat and some members of the Committee discussed the amendments and associated guidance to the Health Research Regulations where explicit consent, or a consent declaration, is not required for pre-screening and retrospective chart review in certain scenarios. A briefing note reflecting this discussion was provided to the HRCDC. It was noted that, following this discussion it was decided that no particular clarification was required from the Department of Health on the amendments and associated guidance notes.

6. **Returning Applications:**

Reference ID:	21-015-AF1/CSO
Lead Applicant:	Dr Andrew McCarren (DCU) Prof. Grace Mulcahy (UCD)
Lead Data Controller:	Dublin City University University College Dublin
Title:	UPCOM (Understanding and Preventing Covid-19 Outbreaks in Meat Processing Plants Prepared for the Future)
Research Objective:	See HRCDC Meeting minutes of 16th November 2021
Reason for Declaration:	See HRCDC Meeting minutes of 16th November 2021
HRCDC Comments:	The Chair introduced the agenda item and reminded the members of the additional information that was requested from the Applicant. The Chair referred to the discussion on this application at the previous meeting and summarised the outstanding matters and the responses 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** • The HRCDC discussed the Applicant's responses with regards the public interest case for this study. It was commented that the Applicant had provided more defined information on the aims and objectives of the study and the use of the CSO data.

	• In addition, it was noted that a report will be provided to the Department of Agriculture, Food and the Marine, should the study generate conclusive findings. The HRCDC discussed that it may be useful to also provide a study report to appropriate health authorities. • Based on the information provided, on balance the HRCDC was of the view that there is a strong public interest case for undertaking this study. **Identifiable data and other datasets** • The HRCDC noted the additional information on the data that will be processed as part this study from the CSO COVID-19 Data Research Hub, from Three.ie and the Department of Agriculture, Food and the Marine. • The HRCDC noted that ethnicity or the electoral division name are not used as input variables for this study and that the study aims to predict outbreaks of COVID-19 rather than the number of cases or the individuals who become infected. **Other** • The HRCDC noted the response provided by the Applicant clarifying the Article 6 legal bases and Article 9 conditions for processing personal data. • The HRCDC noted and agreed with the observations of the Secretariat, highlighted at the 16th November 2021 meeting, regarding technical and more standard safeguards that may need to be considered by the Committee. These observations included enhanced transparency measures and public and patient involvement, as well as the submission of outstanding data protection officer feedback from one of the joint data controllers of the study.
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 14th December 2021 and is valid for one year until 14th December 2022, in line with the duration of the Officer of Statistics appointment made to the Applicant by the Central Statistic's Office (CSO). *NOTE 1:* The consent declaration will not come into effect until Condition 1 is met. *NOTE 2:* The Applicant may submit an amendment request to the consent declaration if an extension to the duration of the consent declaration is required, subject to the Applicant's reappointment as an Officer of Statistics and approval by the CSO.
Conditions Attached:	**Condition 1.** It is a condition that this consent declaration is not effective until final approval to access the COVID-19 Data Research Hub has been granted by the CSO. Confirmation of final CSO approval must be provided to the HRCDC as soon as possible. **Condition 2**. The Applicant is requested to provide a copy of the data protection impact assessment (DPIA) to the Data Protection

	Officer (DPO) of University College Dublin (UCD), as a joint data controller of the study. Feedback on the DPIA from the UCD DPO must be provided to the HRCDC within 1 month of receipt of the decision letter. **Condition 3.** The Applicant is requested to review and enhance the transparency measures on the study's website to ensure there is clarity of information on the purpose of this study, how and where the data is accessed for this study, and the extent of the data that will be processed, including data accessed and obtained from the CSO. This is a reporting requirement of the Annual review.
HRCDC Recommendations:	**Recommendation 1**. For the benefit of the research study and to enhance transparency, where appropriate and feasible to do so the Applicant is recommended to engage with representative groups in the meat factory industry to get their perspective and views on the development of this research study. **Recommendation 2**. In addition to providing a report to the Department of Agriculture, Food and the Marine, the Applicant is also recommended to provide a report and disseminate study findings to relevant health authorities.

7. Amendments

Reference ID:	20-031-AF1/AMD1
Lead Applicant:	Ignacio Martin-Loeches
Lead Data Controller:	St James's Hospital, Dublin
Title:	The effect of fluid resuscitation with 20% albumin versus crystalloid on the microcirculation in septic shock
Research Objective:	Please see minutes of 12th November 2020
Purpose of Amendment:	An amendment to the consent declaration is requested to the proxy assent protocol and allow for deferred proxy assent to be obtained. In addition, the amendment covers additional data processing that is associated with the use of the 'Pulmovista' device. The use of this device in the research study was not outlined in the original submitted HRCDC application form or study protocol.
HRCDC Comments:	The Chair provided an overview of the amendment request and requested members to indicate their approval to amend the conditional consent declaration and invited members to comment. It was the consensus of the HRCDC that further information should first be sought from the Applicant. **Deferred proxy assent** • The HRCDC discussed that proxy assent should only be deferred where it is not possible to obtain proxy assent prior to the participant's enrolment in the study and data processing. • It was highlighted that the amendment is requested to use deferred proxy assent due to the time sensitive nature of study intervention treatment. Specifically, it was noted from the information provided, that treating participants and processing their data as soon as possible, and then subsequently seeking

	deferred proxy assent, would provide more reliable and valuable data for the study. • The HRCDC discussed the reference to telephone assent in the Applicant's responses to the Secretariat's request for further information. The Secretariat commented that Recommendation 1 made by the HRCDC when granting the consent declaration, requested the Applicant to consider how the assent and deferred consent protocol could be implemented in the context of ongoing COVID-19 restrictions. • It was commented that the protocol of telephone assent was not described in the amendment application form or in the Applicant's original HRCDC application. The HRCDC was of the view that the Applicant should confirm that research ethics committee (REC) approval granted for the deferred assent protocol, also covers obtaining proxy assent by telephone. It was also discussed that the Applicant should clarify whether proxy assent was being obtained by telephone to date for this study. • Based on the information provided by the Applicant, the HRCDC discussed that it was unclear what the average timeline is from enrolling the participant in the study to seeking deferred proxy assent. While the HRCDC acknowledged the Applicant's response that the timeframe for this would be variable, it was of the view that specific information should be sought from the Applicant regarding what typical timelines would be. **Exclusion criteria** • From the information provided it was noted that one of the study's exclusion criteria is whether the participant has a known allergy to the albumin treatment. The HRCDC queried how this could be determined prior to the participant's enrolment in the study without consulting with family members or relatives and where family members/relatives are engaged, can assent be obtained at that point in time. **Study information leaflets/consent & assent forms** • The HRCDC noted and agreed with the observations of the Secretariat with regards to the study information leaflets and consent/assent forms. • It was highlighted that while Condition 4 attached to the consent declaration had been met to some extent, there were still discrepancies and inconsistencies in the forms and leaflets that should be addressed by the Applicant. **Pulmovista device** • The HRCDC discussed the use of the Pulmovista device within this study and noted that the updated study information leaflets describe this device as a standard practice in Intensive Care Units (ICUs) across the world.

	• It was queried whether this device is used as part of standard care and treatment in the St James's Hospital ICU as well as in other hospitals, or if it is used primarily for the purpose of research. • The HRCDC was of the view that clarification should be sought from the Applicant on this matter and, if required, the study information leaflet should be updated to reflect whether this device is used for care and treatment or is used primarily for the purpose of this research study. • The HRCDC also commented that the Applicant did not clearly outline what additional personal data associated with the use of the device will be processed, and if such data processing should also be covered by this amendment request.
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information from the Applicant.
Further Information Requested:	**Query 1.** The HRCDC seek further detailed clarification regarding the approximate timelines as to when proxy assent (telephone/verbal or in-person) is typically obtained, after a participant has presented in hospital and been enrolled in the study for treatment. Based on clinical experience, please: (i) provide indicative average timelines and longest timelines as to when proxy assent is obtained, and **(ii)** outline generally the circumstances that may give rise to a significant delay in obtaining proxy assent. **Query 2.** The HRCDC noted from the 'relative assent information' leaflet that participants with an allergy to albumin would be excluded. Please: (i) clarify how it is determined that a participant has such an allergy, and if this determination is made by consulting with family members/carers etc, and (ii) pending the response to part (i) above, if family members are engaged at this point prior to enrolment in the study, can assent be obtained at that point in time? **Query 3.** For the purposes of the understanding the scope of the amendment to the consent declaration, please: (i) provide confirmation (i.e. REC approval letter) that telephone assent has been approved by the research ethics committee, and (ii) clarify if telephone assent has been implemented since the commencement of the study. **Query 4.** For the purposes of ensuring transparency for participants regarding the use of the 'Pulmovista' device and understanding the scope of the amendment request, please: **(i)** comment on the extent to which Pulmovista is routinely used in St. James's Hospital ICU for care and treatment, or if it is used more routinely for research studies,

	(ii) confirm that the additional data processing associated with the use of Pulmovista, should be covered under the consent declaration.

Reference ID:	20-026-AF1/AMD1
Lead Applicant:	Prof John Laffey
Lead Data Controller:	National University of Ireland, Galway
Title:	Charter Trial - Can Nebulised HepArin Reduce acuTE lung injury in Patients with SARS-CoV-2 Requiring Mechanical Ventilation in Ireland (CHARTER-Irl)
Research Objective:	See minutes of 23rd September 2020.
Purpose of Amendment:	For the addition of Connolly Memorial Hospital as a clinical site to the CHARTER-Irl study to improve patient enrolment. The amendment would cover additional data processing at this site.
HRCDC Comments:	The Chair noted that this research study was originally submitted for ethics approval and HRCDC consideration via the integrated COVID-19 National Research Ethics Committee (NREC) - HRCDC application process, dedicated for COVID-19 research in 2020. It was highlighted that an amendment to the COVID-19 NREC ethics approval had been granted for the inclusion of Connolly Memorial Hospital in the study. However, an amendment to the conditional consent declaration made, had not been applied for at the same time, to include the additional data processing at this clinical site. The reasons for this, as outlined by the Applicant, were noted by the HRCDC. The Chair noted that the addition of a clinical site was a routine amendment made to a consent declaration and invited members to comment on the amendment request submitted by the Applicant. It was the consensus of the HRCDC that the amendment to the consent declaration could be approved.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Amendment Duration	The Amendment is made commencing 14th December 2021 and shall be valid until 31st September 2036 or upon confirmation that the data has been irrevocably rendered anonymised or destroyed, or whichever occurs sooner. (This timeline is in line with the duration of the consent declaration)
Other Comments:	The HRCDC commented that the Applicant was not aware that an amendment to the consent declaration was required at the same time as seeking an amendment to the ethics approval. It was discussed that it may not be clear to Applicants who had applied for ethics approval and a consent declaration via the integrated COVID-19 NREC-HRCDC application process, that amendment requests, if required, should be applied for separately to the respective committees.

	It was agreed that the Secretariat would liaise with the Office of the NREC to discuss how best to inform Applicants seeking ethics amendment approvals from the COVID-19 NREC, that they may also need to consider if a separate consent declaration amendment request should be submitted for HRCDC consideration.

8. New Applications

Reference ID:	19-045-AF2
Lead Applicant:	Dr Sharon O'Toole
Data Controllers:	A. Trinity College Dublin (TCD) & St James's Hospital (SJH), Dublin are joint controllers of the DISCOVARY Bioresource. B. The following collaborators are joint controllers with TCD/SJH for the respective academic collaborations. These collaborators are (i) the Royal College of Surgeons in Ireland (RCSI), (ii) University College Dublin (UCD), (iii) the National Institute for Bioprocessing Research & Training (NIBRT), in conjunction with University College Cork and (iv) Georgia Institute of Technology.
Title:	The Gynaecological Cancer Bioresource (DISCOVARY Bioresource) and ongoing studies.
Research Objective:	The Gynaecological cancer bioresource has been in existence since 2004 and currently contains material from over 2500 patients. Gynaecological cancers are difficult to diagnose and treat. Studying proteins in the bloodstream and in tissue might help to develop tests which may identify women who have cancer at an early stage or to decide on how best to treat a patient. In particular some gynaecological cancers such as ovarian cancer have a very poor prognosis (outcome) so any research that can help improve this is crucial to understanding this disease. Current and future research aims to better understand health and diseases and may examine genetic influences related to detection of disease, testing, treatment, quality of life and overall improvement of patient care. It is hoped that a large, organised biobank with real life patient samples and data will speed up this advancement of science and medicine, improving patient outcomes. Bloods and tissue samples have been collected from consented patients undergoing surgery for gynaecological disease and are stored in the bioresource which is used for research.
Reason for Declaration:	Whilst consent to participate in the DISCOVARY Bioresource was obtained from participants from 2004 to 2019, the Applicant has determined that elements of the consent obtained were not fully compliant with the previous data protection Directive for the following reasons: - SJH was not explicitly referenced as a data controller in earlier versions of the patient information leaflets, prior to 2018. - The indefinite duration of the Bioresource was not clearly outlined in earlier versions of the patient information leaflets. - There is a lack of information on who the data may be shared with in the PILs/consent forms previously used

	A consent declaration is still required for the reasons outlined above. The scope of the declaration requested is for the following: (i) for the DISCOVARY Bioresource, the continued storage of the existing personal data, including data associated with the biological samples, and the continued collection of clinical follow-up personal data, (ii) the processing of the DISCOVARY Bioresource personal data for the active gynaecological cancer research studies outlined in the application form. Specifically, the TCD studies, the SJH studies and the collaborations with other academics (RCSI/UCD/NIBRT & UCC/Georgia Tech). Where relevant, results from current studies (e.g. a biomarker results) may be stored as part of the DISCOVARY Bioresource.
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 reminded the members that the 'AF2' applications sought a declaration for studies that commenced prior to the Health Research Regulations. AF2 Applicants considered that consent obtained was compliant with the previous data protection legislation. However, further to the amendments being made, some Applicants have now reviewed the consent obtained, and considered it not in line with the previous data protection legislation and still require a consent declaration. Therefore, the HRCDC must consider these studies and balance the public interest case for the study. **Secretariat overview** • The Secretariat provided an overview of the application and the reasons why the Applicant is seeking a consent declaration. • The Secretariat highlighted to the HRCDC that the scope of the consent declaration would not include any future data processing, including future studies, not outlined in the HRCDC application form and where no REC approval has been granted. • It was also highlighted that any third-party data controller wishing to process personal data form the Bioresource for its own purpose, will need to apply for a consent declaration. In addition, it was clarified that SJH/TCD will need to apply for an amendment to the consent declaration, if made, to process the Bioresource data for its own purpose, as the data controllers for any future study. • The Secretariat also provided an overview of the status of the research studies that are underway with the specified collaborators. It was highlighted that data processing for many of the collaborations is limited to the storage of coded data and

for others the data and associated biosamples have yet to be transferred.

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 strong public interest case for the continuation of the DISCOVARY Bioresource and the processing of personal data from this Bioresource in the ongoing gynaecological cancer studies that were specified by the Applicant.
  It was commented that research in the area of gynaecological cancer is important and that the collection of participant follow-up data for the purpose of this Bioresource was commendable and valuable from a research perspective.

Explicit reconsent

- The HRCDC noted that the participants of the DISCOVARY Bioresource had provided consent prior to their enrolment in the Bioresource and further noted why a consent declaration was requested.
- The HRCDC acknowledged the reasons why it was considered impractical and inappropriate to seek updated explicit consent from participants. This included the number of participants who are enrolled in the Bioresource and the difficulties in seeking re-consent as many participants attend clinical follow up at local clinics rather than St James's Hospital. It was noted that reconsent may not be appropriate as there is a high rate of recurrence of ovarian cancer and many participants have passed away. From the Applicant's response it was noted that attempts to reconsent participants could be undertaken if the opportunity arises. The HRCDC commented that a recommendation could be made for the Applicant to seek reconsent if, in particular, it is known that a participant is attending St James's Hospital for clinical follow-up.

Research Ethics Committee (REC) approval

- It was highlighted that REC approval for the DISCOVARY Bioresource had expired in October 2019 and that no new participants had been recruited since this date. It was also noted that the HRCDC application for the DISCOVARY Bioresource was first submitted in July 2019.
- The HRCDC noted that an extension of the REC approval for the Bioresource had not yet been sought, as the participant information leaflet and consent forms for new participants were being updated and finalised for ethics approval. Notwithstanding this reason, the HRCDC commented that an extension to the

	REC approval for the continuation of the Bioresource must be sought as soon as possible, and within a reasonable timeframe. • The Secretariat highlighted that the collaboration with the National Institute for Bioprocessing Research & Training (NIBRT) with regards to glycosylation work, had not yet commenced data processing and was pending REC approval. It was agreed data processing could not commence for this study until confirmation was provided to the HRCDC that the required REC approval was obtained. **Duration of the consent declaration** • The HRCDC noted and discussed that an indefinite consent declaration was requested for the DISCOVARY Bioresource. Notwithstanding the strong public interest in the Bioresource, the HRCDC was of the view that it would be more appropriate to make a time limited declaration of 10 years and that the Applicant could request an extension by way of an amendment request submission for HRCDC consideration. **Transparency** • It was commented that the website for the DISCOVARY Bioresource should be updated and enhanced to better inform participants and the public about the ongoing work of the Bioresource, how the data and biosamples are being used, including what research studies are accessing the Bioresource. It was further commented that clear information on the governance of the DISCOVARY Bioresource should be provided. • The HRCDC also discussed that consideration should be given to enhancing transparency through linkages with representative advocacy groups and providing information on other relevant websites where appropriate. **Public and Patient Involvement (PPI)** • The HRCDC noted that the Applicant had undertaken a strong level of PPI engagement during the lifetime of the DISCOVARY Bioresource. It was commented that the Applicant should continue to undertake PPI engagement into the future. **Data and biosample security** • It was noted that a backup of the DISCOVARY Bioresource database is saved on an encrypted and stored USB. The HRCDC queried whether alternative, more secure methods could be used to safeguard the data. • The HRCDC noted that biosamples and personal data would be transferred to the relevant collaborating institutions. While it was noted that appropriate agreements are or will be in place for such transfers, including Standard Contractual Clauses for transfers outside the European Economic Area, the HRCDC queried how the physical transfer of Bioresource data and

	biosamples would be securely transferred between the institutions. **Other** • The HRCDC noted and agreed with the observations of the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee. These observations included the implementation of the withdrawal policy referenced by the Applicant, updating the DPIA where necessary, data minimisation and confirmation that the collaborators will also be responsible for compliance with the consent declaration. • It was also discussed that the scope of the declaration should be made clear to the Applicant in the HRCDC decision letter.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration, should be made.
Duration of Declaration:	The consent declaration is made commencing 8th August 2018 and shall be valid until 14th December 2031 or upon confirmation that that personal data has been rendered irrevocably anonymised or destroyed, whichever occurs sooner. The Applicant, on behalf of the data controller may seek an extension to the consent declaration by way of submitting an amendment request to the HRCDC for consideration.
Conditions Attached:	**Condition 1.** No processing (sharing, access to) of data from the DISCOVARY Bioresource can commence for the glycosylation collaboration study with the National Institute for Bioprocessing Research & Training, until the requisite research ethics committee approval has been granted for this study and confirmation of this approval is provided to the HRCDC. **Condition 2.** Where Trinity College Dublin (TCD) and St James's Hospital (SJH) are joint controllers of research studies with the following collaborators: - the Royal College of Surgeons in Ireland, - University College Dublin, - the National Institute for Bioprocessing Research & Training, in conjunction with University College Cork, - Georgia Institute of Technology, the above joint controllers should be made aware of the consent declaration and conditions attached and all joint controllers must support the implementation of and compliance with the consent declaration, as it pertains to the data processing for its respective studies. The Applicant is requested to confirm this will be the case when responding to accept, or otherwise, the HRCDC's decision. **Condition 3.** The Applicant must obtain an extension to the research ethics committee (REC) approval for the DISCOVARY Bioresource as soon as possible and no later than 30th June 2022.

	Once obtained, confirmation of extended REC approval must be submitted to the HRCDC. **Condition 4**. The withdrawal policy, and corresponding procedures, for the DISCOVARY Bioresource should be finalised and implemented as soon as possible. The policy should provide clear information on what will happen to the personal data and associated biosamples from the DISCOVARY Bioresource if a participant wishes to withdraw, including what will happen any data and associated biosamples that maybe processed as part of an ongoing research study. Updates on meeting this condition is a reporting requirement of the first Annual Review. **Note:** A consent declaration cannot override a participant's wish to withdraw from the research study. **Condition 5.** It is important that the data controllers are satisfied that the physical and IT arrangements in place and methods used, are sufficiently secure to protect the storage and transfer of the personal data and associated biosamples. The Applicant is requested to review the physical security arrangements that are in place regarding: i) the encrypted USB drive used as a back-up for the Bioresource database, ii) the physical transfer of data and associated biosamples to the collaborators noted in the application form, including transfer to the Georgia Institute of Technology. It is recommended to carry out this review in consultation with the relevant Data Protection Officer(s) and IT authorities, if necessary. **Condition 6.** The website providing information on the DISCOVARY Bioresource should be updated and enhanced to i) better inform participants and the public about the ongoing work of the Bioresource, the processing of data and the use of biosamples, as well as the research studies that are accessing the Bioresource. ii) provides transparent information on the governance of the Bioresource. To further enhance transparency measures, consideration should be given to exploring if information on the DISCOVARY Bioresource can be disseminated through linkages with representative advocacy groups or through other relevant websites and platforms where appropriate. **Condition 7.** Aligned with the principle of data minimisation, the coded data and associated samples that will be transferred to NIBRT and the Georgia Institute of Technology should be destroyed, irrevocably anonymised or returned by these collaborators when they no longer required by these collaborators for that specific research purpose.
HRCDC Recommendations:	**Recommendation 1.** Where it is known that a participant in the DISCOVARY Bioresource is returning to St James's Hospital for

	clinical follow-up care, the Applicant is recommended to try reconsent the participant where it is considered appropriate and feasible to do so and that does not cause undue harm or distress to the participant. **Recommendation 2.** It is recommended the data protection impact assessment is reviewed and updated where necessary, to reflect the data processing activities undertaken with the joint controller collaborators and ensure any identified data protection risks are identified and mitigated against.

9. Annual Reviews

The Secretariat has received 5 Annual Reviews in advance of the meeting which were deemed satisfactory:

- Ref ID: 19-002-AF1 (Neil Crowhurst, A retrospective case analysis of serious untoward incidents in super catchment mental health services in the HSE SouthEast)
- Ref ID: 19-012-AF2 (Leonie Young, Breast Cancer Proteomics and Molecular Heterogeneity)
- Ref ID: 19-015-AF2 (Mary McCarron, Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing - IDS-TILDA)
- Ref ID: 19-072-AF2 (Eugene Dempsey, Multimodal Assessment of Newborns at risk of Neonatal Hypoxic Ischaemic Encephalopathy - The MONITOR Study)
- Ref ID: 20-030-AF1 (Michael Rafferty, Efficacy, Safety and Tolerability of Nangibotide in Patients with Septic Shock. A Randomized, Double-blind, Placebo Controlled Dose Selection Study - The 'ASTONISH' Study)

10. Activities report

The Secretariat provided a report on its activities to the HRCDC in advance of the meeting. The HRCDC commented that it may be beneficial to upload the resources and links previously provided to the HRCDC on the topic of public and patient involvement (PPI) to the HRCDC website.

11. Overview of 2021 activities

Emily Vereker (EV) & Jonny Barrett (JB) provided an overview of 2021 activities and achievements of the HRCDC and Secretariat and noted the activities that will progressed in 2022. It was noted that the 2021 activities will be detailed further in the HRCDC's 2021 Annual Report which will be developed in Q1 2022. It was further noted that thematic areas and input from HRCDC members will be considered as part of the development of the 2021 Annual Report.

12. Any Other Business

- The Secretariat informed the HRCDC that relevant updates have been made to the HRCDC Application forms. These updates focus primarily on providing additional clarity to Applicants. It was further noted that guidance notes have been developed for Applicants with regards to seeking an amendment to a consent declaration and is now available on the HRCDC website.
- An update was provided on the Statement of Understanding and Data Processing Agreement between the Health Research Board, the Department of Health and the HRCDC. The HRCDC was reminded that these agreements set out the roles and responsibilities of each party in relation the business of the HRCDC and work of the

Secretariat. The Committee where informed that copies of these documents will be circulated to members for any comment, prior to signing by the Chair.

- The HRCDC were asked to forward any updates to their HRCDC website biographies to the Secretariat.
- The Chair noted that many Committee members are approaching the end of their first term of office in Q1 2022 and work was underway regarding the membership for next term.
- The Secretariat reminded the HRCDC to please accept/decline the meeting dates for 2022 that have been circulated to the Committee.
- The Chair thanked the HRCDC and Secretariat for their work throughout 2021 and looked forward to working with members in 2022.

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