HRCDC
Health Research Consent Declaration Committee

Date: 18th May 2021
Location: Videoconference by Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Alyson Bailey
Kevin Clarke
Aideen Hartney
Claire Colins
Evelyn Mahon
Zubair Kabir
Dan Rea
Barry O'Sullivan
Simon Furney (part attendance)
Sheelah Connolly
Cornelius Cooney
Mary Tumelty
Barry Lyons
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions ☒YES

Returning Applications – For Consideration

Applicant	Ref No.	Title
Tom Rogers	21-003-AF1	Investigating the Epidemiology of *Mycobacterium bovis* Infection in Humans
Alistair Nichol	21-004-AF1	AP-recAP-AKI-03-01 (REVIVAL Study)

New Applications - For Consideration

Applicant	Ref No.	Title
Alistair Nichol	21-007-AF1/COV	Irish National Pandemic Biological Samples in Critical Ill COVID-19
Akke Vellinga	21-005-AF1	Collaboration to reduce Antimicrobial use and Resistance and identify opportunities for improvement and Awareness (CARA Study)
Deirdre Murray	19-020-AF2	BASELINE Study ***(APPLICATION DEFERRED TO THE NEXT HRCDC MEETING - DUE TO TIME CONSTRAINTS)***

Meeting Items

1. **Opening**
   The Chair opened the meeting and welcomed the members.
   The Chair congratulated Barry O'Sullivan on his appointment as Chair of the National Research Ethics Committee (NREC) for Medical Devices.

2. **Apologies**
   Kathy Brickell, John Ferguson and John Woods.
   Simon Furney was absent for the last part of the meeting when application 21-005-AF1 was considered.

3. **Disclosure of Interest**
   Claire Colins (CC) declared her interest in one application, 21-005-AF1 'CARA Study'; CC was absent for this part of the meeting.

4. **Minutes of the last meeting**
   Draft minutes of the 13th April 2021 meeting were circulated in advance of the meeting and were agreed by the HRCDC.

5. **General administration matters**
   - Application 20-027-AF1 '*Immune Dysfunction in Acute Brain Injury'*: the HRCDC were informed that a response is now overdue regarding Condition 1 attached to the consent declaration made for this study. It was noted that the Secretariat has sent reminders to the Applicant that a response remains pending. It was agreed that the Chair of the HRCDC would correspond directly with the Applicant on behalf of the HRCDC requesting an update on the progress of this Condition in advance of the next HRCDC meeting.
   - Application 19-027-AF3 *'Identification of predictive and prognostic biomarkers in triple negative breast cancer':* the HRCDC were informed that Condition 4 attached to the consent declaration made for this study, has not been met in advance of the required deadline. It was agreed that the Chair of the HRCDC would correspond directly with the Applicants on behalf of the HRCDC requesting that this Condition is fulfilled, or a substantive response is received, in advance of the next HRCDC meeting.
   - Application 19-085-AF1 *'Blood Biomarkers to Predict Recovery from Ischaemic Stroke'*: the HRCDC was informed of a clerical error noted in the HRCDC meeting minutes of 2nd March 2020 and the Applicant's decision letter. The Secretariat noted that the minutes and decision letter have been corrected and that the Applicant has been informed of this.
   - The Chair informed the Committee that for the purpose of facilitating the Committee's review of new applications, the Secretariat highlighted its observations in the validation sheet regarding potential technical and more standard safeguards for Committee consideration.

6. **Returning Applications**

Reference ID:	21-003-AF1
Lead Applicant:	Tom Rogers

Lead Data Controller:	St. James's Hospital, Dublin
Title:	Investigating the Epidemiology of *Mycobacterium bovis* Infection in Humans
Research Objective:	See HRCDC meeting minutes of 13th April 2021.
Reason for Declaration:	See HRCDC meeting minutes of 13th April 2021.
HRCDC Comments:	The Chair introduced the agenda item and reminded the members of the additional information that was requested from the Applicant. The Chair referred to the discussion on this application at the previous meeting and summarised the outstanding matters and the responses provided by the Applicant. The consensus of the HRCDC was that a Conditional Consent Declaration should be made. The decision was based on the following discussion points: **Public Interest** • To determine the significance of the public interest case for this study, the HRCDC discussed the Applicant's response outlining how the study design and the use of the data available and collected through this process, would sufficiently address the research questions. • It was noted from the Applicant's response that most of the data required for this study is likely to be recorded in the patient's medical chart if they have been reviewed by the Tuberculosis team at St. James's Hospital (SJH). This data would include occupation which is considered an important disease risk factor. The Applicant also explained why other data variables where required for the purpose of this study. Furthermore, the Applicant outlined how reviewing the patient's charts combined with whole genome sequencing of the bacterial isolates, will enable the study to assess the history and development of a patient's infection and identify evidence as to whether a patient's infection corresponds with any potential transmission patterns. It was also noted that the data to be collected closely resembles the data collected in other similar epidemiology studies from other countries, allowing the Applicant to compare Irish and International findings. • The HRCDC acknowledged that the responses satisfactorily provided further detail and clarity to further understand how the study design will address the research question and thus help determine the significance of the public interest case. Based on the responses from the Applicant, the HRCDC was of the view that the study has a strong degree of public interest. **Consent and Transparency** • The HRCDC noted the Applicant's response that participants would not have provided consent for the use of their bio-samples or data at the time the bio-sample was collected for their care and treatment. • The Applicant's response on what further transparency measures could be implemented, beyond a privacy notice of the SJH website, was also discussed. It was noted that study information notices will be placed in relevant clinics at SJH and that the Applicant has

	contacted the Irish Thoracic Society and Irish Lung Foundation about advertising the study on its respective websites. It was commented that this notice could benefit from the inclusion of a statement that if a participant does not contact the study team that their personal data will be processed for this study. • The HRCDC discussed that the additional measures outlined by the Applicant will help to strengthen the level of transparency and awareness of the study. **Data Sources** • From the Applicant's responses it was clarified that data is collected for all participants from the laboratory's 'Telepath' records system. Data from the SJH patient chart is only collected from those participants who attended SJH for their *M. bovis* infection, therefore patient records from other hospitals are not reviewed as part of this study. • In addition, it was noted that the Applicant had clarified that there are no plans to extend the study to other sites outside of SJH.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 18th May 2021 and is valid until 31st May 2023 when the data will be irrevocably anonymised, or until the personal data has been destroyed, whichever occurs sooner.
Conditions Attached:	**Condition 1.** Provisional Research Ethics Committee approval is currently in place. Confirmation of full research ethics approval from St. James's Hospital must be provided to the HRCDC, once granted. The conditional declaration shall not be effective until this condition is met. **Condition 2**The Applicant must implement the enhanced transparency measures as outlined in the responses to the HRCDC, to inform patients and public about the study, the use of their personal data and their data protection rights and how they can exercise these rights. Specifically, the Applicant must provide suitable study information notices in the St. James's Hospital clinics. The Applicant should also continue to engage with third parties regarding the potential to advertise the study on their respective websites. Information on how this condition is being implemented is a reporting requirement of the Annual Review
HRCDC Recommendations:	**Recommendation**: For the purpose of clarity, the Applicant is asked to consider amending the public information notice to state that if a participant does not contact the study team it is assumed they are satisfied to have their personal data and bio-samples processed for the purpose of this study.

Reference ID:	21-004-AF1
Lead Applicant:	Alistair Nichol
Lead Data Controller:	AM-Pharma B.V.
Title:	AP-recAP-AKI-03-01 (REVIVAL Study)
Research Objective:	See HRCDC minutes of 13th April 2021

Reason for Declaration:	See HRCDC minutes of 13th April 2021
HRCDC Comments:	The Chair introduced the agenda item and reminded members of the additional information that was requested from the Applicant. The Chair referred to discussion on this application at the previous meeting and summarised the outstanding matters and the responses provided by the Applicant. The consensus of the HRCDC was that a Conditional Consent Declaration should be made. The decision was based on the following discussion points: **Public Interest** • While the Applicant's responses could have been more robust, the HRCDC was of the view that there is a strong public interest in this clinical trial. Notwithstanding this, issues relating to data security safeguards and other matters need to be enhanced by the Applicant. **International Data Controller** • The HRCDC discussed the Applicant's response as to how AM-Pharma, an international data controller, can ensure compliance with the consent declaration. • It was noted from the Applicant responses that appropriate measures to ensure that Irish participants and those providing assent are informed of their rights and have the means to exercise these rights. These rights are set out in the site-specific study information leaflets. The Applicant confirmed that information regarding the Sponsor's and the hospital's data protection officers, including details of the study's Principal Investigator and a complaints pathway, will be provided. The Applicant further stated that this information can ensure that the Irish sites can support the consent declaration made to the data controller. Reference was also made by the Applicant that these measures reflect the parties' respective legal obligations. • The HRCDC reiterated that the data controller and the parties involved in the study must adhere to and comply with Irish data protection legislation, including the Health Research Regulations and the consent declaration and ensure the data protection rights of participants in Ireland must be upheld. The HRCDC was of the view that the requirement to comply with Irish data protection law must also be clearly reflected in all proxy and participant facing documents. **Data Transfer** • The HRCDC acknowledged the important role the home visits by the Illingworth nurses have within this study. However, based on Applicant's responses, the HRCDC was of the view that the concerns relating to the secure transfer of identifiable and pseudonymised data, to and from the Illingworth Research Group have not been adequately addressed.

	• Specifically, as this is a multi-site clinical trial involving a large volume of personal data, the HRCDC remained concerned that the transfer of data by email may not sufficiently protect the security of the data. It was commented that the use of email, as well as OneDrive, would not be considered good practice and therefore alternative arrangements should be sought for transferring study data electronically between parties. Based on the information provided, the HRCDC also queried if it was necessary to provide both an electronic scan and the paper record of the off-site visit data to the Irish hospital site. • It was also commented that only the minimal amount of data required for the study should be transferred to third parties involved in the trial with the appropriate agreements and terms and conditions also in place governing the transfer and use of the data. **Remote access to data for monitoring** • The HRCDC noted the Applicant's response that remote access to the participant's medical records for the purpose of monitoring the study and data verification maybe undertaken where certain criteria are met, where the hospital site has such capabilities and if such access is allowed in agreement with the site. • It was noted that remote access will only be conducted by employees of Covance, the clinical research organisation, or by regulators. If additional personnel are required to attend, then this would be done in accordance with agreement from the site. Information provided by the Applicant on the security measures in place to ensure secure remote access to records was also noted by the HRCDC. • The HRCDC discussed whether it was appropriate to allow remote access to records for monitoring and data verification. It was noted that remote access for clinical trials has likely increased due to COVID-19. Furthermore, while it was discussed that not every country allows remote access, the Health Products Regulatory Authority (HPRA) has recently provided guidance on this matter[1]. • The HRCDC was of the view that remote access for monitoring and data verification should only be undertaken under exceptional circumstances, where it is necessary to do so and where on-site visits are not possible. **Public and Patient Involvement (PPI)** • The HRCDC discussed the Applicant's response with regards PPI activity. Although the Applicant acknowledged the importance of PPI, reasons why it was not considered appropriate to involve members of the public in the development of this research where noted. However, the Applicant stated that the study can be discussed at the next Clinical Trial's Network PPI meeting. It was further stated that

[1] http://www.hpra.ie/homepage/medicines/regulatory-information/clinical-trials/covid-19-(coronavirus)-and-cts/guidance-on-the-management-of-clinical-trials-during-covid-19

	the Sponsor, AM-Pharma will look into enhancing PPI in other countries. • The HRCDC were of the view that further information on PPI activities could have been provided but acknowledged that in the context of a regulated clinical trial it may not be appropriate to undertake PPI with regards the study's design and development. **Information leaflets and consent/assent forms** • The HRCDC discussed the Applicant's response regarding the study information leaflets. • While references to future research were removed, the HRCDC discussed that the Applicant did not appear to take on board the points raised by the HRCDC as to whether the responsibility and expectations placed on the assenting individual's role in the study are appropriate in an Irish context. It was noted that the Applicant had stated that the information leaflet is an accurate representation of the information that needs to be provided to the poxy in order for them to provide informed assent for data collection and processing. • The HRCDC noted the Applicant's response that the technical information provided to proxy individuals and participants has been simplified where possible but that further measures to simplify will be considered in the next document update. The HRCDC commented that the information leaflets remained overly technical in nature and should be simplified as appropriate and as soon as possible. • In addition, the HRCDC noted that the proxy information leaflet stated that by providing assent for the individual to take part in this clinical trial, that the participant's rights to any commercial value resulting from their bio-samples and data, are waived. The HRCDC commented that statements stating that the participant's rights can be waived by proxy assent are not appropriate and therefore should not be set out in the information leaflet. • The HRCDC was also highlighted that the study information leaflet provides inconsistent information about the retention of the bio-samples and personal data, outlining that they will be discarded after the results are obtained, stored for 5 years or stored for 15 years. • Furthermore, the HRCDC was of the view that specific details should be provided on where the bio-samples and data may be transferred to for the purpose of the study. It was discussed that it should be possible to provide this information as this is a regulated clinical trial. **Consent** • The HRCDC discussed the Applicant's response that only members of the hospital study team will be able to consent participants and therefore Illingworth nurses will not obtain consent at the off-site study visits if the participant has regained decision making capacity. • The HRCDC commented that a patient discharged from hospital after a critical illness may still continue to lack decision-making capacity for a prolonged period of time. Notwithstanding this, the HRCDC was of the view that there may be opportunities to determine if a participant has regained decision-making capacity and

	correspondingly to obtain deferred consent or reaffirm proxy assent for data processing. **Research Ethics Approval** • It was noted that provisional REC approval has been granted for this study. Confirmation of full REC approval will be required.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 18th May 2021 and is valid until explicit consent is obtained or until 31st March 2024 and for 15 years thereafter (until March 2039), or until the personal data has been destroyed or rendered irrevocably anonymised, whichever is sooner.
Conditions Attached:	**Condition 1.** - The means by which data is transferred electronically by email and/or OneDrive, to and from the Illingworth Research Group and the Irish hospital sites for the purpose of the off-site home visits, significantly fall short of the standards required for robust cybersecurity. - Until such time more robust cybersecure methods are employed, the transfer of all identifiable and pseudonymised data must be limited to physical means, including via courier or recorded delivery as described by the Applicant. - For the avoidance of doubt, the transfer of identifiable and pseudonymised data by email and OneDrive must not be carried out. - Should the Applicant subsequently devise and implement an alternative, more secure approach to electronically transferring identifiable and pseudonymised data, between Illingworth and the Irish hospital sites, (i) the HRCDC must be notified and (ii) an updated DPIA and DPO feedback must accompany this notification. It is strongly advised to discuss this matter with the relevant data protection officers. **Condition 2.** It is a condition of the consent declaration that remote (off site) access to Irish participant's medical charts and other documents such as the assent/consent forms, for monitoring and data verification purposes shall not be undertaken, unless in very exceptional circumstances. Remote access should only be permitted under extenuating circumstances, where on-site visits cannot be undertaken. Where remote access for monitoring and data verification purposes must be carried out, it should be aligned with the guidance issued by the Irish Health Products Regulatory Authority (HPRA) (http://www.hpra.ie/homepage/medicines/regulatory-information/clinical-trials/covid-19-(coronavirus)-and-cts/guidance-on-the-management-of-clinical-trials-during-covid-19) As part of the Annual Review the Applicant is required to report on the extent of remote access that has been undertaken with regards participants in Ireland, providing a clear rationale and justification for undertaking this activity.

Condition 3. Only the minimal amount of data required for the study should be transferred to third parties involved in the trial. In addition, appropriate agreements/arrangements, with terms and conditions governing the transfer and use of the data, must be in place between the parties prior to the transfer of any data. Confirmation that the required agreements are in place should be provided to the HRCDC as soon as possible.

Condition 4. Where a participant continues to lack decision-making capacity for a prolonged period of time and where proxy assent remains in place, the HRCDC request that the following actions should be taken as an additional safeguard:

(i) confirmation should be sought from the proxy who provided assent, that they wish for the participant's personal data to continue to be processed as part of this research study. Confirmation should be obtained at an appropriate stage of the study that does not cause undue distress or harm to the individuals concerned.

(ii) further to point (i), where participants have already been discharged from the hospital it should also be determined whether the participant has re-gained decision-making capacity and, where possible to do so, to obtain their deferred consent for data processing. This should be carried out prior to proxy assent being reaffirmed.

The Applicant must report on this as part of the Annual Review, including the number of participants where deferred consent has and has not been obtained.

Condition 5. Confirmation of full research ethics approval from St. Vincent's University Hospital must be provided to the HRCDC, once granted. The conditional declaration shall not come into until this condition is met.

Condition 6. The responses provided by Applicant regarding the information sheet are acknowledged by the HRCDC. The HRCDC requests that the study information leaflets, and assent/consent forms are further reviewed and amended to ensure clarity, transparency and consistency of information for participants and/or individuals providing assent and to ensure they are appropriate for an Irish context. In this context the following observations were made by the HRCDC and should be addressed prior to the commencement of the study:

(i) the information leaflets are overly technical and should be further reviewed for readability to avoid potential confusion where possible,

(ii) the information leaflets set out that the individual providing proxy assent has substantial responsibilities beyond assenting to the participant's inclusion in study and the processing of their data, such as informing the trial doctor about changes to the

	participant's health. These responsibilities and expectations placed on the proxy individual should be removed, where this is not considered appropriate, with due consideration given to what is appropriate in the context of an Irish clinical site involved in this trial. (iii) a proxy individual cannot waive a participant's rights, including rights to any commercial value that may arise from the use of their data and bio-samples. References to such waivers of rights in the proxy information leaflet and assent form should therefore be removed or revised for correctness, (iv) with regards the retention of the bio-samples and personal data, the study information leaflets are inconsistent, stating they are discarded after the results are obtained, stored for 5 years or stored for 15 years. These sections should be amended as appropriate, (v) as this is a regulated clinical trial, it should be feasible to provide specific details on where the bio-samples and data will be transferred to as part of this trial. Ambiguous statements regarding the transfer of data and bio-samples should be avoided, (vi) the statement '*If there is no known objection by your relative to be included'* should be reframed more positively to ask the proxy individual if they believe their relative would wish to participate in this study, (vii) as the data controller is located outside of Ireland, the study information leaflets should clearly reflect and communicate that data processing for the purpose of this study will comply with Irish data protection legislation and that the data protection rights of the study participants in Ireland will be upheld. The Applicant is requested to confirm that the points outlined above are addressed prior to the commencement of the study. Where the above observations cannot be addressed to meet this condition, please provide confirmation that the St. Vincent's University Hospital REC have approved the consent/assent forms for appropriateness for use at an Irish clinical trial site. **Condition 7**. As a reporting requirement of the Annual Review, the Applicant is requested to report on the PPI activities that will be carried out for this study, including the feedback received from the SVUH Clinical Trial Network PPI meeting and any outcomes from consultations with Sepsis groups in other countries.

7. New Applications

Reference ID:	21-007-AF1/COV
Lead Applicant:	Alistair Nichol
Lead Data Controller:	University College Dublin (UCD)
Title:	Irish National Pandemic Biological Samples in Critical Ill COVID-19 (INPBS-COIVD 19)

Research Objective:	Infectious disease is the single biggest cause of death worldwide. New infectious diseases such as COVID-19 require investigation to understand how the infections develops and how it effects patients. This study wishes to develop an understanding of disease processes, such that risk factors for severe illness can be identified and treatments can be developed. It is necessary to understand the infection characteristics associated with a severe infection, how the infection multiples in the patient and how the infection effects the patient. The study aims to understand how the patient responds to the infection and how quickly they mount this response. It hopes to better understand how antibiotics or other therapies work in this instance. It is necessary to understand how the disease is transmitted and the reasons or factors certain people are more prone to the infection.
Reason for Declaration:	A consent declaration is sought for the processing of personal data (accessing, collecting, pseudonymising, transfer, analysis etc) for the purpose of this study where participants lack decision-making capacity to provide consent. The declaration also covers the storage only of personal data for future, unspecified research studies but does not extend to the use or further processing of the personal data in other studies.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee (REC) for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a Conditional Consent Declaration should be made. **Public Interest** • The HRCDC was of the view that the study has a strong degree of public interest. **Scope of the declaration** • The HRCDC commented that the study's activities, and the consent declaration sought, appeared to be open-ended. Specifically, it was noted that the study may involve the future sharing of data and samples with collaborators, including collaborators in the UK and Australia, as well as providing anonymised data to data-sharing repositories. It was unclear the nature of the genetic analysis, if any, that maybe undertaken as part of this study. The HRCDC discussed that further information on collaborations, the type of data to be shared and processed, as well as genetic analysis, could have been provided by the Applicant.

	• It was also noted that the study protocol stated that data may be made available to clinicians in the treating hospital. The HRCDC queried if personal data would therefore be used by these clinicians for further research. • The Secretariat highlighted that from the information provided that the Applicant understood that the scope of the declaration, if made, would be limited to this specific study only. It was noted that research ethics committee (REC) approval currently does not cover collaborations with other institutions, only the research activities undertaken in Ireland. The HRCDC noted that an amendment to the REC approval will be sought should activities with collaborating institutions be undertaken. It was also noted that no whole genome sequencing or genetic variant analysis will be carried out, as confirmed by the Applicant. • The HRCDC discussed that a consent declaration can only cover activities covered by REC approval and therefore the scope of the declaration for this study will be limited to the data processing undertaken as approved by the REC. In addition, the consent declaration will not cover genetic analysis. • A request to amend the consent declaration to cover further data processing with collaborators, providing data to public repositories, or genetic analysis can be submitted by the Applicant for HRCDC consideration subject to REC approval. **Assent and Consent Process** • The HRCDC was of the view that the Applicant should seek to re-affirm proxy assent at an appropriate stage of the study should the participant continue to lack decision-making capacity for a prolonged period of time. • Where the participant has regained decision-making capacity, the HRCDC also stated that the Applicant should seek to obtain deferred consent, where appropriate and feasible. **Data Minimisation** • The HRCDC queried if the personal data, which will be obtained for 15 years after the study, could be anonymised sooner. **Withdrawal from the study** • The HRCDC noted from the information provided that the participant will be provided with options as to whether personal data and bio-samples maybe further used and anonymised, or destroyed/deleted if proxy assent is withdrawn and/or if deferred participant consent is not provided or withdrawn. • It was discussed that a consent declaration cannot be made to override the withdrawal of assent or consent. Therefore, if a participant or their proxy wishes for the personal data to be destroyed rather than anonymised, then a declaration cannot override this choice.

	• It was further discussed that the study information leaflet should make it clear what will happen to the personal data, as well as the stored bio-samples, if assent or consent is withdrawn. **Public and Patient Involvement (PPI)** • The HRCDC noted the Applicant's response that consultations on the assent/consent process and COVID-19 studies have been undertaken previously. In addition, it was noted that this specific study protocol is to be discussed at a future meeting of the Clinical Trials Network PPI group. • The HRCDC commented that the PPI activities undertaken to date appear to be more general and should be specifically carried out for this study to strengthen this activity. **Study information leaflets** • The HRCDC discussed the study information leaflets and assent/consent forms and noted some information was inconsistent, or areas that could be improved, to ensure clarity and consistency of information. • It was noted that the study information leaflets, and assent/consent forms, reference the use of data and bio-samples in future research. The HRCDC re-iterated that a consent declaration cannot cover the processing of data in future unknown research but can cover the storage of data for such purposes. The HRCDC also discussed that more information on the types of future research that maybe undertaken could be provided in the study information leaflet, however it was noted that it is up to the data controller to determine whether the consent obtained for future research purposes is compliant with the Health Research Regulations. • It was also noted that participants in this study maybe co-enrolled in other approved studies, including international trials. The HRCDC discussed that this could be highlighted in the study information leaflets. • The HRCDC was also of the view that more information with regards the potential transfer of data and samples to collaborators for the purpose of this study, including those outside of Ireland in the UK and Australia, should be outlined. In addition, it was discussed that more information on the type of genetic analysis should also be outlined in the study information leaflets, if it will be undertaken as part of this study, • Lastly, it was noted that the consent form states that bio-samples will be stored for 15 years for future research, while the assent forms state an indefinite duration. In addition, no duration for the storage of the data is provided. The HRCDC discussed that clear and consistent information on the storage of the bio-samples and data should be provided. **Other Bio-Sample collection** • The HRCDC noted that the study protocol document references other bio-samples such as urine, stool and cerebral spinal fluid. It

	was discussed that these bio-samples were not noted in the HRCDC application form or study information leaflets, only blood samples were referenced. • The HRCDC discussed that the Applicant should be clear and consistent in the study protocol and information leaflets what bio-samples will be collected as part of this study. If certain types of bio-samples are not collected, then they should not be referenced. **Other** • The HRCDC noted from the study protocol that, where required, a translator maybe involved in the consent process. The HRCDC was of the view that where a translator is a witness for consent, the participant or proxy individual must sign the consent or assent form themselves. This should not be done by the translator on behalf of the participant or proxy, as is inferred in the protocol. • It was noted that the contractual agreement between UCD and St. Vincent's University Hospital is in progress. The HRCDC discussed that the required agreements/arrangements must in place prior to the transfer of data and bio-samples. • The HRCDC discussed the Applicant's request for a consent declaration until the end of the pandemic and an additional 15 years. The HRCDC was of the view that a declaration can be made for an initial 15-year period, with the Applicant invited to submit an amendment if they wish to extend this duration. • 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.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 18th May 2021 and is valid for 15 years until 31st May 2036, or until participant explicit consent has been obtained or the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner. The Applicant may submit an amendment request for HRCDC consideration, to extend the duration of the consent declaration.
Conditions Attached:	**Condition 1.** It is a condition of the consent declaration that the scope of data processing is limited to the data processing activities as approved by the Research Ethics Committee and as described in the HRCDC application form, specifically involving St. Vincent's University Hospital and University College Dublin. For the avoidance of doubt, the consent declaration does not cover: (i) the unspecified future data processing such as pseudonymisation or anonymisation of data for sharing analysis with other collaborators, (ii) genetic analysis and providing data in an anonymised format in data-sharing repositories, (iii) the processing of data in other, separate future research studies beyond the INPBS-COIVD 19 study.

	Condition 2. Where a participant continues to lack decision making capacity for a prolonged period of time and where proxy assent remains in place, the HRCDC request that the Applicant should seek confirmation from the individual who provided proxy assent, that they wish for the participant's personal data to continue to be processed as part of this research study. Confirmation should be obtained at an appropriate stage of the study that does not cause undue distress or harm to the individuals concerned. The Applicant must report on this condition as part of the Annual Review, including the number of participants where deferred consent has and has not been obtained. **Condition 3.** It is a condition of the consent declaration that no transfer of personal data and associated bio-samples can take place until the required contractual agreement is in place between UCD and St. Vincent's University Hospital. Correspondingly, the agreement in place should include appropriate terms and conditions regarding the transfer and processing of data, as well as bio-samples. Confirmation that this agreement is in place should be provided to the HRCDC as soon as possible. **Condition 4.** The Applicant is requested to further strengthen public and patient involvement by ensuring the Clinical Trials Network PPI group are involved in this specific study throughout the lifetime of the study. This is a reporting requirement of the Annual Review. **Condition 5.** It is a condition of this declaration that where a Translator is involved in the assent/consent process that may act as a witness to the consent/assent protocol, that they *do not* sign on behalf of the participant. Only the proxy individual providing assent, or individual consenting should sign, otherwise the consent/assent protocol maybe compromised.
HRCDC Recommendations:	**Recommendation 1.** In line with the principle of data minimisation, the HRCDC recommends that the Applicant considers if the 15-year period for retaining personal data can be reduced (i.e can the personal data be anonymised or destroyed sooner). **Recommendation 2.** The HRCDC recommends that the study information leaflets, and assent/consent forms are reviewed and amended to ensure clarity, transparency and consistency of information for participants and/or individuals providing assent prior to the commencement of the study. In this context the following observations were made by the HRCDC and should be addressed: (i) The statement '*If there is no known objection by your relative to be included*' should be reframed more positively to ask the proxy individual if they believe their relative would wish to participate in this study, (ii) further information regarding potential collaborations with other institutions as part of the INPBS-COVID-19 study, including the proposed National COVID-19 Biobank, and those outside Ireland

	in the UK, such as Sprint-Sari UK, and Australia, should be provided where possible, (iii) if genetic analysis is undertaken as part of this study, clear information should be provided on the type of analysis that will occur, where possible. The applicant should avoid the use of general, ambiguous statements on the type of genetic analysis that maybe undertaken within this study, (iv) it should be highlighted that, participants in this study maybe also be co-enrolled in other approved studies, including interventional trials, (v) the consent forms state that samples will be stored for 15 years for future research, however the assent forms states that samples will be stored indefinitely. This inconstancy should be amended and a specific timeline for the retention of the personal data should also be provided, (vi) it should be clear to the participant and/or proxy individual what samples will be collected as part of this study. The HRCDC noted that other samples, such as urine, stool or cerebral spinal fluid, are detailed in the study protocol but are not mentioned in the study information leaflets, (vii) clear information should be set out with regards what options are available to the participant regarding their personal data and bio-samples if (i) assent is withdrawn or (ii) deferred consent is not provided or later withdrawn, (viii) there should be a clear 'yes' or 'no' option to consent/assent for the processing of data for the study, (ix) reference to the future use of data/samples in the proxy assent documents should be amended to reflect that this consent declaration is for the INPBS-COVID19 study only and does not extend to the processing of personal data in unknown, future research.

Reference ID:	21-005-AF1
Lead Applicant:	Dr Akke Vellinga
Lead Data Controller:	National University of Ireland Galway
Title:	Collaboration to reduce Antimicrobial use and Resistance and identify opportunities for improvement and Awareness (CARA Study)
Research Objective:	The CARA project aims to provide an infrastructure to visualise data in relation to the occurrence and spread of infections and antimicrobial resistance (AMR). HIPE data (Hospital Inpatient Enquiry) is collected by HIPE coders in every hospital in Ireland after which it is combined centrally. The HIPE data set includes demographic, clinical and administrative data of every patient who has been discharged from a hospital. The CARA project wants to use this data to provide visualisations, for instance graphs, which can be viewed by users, such as hospitals or researchers. By analysing and comparing data, it will be possible to identify factors and interventions that influence the spread of (hospital) infections and AMR. Not all the collected HIPE data is relevant for the project, and in general the HIPE data is

	considered anonymous. However, certain combinations of data from HIPE are considered pseudo-anonymous because together they contain more specific information on an individual. This is the reason why the Applicant is applying to the HRCDC for approval to use HIPE data for the CARA project. The Health Pricing Office (HPO), that collects and holds the HIPE data, have identified the request to include the hospital and admission & discharge date as falling under pseudonymised data, and request the approval of the HRCDC to allow these additional variables to be provided to CARA.
Reason for Declaration:	A declaration is being sought to obtain and store pseudonymised HIPE data from the Healthcare Pricing Office (HPO) for the purpose of this study. When obtained the data controller will aggregate and fully anonymise this data, and subsequently provide users (hospitals, researchers, public etc.) with access to this anonymised data, via the CARA data visualisation infrastructure.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee (REC) for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that that a Conditional Consent Declaration should be made. **Public Interest** • The HRCDC discussed the extent to which this study could practically impact the spread of infections and antimicrobial resistance and recognised some potential benefits. It was also noted that there were very low data protection risks and it was not feasible to obtain consent. On balance the HRCDC was of the view that the study was in the public interest. **Data Collection** • The HRCDC noted that the study aims to obtain a significant amount of pseudonymised HIPE data and queried if this could be further minimised. It was discussed if the exact dates of admission and discharge where required or if number of days in hospital would be sufficient. Similarly, the HRCDC queried why data on up to 23 diagnostic procedures and marital status where also required. • On the other hand, the HRCDC commented that the inclusion of these specific variables could provide important information and useful insights into the incidence of infections and antimicrobial resistance, such as with seasonal variations. However, it was agreed that the Applicant should nonetheless consider if the data can be minimised further.

	Withdrawal of data • The HRCDC noted from the information provided, that it was not clear how individuals, whose data is being obtained from the HIPE database, could exercise their data protection rights such as withdrawing from the study. It was noted that the HPO has a procedure to allow participants to withdraw, however, the information provided also states that the HPO are restricted in their ability to take direct action in relation to some participant rights. • The HRCDC was of the view that transparency measures should provide clear and consistent information outlining whether participants can exercise their data protection rights, how this can be achieved, including the right to withdraw from the study and have their data deleted. In addition, any restrictions to these rights should also be very clearly outlined. **Other** • The HRCDC noted the Applicant's response regarding the transparency measures that will be implemented, including via the CARA website. • It was agreed that as part of the Annual Review, the Applicant should report on the progress and details of public and patient involvement, as described in the application form and supporting documentation. • In line with the data protection officer feedback, it was also noted that an appropriate agreement should be in place between NUIG and the HPO regarding the sharing of the HIPE data. The HRCDC also noted the reference to the potential use of other datasets. It was re-iterated that the declaration can only covers the HIPE data obtained from the HPO and no other data sources. Furthermore, the data to be provided to users of the via the CARA data visualisation infrastructure, must be fully anonymised. • 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.
HRCDC Decision:	The consensus of the HRCDC was that that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 18th May 2021 and is valid 5 years for duration of the study, until 31st May 2026, or until the personal data has been irrevocably anonymised or destroyed, whichever is sooner.
Conditions Attached:	**Condition 1.** It is a condition of the consent declaration that the scope of the declaration covers the processing of the HIPE data only and does not cover the processing of data from other sources. In addition, the data provided to users via the CARA data visualisation infrastructure must be fully anonymised. ***Note*:** a consent declaration cannot cover the sharing and/or processing of personal data, including the sharing and processing of pseudonymised data, for future unknown research studies. It is

	therefore important that the data is fully anonymised when provided to users on the CARA infrastructure. **Condition 2**. It is a condition of the consent declaration that no access to and obtaining of data can take place until the required contractual agreement is in place between the Hospital Pricing Office and National University of Ireland Galway. The agreement in place should include appropriate terms and conditions regarding the transfer and processing of data. Confirmation that this agreement is in place should be provided to the HRCDC as soon as possible. **Condition 3.** As part of the Annual Review, the Applicant is requested to report on the public and patient involvement (PPI) activity that has been undertaken for this study. This includes the PPI activities outlined by the Applicant in the HRCDC application form.
HRCDC Recommendations:	**Recommendation 1.** The HRCDC acknowledges the Applicant's response with regards data minimisation. Considering the scale and extent of the data to be collected, the Applicant is requested to consider what data is essential for this study and if the data being obtained can be further minimised. For example, it should be considered whether marital status and exact dates of hospital stay are required. The Applicant is requested to report on what additional data minimisation has be undertaken as part of the Annual Review. **Recommendation 2.** The HRCDC recommends that clear and accurate information is transparently and publicly available regarding the existence of the study, the use of HIPE data for the study and information on data protection rights as appropriate.

8. **Annual Reviews of Declarations**
The Secretariat received 4 Annual Reviews in advance of the meeting all of which were deemed to be satisfactory:
   - 19-023-AF2 (Effect of naïve and pre-activated MSCs on monocyte/ macrophage function in patients with pulmonary and non-pulmonary sepsis)
   - 19-073-AF3 (Cork Epilepsy Incidence Study)
   - 19-085-AF1 (Blood Biomarkers to Predict Recovery from Ischaemic Stroke)
   - 20-006-AF1/COV (A randomized controlled trial of intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness)

9. **Activities report and Upcoming events.**
Emily Vereker (EV) provided an overview of the Activities Report which was provided to the HRCDC. It was highlighted that the webinar series hosted by the Trinity Centre for Ageing and Intellectual Disability regarding amendments to the Health Research Regulations and the topic of consent, was very well attended. In advance of the meeting, the HRCDC were notified of 3 upcoming events:
   - Irish Health Research Forum's 'Advancing Genomics Research in Ireland, Part 2' (12th May 2021)

- ALLEA-EASAC-FEAM discussion event on International Health Data Transfers (3rd June 2021)
- National Neurogenomics Conference (11th June 2021).

10. Any Other Business

- The HRCDC was informed of the recent announcement from the Office of National Research Ethics Committee (NREC) with regards the appointment of new members to their committees (https://www.nrecoffice.ie/committees/nrec-ct/nrec-ct-b-members/)
- The HRCDC was informed that the Research Data Governance Board has convened for the first time where applications seeking approval to access the CSO's COVID-19 Data Research Hub, where considered. The HRCDC where reminded that applications for a consent declaration will also be required for these studies.
- The HRCDC were reminded that the next presentation as part of the HRCDC Speaker Series has been confirmed for 22nd June 2021, on the topic of biobanks.

*** The Chair closed the meeting***