HRCDC
Health Research Consent Declaration Committee

Date: 20th May 2020
Location: Videoconferencing

Minutes of the Meeting

HRCDC Attendance

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

Quorum for Decisions ☒YES

New Applications - For Consideration

Applicant	Ref No.	Title
Cliona Ni Cheallaigh	20-012-AF1/COV	COVID-19 Bioresource
Joe Eustace	20-013-Af1/COV	Public Health Emergency SOLIDARITY TRIAL

Live Declarations - For Information

Applicant	Ref No.	Title
Dr Bairbre McNicholas	19-041-AF3/COV	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**, Simon Furney

   (** MK submitted written comments for 20-012-AF1/COV which were considered at this meeting)

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

4. **Minutes of the last meeting**

Draft minutes of the 13th May 2020 meeting were circulated in advance of the meeting and were agreed by the HRCDC.

5. Matters Arising

The Chair raised the matter of the time taken in HRCDC meetings in relation to discussing the detail of the consent/assent forms and information leaflets, for the purpose of ensuring appropriate safeguards were in place for study participants. It was discussed that very detailed conditions and recommendations were being attached to some consent declarations in relation to the leaflet and forms. It was suggested that if significant issues noted, an option might be that a more general condition could be attached to the consent declaration. The condition could be to request the Applicant to consult with Patient and Public Involvement (PPI) groups and/or relevant advocacy groups regarding the development of these documents. This would be might be more appropriate in helping the Applicant and participants better in ensuring best practice is implemented.

6. New Applications

Reference ID:	20-012-AF1/COV
Lead Applicant:	Cliona Ni Cheallaigh
Lead Data Controller:	St. James' Hospital
Title:	COVD-19 Bioresource.
Research Objective	Principal Investigators at St James's Hospital who will require samples and data from COVID-19/ SARS-CoV-2 patients for research are collaborating on a single project entitled 'COVID-19 Bioresource'. This will involve a single sample and data collection point, with a single consent process linked to several project arms conducted by St James's Hospital investigators in collaboration with Trinity College Dublin. Given the importance of COVID-19 research, and the limited time/ cohort for sample collection, this project will also establish a biobank of samples and a data registry that will be available to other researchers in Trinity/SJH and other institutions. This study will involve sample collection (blood, urine, respiratory mucus) and data collection (relevant to COVID-19 exposure risk, infection, diagnosis and symptom severity).
Reason for Declaration	A consent declaration is being sought for the following data processing activities where participants are unable to provide consent due to lack of decision-making capacity: i) The collection of personal identifiable data solely for the purpose of linking to biosamples collection, where next-of-kin assent has been obtained. ii) The collection of personal data from participant medical records and transfer of coded data to a local study database, where next-of-kin assent has been obtained.
HRCDC Comments:	As previously discussed with the HRCDC (Meeting Minutes of 13.05.2020), the Chair noted the urgency of the application and deemed it appropriate to consider the application by written procedure, outside of the dedicated COVID-91 meetings. All members were asked by email correspondence to confirm if they were favourably disposed or not, to making a declaration, and to indicate any conditions or recommendations that should be considered. Given the need to discuss the application further due

	to HRCDC queries, a decision was made at this meeting rather than by written procedure. Based on the information provided by the Applicant, it is the consensus of the HRCDC that a conditional declaration should be made based on the following discussion points; **Public Interest:** • The HRCDC were of the view that the study of developing a bioresource for COVID-19 specific biosamples and data was in the public interest case due to the ongoing COVID-19 health emergency, and that the study was low-risk from a data protection perspective. • The HRCDC also noted the time sensitive nature of the study and why it was important to begin the collection of personal data and associated biosamples as soon as possible, until such time as the participant regains capacity to provide consent. **Consent/Assent process:** • It was commented that the consent and assent protocol has been carefully considered by the Applicant and provides flexibility with regards consenting or assenting to certain types of personal data collection. • It was commented that the Applicant should assure that there is no legally appointed representative/enduring power of attorney available, prior to seeking asset from the participants next-of-kin. • The appropriateness of using email to obtain consent was queried and whether this presented a security risk. However, it was considered a useful means to forward study information leaflets and consent/assent forms in light of infection risks posed by COVID-19. **Study Information Leaflet:** • It was the view that study information leaflets and consent and assent forms are clear and the inclusion of the patient withdrawal form was welcomed. • It was also noted that more clarity if possible, should be provided on what future research will be undertaken, including what kind of studies may be undertaken by third parties. **Public and Patient Involvement (PPI):** • The HRCDC noted the Applicant's response that a Patient representative shall be on the Steering Committee of the Bioresource and this was commended. • However, the HRCDC didn't accept the Applicant's view that PPI was not necessary at this stage of the study and considered PPI should be enhanced for the study and fully addressed as part of any future HRCDC application. **Biosamples and Personal Data**

	• Where the participant lacks decision-making capacity, it was not clear if personal data and/or biosamples has already been collected where next-of-kin assent has been obtained. • It was also not clear who will have access to the biosamples and associated personal data while it is stored, before the participants regain capacity to consent. • It was commented that when the participant regains capacity and wishes to withdraw from the study it is not clear what happens to the samples in such circumstances and the timeline for destroying the personal data and associated samples. **Other:** • Although not within the HRCDC's remit, it was commented that more clarity could have been provided on the study design: how control groups and follow up patients of 'symptomatic homes' (positive for COVID-19 but not hospitalised) are identified and the number of total participants. • The HRCDC noted that the Bioresource is collecting large data sets which should be minimised where possible eg avoid collecting date-of-birth.
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 20th May 2020 and shall be valid until such time the participants regain decision-making capacity to provide explicit consent.
Conditions Attached:	**Condition 1:** It is a condition of this declaration that data processing is strictly limited to the collection and storage only of; i) personal data related to biosample collection; and ii) all personal data uploaded onto the research study database, until such time until such time individuals regain capacity to consent. It must be explicitly clear on all records of data collected that further use is not permitted until explicit consent is sought. **Condition 2:** Other than those strictly permitted to manage the Bioresource, there should be no access and use by any party, including third parties, to personal data and associated biosamples until the participants regain capacity and provides their consent. **Condition 3:** A subsequent application or amendment as appropriate must be submitted to the HRCDC for any further processing of the personal data and associated biosamples collected for further research, where individuals do not regain capacity to consent. **Condition 4:** The HRCDC has noted and acknowledges that there will be a patient representative on the Steering group for the Bioresource. However, the level of public and patient involvement (PPI) in the development of this study should be 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* should be considered as

	should the dissemination of study findings with participants, their families and PPI groups. The Applicant should also be aware of the recent statement made by the Irish Platform for Patient Organisations, Science and Industry (IPPOSSI), setting out the importance of understanding the patient perspective during the COVID-19 pandemic. The Applicant is requested to report on efforts to enhance PPI as part of the Annual Review.
HRCDC Recommendations:	**Recommendation 1:** Where the participant regains capacity and wishes to withdraw from this study, the approximate timeframe for removing personal data and associated biosamples should be explicitly set out in information leaflets. **Recommendation 2:** The Applicant should always confirm if there is a legally authorised representative available, prior to seeking next-of kin or friend assent. **Recommendation 3:** The Applicant should consider the appropriateness of seeking consent or assent by email and any potential privacy issues. **Recommendation 4**: Given the large-scale collection of personal data for the COVID Bioresource overall, it is recommended to consider ensuring only as minimal data as possible is collected, such as, for example, record year of birth as opposed to date of birth. **Recommendation 5**: Given the scope of the COVID19 Bioresource and its purpose to facilitate research of such public importance, it is recommended that the Applicant enhance the transparency of the Bioresource and research projects it supports, for the general public and patients. This could be achieved through, for example, the use of public notices in hospitals and the development of a website where possible.

Reference ID:	20-013-AF1/COV
Lead Applicant:	Prof. Joe Eustace
Lead Data Controller:	University College Cork & Department of Health
Title:	WHO Solidarity Trial
Research Objective	Coronavirus disease 2019 (COVID-19) is a respiratory-like illness which was first identified in Wuhan, China in December 2019. It has quickly spread across the world and the World Health Organisation (WHO) declared it a pandemic in March 2020. COVID-19 is estimated to infect between 10-40% of the population and potential fatality for COVID-19 ranges from 1->3%. The first COVID-19 positive patients in Ireland were identified in March 2020. In early 2020, there were no approved anti-viral treatments for COVID, and WHO expert groups advised that four re-purposed drugs, Remdesivir, Lopinavir (given with Ritonavir, to slow hepatic degradation), Interferon (β1a), and chloroquine or hydroxychloroquine should be evaluated in an international randomised trial. SOLIDARITY is the WHO international

	randomised clinical trial of additional treatments for COVID-19 in hospitalised patients who are receiving the local standard of care. SOLIDARITY will test the effectiveness of the four re-purposed drugs mentioned above to treat COVID-19.
Reason for Declaration	A declaration is being sought for the purpose of processing (collecting, storing and pseudonymising, analysing, transferring, archiving) personal data of study participants who lack decision-making capacity.
HRCDC Comments:	The Chair introduced the research study and requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that a conditional declaration should be made; **Public Interest** • The HRCDC discussed and agreed that due to the nature of the clinical trial and research being carried out on a global scale to develop treatments for COVID19, and including Ireland's ability to participant, the study was of significant public interest. **Consent and Assent Protocols** • The HRCDC discussed the consent and assent forms and protocols being adapted from the WHO protocol. From the information provided, the practice of photographing and then destroying consent forms and leaflets was not considered practical and may lead to insufficient records of consent being obtained. • It was discussed that best practice should ensure that researchers, participants and those providing assent should have a copy of consent documentation and despite the contagious hospital environment due to coronavirus, it is feasible to achieve this. **Information leaflets and Consent forms** • The HRCDC discussed the content of the information leaflets and consent forms. It was noted that the same information leaflet and consent form would be provided to both participants and next-of-kin/individuals providing assent. The HRCDC discussed that separate, tailored information should be provided to participants who regain capacity and individuals providing assent. • Specific concerns were highlighted regarding the information which informed patients of the risks or side effects of the treatments being trialled. It was considered that individuals providing assent may need further clarity and guidance given the role and responsibility of those assenting on behalf of the participant. • The HRCDC noted from the information provided in both the application form and Data Protection Impact Assessment form that there appeared to be inconsistencies and lack of clarity as to what happens to personal data is a consent or assent if withdrawn from the study and the data retention period.

	Public and Patient Involvement (PPI) • The HRCDC noted that that Applicant has commenced engaging with the patient support group, ICUSteps. It was discussed that PPI for the study should be further enhanced and the study would benefit from having a public/patient representative on the Oversight Group for the clinical trial. • It was also noted that a communication strategy was being developed by the Oversight Group, which would further enhance transparency and visibility for both the public and patients involved. **Data Minimisation** • The HRCDC discussed the extent of data that would be uploaded to the WHO database as evidence of patient consent or legal representative assent. It was agreed that both the medical record number (MRN) and study ID should not both required, but only the study ID. **Other** • Given that this clinical trial and research study was large scale and multi-site, it was queried how a consistent standard of data protection safeguards and best practice could be guaranteed across all hospital sites involved in the clinical trial. • It was noted that the Privacy notice highlighting COVID19 research references the HRCDC as having role in permitting research to take place where consent can not be obtained. It was agreed that this statement should be amended to specify for 'data processing' for research.
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 20th May 2020 and shall be valid for 5 years after the study has been completed. If an extension the declaration is required, an amendment to the declaration should be submitted to the HRCDC for consideration
Conditions Attached:	**Condition 1. Public and Patient Involvement (PPI):** The HRCDC acknowledges that engagement with the patient support group *ICUsteps* has commenced. The Applicant is asked to further enhance the level of PPI in the development of this study. In particular, the HRCDC requests that a PPI representative is brought onto the Oversight Group to provide patient and public representation, if this representation is not already in place. Engagement with other representative groups where possible should be considered. Dissemination of study findings with participants, their families and PPI groups should also be carried out to strengthen patient and public engagement. The HRCDC notes the recent statement made by the Irish Platform for Patient Organisations, Science and Industry (IPPOSSI), setting out the importance of understanding the patient perspective during the

	COVID-19 pandemic. The Applicant is requested to report on efforts to enhance PPI as part of the Annual Review. **Condition 2**. **Data Minimisation:** The HRCDC requests that data minimisation safeguards are further enhanced by ensuring that only the Patient Study ID number is noted on Form A and not the Medical Record Number/hospital chart number. **Condition 3. Consent and Assent Protocols:** The HRCDC has requested that the Applicants review and amend specific consenting and assenting protocols as follows; <u>Assent:</u> - Separate study information leaflets and assent forms should be developed for those individuals who are providing assent by telephone. - To ensure the individual has time to reflect on the information verbally given by the research team, the study information leaflets should be sent to the individual providing assent by email/electronically or post where appropriate and as safe to do so. - The individual providing assent should be asked if their relative/friend/cared has ever discussed views on research or their 'will and preference' on this area. - Assent obtained by telephone should be witnessed where possible, for record purposes. <u>Consent:</u> - It is not clear from the consent protocol if sufficient paper or photocopy records of the signed consent forms are kept by both the participant and research team. It is not clear if the participant will have a copy of the Patient information leaflet for their own records. The consent protocol should be carefully reviewed to ensure informed consent is recorded adequately for the benefit of both the research team and the participant. - Where a participant regains capacity to consent, they should be provided with a specific 'continuation in the study' consent form and information leaflet, which clearly explains what has happened to them, how they became enrolled in the study and by whom, and their options going forward. **Condition 4. Information Leaflets and Consent/Assent Forms:** The HRCDC has requested that the study information leaflets and accompanying assent and consent forms, should be carefully reviewed and amended as necessary to ensure there is clarity and consistency of information provided to the participants or individual providing assent. This will ensure there is an appropriate level of transparency and allow informed consent and the safeguard of assent to be obtained for the study. More specifically the following information points should be addresses; - The information leaflets describe what side effects may occur, how a participant may join the study and then learn more about the specific risks of treatment they are receiving. This section of the form should be revised and tailored for individuals who are providing assent.

	- The information leaflets should more clearly explain if personal data is archived or destroyed in scenarios where i) assent is not provided ii) the participant withdraws from the study at any stage and ii) the participant becomes deceased. - The Information leaflets states that data will be retained for 25yrs, which is misaligned with the information set out in application form stating that data will be archived for 5yrs after the study has commenced. This should be corrected.
HRCDC Recommendations:	**Recommendation 1:** As this is a largescale multi-site clinical trial, the HRCDC recommends that the Data Controllers ensure that all information set out in data protection policies and other protocols is clear and consistent across all hospital sites participating in the trial. **Recommendation 2**: In line with the information available on the World Health Organisation website which states '"*Solidarity" clinical trial for COVID-19 treatments',* it should be transparent in all communications that this study is a multi-site *clinical trial*. **Recommendation 3:** 'The Privacy Notice for COVID -19 Research' should be revised for clarity to state 'that an independent committee (Health Research Consent Declaration Committee) may allow *your personal data to be used for* the research study ~~to take place~~ without your consent.' (The HRCDC role specifically relates to data processing for health research). It should also be made clear that assent from a next-ok-kin or suitable individual will be sought as a safeguard and to ensure their will and preference can be taken into consideration. **Recommendation 4:** It is noted that a communication strategy will be put in place by the Oversight Group. It is recommended that the details of the progress and implementation of this strategy is provided to the HRCDC as part of the Annual Review.

7. Live Declarations

Reference ID:	19-041-AF3/COV
Lead Applicant:	Dr Bairbre McNicholas
Lead Data Controller:	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)
Application Summary:	See HRCDC Meeting minutes of 6th May 2020
Points to Discuss	The HRCDC decision of Wednesday May 13th requested that the Applicant make amendments to the next-of kin assent and information leaflets and consent forms and submit to the HRCDC prior to the commencement of the study.
HRCDC Comments:	The HRCDC reviewed the resubmitted patient consent form and next-of-kin information leaflets and noted that some areas of the forms still require revisions in line with the conditions attached to the declaration to ensure patients and next-of-kin are fully informed with clear information.
HRCDC Decision:	It was agreed that the Applicant should be asked to submit the forms for review by an appropriate PPI group or equivalent to

	ensure the information is clear from the participants perspective and that the next-of-kin or individual providing assent is fully informed. This engagement is a reporting requirement for the Annual Review.

8. Any other Business

a. The HRCDC noted that correspondence from Applicants accepting declarations and reporting updates on conditions and recommendations of a consent declaration, are put on the agenda of the HRCDC meetings. The HRCDC agreed to mandate the Secretariat to consider if the conditions and recommendation have been met and unless there are substantive issues for consideration, there is no need to highlight to the HRCDC.

b. The Chair highlighted that some members of the HRCDC, Secretariat and National Research Ethics Committee will meet to discuss consenting and assenting practices that both committees are seeing through applications being submitted. The meeting will enable both committees to discuss commonly observed practices and what possible actions can be taken to facilitate researchers implanting best practice for seeking consent/assent nationally.

The Chair closed the meeting.

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