HRCDC
Health Research Consent Declaration Committee

Date: 10th May 2022
Location: Health Research Board

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Aideen Hartney
Alyson Bailey
Claire Collins
Barry O' Sullivan
Sheelah Connolly
Simon Furney
Dan Rea
Zubair Kabir
Mary Tumelty
John Woods
Barry Lyons
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Also in attendance

Name	Position/Reason for attending
Annie Sorbie	*Guest speaker/Observed first half of the meeting*

Quorum for Decisions
☒YES

New Applications – For consideration

Applicant	Ref No.	Title
Iracema Leroi (St James's Hospital) & Caroline Mason (EU Contact for Otsuka)	22-003-AF1	A Phase 3, multi-center, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of AVP-786 for the treatment of agitation in patients with Alzheimer's Disease

New Amendments - For consideration

Applicant	Ref No.	Title
Eve Griffin, Paul Corcoran	19-021-AF3/AMD1	National Self Harm Registry

Meeting Items

1. **Opening**
   The Chair opened the meeting and welcomed the members. The Chair also welcomed Dr Annie Sorbie (University of Edinburgh) as an observer for the first part of the meeting.

2. Apologies
Cornelius Cooney, Kathy Brickell

3. Disclosure of Interest
- **19-021-AF3/AMD1 (National Self Harm Registry):** Zubair Kabir (ZK) disclosed an interest in this amendment request and was absent for this part of the meeting. Barry O'Sullivan (BOS) informed the HRCDC that the National Self Harm Registry is based at the offices of his employer, University College Cork. The HRCDC was of the view that there was no conflict of interest that would require BOS to abstain from the discussion of this agenda item.
- **22-003-AF1 (AVP-786 study):** ZK disclosed that he professionally knows the researchers named in this application, however he is not involved in the study. It was agreed there was not a conflict of interest that would require ZK to abstain from the discussion on this application.

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

5. Matters arising
- Further to the HRCDC meeting of 12th April and Condition 1 attached to the consent declaration for 22-001-AF1/CSO, the requirements regarding research ethical approval from Applicants was discussed.
- Although research studies may apply for and receive an exemption' from full ethical review and obtain approval from the Chair of the REC, the HRCDC agreed that it is a requirement that studies seeking a consent declaration from the HRCDC must undergo full ethical review from the relevant REC. Full ethical review is considered an appropriate safeguard where participants are unable to provide consent for the processing of their personal data.
- For consent declaration amendment requests, an exemption from full ethical review and approval from the Chair of the relevant REC may be acceptable subject to the nature and context of the amendment. This will be considered on a case-by-case basis.
- The Secretariat will review the consent declaration application forms to ensure the requirement regarding REC approval is clearly outlined.

6. New Applications

Reference ID:	22-003-AF1
Lead Applicant:	Iracema Leroi (National Coordinating Investigator – SJH) Caroline Mason (EU Lead for Otsuka)
Data Controllers:	1. Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC) 2. Avanir Pharmaceuticals Inc. (Avanir)
Title:	A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of AVP-786 for the treatment of agitation in patients with Alzheimer's Disease

Research Objective:	AVP-786 is being developed by Avanir for the treatment of neuropsychiatric conditions. This study is designed to evaluate the efficacy, safety, and tolerability of AVP-786 for the treatment of agitation in patients with dementia of the Alzheimer's type.
Reason for Declaration:	The scope of the consent declaration is for the processing of personal data (access, collection, transfer, analysis) for the purpose of this specific trial and for data storage after the study concludes, where participants lack decision-making capacity to provide explicit consent. Personal data is collected from several sources outlined by the Applicant including medical records, diaries, questionnaires/interviews. The study will be undertaken in Ireland at 4 participating sites: St James's Hospital Dublin, Mercy University Hospital Cork, St Finbarr's Hospital Cork & Tallaght University Hospital.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval, or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Secretariat provided an overview of the data controllership for this study. It was highlighted that the joint data controller Avanir Pharmaceuticals Inc. (Avanir), is an affiliate of fellow joint data controller Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC). It was also noted that conditional research ethics committee (REC) approval had been obtained for this study, and that the Applicant had provided responses to the REC's queries. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a conditional declaration should be made. **Public Interest** • The HRCDC discussed the public interest case for this study and commented that the application was relatively complex to follow in certain sections. • The HRCDC discussed the aims of this clinical trial and the potential benefits it had for future Alzheimer's patients. It was highlighted that the number of participants that will be recruited in Ireland as part of this wider international study is relatively low (n=29). However, it was also discussed that the inclusion of Irish participants in an international trial, even if a relatively small number, was also important from the perspective of researchers and participants in Ireland • In addition, the HRCDC commented that participants who may lack decision-making capacity should not be excluded from participating in and contributing to important health research studies, subject to the appropriate safeguards being in place.

	• On balance the HRCDC consensus was that there is a strong public interest case for undertaking this study in Ireland, subject to the Applicant addressing important matters relating to the proxy assent process, study information leaflets and other data protection areas. **REC approval & scope of the declaration** • It was noted that provisional ethical approval had been obtained from the joint St James's Hospital/Tallaght University Hospital (SJH/TUH) REC. The HRCDC queried whether it should have undergone ethical review by the National Research Ethics Committee for clinical trials as a multi-site study. It was clarified that ethics approval applications for clinical trials of medicinal products could still be submitted to local regulated RECs up until January 2022. • The HRCDC discussed that the consent declaration will not come into effect until full REC approval from the SJH/TUH REC is obtained and confirmation of such is provided to the HRCDC. • The Applicant's responses to the SJH/TUH REC queries on the use of audio recordings were noted. It was highlighted that these recordings are used for quality purposes to assess the administration of the study interviews. It was discussed that the use of audio recordings will not be covered by the scope of this consent declaration until confirmation is provided that full ethical approval covers the use of such recordings. • It was also emphasised that the scope of the declaration is limited to this specific trial and does not cover the processing, including transfer, of the personal data for other purposes. Personal data from other sources, such as social media and other third party sources is also not covered, in line with the information provided from the Applicant. **Proxy assent/consent process** • The HRCDC discussed the proxy assent and consent process that was outlined by the Applicant. It was discussed that a functional assessment is used to determine a participant's decision-making capacity. • It was further noted that there is an assumption by the Applicant that participants who lack decision-making capacity will not regain capacity to provide consent during the study, due to effects of their Alzheimer's disease. The HRCDC commented that decision-making capacity may fluctuate over time. Therefore, it should not be automatically assumed that a participant would not regain decision-making capacity to provide consent at some point during the study. • Where a participant lacks decision-making capacity to provide explicit consent, it was discussed that proxy assent for data processing on the participant's behalf will be obtained from a legally designated representative as defined under EU Clinical

	Trial Regulation No 536/20143[1] and under Irish law S.I 99 of 2022[2]. The HRCDC commented that the definition of a legally designated representative encompasses the participant's family, friend or a medical practitioner who is not involved in the conduct of the trial. • It was also highlighted that the representative maybe different to the participant's caregiver, who will be responsible as a caregiver for completing study-related diaries and will participate in the study interviews and assessments. It was noted that separate consent will be sought from the caregiver with regards their own participation in this study. • The HRCDC queried the extent to which participants with diminished decision-making capacity will be supported and involved in the consent and assent process, to the greatest extent that is possible. Similarly, it was queried the extent to which the participant's family and friends will be engaged with during this process. • Given the nature of this study, including the number of study activities, visits and assessments that will be undertaken, the HRCDC was of the view that the Applicant should ensure that all participants at every level of capacity are provided with sufficient supports and given every opportunity to engage in the consent and assent process to the greatest extent possible, and for their views to be respected. It was discussed that this approach aligns with the principles outlined in the Assisted Decision Making (Capacity) Act 2015, which is to be enacted shortly. • Further, and aligned with the definition under Irish law, the HRCDC was of the view that the Applicant must ensure that the representative identified to provide proxy assent for data processing on behalf of the study participant who lacks decision-making capacity, should be the person best placed to understand and interpret the participant's will and preference. **Study Information Leaflets** • It was highlighted that a single study information leaflet and assent/consent form is used to obtain both (i) consent/assent from the study participant with Alzheimer's disease and (ii) proxy assent from the legally appointed representative on behalf of a participant who lacks decision-making capacity. • The HRCDC was of the view that a separate, specific proxy information leaflet and assent form for the legally designated representative should be developed and used in this study. • The HRCDC also noted that the submitted study information leaflet was lengthy and complex and may be challenging to process by participants with Alzheimer's disease who may have

[1] https://ec.europa.eu/health/system/files/2016-11/reg_2014_536_en_0.pdf
[2] https://www.irishstatutebook.ie/eli/2022/si/99/made/en/print#:~:text=No.-,99%2F2022%20%2D%20European%20Union%20(Clinical%20Trials%20on%20Medicinal%20Products,Use)%20(Principal)%20Regulations%202022&text=%E2%80%9CIris%20Oifigi%C3%BAil%E2%80%9D%20of%204th%20March%2C%202022.&text=1.,)%20(Principal)%20Regulations%202022.

	diminished decision-making capacity. It was commented that this would likely impact on the ability of a participant with diminished decision-making capacity to understand the purpose of the study, the processing of their personal data and would affect their overall level of engagement in the decision-making process. • The HRCDC was therefore of the view that the Applicant should develop and employ more appropriate and accessible study documentation as applicable, for participants who may have diminished, or who lack, decision-making capacity. • The HRCDC was of the view that the study information leaflets should also provide additional clarity on key areas including further details on the parties involved in the study, the legal basis for data processing and what will happen the personal data if a participant or their legally designated representative withdraws their consent/assent. It was also commented that the PILs should be amended regarding references to future use of data and note who is responsible for covering costs should an adverse event occur during the study**.** **Public & patient involvement (PPI)** • The HRCDC commented that the study had not undertaken nor is planning public, patient and carer involvement activities. • Given the research area and the nature of this study, it was the view of the HRCDC that it would be feasible for the Applicant to undertake PPI engagement with individuals and appropriate representative groups such as the Alzheimer's Society of Ireland. • It was discussed that PPI engagement would help inform the assent/consent process and the development of more suitable study information leaflets. **Role of Irish sites & data agreements/arrangements** • The HRCDC queried the role of the Irish hospital sites in this study and whether they should be joint data controllers alongside the two named joint data controllers from the USA. It was highlighted that the hospital sites are not joint controllers of this study. The Applicant had confirmed that (i) agreements will be place with the Irish hospital sites and (ii) the Irish hospital sites will support the implementation of the consent declaration. • It was commented that the study should ensure the appropriate and necessary data agreements and arrangements are in place, including joint controller arrangements and agreements necessary for the transfer of personal data outside the EEA (i.e. Standard Contractual Clauses). • It was further discussed that the transfer of personal data outside the EEA should take into account the latest requirements arising from the 'Schrems II' decision of the European Court of Justice, including the requirement to undertake an assessment of the level of data protection provided in the third country where data is transferred to.

	Study monitoring • From the information provided it was noted that on-site and remote monitoring will be undertaken as part of this study and that monitors will be provided with access to the participant's medical records for quality assurance purposes. • The HRCDC queried the safeguards that will be place with regards monitoring activities and access to participant records, including where access to medical records would be provided remotely. • On balance and given the low number of participants who will be recruited in Ireland, it was the view of the HRCDC that direct access to medical records should not be provided remotely to the study monitors, and access should therefore be limited to on site monitoring. The HRCDC further commented that appropriate security and safeguard arrangements should be in place for all monitoring activities. **Other** • The DPIA referenced that study records at an Irish site may be transferred to Avanir should the PI no longer be in a position to retain them. The HRCDC discussed that study records should not be transferred to Avanir or OPDC. • The HRCDC was of the view that audio recordings, if approved by the REC, should not record identifiable or unnecessary data. If such data is recorded, then it should be deleted. • 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 obtaining confirmation on authorised signatures, the DPIA and data protection officer feedback, as well as data minimisation. • The HRCDC noted that the Applicant's response to the REC's queries which states that the HRCDC has evaluated and approved the study's data collection methods. It was discussed that the role of the HRCDC should be clarified to 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 10th May 2022 and is valid for the duration of the clinical trial (July 2022 – July 2025) and for 20 years thereafter for data archiving (until 31st July 2045), or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner. The consent declaration will only come into effect when the Applicant has received confirmation from the HRCDC of a satisfactory response to the conditions attached.
Conditions Attached:	Prior to this consent declaration becoming operational, a detailed and satisfactory response must be submitted by the Applicant to the HRCDC on Conditions 1-3 noted below. For the avoidance of doubt the processing of personal data for the purpose of this study

	is not covered by this consent declaration until such responses are received and are considered satisfactory by the HRCDC. **Condition 1.** (i) to ensure that the will and preference of participants can be heard and respected to the greatest extent possible, detailed information is required as to how the study will meaningfully involve and support all participants during the consent and assent process, irrespective of their determined level of decision-making capacity. (ii) the HRCDC requests an assurance that participant decision-making capacity will be reviewed at appropriate timepoints during the study, and deferred participant consent obtained wherever possible. (iii) where proxy assent for data processing is to be obtained from a legally designated representative as defined under Irish law for the purpose of clinical trials, information is required on how it will be determined that the proxy identified for the purposes of data processing is the person best placed to understand and interpret the participant's will and preference; this applies whether the identified proxy is a family member, friend, or a clinician. (iv) provide information on how study will meaningfully engage with and support the participant's family throughout the assent/consent process and during the study, in particular, where the participant lacks decision-making capacity and where proxy assent will be obtained from a clinician. **Condition 2.** Further to Condition 1, the Applicant is requested to: (i) develop and utilise a more appropriate, accessible, and easier-to-read study information leaflet and consent and assent forms, as applicable, that is suitable and tailored for participants with Alzheimer's disease who may have diminished, or who lack, decision-making capacity. (ii) when seeking proxy assent for data processing from a legally designated representative, to employ a specific proxy information leaflet and assent form that is separate to the study documents provided to the study participant. Separate documents should therefore be used when obtaining (a) consent/assent from participants with Alzheimer's disease and (b) proxy assent from the representative. (iii) review and amend accordingly, the study information leaflets and consent/assent forms for clarity and consistency of information as follows; (The Data Protection Officer and Research Ethics committee should be consulted, as necessary): • note the specific GDPR Art.6 legal basis and Art.9 relevant condition for data processing, • clearly outline the parties that are involved in the study, their location, and their role in this study. This includes the joint data controllers, the data processors (contract research

	organisation, laboratory, audio recording reviewers etc.) and all the participating Irish hospital sites, • for the proxy information leaflet and assent form, amend or delete the options provided with regards the future use of personal data, as the scope of the consent declaration for participants who lack decision making capacity to provide explicit consent is limited to data processing for the purpose of this Phase 3 AVP-786 clinical trial and subsequent data archiving only. Proxy assent for data processing from a legally designated representative including for future research purposes, has no lawful basis, • provide information on who is responsible for any costs should an adverse event occur during the trial, • clearly outline what will happen the already collected personal data, including the audio recordings, if participant consent or proxy assent from the legally designated representative, is withdrawn. Where the personal data cannot be deleted and will continue to be stored and processed, the Applicant must ensure that the reasons for this are clearly noted in the consent/assent documentation. Note: data controllers that wish to continue to process personal data of participants after assent/consent is withdrawn are responsible for ensuring they are compliant with data protection legislation. • more generally, review the study information leaflets and assent/consent forms to ensure there is clarity and consistency of information that aligns with the data processing activities to be undertaken (e.g., data retention period) and that information is provided in an understandable manner. **Condition 3.** Public, patient and carer involvement (PPI) is considered an important activity by the HRCDC and is viewed as a key data protection safeguard in situations where the participant cannot provide consent. It is condition of this declaration that PPI activities are undertaken with relevant individuals and/or representative groups of the study participants (e.g., Alzheimer's Society of Ireland) to discuss the inclusion and meaningful engagement of participants in the study's consent/assent process (Condition 1) and the development of more appropriate, accessible and easier to read study information leaflets and consent/assent forms for participants (Condition 2). Further to Conditions 1-3, the following conditions are also attached: **Condition 4.** Full research ethics committee approval must be obtained from the St James's Hospital/Tallaght University Hospital joint REC, and confirmation of this full approval is to be submitted to the HRCDC as soon as is practicable.

	In addition, the scope of this consent declaration does not cover the use of audio recordings until confirmation is provided that the full approval from the St James's Hospital/Tallaght University Hospital REC covers this data processing. **Condition 5.** When accepting, or otherwise responding, to this consent declaration, the Applicant is requested to confirm that joint data controller Avanir Pharmaceuticals Inc., as an affiliate of Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC), is authorised to sign the HRCDC application form and provide DPO feedback on behalf of OPDC. If this is not the case, then a signature and DPO feedback on behalf of OPDC is required to be submitted to the HRCDC. The consent declaration will not be in effect until this condition is met. **Condition 6.** The Irish Hospital sites should be made aware of the consent declaration and conditions attached. Further the joint controllers and the Irish hospital sites must support the implementation of and compliance with the consent declaration. **Condition 7.** All appropriate contractual legal arrangements regarding the processing and use of personal data (i.e., joint data controller arrangement, data processing agreement, data transfer agreements) are to be in place with between the relevant institutions. The Applicant should also ensure that the relevant data protection requirements are met for the transfer and processing of personal data outside the EEA for the purpose of this study. This includes the requirements outlined in Chapter V of the GDPR and having due regard to the requirements arising from the 'Schrems II' decision of the European Court of Justice. **Condition 8.** It is a condition of the consent declaration that remote (off site) access to Irish participant's medical charts for the purpose of monitoring shall not be undertaken. The Applicant should also ensure that appropriate security and safeguard arrangements are in place and adhered to for all monitoring activities. Information on meeting this Condition is a reporting requirement of the Annual Review. **Condition 9**. Subject to Condition 4 being met, appropriate safeguards should be implemented to prevent the audio recording of identifiable data and data that is irrelevant for the purpose of this study. Should such data be recorded then the audio should be deleted. **Condition 10.** It is a condition that study records are not transferred to Avanir or OPDC if the Principal Investigator is no longer in a position to retain these records. Records should instead continue to be retained at the local site.

	Condition 11. Aligned with the principle of data minimisation, personal data, including pseudonymised data, should be retained and processed only for the minimum period of time that is necessary. This includes data transferred/accessed by relevant parties such as the laboratory analysing the collected bio-samples, monitors and the company reviewing audio-recordings.
HRCDC Recommendations:	**Recommendation.** The Applicant should review and where necessary, update the DPIA to ensure it is applicable and reflects data processing activities, risks and mitigating actions across all the Irish hospital sites involved in this study.

7. Amendments

Reference ID:	19-021-AF3/AMD1
Lead Applicant:	Eve Griffin, Paul Corcoran
Data Controller:	National Suicide Research Foundation (NSRF)
Title:	National Self Harm Registry
Research Objective:	See minutes of 2nd March 2020 & 30th April 2020
Purpose of Amendment:	The consent declaration was made for an initial period of 2-years. The purpose of the amendment is (i) to extend the duration of the consent declaration and (ii) for a change in data processor relating to the data transfer system used by the Registry.
HRCDC Comments:	The Chair introduced the amendment request. The Secretariat were invited to provide further details on the purpose of the amendment and the progress made to date by the Applicant to meet Condition 1 and Condition 2 attached to the consent declaration, as outlined in their previously submitted Annual Reviews. It was highlighted that the COVID-19 pandemic had impacted the work of the Registry and the progress made to meet the attached Conditions over the previous 2 years. The HRCDC discussed that extending the duration of the consent declaration would consider the progress made by the Applicant to meet these conditions. **Public, patient, and carer involvement - PPI (Condition 1)** • It was highlighted that the National Suicide Research Foundation (NSRF) had set up an internal advisory group on establishing an organisational level PPI panel, now known as the 'Lived Experience Panel'. Supporting materials for this Lived Experience Panel have been developed by the advisory group, and the NSRF are to appoint a national co-ordinator to recruit panel members and support their operations. • It was further highlighted that a PPI sub-panel for the National Self-Harm Registry has been established. Some representatives from mental health organisations and family members have been recruited. It was also noted that invitations have been issued to recruit other representative individuals to this PPI sub-panel. **Transparency Measures (Condition 2)**

	• The HRCDC were informed that the Applicant had developed a draft poster and information leaflet on the Registry for use in the hospital sites, however challenges due to the COVID-19 pandemic meant the roll-out of these materials has not been fully implemented. • The Applicant stated that work was ongoing with hospital personnel to ensure robust transparency arrangements are in place. The Applicant also stated that these materials will be updated to clearly outline that personal data will be deleted from the Registry should a participant wish to withdraw. • It was highlighted that to date information on the Registry has not been provided on relevant third-party websites. The provision of information to self-harm patients upon their discharge from hospital will also be explored with the HSE. Based on the information provided, it was the consensus of the HRCDC that an amendment to the consent declaration can be approved. The decision was based on the following discussion points: **Progress on attached conditions** • The HRCDC discussed the progress that has been made to date on enhancing the level of PPI engagement and implementing transparency. • Notwithstanding this and the challenges from the COVID-19 pandemic, and the resources spent to date by the Applicant, the HRCDC discussed that it was unsatisfactory that important safeguards of enhanced PPI activities and transparency measures have yet to be fully implemented, while personal data continued to be collected and processed over the last two years. • It was commented that while strong PPI measures are currently being established within the NSRF, further progress should have been made since the consent declaration was made in April 2020. • In addition, the HRCDC commented that it should have been feasible for the Applicant to progress the implementation of enhanced transparency measures within the hospital sites. Where this was delayed, it was the view of the HRCDC that the Applicant should have endeavoured to enhance transparency by other means, including providing information on relevant third-party websites, as was referenced in Condition 2. • Given the public interest case for the Registry, on balance with the level of progress made to meet the attached conditions, the HRCDC discussed that the consent declaration can be extended for 1 year, subject to the Applicant sufficiently progressing Condition 1 and Condition 2 and providing an interim report to the HRCDC by the end of 2022. **Data Security** • The HRCDC commended the work undertaken by the Applicant on the implementation of an updated data transfer system. It

	was commented that this new system would provide strong security measures to protect the personal data.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Amendment Duration:	The Amendment is made commencing 10th May 2022 and shall be valid for one year until 10th May 2023. (This timeline is an extension to the duration of the consent declaration) NOTE: This extension is subject to the submission of a satisfactory midterm report by the Applicant (See Condition 1).
Conditions Attached:	**Condition 1.** The Applicant is required to make satisfactory progress regarding Condition 1 (enhanced PPI activities) and Condition 2 (enhanced transparency measures) that were attached to the consent declaration of 30th April 2020. Specifically, a midterm report must be submitted to the HRCDC by 31st December 2022, detailing the progress made to meet these conditions. For the avoidance of doubt the continuation of the consent declaration for the National Self-Harm Registry is subject to a satisfactory midterm report being received from the Applicant.

8. Guest speaker

The HRCDC meeting was adjourned for a period for a presentation by Dr Annie Sorbie (University of Edinburgh) on '*Exploring the Public Interest in Health Research Regulations'*.

9. Reflection on HRCDC business

- The Chair highlighted the feedback that been provided previously from members regarding the operations of the HRCDC, including the format and processes of the HRCDC meetings, and invited members to provide further comments and suggestions.
- It was discussed whether it would be beneficial to undertake a thematic-based approach when undertaking the roundtable discussion on HRCDC applications, for example discussing public interest, followed by technical safeguards and participant safeguards. It was commented that this format could be trialled at a future HRCDC meeting.
- It was the view of the HRCDC that the expertise and experiences of all members are being drawn upon effectively and that the consideration of all applications takes on board the voices of all members.
- It was further commented that conditions are carefully considered as appropriate safeguards. In this context, the HRCDC discussed what additional, appropriate information could be provided to assist researchers in completing the HRCDC application form and to help individuals better understand the importance of safeguards such as transparency measures and PPI engagement. It was commented that an exemplar application form could be developed to provide researchers with a view of what is expected when completing the HRCDC application form as well as wider public awareness activities.

- The HRCDC commended the work and support provided by the Secretariat and stated that their technical observations on applications are useful. The HRCDC also expressed satisfaction with the technical infrastructure in place for the meetings.
- On future meetings, it was agreed that meetings would continue to be held via videoconference, with the exception of 2 in-person meetings a year (May & December) subject to public health guidance.

10. Annual Reviews

The Secretariat has received 4 annual reviews in advance of the meeting which were deemed satisfactory:

- Ref ID: 20-006-AF1/COV: Gerard Curley, A randomized double-blind placebo-controlled trial of intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness
- Ref ID: 20-010-AF1/COV; Linda Coate, COVID-IYON Study
- Ref ID: 20-031-AF1; Ignacio.Martin-Loeches, Fluid resuscitation in Septic Shock
- Ref ID: 20-037-AF1/COV; Emer Doheny, Home monitoring of respiration in COVID-19

11. Activities report and events of interest

- The following upcoming events of interest and other relevant updates where noted:
  - **Notification of upcoming legalisation**: General Scheme of a Health Information Bill: https://www.gov.ie/en/press-release/3d605-minister-donnelly-receives-cabinet-approval-to-develop-new-health-information-legislation/
  - **Healthcare Informatics Society of Ireland** 'Sharing is Caring: Data Interoperability in Healthcare'; Friday 6th May @12:30pm (https://www.hisi.ie/events/sharing-is-caring-data-interoperability-in-healthcare-2187)
  - **Irish Health Research Forum** 'Embedding Research in the Irish Health Service' [In person event @Spencer Hotel Dublin, spaces maybe limited]; Wednesday May 11th, 9:30am-1pm (https://hrci.ie/embedding-research-in-the-irish-health-service/)
  - **The HRB National Clinical Trials Office (NCTO),** International Clinical Trials Day, National Conference - “Clinical Research in Ireland 2022”; Thursday May 12th - all day (https://conference.ucc.ie/ncto-2022-online-conference/ncto2022/Site/Register)
  - **Articles/Blogs**: A HRB blog post on the importance of clinical trials and research in the area of dementia (https://www.hrb.ie/news/blog/article/alzheimer-s-disease-the-road-to-a-cure/).

12. Any Other Business

- The HRCDC were informed of staffing updates within the Secretariat. Programme Manager of the Secretariat, Emily Vereker (EV), has been temporarily assigned to the National Office for Research Ethics Committees. The HRCDC congratulated EV and wished her the best during her temporary assignment. The Chair thanked Jonny Barrett (Programme Officer) and Caroline Byrne (Administrative Assistant) for continuing the Secretariat’s work over the coming months.

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