HRCDC
Health Research Consent Declaration Committee

Date: 4th October
Location: Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Alyson Bailey
Kathy Brickell
Sheelah Connolly
Zubair Kabir
Cornelius Cooney
Mary Tumelty
John Woods
Barry Lyons
Jonny Barrett (Secretariat)
Noreen O'Brien (Secretariat)
Marta Pisarska (Secretariat)

Quorum for Decisions
☒YES

Returning Applications - For Consideration

Applicant	Ref No.	Title
Alistair Nichol	20-024-AF1/COV/AMD1	Genetics of Mortality in Critical Care (GenOMICC)
Gianpiero Cavalleri	22-010-AF1	Blockchain and AI Enabled Stratified Trials System (BESTS): A pilot study

New Amendments - For Consideration

Applicant	Ref No.	Title
Jochen Prehn, Deborah McNamara	19-031- AF2/AMD1	Bowel Disease Bio-Resource Development Identification of Potential Biomarkers for Bowel Disease
Fergus McCarthy	19-019-AF2/AMD1	IMPROVED Study (Improved Pregnancy Outcomes by Early Detection) Ireland
Ignacio Martin-Loeches	19-086-AF1/AMD2	Sepsis Immunosuppression in Critically Ill Patients

Meeting Items

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

2. **Apologies**
   Evelyn Mahon, Aideen Hartney, Simon Furney, Claire Collins, Barry O' Sullivan, Dan Rea, Caroline Byrne (Secretariat)

3. **Disclosure of Interest**

- **20-024-AF1/COV/AMD1:** Kathy Brickell (KB) declared her interest in this application and was absent for this part of the meeting
- **19-019-AF2/AMD1:** Zubair Kabir (ZK) informed the HRCDC that he knows the researcher involved in this study in a professional capacity, and that his employer is the data controller, UCC. ZK confirmed he is otherwise not involved in this study. It was determined that there was no conflict of interest and ZK was present for this part of the meeting.

4. Minutes of the last meeting

Draft minutes of 9th September 2022 were circulated in advance of the meeting and were approved by the HRCDC.

5. Matters arising

It was noted that the matter of the quality of applications submitted to the HRCDC, and of procedures regarding consent declaration amendment requests and considering applications by written procedure, are to be discussed at a future HRCDC meeting.

6. Returning Applications:

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 the amendment	See minutes of 6th September 2022
HRCDC Comments:	The Applicant submitted correspondence requesting the HRCDC to reconsider its decision which requested the submission of a new HRCDC application form. The Applicant outlined their justifications for their request, including that the international study protocol for GenOMICC encompassed other disease areas. Further information was also provided by the Applicant in relation to the public interest case for expanding the study into new disease areas, in addition to more information on public and patient involvement and transparency. The Chairperson reminded the committee of the discussion at previous meeting and why the Applicant was requested to submit a new HRCDC application form, in particular due to the scale of the amendment that was requested. It was highlighted that while the international protocol may include other disease areas, COVID-19 was the only disease detailed in the original HRCDC application, and therefore the original consent declaration was considered and made in this context. Further to the Applicant's correspondence, the guidance document for Applicants seeking amendments to a consent declaration was circulated for information to the HRCDC. It was noted that an example for when an amendment should be submitted included *'a change in the purpose of the study'*, among others.

	The HRCDC considered the Applicant's request and discussed if the changes to the study could be approved without the submission of a new HRCDC application form. It was noted that all the information that would be provided in a new application form could be sought, if necessary, by way of requesting further information. The Chairperson outlined that the HRCDC could request further information from the Applicant or decide on the amendment based on the information available or that the request to submit a new application form could remain unchanged. Based on the information that has been provided by the Applicant and given the existing guidance notes for Applicants on seeking an amendment to a consent declaration, it was the view of the HRCDC that a decision could be made without a new application form being submitted. It was noted that this does not set a precedent for future amendment applications. Following the HRCDC's decision, the Chairperson requested each HRCDC member to indicate whether the consent declaration should be amended, taking into account the previous and additional information provided by the Applicant. After discussing the application, and based on the information provided, it was the consensus of the HRCDC that the amendment request should be approved with appropriate conditions attached to the declaration. **Public Interest Case** • The HRCDC discussed the Applicant's response regarding the public interest case for expanding the GenOMICC study to other disease areas beyond COVID-19. • Based on the information provided it was the view of the HRCDC that there is a strong public interest case in expanding the GenOMICC study. **Additional Disease Areas** • Of the new additional disease areas and participant cohorts to be examined as part of the GenOMICC study, it was discussed that some appeared to be very broad and open-ended, specifically participants with '*emerging infection*' and '*emerging critical illness syndrome'*. It was discussed that these open-ended disease categories could cover a considerable number of undefined diseases and study participants. • On balance, the HRCDC was of the view that it would not be appropriate to amend the consent declaration to include open-ended disease areas and participant cohorts, and therefore the scope of the amendment would be limited to those specific and defined diseases and conditions noted by the Applicant. However, the HRCDC commented that further amendment requests can be submitted for consideration once the Applicant has identified more defined diseases that could fall under the categories of *'emerging infection'* and '*emerging critical illness syndrome'*. **Information leaflet**

	• Providing clear information regarding withdrawing from the study and what will happen the personal data is important. It was commented that the information provided in the study information leaflets on withdrawing consent and what happens the personal data thereafter, could be reframed so that it is made clearer to the individual that personal data can be deleted if they wish. It was commented that no unintended pressure should be placed on the individual for the continued processing of personal data after withdrawal. **Public and patient involvement** • The Applicant's response on the PPI activities that have and will be undertaken were noted. While support for this study from PPI representatives is welcomed, it was commented that the public interest case in a health research study remains the primary consideration for the HRCDC. • The HRCDC discussed that PPI engagement should continue throughout the study, where appropriate and feasible. **Other** • The HRCDC were reminded that the changes made to the study are covered by amended research ethics committee (REC) approval from the National Research Ethics Committee for COVID-19. It was highlighted that the Health Research Regulations requires the study to have received REC approval. In addition, the HRCDC were reminded that the data processing activities remain unchanged from the original application. • It was discussed that as part of the Annual Review, the Applicant should continue to report on the number of participants who do not regain decision-making capacity and who continue to be covered by the consent declaration, as per the condition attached to the original consent declaration. • The HRCDC noted and agreed with the observations of the Secretariat, highlighted on 6th September HRCDC meeting, regarding technical and more standard safeguards that may need to be considered, specifically observations on reviewing and updating the DPIA as required, and providing missing data controller signatures.
HRCDC Decision:	The consensus of the HRCDC was that the amendment to the Conditional Consent Declaration should be approved.
Amendment duration	The Amendment is made on 4th October 2022 and is valid until 31st August 2029 and for 10 years thereafter (31st August 2039) or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner *(this is the same duration as the original consent declaration).*
Conditions Attached:	**Condition 1.** The scope of the consent declaration is amended to cover the following defined disease areas outlined in the information provided by the Applicant to the HRCDC: (i) Influenza, (ii) Secondary pneumonia, (iii) Cellulitis, (iv) Pneumonia,

	(v) Pancreatitis, (vi) Life threatening complications of vaccines against COVID-19. The consent declaration <u>does not cover</u> the following open-ended disease areas/categories (i) emerging infection and (ii) emerging critical illness syndrome. **Condition 2**. The following section in the study information leaflet is noted: "*If you withdraw your relative from the study, pseudonymised data recorded up to the point of withdrawal will be included in the study analysis unless you request otherwise. We will also seek your permission to continue to collect patient data during their hospital admission and to follow up to ascertain their long-term health status as we would like to keep and use the information about your relative that we have already obtained"* The HRCDC is of the view that the above statement may unintentionally pressurise individuals to provide permission for the study to continue to process personal data after they have decided to withdraw. While it is important to clearly outline if the study would like to continue to process personal data after withdrawal, it is also important to ensure that the individual understands that the personal information can still be deleted if this is their wish. If it is the wish of the individual to have the personal data deleted and no longer processed, then this should occur until the point in the study where it is no longer possible to do so. The Applicant is therefore requested to reframe the above statement, and overall review the study documentation, to ensure it is clear that the personal data can be deleted and that individuals are not pressurised to provide permission for the continued processing of personal data after they withdraw. ***Note:*** It is acknowledged that relevant GDPR derogations may apply and at a certain point in the study it may not be possible to delete or otherwise cease to process personal data even when requested to do so by an individual. It is important that information on this is also provided in the study documentation. **Condition 3.** As per Condition 3 attached to the original declaration, the Applicant is requested to continue to report in the Annual Review on the proportion of participants who do not regain decision-making capacity and whose personal data therefore remains subject to the consent declaration that has been made. This applies to the original participant cohort recruited due to COVID-19 and those recruited under the new disease areas. **Condition 4.** Signatures on the amendment request form have been provided on behalf of St Vincent's University Hospital. Authorised signatures from the other joint data controllers, University of Edinburgh and NHS Lothian Health Board, must also be submitted to the HRCDC as soon as practicable and within 2 months of receipt of this decision letter.

HRCDC Recommendations:	**Recommendation 1:** The Applicant is requested to continue PPI engagement throughout the study's lifetime. **Recommendation 2.** It is recommended that the updated DPIA covering the expansion of the study has been reviewed by each of the joint data controllers of the study.

Reference ID:	22-010-AF1
Lead Applicant:	Gianpiero Cavalleri
Lead Data Controller:	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:	See HRCDC minutes of 6th September 2022
Reason for the Declaration	See HRCDC minutes of 6th September 2022
Points to Discuss:	The HRCDC considered the Applicant's response to the HRCDC's request for further information in the decision letter of 13th September 2022.
HRCDC Comments:	The Chair introduced the agenda item and reminded members of the further information that was requested from the Applicant, including further information to help determine the public interest. The Chair invited members to comment on the Applicant's responses and requested each HRCDC member to indicate whether a consent declaration should be made. The HRCDC commented that while the Applicant had addressed some of the HRCDC's concerns, the consensus of the HRCDC was that no Declaration should be made. The decision was based on the following discussion points: **Public interest case** • The HRCDC reviewed and considered the additional information provided by the Applicant regarding the public interest case for (i) the BESTS platform more generally and (ii) testing/piloting the BESTS platform utilising the personal data of participants who lack decision-making capacity. It was acknowledged that additional information was provided by the Applicant on these matters, and it was further acknowledged that inclusion in research is important. • While the Applicant's response that individuals who lack capacity may benefit the most from the BESTS platform was noted, the HRCDC discussed that this specific study remains focused on testing the platform's technology. Based on the information provided by the Applicant, the HRCDC was of the view that the public interest case for including participants who lack decision-making was not sufficient, including when considering the high volume of data to be processed from this cohort, including particularly sensitive data such as whole genome sequencing, for which the participant is unable to provide explicit consent for.

	• The HRCDC also commented that it was not clear how the inclusion, experiences, and processing of personal data of participants who lack decision-making capacity, and the experience of their carers, would provide significantly different study findings compared to if the trial was to include participants who have decision-making capacity only. • On balance, the HRCDC was of the view that the public interest case for processing the personal data of participants who lack decision making capacity in the testing of the BESTS platform technology was not sufficient to make a consent declaration, and did not significantly outweigh the participants data protection rights and interests. **Data Security** • The HRCDC queried the security of the data and sample collection processes, including the use of hand-written notes, recordings, and the use of postal sample kits **Other** • The HRCDC commented that the Applicant had addressed some of the concerns raised including with regards that the security of the platform may be tested using real participant data and how decision-making capacity was to be determined. The Applicant confirmed the platforms security would not be tested using the participant's real data and provided information outlining the process for determining decision-making capacity. • The Applicant's response regarding the further use of the personal data beyond the purposes of testing the BESTS platform was noted. • It was commented that the study information leaflet and assent form for the proxy, where the participant lacks decision-making capacity, reads in places like a consent form for the participant.
HRCDC Decision:	The consensus of the HRCDC was that No Consent Declaration should be made

7. Amendments:

Reference ID:	19-031-AF2/AMD1
Lead Applicant:	Professor Jochen Prehn, Professor Deborah McNamara
Lead Data Controller:	Royal College of Surgeons in Ireland Beaumont Hospital
Title:	Bowel Disease Bio-Resource Development: Identification of Potential Biomarkers for Bowel Disease
Research Objective:	See minutes of meeting 17th October 2019
Purpose of Amendment:	The amendment is requested to extend the duration of the consent declaration by an additional 2 years, beyond the initial 3-year duration that was made. The Applicant was invited to submit an amendment request to extend the duration in the original HRCDC decision letter, where the HRCDC would consider any new national policy and regulatory developments in the area of biobanking.

HRCDC Comments:	The Chairperson introduced the amendment and noted that it was a technical amendment to extend the duration of the consent declaration that was previously made. The Chairperson requested the HRCDC to confirm whether the amendment should be approved. The HRCDC queried the status and progress made regarding the conditions attached to the previous consent declaration. It was noted that the Applicant had been progressing and meeting the conditions, as outlined in their Annual Reviews. It was the consensus of the HRCDC that the amendment should be approved.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Amendment duration	The Amendment is made commencing 6th October 2022, and the consent declaration shall be valid for a further 2 years until 6th October 2024 *(This timeline is an extension to the duration of the consent declaration)*

Reference ID:	19-019-AF2/AMD1
Lead Applicant:	Dr Fergus McCarthy
Lead Data Controller:	University College Cork
Title:	IMPROVED Study (Improved Pregnancy Outcomes by Early Detection) Ireland
Research Objective:	See minutes of meeting 2nd March 2020
Purpose of Amendment:	A consent declaration has been obtained for the IMPROvED Pregnancy Study. Pregnant women were followed in the IMPROvED study from the first trimester, with detailed information and biological samples collected throughout pregnancy to investigate pregnancy complications. Iron deficiency is the most common micronutrient deficiency in the world, with pregnant women and infants the most vulnerable. Iron deficiency has lasting health consequences for both the mother and her child, but particularly for the development of the child's brain. In the IDEA project, the data controller, UCC, is seeking to construct and validate a screening tool to identify pregnant women and infants at an increased risk of iron deficiency. The purpose of this amendment request is to process personal data from the IMPROVED study for the purpose of the IDEA study.
HRCDC Comments:	The Chairperson introduced the amendment request, and the Secretariat provided an overview of the IDEA study. It was highlighted that the IDEA study is an internal UCC study, with separate REC approval and study protocol from the IMPROVED study. The Applicant outlines that the purpose of the IDEA study, aligns directly with the purpose and objectives of UCC's IMPROVED study, focusing on tests on pregnancy complications. The HRCDC were informed that the IDEA study is already covered by amendments made to 2 other UCC consent declarations: the BASELINE study (19-020-AF2) and the SCOPE study (19-070-AF2). The amendments previously made to the BASELINE and

	SCOPE studies covers the use of data from these 2 studies for the purpose of the IDEA study. The Chair requested each HRCDC member to indicate whether the amendment to the 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 the amendment should be approved with relevant conditions attached to the declaration. **Public interest case** • Based on the information provided, the HRCDC was of the view that there is a strong public interest case for processing personal data from the IMPROVED study for the purpose of the IDEA study. **Previously Attached Conditions** • It was noted that no conditions were attached to the consent declaration previously made for the IMPROVED study, however conditions were attached to the consent declaration and the amendments previously made to the BASELINE and SCOPE studies. • It was queried what conditions attached to BASELINE and SCOPE, if any, may be relevant and suitable safeguards to consider for this amendment to the IMPROVED consent declaration. It was commented that many of the previous conditions attached where specific to the consent declaration and amendments for BASELINE and SCOPE, however where infant data from the IMPROVED study is to be processed as part of the IDEA study, it would be appropriate to request the applicant to seek reconsent from participants once they turn 18-years old, as was requested for BASELINE and SCOPE. It was commented more generally that reconsenting children when they turn 18-years old, where feasible, is an important principle in research. **Transparency measures** • It was noted that the UCC INFANT centre website had been updated to provide further information on the IDEA study, including the processing of personal data from the IMPROVED study. It was discussed that transparency measures should continue to be maintained and further potential measures explored. **Data Minimisation** • The HRCDC discussed the importance of data minimisation and queried whether the data could be anonymised or deleted sooner. • The Secretariat noted updates provided by the Applicant on the anonymisation of the personal data from the IMPROVED study that was provided in their submitted Annual Reviews. It was further highlighted that a recommendation regarding data minimisation had been attached to the BASELINE and SCOPE consent declarations and could be attached to this amendment.

	Scope of the declaration • It was noted that the amended REC approval covers the use of the IMPROVED data for the IDEA study, for those participants who were recruited using version 3 of the consent documentation or later. The HRCDC confirmed that the scope of the amendment would align with this REC approval.
HRCDC Decision:	The consensus of the HRCDC was that the amendment to the Consent Declaration should be approved.
Amendment duration	The Amendment is made commencing 4th October 2022 and is valid until 30th June 2036 or until the point where the personal data has been irrevocably anonymised or destroyed *(this duration relates specifically to this amendment i.e., to process personal data from the IMPROVED study for the purpose of the IDEA study).*
Conditions Attached:	**Condition 1**. With regards the personal data of infants recruited to the IMPROVED study that is processed for the IDEA study under this amendment, the Applicant must ensure that a re-consent protocol is designed and implemented so that these children are given the opportunity to provide their explicit consent for data processing when they turn 18 years of age, should their personal data continue to be processed. Attempts to obtain their consent must be made within one year of the participant turning 18. The Applicant must report on this activity as part of each Annual Review, including where attempts to seek consent are unsuccessful *(Please also see Recommendation 1)* **Condition 2.** The Applicant is requested to ensure that clear transparency measures continue to be implemented and maintained for the IDEA study and the use of personal data from the IMPROVED study. Transparency measures should inform participants about a number of areas including the ongoing use of their data as part of the IDEA study, the dissemination of research findings, their data protection rights and withdrawal from the study. Consideration should be given to exploring and enhancing transparency via other appropriate measures, where feasible and appropriate, including through PPI engagement.
HRCDC Recommendations:	**Recommendation 1.** Reconsenting children when they turn 18-years old, where feasible, is considered an important principle in research. Further to Condition 1, the Applicant is also recommended to re-consent children when they turn 18 years of age for the continued processing of their personal data for the IMPROVED study more generally and, if relevant, the processing of their IMPROVED data in other research studies (i.e., obtain explicit consent). **Recommendation 2.** In line with the principle of data minimisation, the Applicant is requested to consider whether the personal data from the IMPROVED study can be irrevocably anonymised sooner.

Reference ID:	19-086-AF1/AMD2
Lead Applicant:	Ignacio Martin-Loeches
Lead Data Controller:	St. James's Hospital
Title:	Sepsis Immunosuppression in Critically Ill Patients

Research Objective:	See minutes of meeting 2nd March 2020
Purpose of Amendment:	The amendment is requested for the following changes to the study: (i) the addition of new study collaborators (i.e., data processors), (ii) an expansion of the number of study participants to be recruited, (iii) an extension of the duration of study/declaration and (iv) the use of verbal/telephone assent.
HRCDC Comments:	The Chairperson introduced the amendment request and an overview of the purpose of the request was provided. The Chairperson requested each HRCDC member to indicate whether the consent declaration should be amended. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that the amendment request should be approved with appropriate conditions attached to the declaration. **Public Interest** • Based on the information provided, the HRCDC was of the view that there is a strong public interest in expanding and extending the study. **Scope of the amendment** • From the response provided by the Applicant, only participants recruited after the study received amended approval from the REC, and using the new information leaflets, would have their personal data shared with and processed by the new additional collaborators. The HRCDC discussed that the scope of the amendment for the processing of personal data by the new collaborators would not extend beyond this scope **Assent/Consent process** • The HRCDC discussed the process undertaken regarding the telephone/verbal assent process. It was noted that the study documentation would be left at the patient's bedside. • The HRCDC commented that where telephone/verbal assent is obtained, copies of the study information leaflet and assent form should be forwarded to the individual providing proxy assent, and a signed copy returned to the research team. It was discussed that care should be taken when using important study documentation. **Study information leaflet** • It was noted that the term 'you' and 'yours' were used incorrectly within the proxy information leaflet and assent form and should be amended where appropriate. • It was commented that the information leaflet should be amended to outline that up to 300 patients per group, not 150, will be recruited to the study, to align with the information provided to the HRCDC. • In addition, it was commented that the information on the samples to be collected, and subsequently processed by the collaborators, should be reviewed and simplified where possible, as the information was considered very technical in nature.

	Data agreements/arrangements • The HRCDC queried whether the necessary agreements are in place regarding the transfer and use of data to the new collaborators/data processors. • It was noted that the agreements are in process however they must be in place prior to the transfer of the data. It was also discussed and emphasised that the agreements/arrangements must cover the transfer and processing of the data, in addition to the bio-samples, and outline what will happen to the data and samples once the role of the data processors has concluded. It was further noted that the necessary agreements/arrangements must be in place for the transfer of data outside the EEA, for example standard contractual clauses. **Other** • The HRCDC discussed the delay in submitting the amendment request form for consideration to the HRCDC and was of the view that the delay should be highlighted to the Applicant within the decision letter. • 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 submitting the updated DPIA.
HRCDC Decision:	The consensus of the HRCDC was that the amendment to the Conditional Consent Declaration should be approved.
Amendment duration	The Amendment is made commencing 4th October 2022 and the consent declaration is valid until 30th April 2029, or until the point where the personal data has been irrevocably anonymised or destroyed *(this is an extension of the duration of the consent declaration initially made).*
Conditions Attached:	**Condition 1**. It is a condition that the appropriate and necessary agreements and arrangements governing the transfer and processing of personal data, including pseudonymised data, are in place between the data controller of the study, St James's Hospital, and the new additional collaborators/data processors. Such agreements should also outline what will happen the personal data sent to the collaborators once their role in the study has concluded (i.e., whether the data will be deleted or returned). In addition, where data is transferred to collaborators outside the EEA, the necessary GDPR Article 5 legal basis and arrangements must also be complied with (e.g., standard contractual clauses). The transfer of data should not occur prior to the required agreements being in place and the HRCDC should be informed once the agreements/arrangements are in place. For the avoidance of doubt the agreements and arrangements must cover the transfer and use of data not just bio-samples. The Applicant should discuss this matter with their DPO. **Condition 2.** Where telephone/verbal assent is obtained, copies of the study information leaflet and assent form should be forwarded

	to the individual providing proxy assent, and a signed copy returned to the research team for record purposes. **Condition 3.** With regards the study information leaflet, the Applicant is requested to review and amend the following - Review and amend the use of 'you' and 'your' in the proxy/NOK information leaflet and assent form. For example, the information leaflet for the proxy/NOK incorrectly refers to collecting '*your samples'* and collecting data '*on your medical condition'*. The proxy is providing assent on behalf of the participant who lacks decision-making capacity; they are not providing consent for use of their own samples and data. - To align with the information provided to the HRCDC, the information leaflet should be amended to state that up to 300 patients per group, not 150, will be recruited to the study. - The information on the samples to be collected, and subsequently the processing undertaken by the collaborators, should be reviewed and simplified where possible, as the current information is considered quite technical and hard to follow. **Condition 4**. The DPIA which has been updated must be submitted to the HRCDC as soon as practicable and within 2 months form the receipt of this decision letter.

8. Annual Reviews

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

- **Ref ID:** 19-003-AF2 (TEAM study)
- **Ref ID:** 19-038-AF1 (The Genomic Basis of Alzheimer's Disease in Ireland) *(The HRCDC were informed that a consent declaration is no longer required for this study)*
- **Ref ID:** 19-062-AF1 (The relationship between Sub Epidermal Moisture (SEM) measurement and Inflammatory markers in the early identification of Pressure Ulcers)
- **Ref ID:** 19-070-AF2 (SCOPE Study)
- **Ref ID:** 20-004-AF1/COV (Outcomes for Older People with Cognitive Impairment Attending the Emergency Department (ED)
- **Ref ID:** 20-026-AF1/COV (CHARTER-Irl)
- **Ref ID:** 21-010-AF1 (AVERT DOSE)

9. Activities report and events of interest

The following upcoming events of interest and other relevant updates where noted:

- **Event:** National Office webinar: learnings, insights and next steps; 27th October, 10am-1pm (https://www.nrecoffice.ie/national-office-webinar-learnings-insights-and-next-steps/)
- **Event:** Irish Health Research Forum – '*More than publications: Maximising societal benefit from health research'*; Ashling Hotel Dublin, Thursday 10th November @ 9:30-13:00 (https://www.eventbrite.ie/e/more-than-publications-maximising-societal-benefit-from-health-research-registration-404107726087)

10. Any Other Business

(i) Amendment Request procedure and guidance

The HRCDC noted that it was agreed on 6th September HRCDC meeting that the procedure for consent declaration amendments would be reviewed and revised as appropriate. It was agreed that the amendment request form and guidance would be updated immediately to note that the HRCDC reserves the right to request the submission of a full application form, if this is deemed appropriate in the context of the scale of the amendment that is requested.

(ii) HRCDC meetings

- The HRCDC were reminded that 13th December HRCDC meeting will be in-person.
- The Chairperson discussed the matter of meeting dates for 2023. The HRCDC were asked whether Tuesday mornings remains suitable for meetings. The Secretariat will forward a poll to the HRCDC regarding specific dates for 2023.

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