HRCDC
Health Research Consent Declaration Committee

Date: 13th May 2020
Location: Teleconferencing by Skype

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Kevin Clarke
Claire Collins
Sheelah Connolly
Simon Furney
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
Ana Rakovac	20-008-AF1/COV	Clinical, laboratory and radiological characteristics as predictors of outcome in patients with COVID-19

Meeting Items

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

2. **Apologies**
   John Ferguson, Malcolm Kell

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

4. **Minutes of the last meeting**
   Draft minutes of the 6th May 2020 meeting were circulated in advance of the meeting and were agreed by the HRCDC.

5. **New Applications**

Reference ID:	20-008-AF1/COV

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Lead Applicant:	Ana Rakovac
Lead Data Controller:	Tallaght University Hospital
Title:	Clinical, laboratory and radiological characteristics as predictors of outcome in patients with COVID-19
Research Objective	This study aims to assess the general state of health of individuals with COVID-19 before they became infected, their metabolic status, past medical history, medication intake as well as biomarkers (blood tests) clinical and radiological findings obtained as part of the routine COVID-19 healthcare in Tallaght University Hospital. The study will also save surplus plasma and serum from samples used for routine investigation and will take additional blood samples for later analysis. The study will create a biobank from these samples to be used in additional later research, as needed.
Reason for Declaration	A consent declaration is sought for processing personal data of unconscious patients and those who lack decision-making capacity to provide explicit consent. The data processing activities to be undertaken include: • The collection, pseudonymisation and processing of personal data from the participant's medical record, including radiological and laboratory data • Continued collection of data post-discharge to determine medium-term outcomes, where this applies. • The processing of personal data associated with blood samples to be analysed. • The storage only of personal data for future research.
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 that while the research question outlined in the application was not very specific and the objectives were quite broad, the study was of strong public interest given the ongoing COVID-19 pandemic. It was further commented that COVID-19 is a complex disease and broad research objectives could be considered justified. **Patient and Public Involvement (PPI)** • HRCDC discussed that the Applicant could enhance the level of PPI for this study. It was commented that the Applicant could be made aware of the recent statement made by the Irish Platform for Patient Organisations, Science and Industry (IPPOSI), setting out the importance of understanding the patient perspective during the COVID-19 pandemic. **Consent and Assent for Data and Biosample Collection** • The HRCDC discussed the participant consent and next-of-kin assent protocols for the study. It was noted from the information provided by the Applicant, that where next-of-kin did not provide

	assent, biosamples and personal data will continue to be collected and stored until such time the participant regains capacity to provide consent. Where no assent has been obtained and the participant becomes deceased, all personal data and biosamples will be destroyed. The HRCDC discussed the appropriateness of proceeding with collecting and retaining biosamples and personal data where next-of-kin assent was not provided. • The HRCDC discussed that the timelines were unclear as to when assent and or participant consent, would be obtained and at what stage of the care and treatment of the patient. • It also discussed that biosamples taken from patients may not be immediately pseudonymised at the hospital site for this study due to constraints on the laboratory facilities. **Data Minimisation** • The HRCDC noted that a considerable amount of sensitive personal data is being collected for the study, including ethnicity, address and socio-economic situation. It was discussed that the broad research objectives and unspecific research question may explain the extent of data being collected for the purpose of fully understanding the complexity of COVID-19. • It was discussed that if the study objectives were more clearly defined with specific research questions, this would help focus on minimising data needed to address the research objective. **Data Transfer** • The HRCDC discussed the involvement of local collaborators in the study who would be accessing data and associated biosamples for analysis. It was discussed that collaborators would have access to a significant amount of pseudonymised data. From the information provided, samples with a data code only, would also be transferred to an academic laboratory in the Harvard University, in the United States (US) which is run by one of the Irish collaborators. It was unclear how anonymised the data was when transferred to the collaborators and why it was necessary to transfer coded samples for study analysis to the collaborator's US laboratory • The Secretariat referenced the Applicants' response to the Secretariat queries on this matter and clarified that only pseudonymised samples and data would be transferred to local and international collaborators. The Secretariat also highlighted feedback from the Data Protection Officer (DPO), where it was noted that any transfer of personal data to the US will need to consider an appropriate legal basis for doing so. The DPO feedback referenced the US privacy shield as well as material and data transfer agreements. It was highlighted that appropriate contractual arrangements are being progressed with the collaborators institutions. • It was further discussed that the research ethics approval has been granted for the inclusion of these collaborators to carry out

	analysis on the samples. The DPO feedback noted that the transfer of samples and personal data to the US will require a REC amendment. **Study Information Leaflets and Transparency:** • The HRCDC broadly discussed the variety of information leaflets and consent/assent forms being used for the study participants. It was discussed that some of the forms and leaflets lacked clarity and transparency on certain aspects of the study. • The HRCDC considered that the information leaflets should specifically state that biosamples will be transferred to the US for analysis. In addition, it was discussed that next-of-kin information leaflets should clearly outline what steps will be taken if their relative/friend does regain capacity. Furthermore, the information on consent for future research was not clear, including whether future research is limited to COVID-19 related research. **Other** • The HRCDC discussed that aspects of the study were unclear from the information provided, including how follow-up data collection with participants was being managed, either through hospital clinics or GPs. • The nature of the study and numbers of participants for recruitment was also discussed and queried. It was noted that details were more clearly outlined in the Patient Information Leaflets (PILs). • The HRCDC queried the length of the declaration required as patients would be requested to provide further personal data at a two year follow up clinic. The Secretariat highlighted the Applicant's response that a declaration is required until the end of 2025. It was discussed that if personal data is needed to be processed, including retained, without participant consent after this time then the Applicant may seek an amendment to the declaration.
HRCDC Declaration Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Conditional Declaration is made commencing 13th May 2020 and is required for 5 years after the study concludes at the end of 2020 (until December 2025), after which the personal data will be destroyed.
Conditions Attached:	The following specific conditions have been attached to the Declaration as follows: **Condition 1.** It is a condition of this declaration that, if the next-of-kin does not provide assent for the study, the personal data collected for this study up that point, including personal data associated with the biosamples should be deleted. For the avoidance of doubt the processing, including retention, of personal data where next-of-kin assent is not provided will not fall under the scope of the declaration.

	(**Note for context**: Assent from an appropriate and suitable individual who can indicate the will and preference of the participant is considered an important data protection safeguard. Therefore, the HRCDC are of the view that it would not be appropriate to process personal data, including retaining personal data that has been collected, if next-of-kin assent is not provided.) **Condition 2.** All biosamples and associated personal data should be pseudonymised at the hospital site, to ensure data protection safeguards are in place, as soon as practicably possible. **Condition 3**. The HRCDC request that, where a patient continues to lack capacity for a prolonged period of time and where the next-of-kin assent remains in place, as an additional safeguard the Applicant should seek confirmation from the next-of-kin (or individuals) who provided assent, that they wish for the study 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. **Condition 4:** The Applicant is requested to ensure that appropriate agreements, governing the transfer and use of personal data and samples, are in place between the data controller of the study and those who will receive personal data and samples. Where appropriate this should include suitable safeguarding arrangement to ensure the anonymity of participants, where relevant. **Condition 4:** It is a condition of the declaration 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* 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 (IPPOSI), 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 5**. For the avoidance of doubt the scope of this declaration applies only to scope of the existing Research Ethics Committee (REC) approval. Any additional activity, such as transfer of identifiable personal data to the US will require an amendment to the declaration following any REC approval. **Condition 6**. 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; - It should be transparent that biosamples and coded personal data are being transferred to collaborators, including outside of Ireland to the US

	- It should be transparent to the next-of-kin what will happen to the personal data and biosamples collected, if the participant regains capacity, and does or does not provide consent to continue in the study. It should also be clear what shall happen if the participant does not regain capacity. - The section on 'future research' should be more clearly described as it confusing to follow. - The HRCDC's role is inaccurate and should be amended in consultation with the Secretariat. - In general, more accessible and less technical language should be utilised within the information leaflets regarding data protection rights and the lawful basis for the study, rather than referencing GDPR.
HRCDC Recommendations:	**Recommendation 1.** The Applicant is recommended to carefully consider more specific and clearly defined research questions, in order to determine what minimal data should be collected and used for attaining the research objective. It should also be considered if data being collected could be more generalised, such as collecting geographical location rather than the participant address. **Recommendation 2.** The Applicant should ensure that when seeking assent, from 16/17yr over participants, care should be taken as to the needs of those individuals to avoid causing any unnecessary distress. **Recommendation 3**. The Applicant is recommended to consider developing a more tailored data protection policy focused on the study itself rather than rely on the Hospital data protection policy, which is more generalised and does not accurately or transparently reflect the data processing activities of this study. The Applicant should consider discussing more broadly with the Data Protection Officer how transparency measures could be improved upon for this study.

6. Any other Business

- The HRCDC discussed the possibility of having to consider an urgent COVID_19 application, even earlier than the weekly scheduled Wednesday meetings. It was discussed that if the application was complete and robust with no further queries required, the HRCDC may be in a position to consider quickly, possibly by written procedure.