HRCDC
Health Research Consent Declaration Committee

Time: **9:00am - 11:00am**
Date: **Wednesday, 6th May 2020**
Location: **Videoconference meeting**

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Kevin Clarke
Claire Collins
John Ferguson
Simon Furney
Aideen Hartney
Zubair Kabir
Barry O' Sullivan
Dan Rea
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)

Quorum for Decisions
☒YES

New Applications considered at this meeting:

Applicant	Ref No.	Title
John Laffey / Bairbre McNicholas	19-041-AF3/COV	The role of T-Regulatory and Mononuclear Phagocyte Cells causing Immune Dysfunction in Sepsis (A study on the role of immune dysfunction in sepsis and COVID-19)

Meeting Items

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

2. **Apologies**
   Malcolm Kell, Sheelah Connolly

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

4. **New Applications**

Reference ID:	19-041-AF3/COV
Lead Applicant:	John Laffey / Bairbre McNicholas

Lead Data Controller:	Saolta Hospital - Galway University Hospital
Title:	The role of T-Regulatory and Mononuclear Phagocyte Cells causing Immune Dysfunction in Sepsis (A study on the role of immune dysfunction in sepsis and COVID-19)
Research Objective:	This is a study on the role of the immune system in patients with sepsis and with COVID-19 pneumonia. People who get an infection that results in a condition called sepsis are at a high risk of death. It is believed that a defective response by the immune system to uncontrolled infection results in sepsis. The aim of this study is to determine changes in immune cells in response to sepsis and to gain a better understanding of how the immune system affects recovery following sepsis. The role of the immune system in causing kidney injury and loss of muscle mass following sepsis is also poorly understood and is another objective of this study. The study will be carried out by isolating immune cells and serum from patients with sepsis and acute kidney injury, as well as control cases that include healthy controls and other patients admitted to the ICU. Phenotypic, genetic and functional characterization will be undertaken to demonstrate distinct changes in these cells.
Reason for Declaration	A declaration is requested for this study where it is not possible to obtain informed consent from participants due to the nature of their illness, the risk of viral transmission, and/or because they lack decision-making capacity. The data processing activities within the scope of the requested declaration includes the collection, pseudonymisation and analysis of personal data and biosamples associated with personal data. In addition, the study will collect and analyse data on the long-term outcomes of the participants. The retention of personal data for future research is also within the scope of the declaration. The declaration will not extend to the further processing.
HRCDC Comments:	The Chair introduced the research study. The following points were highlighted to the HRCDC: • Based on the information provided in the application research ethics approval was granted before the Health Research Regulations came into effect (8th August 2018) and no consent had been obtained in line with previous data protection legislation. • Two application forms were provided to the HRCDC for consideration; (i) the Applicant's initial HRCDC application submitted July 2019 seeking a consent declaration for the main Sepsis study and (ii) the integrated HRCDC-National Research Ethics Committee (NREC) application that seeks an amendment to include COVID-19 participants in the main Sepsis study. • The scope of the declaration is for the processing of personal data for COVID-19 and non-COVID-19 participants; approval from the NREC on the amendment is currently pending. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application in detail, and based on the information provided by the

	Applicant, it was the consensus of the HRCDC that a consent declaration could be made: **Public Interest** • The HRCDC discussed the public interest case and commented that more information could have been provided by the Applicant regarding the additional scientific value for processing the personal data of COVID-19 participants. • The HRCDC discussed that the overall study proposal and design could have been more clearly outlined and some inconsistencies in the information provided were noted. • However, the HRCDC discussed that COVID-19 is a novel disease with limited research findings and that it would be beneficial to examine this disease in the context of this exploratory sepsis study. • On balance the HRCDC was of the view that the Applicant had made a sufficient public interest case and that there is a public interest in this study. **Deferred consent and assent protocol** • The HRCDC discussed the next-of-kin assent and deferred consent protocol that will be implemented. The Applicant referenced that the participant and/or next-of-kin will be informed of their inclusion in the study as soon as possible and provided with the option to withdraw. The HRCDC also discussed the Applicant's reference to a '*waiver of consent'* and commented that it was not clear what this was referring to. • The HRCDC re-emphasised that it is important that the next-of-kin and/or participant are asked clearly to provide assent or consent for data processing within this study, and not just informed that they have been included in the study and given the option to withdraw. • From the Applicant's response to the Secretariat queries, it was highlighted that assent from the next-of-kin will be requested in all circumstances. It was also highlighted that the HRCDC application form references that consent to continue in the study will be sought from the participant when they regain capacity. • Due to the risk of transmission posed by COVID-19 it was also discussed that verbal next-of-kin assent or verbal participant consent could be obtained. The Secretariat discussed that it is up to the data controller of the study to determine whether the protocol for obtaining verbal consent directly from the participant is sufficient to meet the standards of explicit consent. Informed verbal consent that was recorded could constitute valid explicit consent. • The HRCDC discussed that there may be a time delay before participant consent or next-of-kin assent could be obtained. In some scenarios it may be feasible to obtain consent or assent within 24-48hrs, but no later than 72hrs after participants have been enrolled into the study, depending on the critical care situation. In addition, explicit consent to continue in the study

	must be sought from the participant, either verbally or written, when they regain capacity. • The HRCDC also considered that it would be an appropriate safeguard to re-affirm next-of-kin assent in circumstances where the participants lack decision-making capacity for a prolonged period of time. **Use of Personal Data & Withdrawal of consent** • The HRCDC queried the extent to which the participant's personal data would be processed before next-of-kin assent or participant consent is obtained. • The HRCDC also discussed the Applicant's response to the Secretariat queries with regards to what happens the personal data if next-of-kin assent or participant consent is not provided or is later withdrawn. • It was discussed that although it may be appropriate to collect and store personal data for a period before seeking assent or consent, further data processing, including analysis, should not be undertaken until assent or consent has been obtained. The HRCDC was also of the view that the personal data which has been collected for the study should be deleted if next-of-kin assent/participant consent is not provided. • The HRCDC also commented that the study information leaflets do not provide information or options on what will happen the personal data if next-of-kin assent or participant consent is later withdrawn, or if deferred consent to continue in the study is not provided when the participant regains capacity. • It was considered that the study information leaflets, and consent forms should be amended to clearly inform participants and/or their next-of-kin about what will happen to the personal data in such circumstances. Furthermore, it was discussed that participants and/or their next-of-kin should be informed at what point in the study timeline when it may not be possible to delete the data that has been collected. **Study Information Leaflets and Consent Forms** • The HRCDC discussed other details outlined in the study information leaflets and consent forms. • It was highlighted that different versions of these documents have been provided. It was also not clear if specific versions of the information leaflets and consent forms were used to obtain either next-of-kin assent or participant consent from the COVID-19 or non-COVID-19 participant group. • The HRCDC was of the view that the information leaflets could provide additional clarity to participants and/or their next-of-kin on the scientific benefit of study, including the benefit of including COVID-19 patients in the study. • It was also discussed that the documents should accurately describe the data processing activities to be undertaken for each cohort, including the storage of personal data for future use. Although outside of data processing, the HRCDC also noted that

	other, non-blood samples maybe collected as part of this study but are not described in the information leaflets provided. • In addition, the HRCDC highlighted that one version of the next-of-kin information leaflet and assent form describes the study in the second person, i.e. referring to '*your data'* instead of '*your relative's data'* • Regarding the disclosure of data section in the information leaflets, the HRCDC queried what was meant by *'relevant industrial bodies'.* • The HRCDC was of the view that the study information leaflets and consent forms should be amended to ensure clarity and consistency of information for the participant and/or their next of kin on all activities being carried out, both data processing and samples being collected. • Furthermore, the HRCDC discussed that the relevant study information leaflet and consent or assent form should be provided to the participant or their next-of-kin at the time of consent/assent. It was also considered that where consent or assent is to be obtained verbally then an appropriate script that aligns with the study information leaflets and assent forms, could be used to ensure that individuals fully understand the study and use of personal data. • It was considered that the Applicant should revise study information leaflets and consent forms and provide to the HRCDC before they are used in the study. **Public and Patient Involvement (PPI)** • The HRCDC was of the view that although the study had undertaken some consultations with patients and their families, further public and patient involvement should be undertaken within this specific study. • The HRCDC considered suitable PPI groups that could be engaged included ICUSteps and the PPI Ignite group at the National University of Ireland, Galway (NUIG). **Other** • The HRCDC queried the exit strategy for this study as it was unclear. It was highlighted that where participants continue to lack decision making capacity that the data will be anonymised in 15 years by destroying the master list containing personal identifiers. • The Secretariat discussed that where next-of-kin assent has been obtained, the scope of the declaration will cover the ongoing storage of personal data for future research but will not extend to the processing, including transfer, of personally identifiable data for future, unknown and undefined research studies. The Secretariat highlighted that this has been communicated to the Applicant.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.

Duration of Declaration:	The Declaration is made commencing 6th May, 2020 and shall be valid until consent can be obtained from the participant or 15 years after the study concludes in August 2021 (31st August 2036), or upon confirmation that the personal data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	The following specific conditions have been attached to the Declaration as follows: **Condition 1: Consent/Assent** • The HRCDC has requested that where the participant lacks decision-making capacity, the next-of-kin/relative assent, must be sought and obtained as soon as possible and at maximum within 72hrs of the participant's enrolment into the study. • Where participant consent or next-of-kin/relative assent cannot be obtained in person due to the risk of transmission posed by COVID-19, then it should be obtained verbally in an appropriate manner, where possible, and within 72hrs of the participant's enrolment in the study. • Until consent/assent has been obtained, no personal data collected should be further processed and analysed. Where consent/assent for the processing of personal data is not provided then the participant's personal data that has been collected up to this point for the study must be deleted and not included in the study. • Where the participant regains capacity, consent to continue processing their personal data must be obtained. A clear process must also be put in place and communicated to the participant with regards to what happens their personal data if they do not wish to continue in the study (please see Condition 2 for more information). • The HRCDC has requested that, where a participant continues to lack capacity for a prolonged period of time and where the next-of-kin/relative assent remains in place, the following action should be taken as an additional safeguard: The Applicant should seek confirmation from the next-of-kin/relative 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 those individuals who have provided assent. • The Applicant must ensure that the relevant version of the study information leaflets, and consent/assent forms (i.e. COVID-19 or non-COVID-19 cohort), are used and provided to the participant or their next-of-kin/relative at the time of seeking either consent or assent. Where consent or assent is to be obtained verbally, an appropriate script that aligns with the study information leaflets and assent forms, should be considered for use, to ensure that individuals fully understand the study and use of personal data and that the information provided is consistent for all participants.

	The study must also ensure that verbal consent or assent is appropriately recorded to ensure consent is valid. **Condition 2: Information Leaflets and Consent/Assent Forms** The HRCDC requests the Applicant to review and amend accordingly, the study information leaflets and consent/assent forms to incorporate the following points for clarity and consistency of information; ***(The Data Protection Officer and Research Ethics committee should be consulted, as necessary***): • Provide additional clear information on the purpose and scientific benefit of this study for both COVID-19 and non-COVID-19 patients. • Ensure that the information provided to obtain participant consent or next-of-kin/relative assent, accurately outlines and reflects the data processing activities and biosample collection and analysis that will be undertaken, and is specific to the participant reviewing the information. ; this includes, where relevant, if genetic analysis of bio-samples is being carried out, and if follow-up personal data is being collected and processed. • Provide clear information on what will happen to the personal data and bio-samples collected for the study if the participant, once they regain capacity, does not provide consent to continue in the study or if consent or next-of-kin assent is withdrawn. Information leaflets should indicate the point in the study timeline where it is not possible to delete the data that has been collected (this process should be aligned with individual's data protection data rights to erasure, as outlined in GDPR) • Although the collection and retention of biosamples alone is not data processing and falls outside the Health Research Regulations, the study information leaflets and consent/assent forms should clearly outline what bio-samples are or will be collected and retained as part of this study, including any samples collected at follow-up clinic visits. • Ensure that the study information leaflet and consent/assent forms provide clear information and options with regards the storage and future use of personal data and the associated bio-samples collected. • Provide further clarity on the disclosure of personal data to third parties. Specifically, it is not clear what is meant by '*relevant industry bodies'* • Ensure that the correct perspective is used within these documents i.e. the next-of-kin assent forms should not refer '*my data*' or '*your data*' The Applicant is required to implement the above amendments and provide a copy of the updated information leaflets and consent forms to the HRCDC in advance of using them in the study.

	Condition 3: Appropriate agreements or contractual arrangements must be in place regarding the transfer of personal data and samples to and from collaborating sites. This includes the transfer from the Galway University Hospital site to the National University of Ireland, Galway (NUIG), including samples and associated data collected and transferred from the 6 & 12 month General Practitioner visits. (Note: it is noted that the Applicant highlights that NUIG will not receive personally identifiable data and samples. However appropriate material and data transfer agreements should be in place setting out terms and conditions of use, to ensure the anonymity of the participants is safeguarded). **Condition 4:** The HRCDC requests that the level of public and patient involvement (PPI) in the development of this study is enhanced to ensure knowledge in context and experience can be gained through direct engagement with the public and patients. Engagement with representative groups such as ICUsteps and the PPI Ignite group at the NUIG should be considered.

5. Any other Business

- The HRCDC were informed of a factual error in the minutes of the 17th October 2019 HRCDC Meeting. It was noted that this error was corrected, and the updated minutes are now on the HRCDC website.