HRCDC
Health Research Consent Declaration Committee

Date: 9th May 2023
Location: The Health Research Board

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Sheelah Connolly
Simon Furney
Aideen Hartney
Zubair Kabir
Cornelius Cooney
Mary Tumelty
John Woods
Barry Lyons
Bríd Burke (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES

New Amendments - For Consideration

Applicant	Ref No.	Title
Caroline Mason	22-003-AF1/AMD1	A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of AVP-786 (deudextromethorphan hydrobromide [d6-DM]/quinidine sulfate [Q]) for the treatment of agitation in patients with dementia of the Alzheimer's type
Paul Corcoran	19-021-AF3/AMD2	National Self-Harm Registry Ireland
Gerard Curley	19-023-AF1/AMD2	Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis.

Meeting Items

1. **Opening**
   The Chairperson opened the meeting and welcomed the members. The Chairperson and the HRCDC members welcomed the new Secretariat Programme Manager, Bríd Burke.

2. **Apologies**
   Dan Rea, Barry O' Sullivan

3. **Disclosure of Interest**
Zubair Kabir (ZK) declared his interest in application 19-021-AF3/AMD2 (the National Self-Harm Registry Ireland). ZK was absent during the meeting when this application was considered.

4. **Minutes of the last meeting**
Draft minutes of 29th March 2023 were circulated in advance of the meeting and were approved by the HRCDC.

5. **Matters arising**
The HRCDC were informed that the 2022 HRCDC Annual Report was submitted to the Department of Health and will be uploaded to the HRCDC website.

6. **Responses to Conditions from Consent Declarations.**
Application 22-003-AF1 (A Phase 3, multi-center, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of AVP-786 (deudextromethorphan hydrobromide [d6- DM]/quinidine sulfate [Q]) for the treatment of agitation in patients with dementia of the Alzheimer's type):
   - The Secretariat circulated the responses provided by the Applicant to each of the attached conditions. It was noted that the Applicant had developed new study documentation as requested in the HRCDC's original decision letter, and that they had also provided information with regards to determining the participant's will and preferences, the proxy assent process and involvement of family members and PPI engagement, among others.
   - On the study information leaflets, the Secretariat informed the HRCDC that while this condition had largely been addressed, there remain some errors or inconsistencies that will be highlighted to the Applicant for addressing, for example inconsistencies on the legal basis referenced in the study documentation.
   - On determining the will and preferences of participants who lack decision-making capacity, the Applicant stated that they will request the participant's named healthcare or care professional, who knows the person well, to be present during the consent process. It was also noted that the participation of family or close friends, if available, will be welcomed in the consent process. The HRCDC commented that the balance on who will be involved in helping to determine the participant's will and preferences appeared more weighted towards the medical or care professionals. It was discussed that the process for determining the participant's will and preference should not be weighted towards medical or care professionals but involve the family and participant, and that family or close friends should always be invited by the study to help determine the participant's will and preferences. In addition, it was commented participants should not feel under any undue or unintentional pressure to agree to be enrolled in the study and that proxy assent should be sought from an individual who understands the participant's will and preferences.
   - On the matter of determining decision-making capacity, it was also re-emphasised that decision-making capacity of those who lack-decision making capacity needed to be reassessed during the course of the study to determine if the participant has regained decision-making capacity and can provide explicit consent; it was noted that the Applicant's responses focuses heavily on assessing the capacity of those who had capacity at the point of study enrolment, but who may later lose capacity. The HRCDC further noted the reference to undertaking informal capacity re-assessments at each contact after study enrolment. The HRCDC commented that a capacity assessment is

not an informal process and therefore capacity to consent should be assessed in a formal manner.

- The HRCDC also asked about the public and patient engagement that had occurred with Dementia Trials Ireland. It was commented that Dementia Trials Ireland have a strong patient representative group and therefore the engagement that had occurred was satisfactory.
- The original consent declaration decision letter noted that the study could not proceed prior to responding to the attached conditions; therefore, it was commented that the Applicant will be informed that the responses to the conditions have been noted so that the study may proceed. Notwithstanding this, it was discussed that the response to the Applicant will also communicate the HRCDC's comments on determining will and preference, involvement of family and decision-making capacity and will reinforce that the conditions attached, including the principles outlined in Condition 1 (consent/assent process) and Condition 3 (PPI engagement), must be progressed and complied with during the study and reported on in the Annual Review.

7. Amendments:

Reference ID:	22-003-AF1/AMD1
Lead Applicant:	Caroline Mason
Lead Data Controller:	Otsuka Pharmaceutical Development & Commercialization Inc. (OPDC) (Note: Avanir Pharmaceuticals is no longer involved in this study)
Title:	A Phase 3, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of AVP-786 (deudextromethorphan hydrobromide [d6- DM]/quinidine sulfate [Q]) for the treatment of agitation in patients with dementia of the Alzheimer's type
Research Objective:	Please see HRCDC minutes of 10th May 2022.
Purpose of Amendment:	The amendment to this declaration is due to (i) the change in the controllership of the study from joint controllers to a single data controller and (ii) data processors who were not outlined in the original HRCDC application form.
HRCDC Comments:	The Chairperson introduced the amendment application. It was highlighted that the change in data controllership is due to Avanir Pharmaceuticals having been incorporated into OPDC; it was noted that this meant that Avanir ceases to exist as a separate entity. On the matter of the data processors, the Secretariat highlighted that these had been identified from the Applicant's responses to the conditions that were attached to the consent declaration. The Secretariat noted that these new processors included laboratories processing samples and associated data as well as two parties involved in participant pre-screening and recruitment. The Chairperson requested each HRCDC member to indicate whether the amendment should be approved. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a formal decision should be deferred pending the receipt of further information. **Role of the data processors**

	• The role of some of the data processors listed by the Applicant, including their access to personal data, were discussed by the HRCDC, specifically the two parties outside the EEA who are involved in providing support for pre-screening and recruitment. • It was noted that one of these parties will provide administrative support if this is requested by a hospital site. While the Applicant states that they will not remove data from the hospital site, their role involves accessing personal data on-site to perform tasks relating to study recruitment. This includes identifying and communicating with individuals who may be eligible for and interested in the study. The role of the second party also relates to participant engagement via a central media advertising campaign and sending participants reminders about study appointments. The Applicant outlined that the recruitment materials to be used by this processor are currently under ethical review. • Based on the information provided, the HRCDC discussed the reasons for employing these two data processors. It was noted that they could enhance and support patient recruitment and engagement which could potentially benefit the study. However, the HRCDC was of the view that more information on the role of these parties, and their access to and processing of personal data could have been provided, including a copy of the study protocol. • It was also queried if their roles in the study were necessary given that only a small number of participants will be recruited to the study in Ireland. In this context the HRCDC questioned why such parties external to the recruiting sites in Ireland, would need to be involved in pre-screening and participant engagement and therefore be given access to personal data, including on-site access. It was queried why access to patient data for pre-screening and participant engagement couldn't be undertaken by the staff at the local site. • On balance while the Applicant had provided some details on these two parties, the HRCDC was of the view that additional information should be requested, including a copy of the study protocol that details their role in the study, and information on who will have oversight of these parties. • Further to the two data processors involved in pre-screening and participant engagement, the HRCDC was also of the view that additional information should be requested on the laboratory service provider that will be undertaking pharmacogenomic analysis. **Ethics approval** • The HRCDC queried the status of the ethics approval for this study, including with regards the change in data controllership and the other data processors. The Applicant stated that REC approval for the change in the data controllership was pending and noted the ethics process with regards the data processors.

	• It was discussed that the requisite ethics approval would be required for the change of data controllership. **Legal Agreements** • The HRCDC discussed that the required data agreements and arrangements would need to be in place with the data processors prior to them accessing, receiving, or otherwise processing personal data. The Applicant had outlined that the agreements, including EU standard contractual clauses for processing data outside the EEA, would be in place. With regards the parties that will be accessing identifiable data, including accessing data on-site, the Applicant also noted that the required data and confidential agreements will be implemented. • It was also highlighted that Condition 7 attached to 22-003-AF1 required the appropriate agreements to be in place and that ensuring the appropriate agreements are in place is a standard condition attached to all consent declarations. **Other** • The HRCDC expressed some concern that the additional data processors and the need for an amendment were identified by the Secretariat and not by the Applicant/data controller. It was discussed that it is up to the data controller(s) of the study to ensure all data processors have been outlined.
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information should be made.
Request for Further Information:	**Point 1.** The HRCDC requests further detailed information on the role and clinical supervision of (i) WCG ThreeWire and (ii) Clinical Trial Media in this research study with regards the pre-screening, recruitment, and engagement of participants in Ireland. In addition, the Applicant is also requested to submit the study protocol document that should outline the role of WCG ThreeWire and Clinical Trial media. When providing more detailed information on the role and clinical supervision of WGC ThreeWire and Clinical Trial Media, the following points should also be clearly addressed as part of your response: - Please detail the personal data that will be accessed, shared or otherwise processed by these parties. - Should they be involved in the study, will these parties be responsible for identifying (and contacting/recruiting) potentially eligible participants, or will they be providing support to the local sites on this matter i.e., the identification of participants will still be the lead responsibility of the hospital staff. - Further, the original application outlined that potential participants were to be identified from those attending the hospital sites (i.e., memory clinics). Where WCG ThreeWire and Clinical Trial Media are involved in the study, will potential

	participants be identified from elsewhere? E.g., nursing homes. - In the context that only a small number of participants are to be recruited to the study in Ireland, please outline why the involvement of, and processing of personal data by WCG ThreeWire and Clinical Trial Media is required. Can the activities of these two parties not be undertaken by the staff at the Irish sites? **Point 2.** The HRCDC requests the Applicant to provide additional information on the role of the data processor Invitae Corporation, including further details on the pharmacogenomic analysis that will be undertaken by this party and the data and samples involved i.e., data/samples sent to, analysed and results generated by Invitae Corporation and the purpose of this processing in the context of this specific trial.

Reference ID:	19-021-AF3/AMD2
Lead Applicant:	Paul Corcoran
Lead Data Controller:	National Suicide Research Foundation
Title:	National Self-Harm Registry Ireland
Research Objective:	Please see HRCDC Meeting minutes of 2nd March 2020 and 30th April 2020.
Purpose of Amendment:	The amendment is sought to extend the duration of the consent declaration; the Applicant requests an indefinite consent declaration.
HRCDC Comments:	The Chairperson introduced the amendment application. The HRCDC were reminded of the concerns that were raised when the previous amendment was considered on 10th May 2022 i.e., (19-021-AF3/AMD1), regarding the progress made by the Applicant/data controller to enhance transparency measures and public and patient (PPI) engagement. Given these concerns, an extension to the consent declaration of 1 year was made by the HRCDC on 10th May 2022, and it was communicated to the Applicant that satisfactory progress needed to be made on transparency measures and PPI engagement prior to the HRCDC considering a further amendment to extend the consent declaration. Along with the amendment request form, the Secretariat circulated the Annual Review and other updates provided by the Applicant on the progress that has been made in the last 12 months to enhance transparency and PPI activities. The Chairperson requested each HRCDC member to indicate whether the amendment request should be approved. After discussing the application and the Annual Review submitted by the Applicant, it was the consensus of the HRCDC that the amendment to extend the consent declaration should be approved. **Progress on conditions**

	• Based on the information provided, on balance the HRCDC was of the view that the Applicant has made significant progress to enhance transparency measures and conduct PPI engagement. • It was noted that the website had been enhanced as requested by the HRCDC, with clearer information provided on the purpose of the register, where the data is sourced and how a participant can exercise their data protection rights, including the right to withdraw. Further, the Applicant provided updates on the provision of transparency measures within the hospitals. The HRCDC also commented positively on the communications that had been undertaken via social media, and the reach of such communications. • It was commented that the Applicant should ensure that the website, other transparency measures and the information provided to the public and to patients continue to remain current and up to date. In addition, the Applicant outlined the engagements they have had to date with relevant third-party organisations to provide information about the register on their websites, and that these discussions remain in progress. The HRCDC further noted that other suggested actions are still being explored, including providing information leaflets to self-harm patients at an appropriate point in time. It was discussed that these discussions should be expediated and that any information provided directly to participants should include a link to the Self-harm Register website. • On PPI activities, the HRCDC discussed and noted the PPI group that has been convened by the data controller, including the members of this group, the feedback that has provided to date and the plans for future engagement. Notwithstanding the engagement that has occurred to date with this group, it was not clear to the HRCDC whether each meeting with this panel will include at least one member who is a person with lived experience of self-harm or a family member of such an individual. It was commented that meetings with this PPI panel should include at least one self-harm patient or family member, in addition to those form relevant representative organisations. • Overall, the HRCDC noted the very positive progress that had been made by the Applicant to enhance transparency and PPI engagement. It was also discussed that the conditions on transparency and PPI will remain valid for the duration of the consent declaration and will be a reporting requirement of the Annual Reviews. As part of the Annual Review the Applicant will expected to report on the engagement that has occurred with the PPI panel, including the numbers at each meeting and will also be expected to provide updates on how the feedback from the PPI engagement have been taken on board and implemented, where relevant. **Duration of declaration**

	• The HRCDC was of the view that an indefinite consent declaration should not be made; instead, it would be more appropriate to allow for an extension of 10 years. **Data Security** • The Annual Review submitted by the Applicant noted a potential data security issue that had arose regarding the use of an unencrypted USB memory stick. The HRCDC was of the view that the Applicant/data controller should review the use of USB memory sticks in this study and explore if alternative more secure methods or platforms for data transfer can be utilised.
HRCDC Decision:	The consensus of the HRCDC was that the amendment request should be approved.
Conditions Attached:	**Condition 1**. The previous Conditions on transparency (Condition 1) and PPI engagement (Condition 2) continue to remain valid for the duration of the consent declaration and remain a reporting requirement of the Annual Reviews. In this context, please note the following points that should also be addressed/progressed, with updates provided in the Annual Review: - The Applicant must ensure that the transparency measures and information provided to patients and the public remain up-to-date and fit for purpose, including the information provided on the National Self-Harm Registry website, social media, hospital sites, other third-party websites etc. - The Applicant should continue to engage with third parties on providing information about the Register on their respective websites. The Applicant should also expedite the discussions on providing information about the Register (e.g., information leaflets) directly to self-harm patients at an appropriate point in time. Where this is approved, such leaflets that may be provided to patients should include a link to the National Self-Harm Register website. - On the PPI panel, to ensure that the voices of those who have lived experienced self-harm can be heard, panel meetings should include at least one person who has such experience of self-harm or a family member. As part of the Annual Review, the Applicant is requested to provide information on the meetings and engagements that have occurred with this PPI panel, the numbers of panel members who attended such engagements and updates on how the feedback from the PPI engagement have been taken on board and implemented, where relevant.
HRCDC Recommendations:	**Recommendation.** The HRCDC recommends that the Applicant/data controller review the use and security of USB memory sticks in this study and explore alternative, more secure options for the sharing and transfer of data such as an encrypted platform. The Applicant is requested to report on this Recommendation as part of the Annual Review.

HRCDC
Health Research Consent
Declaration Committee

Reference ID:	19-023-AF1/AMD2
Lead Applicant:	Gerard Curley
Lead Data Controller:	Beaumont Hospital
Title:	*Old Title:* Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis. *New Title:* Inflammatory Responses to Critical Illness
Research Objective:	Please see HRCDC minutes of 2nd April 2020
Purpose of Amendment:	The amendment is requested for the addition of a new processor/collaborator in Canada who will process plasma samples and associated data on behalf of the data controller. The Canadian party will receive the pseudonymised sample code and the data controller will receive back data relating to immune dysfunction following exposure of endothelial and epithelial cells to plasma from patients with sepsis. The scope of the study has correspondingly expanded to include the examination of endothelial and epithelial cells – this was not outlined in the original HRCDC application.
HRCDC Comments:	The Chairperson introduced the amendment application, and the Secretariat informed the HRCDC of the scope of the amendment that was requested. The Chairperson requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a formal decision should be deferred pending receipt of further information. **Scope of the amendment** • The HRCDC discussed the scope of the amendment request and the nature of the changes made to the study. It was noted that the expanded research area and activities, and the transfer of data and associated samples to the data processor in Canada, applied only to prospective study participants i.e., the new activities and the transfer of data/samples to Canada would not be applicable to the participants who were already recruited to the study. • Based on the information provided in the amendment request form and supporting documentation, the HRCDC commented that the amendment relates not just to the addition of a new data processor, but that study is seeking to expand into an additional area and include a potentially new patient population. It was therefore queried if this is an expansion/extension of the current study, sub-study, or a new research study. Accordingly, the HRCDC discussed if a new HRCDC application form should be submitted for consideration, as opposed to an amendment request form. • The HRCDC determined that more information should be requested on the new research activities, by way of submission of the updated study protocol and to request the Applicant to outline if this new activity is a sub-study or an expansion of the existing research and to provide additional information on the patients who will be recruited.

Study Information Leaflets and Consent Forms

- The HRCDC discussed the latest versions of the study information leaflets and assent/consent forms that were submitted by the Applicant. It was noted that the latest versions included some new, tracked-changed information with regard the new data processor in Canada.
- However, the HRCDC also noted that some changes that were requested as a Condition and Recommendation attached to the original consent declaration decision and the first amendment (AMD1) had not been fully implemented; specifically, the term 'consent', rather than 'assent', was still incorrectly used throughout the information leaflet when referring to the next-of-kin. The HRCDC commented that this needed to be addressed by the Applicant.
- Further, while acknowledging that the study has been recruiting participants, given the changes to research, prospective participant recruitment and to ensure the information leaflets are clear and fit-for-purpose, the HRCDC was of the view that the study information leaflets and proxy assent/consent forms for the prospective participants should be reviewed and substantially revised by the Applicant/data controller.
- It was commented that the study information leaflets were quite technical in nature regarding the purpose and aims of the study and should be made easier to read for participants and/or the individuals providing proxy assent on their behalf. In this context, it was commented that more transparent and clearer information needed to be provided on the role of the data processors/collaborators in this study, including the new processor in Canada, what samples and associated data they will be receiving and for what purpose, as well as the benefits of including this processor and this new research activities. Information on how the data and samples are to be transferred/shipped should also be provided.
- It was also noted that the study documentation referenced that the results collected are in the 'ownership of Prof. Curley's lab group'. The HRCDC discussed that this is an unusual statement to include in the information leaflets as the data controller of the study is Beaumont Hospital and not an individual or team of researchers. It also remains that individuals have rights when it comes to their personal data and overall, this statement in the study document maybe therefore be confusing in the context of a participant's rights. It was also commented that careful consideration should be given to ensuring that the content of the documentation does not unintentionally pressurise or coerce participants or their next-of-kin to provide their consent or proxy assent.
- The HRCDC was of the view that the information on using the participant's data and samples for future research in the consent/assent documentation was not clear, and was potentially confusing. Under the 'consent to future uses' section, the study

	information leaflet references that biological material collected during this study will not be used in future research outside the scope of this study. However, the proxy assent/deferred consent forms provide a checklist with several 'yes/no' options presented for future contact, storage and future use of the data and samples. The Consent to Future Uses section also separately refers to the results being used to 'inform future research' and that results may be shared with commercial entities. • It was discussed that the Applicant should review and amend the information and options provided on potential future use of the personal/pseudonymised data and the associated samples. In this regard careful consideration should be given to providing clear and consistent information on what future research might be undertaken with the participant's personal/pseudonymised data (e.g., what areas of research) and what parties may be involved in such future research and receive personal/pseudonymised data on the participant. In addition, the Applicant should review the wording, and the number, of 'yes/no' options provided on potential future research; in general, the Applicant should ensure that that the individual is provided with clear information and options with regards to what they are being asked to provide consent for when it comes to processing personal data and samples for future research. Any permissions for future research and areas of research should be as clear as possible and also consent should be unbundled. • It was further commented that as proxy assent cannot cover the processing of data in future research, the Applicant should consider removing references to future research from the proxy documentation. • It was noted that the DPIA stated that the patient names infers gender, which the study wishes to collect in order to assess potential differences in the response to sepsis and sepsis treatment. The HRCDC discussed that name may not always infer gender but noted however that participant 'sex' alongside their name and age, where outlined as data variables to be collected in the HRCDC application and where already noted in the study information leaflets. It was commented that the Applicant must ensure it is applying the principle of data ministration to the demographic data to be collected and clearly outline in the study information leaflets what demographic variables will be collected for this study, including sex or gender. It was further noted that section on the demographic information to be collected does not outline that address is also captured; while address is referenced elsewhere, it was commented that the information to be collected, including demographic data, should be clearly outlined in a single section of the study information leaflet to avoid confusion. • The HRCDC was of the view that the study documentation needed to be revised and amended by the Applicant, with the revised versions submitted to the HRCDC prior to making a decision on this amendment request. The HRCDC was also of

	the view that the study documentation should be reviewed by an appropriate public and patient representative to ensure it is suitable for use. **Other** • It was noted that the latest version of the data protection impact assessment (DPIA) stated that the study will seek, *"explicit informed consent from individuals or next-of-kin, if necessary, for the processing of their data*" but elsewhere it stated that participants will be unable to provide consent given the nature of their condition. It was commented that this discrepancy should be highlighted to the Applicant. • The Applicant's documents also referenced that '*an individual may act on another's behalf to access data if they are a legally approved representative'*. The HRCDC queried if this was correct; it was commented that an individual may not have the right to access another person's data. • It was discussed that there is an adequacy agreement in place for Canada that applies to commercial organisations only. Accordingly, if this is not applicable than standard contractual clauses should be put in place.
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information.
Further Information Requested:	**Point 1.** The inclusion of the Canadian data processor and the subsequent changes to the scope of research activities are noted by the HRCDC. Notwithstanding this, the HRCDC requests further detailed information on this additional, new activity. Specifically: - The Applicant is requested to comment/provide information on whether this additional activity/scope as described in the HRCDC amendment form is a 'sub-study' to the protocol and research originally outlined to the HRCDC, or is an expansion of the original study. Please also comment on the cohort/category of patients who will be recruited as a result of this new research activity i.e., have the category or type of patients to be recruited changed from those outlined in the original application. - Please provide the updated protocol that fully detail these new research activities as well as the role of Canadian data processor. **Point 2.** Given the changes and expansion of the research activities to occur, the prospective participants to be recruited, and the importance of ensuring that the information leaflets are clear and fit-for-purpose, the HRCDC was of the view that the study information leaflets and proxy assent/consent forms for the prospective participants should be reviewed and more substantially revised by the Applicant/data controller. In this regard, the following observations have been made by the HRCDC and should be addressed: - the study information leaflets were deemed quite technical in nature, including on the purpose and aims of the study. Therefore, the content should be made easier to read for

	participants and/or the individuals providing proxy assent on their behalf. - more transparent and clearer information should be provided on the role of the data processors/collaborators in this study (including the new processor in Canada), what samples and associated data they will be receiving and for what purpose, as well as the benefits of including such processors. More information should also be provided on the new research activities to be undertaken. In addition, information on how the data and samples are to be transferred/shipped should be outlined. - changes that were requested as a Condition and Recommendation attached to the original consent declaration decision and the first amendment (AMD1) have not been fully implemented; specifically, the term 'consent', rather than 'assent', is still incorrectly used throughout the information leaflets for both the participant and the proxy, when referring to the next-of-kin providing permission on behalf of the participant who lacks decision-making capacity. This needs to be fully addressed by the Applicant across all study documentation i.e., the term 'proxy assent', not consent, should be used where referring to the permission provided by the next-of-kin. - The documentation references that the results collected are in the '*ownership of Prof. Curley's lab group'*. This is an unusual statement to include as the data controller of the study is Beaumont Hospital and not an individual or team of researchers. It also remains that individuals have rights when it comes to their personal data and this statement may be confusing in the context of a participant's rights. - Consideration should be given to ensuring that the content of the documentation does not unintentionally pressurise or coerce participants or their next-of-kin to provide their consent or proxy assent. - Participant address is to be collected but is not referenced in section in the study information leaflets that details the demographic information to be collected. Further the DPIA submitted, stated that name infers gender, however participant 'sex' is also noted in the information leaflet as data variable to be collected. The data variables to be collected, including demographic data, should be clearly outlined in a single section of the study information leaflet. Further the Applicant must ensure that is it is applying the principle of data ministration to the demographic data to be collected i.e., if the name is used to infer gender, is it necessary to collect participant 'sex' as a separate variable. (*Note: the HRCDC is of the view that participant name may not necessarily imply a person's gender).* - the information on future use of samples and associated data is not clear and is confusing, for example: o Under the 'consent to future uses' section, the information leaflet references that biological material collected during this

	study will not be used in future research outside the scope of this study. ○ However, the proxy assent/deferred consent forms provide a checklist with several 'yes/no' options presented for future contact, storage and future use of the data and samples. ○ The Consent to Future Uses section also separately refers to the results being used to 'inform future research' and that 'results' may be shared with commercial entities. It is not clear if this means that participant personal or pseudonymised/coded data will be shared for future research. The Applicant is requested to review and amend the information and options provided on the potential future use of the participant's personal/pseudonymised data and the associated samples. Careful consideration should be given to providing clear and consistent information on what future research might be undertaken with the participant's personal/pseudonymised data (e.g., what areas of research) and what parties may be involved in such future research and receive personal/pseudonymised data on the participant. The wording, and the number, of 'yes/no' options provided on potential future research should be reviewed and amended where required to ensure that individuals are clear with regards to what they are being asked. Permissions for future research and areas of research should be as clear as possible and unbundled. As proxy assent cannot cover the processing of data in future research the Applicant should also consider removing references to future research from the proxy documentation. When revised the study documentation should be reviewed by an appropriate PPI representative to ensure it is suitable. The Applicant is required to submit the revised study information leaflets and assent/consent forms to the HRCDC so that they may be reviewed by the HRCDC prior to making its decision.
HRCDC Comments	The DPIA states the following: (i) the study will seek, "explicit informed consent from individuals or next-of-kin, if necessary, for the processing of their data" however elsewhere it states that participants will be unable to provide consent given the nature of their condition and (ii) 'an individual may act on another's behalf to access data if they are a legally approved representative' The Applicant is requested to review and amend these statements, where necessary. On point (i) consent cannot be obtained from those who lack decision-making capacity or from a proxy. On point (ii), the Applicant is asked to consider the accuracy of whether an individual does have the right to access another person's data.

8. Annual Reviews

The Secretariat has received 9 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID: 19-019-AF2** (*Prof Fergus McCarthy; IMPROvED Study)*
- **Ref ID: 19-022-AF2** *(Prof Rose Ann Kenny; TILDA study)*
- **Ref ID: 19-027-AF3** (*Prof Sharon Glynn; Identification of predictive and prognostic biomarkers in triple negative breast cancer*)
- **Ref ID: 20-005-AF1/COV** *(Prof Paddy Mallon; All Ireland Infectious Disease Cohort Study)*
- **Ref ID: 20-006-AF1/COV** (*Prof Gerard Curley; A randomized double-blind placebo-controlled trial of intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness*)
- **Ref ID: 20-008-AF1/COV** (*Dr Ana Rakovac; Clinical, laboratory and radiological characteristics as predictors of outcome in patients with COVID-19*)
- **Ref ID: 20-022-AF1** (*Prof Alistair Nichol; Clinical evaluation of a POC assay to identify phenotypes in the Acute Respiratory Distress Syndrome - PHIND Study***)**
- **Ref ID: 21-002-AF1** (*Prof Alistair Nichol, Mega-ROX)*
- **Ref ID: 22-001-AF1/CSO** (*Prof Patricia Fitzpatrick; Study of the impact of lifestyle factors on COVID-19 outcomes*)

The Secretariat informed the HRCDC that a consent declaration is no longer required for 20-008-AF1/COV and that the personal data of those who lack decision-making capacity, who were covered by the declaration, have been deleted by the data controller.

An update was provided on 19-019-AF2 regarding the potential anonymisation of the data. It was noted to the HRCDC that the Secretariat has requested the Applicant to confirm if an amendment request is or is not required for this activity.

9. Activities report and events of interest.

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

- *News:* Health Information and Patient Safety Bill general scheme approved by cabinet: https://www.gov.ie/en/press-release/13b1f-minister-donnelly-receives-cabinet-approval-for-the-general-scheme-of-a-health-information-bill/
- *New publication*: Health Research Charities Ireland 'More than publications: Maximising societal benefit from health research November 2022'. https://hrci.ie/more-than-publications-maximising-societal-benefit-from-health-research/
- *Event*: Irish Health Research Forum: 09:30 - 13:00, Thursday, 11th May 2023 In person event 'Research Ethics in Ireland: How do we strengthen and harmonise the system?', The Ashling Hotel: https://www.eventbrite.ie/e/research-ethics-in-ireland-how-do-we-strengthen-and-harmonise-the-system-registration-607300802047
- The Secretariat provided a summary of the IPPOSI event it attended on 'Sharing Health Data' that occurred on Wednesday 3rd May.

10. Any Other Business

- **HRCDC website:** The Secretariat informed the HRCDC that a key work package this year is a review and update of the HRCDC's website. In advance of this work the Secretariat asked the Committee for their high-level suggestions/comments on the website, including on what improvements or changes they would like to see.

- **Assisted Decision-Making Act:** The Secretariat provided an update to the HRCDC on the engagements it has had with stakeholders regarding the interplay between the Health Research Regulations 2018 and the Assisted Decision-Making Act, including initial discussions with the Department of Health. The Secretariat informed the HRCDC that it is currently awaiting on formal written information from the Department on this matter. The Chairperson discussed that the topic will be tabled again at a future HRCDC meeting.
- **HRCDC Membership:** The Chairperson informed the HRCDC that Claire Collins has stepped down as a committee member. The Chairperson and the HRCDC acknowledged and thanked Claire for the time, dedication and expertise she brought to the Committee. The Chairperson informed the HRCDC that a process is underway to identify and recruit some additional members to the Committee.
- **Non-responding applications:** The Secretariat updated the HRCDC on the actions that have been taken for non-responding applications that remain queued for HRCDC consideration. It was highlighted that there is one new application and two amendment requests that are dormant. The Secretariat has contacted these Applicants and if no response is provided then they will be deemed withdrawn as per the HRCDC's standard operating procedures.
- **Reminder:** The Chairperson reminded the committee to please complete the Disclosure of Interest and Decision Time Policy sent by the Secretariat. The Committee were also asked if they have any suggestions for future topics of interest for presentations, and to forward these to the Secretariat.
- The Secretariat asked the members present to leave their iPad and informed them that new updates and/or devices may need to be issued to ensure continued data security.

11. Presentation

A presentation was delivered by Dr Emily Vereker, Head of the Office for National Research Ethics Committees.

****The Chairperson closed the meeting****