HRCDC
Health Research Consent Declaration Committee

Date: 4th September 2020
Location: Videoconference

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kathy Brickell
Kevin Clarke
Claire Collins
Aideen Hartney
Dan Rea
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Genevieve Osanife (Secretariat)

Quorum for Decisions ☒YES

New Amendments - For Consideration

Applicant	Ref No.	Title
Mary McCarron	19-015-AF2/AMD1	Intellectual Disabilities Supplement to The Irish Longitudinal Study on Ageing (IDS -TILDA)
Ger Curley	19-023-AF2/AMD1	Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis
Ger Curley	20-006-AF1/COV/AMD1	A randomized double-blind placebo-controlled trial of intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness.

New Applications - For Consideration

Applicant	Ref No.	Title
Alistair Nichol	20-024-AF1/COV	Genetics of Mortality in Critical Care (GenOMICC)
Alistair Nichol	20-022-AF1	Clinical evaluation of a POC assay to identify phenotypes in the Acute Respiratory Distress Syndrome (PHIND study)
Conor McAloon	20-025-AF1/COV	Using contact tracing data to gain insights into the epidemiology of COVID-19 infection in Ireland
Cara Martin John O'Leary	19-016-AF2	CERVIVA - HPV Primary Screening Pilot Study

Meeting Items

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

2. Apologies

Sheelah Connolly, Zubair Kabir, Simon Furney, John Ferguson, Malcolm Kell, Barry O'Sullivan

3. Disclosure of Interest

Kathy Brickell declared her interest in applications 20-024-AF1/COV and 20-022-AF1 and was absent during the meeting when these applications were considered.

4. Minutes of the last meeting

Draft minutes of the 28th July 2020 meeting were circulated in advance of the meeting and were agreed by the HRCDC.

5. Amendments

Reference ID:	19-015-AF2/AMD1
Lead Applicant:	Mary McCarron
Lead Data Controller	Trinity College Dublin
Title:	IDS-TILDA
Research Objective:	See HRCDC minutes of 17th October, 2019
Purpose of Amendment:	The Applicant requests an amendment to the existing consent declaration for the following reasons: • The assent/consent protocol has been amended to include telephone consent/assent. • The study protocol has been amended to incorporate questions on participant's experience of COVID-19.
HRCDC Comments:	The Chair requested each member to indicate whether the request for the amendment should be approved. It was the consensus of the HRCDC that the amendment to the consent declaration could be made.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended as requested by the Applicant.
Amendment Duration	The Amendment is made commencing 4th September 2020 and shall be valid until 31st October 2021 and 5 years thereafter (until 31st October 2026) or upon confirmation that the data has been rendered anonymised, or whichever occurs sooner (This timeline is in line with the duration of the consent declaration).

Reference ID:	19-023-AF2/AMD1
Lead Applicant:	Ger Curley
Lead Data Controller	Beaumont Hospital
Title:	Effect of naïve and pre-activated MSCs on monocyte/macrophage function in patients with pulmonary and non-pulmonary sepsis
Research Objective:	See HRCDC minutes of 2nd April, 2020
Purpose of Amendment:	The Applicant requests an amendment to the existing consent declaration for the following reasons: • The assent/consent protocol has been amended to include telephone consent/assent. • The protocol has also been amended to include deferred next-of-kin assent; in the rare case where it is not possible to obtain next-of-kin assent, the participant who lacks decision-making capacity may be

	enrolled in the study and their data processed, with next-of-kin assent obtained as soon as possible.
HRCDC Comments:	The Chair requested each HRCDC member to indicate whether the request for the amendment should be approved. It was the consensus of the HRCDC that the amendment to the consent declaration decision could be made. **Deferred next-of-kin assent:** • The HRCDC discussed the amended next-of-kin assent protocol and was of the view that obtaining telephone assent was appropriate given the risks posed by COVID-19. • The importance of obtaining next-of-kin assent as an appropriate safeguard to protect the data rights of the study participants was also discussed. • The HRCDC was of the view that, wherever possible, assent should be obtained in advance of data processing where the participant lacks decision-making capacity. It was further discussed that there may be situations where it is not possible to immediately contact the next-of-kin to obtain their assent and therefore such assent could be deferred. • The HRCDC noted the Applicant's response that deferred assent is expected to be a very rare occurrence and that every effort will be made to obtain assent. **Study Information Leaflets & Assent/Consent Forms:** • Where assent is obtained by telephone, the HRCDC discussed that copies of the study information leaflet and assent form should be sent to the next-of-kin, signed and returned as a record of the assent obtained for the study. • The HRCDC noted that the term 'consent', rather than 'assent', is used in the documents provided to the next-of-kin. • It was also noted that the 'consent to continue' documents for participants who regain decision-making capacity, should clearly inform participants that they are asked to provide consent for the use of biosamples that have already been collected, rather than newly collected biosamples.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended as requested by the Applicant.
Amendment Duration:	The Amendment is made commencing September 4th, 2020 and shall be valid until 31st May 2021 and 15 years thereafter (until 31st May 2036), or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner (This timeline is in line with the duration of the consent declaration)
Conditions Attached:	**Condition 1.** Where it is not possible to obtain next-of-kin assent and the participant has been enrolled into the study on the basis of deferred assent, the Applicant is requested to continue to make every effort to obtain deferred next-of-kin assent as soon as possible. **Condition 2.** The Applicant is requested to report on the proportion of participants who have been enrolled into the study on the basis of deferred next-of-kin assent, as a reporting obligation under the Annual

	Review. Notwithstanding the above reporting requirement, the Applicant is requested to notify the HRCDC immediately should the study become more regularly reliant on deferred next-of-kin assent for the processing of the participant's personal data, and outline what factors have contributed to this situation and what efforts have been made to meet Condition 1. *Note for context:* The HRCDC notes the Applicant's response that relying on a model of deferred next-of-kin assent is expected to be a rare occurrence, therefore the amendment to the initial HRCDC conditional declaration has been made on this basis
HRCDC Recommendations:	**Recommendation 1.** Where assent is obtained via telephone, the HRCDC recommends, for the purpose of record keeping, that copies of the study information leaflets, and assent forms, are forwarded to the next-of-kin and correspondingly signed and returned to the study team. **Recommendation 2.** The HRCDC recommends that the study information leaflets and accompanying assent and consent forms, are carefully reviewed and amended as necessary, to ensure there is clarity and consistency of information provided to the participants or their next-of-kin. This will ensure there is an appropriate level of transparency. Specifically, the following points should be considered; - The use of the term 'assent' rather than 'consent' in the next-of-kin assent study documents; - Clarity that consent to continue from the participant who regains decision-making capacity, is requested for the use of study biosamples that have already been collected, and not new biosamples.

Reference ID:	20-006-AF1/COV/AMD1
Lead Applicant:	Ger Curley
Lead Data Controller	The Royal College of Surgeons in Ireland
Title:	A randomized double-blind placebo-controlled trial of intravenous plasma-purified alpha-1 antitrypsin for severe COVID-19 illness.
Research Objective:	See HRCDC minutes of 15th April, 2020
Purpose of Amendment:	The Applicant requests an amendment to the existing consent declaration for the following reasons: • The addition of three hospital sites to the study (St. James' Hospital, Dublin; Galway University Hospital; Mater Misericordiae University Hospital) • An extension of the duration of the declaration until 31st January 2021 and for 10 years thereafter.
HRCDC Comments:	The Chair requested each HRCDC member to indicate whether the request for the amendment should be made. It was the consensus of the HRCDC that the amendment to the consent declaration decision could be made.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended as requested by the Applicant.
Amendment Duration:	The Amendment is made commencing 4th September 2020 and shall be valid until 31st January 2021 and 10 years thereafter (until 31st

	January 2031), or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner (This timeline is an extension to the duration of the consent declaration)

6. New Applications

Reference ID:	20-024-AF1/COV
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St. Vincent's University Hospital (SVUH: Irish Lead) University of Edinburgh NHS Lothian Health Board
Title:	Genetics of Mortality in Critical Care (GenOMICC)
Research Objective:	Research has found that when individuals get an infection the extent to which they get sick (their susceptibility) varies depending on the person's genetics (their DNA). Most cases are mild, but some people become very unwell. Individuals who get a more serious infection are considered to be more 'susceptible' to the pathogen (the organism e.g. bacteria, virus) causing the infection. Research has found that this susceptibility is specific to the cause of the infection. The likelihood of the patient doing well and recovering may also be related to their genetics among other factors. If these genetic factors which make an individual more susceptible could be identified, then treatments which could make the susceptible patient more similar to people who have a mild infection could be developed. The study will look at genetic factors which make a patient more susceptible to critical illness from COVID-19 and genetic factors which may influence their recovery with the hope that such findings may further understanding of this infection and support future development of treatments. COVID-19 is a lung infection caused by a novel Coronavirus. Most patients experience a mild illness, but some patients become critically ill. The study will try to determine why this is the case.
Reason for Declaration:	For the purpose of collecting, storing, pseudonymising, analysing, sharing and archiving personal data of participants in the GenOMICC study, who lack decision-making capacity and who are COVID-19 positive. The declaration will also cover the storage only of personal data for future use.
HRCDC Comments:	The HRCDC noted that ethics approval has been granted 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 declaration should be made. **Public Interest**

	• The HRCDC was of the view that the study was of strong public interest given the ongoing COVID-19 pandemic. **Scope & Duration of Declaration** • The HRCDC noted that although the study included the collection and analysis of biosamples, the consent declaration is made for the processing of personal data only. • The HRCDC also discussed the duration of the declaration requested, until 2039. With regards future sites that may be added to the study at a later date, the Secretariat highlighted that the inclusion of additional sites will require Research Ethics Committee (REC) approval and a request to amend the consent declaration. **Data processing agreements/arrangements** • The HRCDC noted that data and biosamples are transferred outside of Ireland to the UK. It was queried why biosamples were remaining in Edinburgh and not being returned to Ireland. • The HRCDC discussed the importance of ensuring that the appropriate agreements/arrangement are in place to govern the transfer and use of data and biosamples. The Data Controllers should take into account the post-Brexit transition period and implement appropriate data protection requirements as necessary. **Study Information Leaflets and Assent/Consent Forms** • The HRCDC discussed that participants and/or their next-of-kin are asked to provide consent/assent to allow regulators access to their medical records, where necessary. The HRCDC queried whether the University of Edinburgh would be granted access to the records of participants from SVUH. The Secretariat noted the Applicant's responses that the University of Edinburgh is provided with pseudonymised data. • The HRCDC was also of the view that the study information leaflets could provide further clarity with regards withdrawing from the study. • It was noted that the study information leaflets incorrectly state SVUH REC approved the study, and not the COVID-19 National REC. **Participants who do not regain capacity** • Where a participant lacks-decision making capacity for a prolonged period of time the HRCDC discussed that it would be appropriate to reaffirm next-of-kin assent at an appropriate point in time as the study progresses. • It was further discussed that, as part of the annual review, it would be useful for the HRCDC to understand the proportion of participants who do not regain decision-making capacity and whose personal data are therefore the subject of this declaration. **Data Protection Officer Feedback** • The Secretariat highlighted that Data Protection Officer feedback on behalf of the NHS Lothian Health Board remains pending. **Public and Patient Involvement**

	• The HRCDC commented that the level of public and patient involvement in the study was very strong.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Conditional Declaration is made commencing 4th September 2020 and is valid until 31st August 2029 and for 10 years thereafter (31st August 2039) or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1.** All necessary contractual arrangements including joint data controller arrangements, must be in place with the relevant institutions regarding the governance, transfer and use of personal data and associated biosamples for this research study. The Data Controller should ensure the terms of any transfer of personal data has regard for the post-Brexit transition period. - For the avoidance of doubt the sharing and transfer of personal data and associated biosamples to other data controllers and processors cannot commence until this condition is confirmed to be met by the HRCDC, as substantiated by the Applicant. - It is advisable to discuss this condition with the relevant Institution's legal office and Data Protection Officers, as appropriate. **Condition 2**. The data protection officer (DPO) feedback on the data protection impact assessment, on behalf of the joint data controller NHS Lothian Health Board, must be provided to the HRCDC prior to the sharing and transfer of personal data to this Data Controller, in line with the timeline for meeting Condition 1. This feedback provided by the DPO, should note any data protection risks and mitigating actions, that has or will be sufficiently addressed or implemented by the Applicant. **Condition 3.** The Applicant is requested to report in the annual review on the proportion of participants who continue to lack decision-making capacity and whose personal data therefore remains subject to the consent declaration that has been made.
HRCDC Recommendations:	**Recommendation 1.** The HRCDC recommends that the study information leaflets and accompanying assent and consent forms, should be carefully reviewed and amended as necessary to ensure there is clarity of information provided to the participants or their next-of-kin. Specifically, the following points should be considered; - Provide additional clarity to participants and their next-of-kin regarding the practical steps to take if they wish to withdraw from the study - Amend the documents to clarify that REC approval was provided by the National REC for COVID-19 and not the St. Vincent's University Hospital REC. - Ensure the information provided accurately reflects what parties are accessing or inspecting medical records for the purpose of the study. **Recommendation 2.** Where a participant continues to lack capacity for a prolonged period of time and where the next-of-kin assent remains in place, the Applicant should seek confirmation from the individual 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.

Reference ID:	20-022-AF1
Lead Applicant:	Alistair Nichol
Lead Data Controller:	St Vincent's University Hospital, Dublin Queen's University Belfast Belfast Health and Social Care Trust
Title:	Clinical evaluation of a POC assay to identify phenotypes in the Acute Respiratory Distress Syndrome (PHIND study)
Research Objective:	Severe lung failure called acute respiratory distress syndrome (ARDS) is frequently encountered in intensive care units throughout the world. Various causes such as infection in the lung or elsewhere in the body, trauma, blood transfusion etc. can lead to this clinical condition. While supportive care has improved the outcomes, there is still no definitive drug-based treatment for this condition. Current treatment is limited to supportive care with lung support (ventilation), antibiotics and other routine care as required. The research efforts of the critical care community over the last decade has led to the identification of sub-types of ARDS that might help to provide personalised therapy and reduce death and disability. The laboratory tests required to identify patients of a specific sub-type are currently not available as a routine test or a rapid bedside test. Rapid bedside identification of patients with a specific sub-type of ARDS could influence the therapy provided to them including drug therapy and enable the development of newer therapies. This trail aims to test blood samples from patients with ARDS to confirm the presence of the subtypes of ARDS identified in previous studies and test a novel rapid bedside test. From this the study hopes to work out how accurate or useful these new tests might be. This study is observational in nature and the results of these new tests will not change the care received.
Reason for Declaration:	A consent declaration is required for the processing of personal data of participants who lack decision-making capacity. The data processing activities include: - Processing personal data for the purpose of the trial (i.e. access, collection, pseudonymisation, transfer, analysis and archiving of personal data obtained from the patient and hospital records as well as their relative or decision maker) - Collecting and analysing survival data from the participant's GP - Storage of personal data only for future research (including personal data associated with the samples)
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by 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 declaration should be made. **Public Interest** • The HRCDC was of the view that the study had a strong public interest case. **Data Flow & Sharing** • The HRCDC discussed the data flow and the parties involved in the study. From the information provided by the Applicant, the Secretariat highlighted that there are three joint data controllers of the study where data and biosamples collected from Irish participants at St. Vincent's University Hospital (SVUH) are transferred to two joint controllers in Northern Ireland for analysis. • It was noted that pseudonymised data is initially transferred to the Northern Ireland data controllers and governance arrangements are in place between the parties. • The HRCDC noted that personal, identifiable data is also transferred to the Northern Ireland data controllers for the purpose of contacting the participant's General Practitioner for the 60-day follow up data collection, in situations where this data cannot be obtained from the participant's medical record. • For those who lack decision-making capacity and taking into account the relatively low number of participants that will be recruited, the HRCDC queried whether the follow-up data collection could be undertaken by the research team in SVUH, therefore negating the need for their identifiable data to be transferred outside of the jurisdiction. **Consent/Assent Process** • Based on the information provided it was noted that if next-of-kin assent or consent is not obtained within 7 days of enrolment then the data and biosamples collected are not further processed and are destroyed. Furthermore, data and biosamples are not transferred without assent/consent having first been obtained. • Although outside the scope of the Health Research Regulations, the HRCDC queried whether the personal data and biosamples of individuals who pass away before 7 days are included in the study with or without obtaining next-of-kin assent. **Study Information Leaflets & Assent/Consent Forms** • The HRCDC noted that the study information leaflets provide a link to a Queens University Belfast data privacy notice. It was commented that it would be appropriate for Irish participants from SVUH to also be referred to the SVUH privacy webpage, as well as the SVUH Data Protection Officer (DPO), in the event they wish to exercise their data protection rights. • It was also noted that the study information leaflet and assent/consent forms state that the 60-day follow up will be conducted by researchers at SVUH, rather than those from Queens University Belfast / Belfast Health and Social Care Trust.

	Participants who do not regain capacity • Where a participant lacks-decision making capacity for a prolonged period of time, the HRCDC discussed that it would be appropriate to reaffirm next-of-kin assent at an appropriate point in time as the study progresses. • It was further discussed that, as part of the annual review, it would be useful for the HRCDC to understand the proportion of participants who do not regain decision-making capacity and whose personal data are therefore the subject of this declaration. **Data Protection Officer Feedback** • The Secretariat highlighted that DPO feedback on the data protection impact assessment and a signature on the HRCDC application form on behalf of the Belfast Health and Social Care Trust remains pending.
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 4th September 2020 and is valid until 31st December 2026 or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1.** For participants who lack decision-making capacity and next-of-kin assent has been obtained, the scope of this declaration does not extend to the sharing of personally identifiable data (e.g. names, address) with data controllers outside the jurisdiction of the State for the purpose of collecting the 60-day follow-up data. This is an important safeguard in line with the data protection principle of data minimisation. *Note for context:* the HRCDC notes the information provided by the Applicant which states that personally identifiable data is shared with parties in Northern Ireland for the purpose of collecting the 60-day follow-up data from the participant's GP, where this data is not available in their medical records. The HRCDC is of the view that personally identifiable data should only be transferred/shared with data controllers outside the State only when it is necessary to do so. Correspondingly, and having regards to the total number of participants that will be recruited across the UK and Ireland, the HRCDC are of the view that the 60-day follow-up data collection of Irish participants could be conducted by SVUH, therefore mitigating the need to transfer personally identifiable data outside the State. **Condition 2.** Where the participant passes away within the 7 days of study enrolment, relative assent should still be sought to process the participant's personal data for the purpose of this study. **Condition 3.** All necessary contractual arrangements including joint data controller arrangements, must be in place with the relevant institutions regarding the governance, transfer and use of personal data and associated biosamples for this research study. The Data Controller

	should ensure the terms of any transfer of personal data has regard for the post-Brexit transition period. - For the avoidance of doubt the sharing and transfer of personal data and associated biosamples to other data controllers and processors cannot commence until this condition is confirmed to be met by the HRCDC, as substantiated by the Applicant. - It is advisable to discuss this condition with the relevant Institution's legal office and Data Protection Officers, as appropriate. **Condition 4**. The data protection officer (DPO) feedback on the data protection impact assessment, on behalf of the joint data controller Belfast Health and Social Care Trust, must be provided to the HRCDC prior to the sharing transfer of personal data to this Data Controller, in line with the timeline for meeting Condition 1. This feedback provided by the DPO, should note any data protection risks and mitigating actions, that has or will be sufficiently addressed or implemented by the Applicant. **Condition 5.** An authorised signature on the HRCDC Application on behalf of Belfast Health and Social Care Trust, must be provided in line with the timeline of Condition 4. **Condition 5.** As part of the annual review the Applicant is requested to report on the proportion of participants who continue to lack decision-making capacity and whose personal data therefore remains subject to the consent declaration that has been made.
HRCDC observations/ Recommendations:	**Recommendation 1.** Where a patient continues to lack capacity for a prolonged period of time and where the next-of-kin assent remains in place, the Applicant should seek confirmation from the individual 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. **Recommendation 2.** The Applicant is requested to review and amend the study information leaflets provided to participants to ensure that there is clarity and consistency of information that aligns with the data processing activities to be undertaken. Specifically, where study participants who are in a position to provide explicit consent and are not covered under this consent declaration, it should be clear from the information leaflets that personally identifiable information may be shared with researchers in Northern Ireland for the purpose of conducting the 60 day follow-up by contacting their GP.

Reference ID:	20-025-AF1/COV
Lead Applicant:	Conor McAloon
Lead Data Controller:	University College Dublin
Title:	Using contact tracing data to gain insights into the epidemiology of COVID-19 infection in Ireland
Research Objective	Over the course of the COVID-19 pandemic, a number of mathematical models have been developed to aid with decision-making. These

	models require knowledge of a number of parameters which describe how the virus behaves in the population. Irish models have used values from international scientific literature. However, some of these values may not be accurate for Ireland and may change over the course of the outbreak. During the COVID outbreak in Ireland, contact tracing data was collected at a number of call centres throughout the country. Through these calls, a range of data are collected including the most likely source, onset and description of clinical signs and dates and type/nature of contacts. These data are held by the Central Statistics Office (CSO). Using this data in a pseudonymised data format this study will link transmission 'pairs' (that is primary and secondary cases) within the dataset. A range of values of epidemiological interest will be calculated. Next, the data will be investigated to isolate cohorts of testing that might further answer additional questions relating to the proportion and infectiousness of individuals who were infected but did not show clinical signs. A recent summary of the international literature has highlighted a lack of evidence to support assumptions regarding the infectiousness of asymptomatic individuals. This proposed study of Irish data might shed further light on these influential parameters and will refine estimates from the international literature for use in the Irish population.
Reason for Declaration	The data controller seeks to access and analyse COVID-19 contact tracing data in a pseudonymised format for the purpose of this study. Pseudonymised data will be accessed via the CSO remote platform.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted 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 consent declaration should be made. **Public Interest** • The HRCDC was of the view that there was a strong public interest case for this study. **Rationale for seeking a Declaration** • The HRCDC discussed the reasons why the Applicant was seeking a declaration. While anonymised/aggregated data will be extracted from the CSO platform, with checks to ensure no personally identifiable data is included, pseudonymised data is being accessed via the CSO remote platform, with the master list retained by the CSO. It was noted from the information provided that potentially identifiable data may inadvertently be included in the remote platform and hence accessible to the Applicant.

	• It was noted that it is up to each data controller undertaking a health research study to determine whether a consent declaration is required. **Data Protection Measures** • The HRCDC discussed the measures that are in place to protect the identity of the participants including the pseudonymisation of the data, access restrictions via the CSO remote platform and controls regarding data extraction. • The HRCDC was of the view that the measures in place provided appropriate and relatively strong data protection safeguards. **Transparency measures** • The HRCDC noted the Applicant's response with regards transparency measures. It was discussed that the study could benefit from publishing or providing information regarding the study on relevant websites, including the University College Dublin website.
HRCDC Decision:	The consensus of the HRCDC was that a Declaration should be made.
Duration of Declaration:	The Declaration is made commencing September 4th, 2020 and is valid until 1st October 2020.
HRCDC Recommendations:	**Recommendation 1.** The Applicant is requested to consider enhancing the transparency measures to inform participants and the public about the study. For example, consideration should be given to providing information and/or publishing study findings on the website of the data controller, University College Dublin.

Reference ID:	19-016-AF2
Lead Applicant:	Cara Martin John O'Leary
Lead Data Controller:	Trinity College Dublin The Coombe Women and Infants University Hospital The Health Service Executive (CervicalCheck)
Title:	CERVIVA HPV Primary Screening Pilot Study
Research Objective	The current method of examining smear test samples is called PAP test where the cells from the smear test sample are looked at under a microscope to check for abnormalities. HPV testing is a slightly different way of examining the smear test sample. It involves a test that looks for the presence of Human Papillomavirus (HPV). HPV is a common virus that is linked with changes in the cells of the cervix (neck of the womb) and cervical cancer. Research has shown that HPV testing has many benefits over the PAP test. To ensure HPV testing is effective, researchers need to find out which HPV positive samples are likely to develop into cancer. This study is examining different ways to screen for cervical cancer using HPV tests and using additional tests to look for specific markers that we know are linked to HPV infection. By following women to see what happens over the course of several smear tests the researchers will be able to determine how useful these new approaches to cervical screening are.
Reason for Declaration	A consent declaration is required for the continued data processing activities that include the ongoing storage and analysis of participant

	data that has already been collected as well as the collection, pseudonymisation, transfer and analysis of follow-up data for the purpose of completing the study. This study commenced prior to the new Health Research Regulations 2018 and consent was compliant under the previous data protection legislation.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted 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 reminded the members that the Applicant had obtained consent compliant with the previous Data Protection legislation, under the Health Research Regulations, a public interest case is not an applicable factor in the HRCDC decision making process. 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 declaration should be made. **Re-consenting Participants and Transparency Measures** • The HRCDC discussed the Applicant's reasons why re-consenting participants was not possible. It was noted that the study had finished recruiting participants in April 2018 and that of the over 12,000 participants who had provided consent, the Applicant states that none have withdrawn their consent. • The HRCDC further commented that the reasons for seeking a consent declaration such as information gaps with which could be addressed via transparency notices on relevant websites. • In addition, the HRCDC was of the view that transparency measures could be further enhanced by disseminating the findings from the study via the controller's websites. **Governance Agreements/Arrangements** • The HRCDC discussed the Applicant's responses with regards the progress made on the data governance agreements/arrangements between the joint data controller and processor parties. • The HRCDC noted the DPO feedback which highlighted the need for putting in place appropriate data sharing agreements between the three data controllers. • It was discussed that a standard condition of all consent declarations is that the required agreements and arrangements must be in place for the purpose of undertaking the specific research study, which includes joint data controller arrangements and data processing agreements as is required. **Public and Patient Involvement** • The HRCDC commented that the level of public and patient involvement in the study was relatively strong.

	REC Approval • The HRCDC acknowledged that REC approval letters dated February 2015 and June 2017 have been provided. • Considering the duration of the consent declaration that is requested, the HRCDC discussed that it would be appropriate to request confirmation from the Applicant that the REC approval in place remains valid and up-to-date and that any amendments that have been made to the study have been reviewed and approved by the REC.
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 8th August 2018 and is valid until 31st December 2028 and for 5 years thereafter (until 31st December 2033) or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1.** The HRCDC has requested that all appropriate contractual arrangements (legal agreements) must be in place with the relevant institutions, regarding the governance, transfer and use of personal data and samples for the purpose of this research study, including an appropriate joint data controller arrangement between the three joint data controllers of this study. Confirmation that these agreements are in place must be provided to the HRCDC by 30th November 2020. It is advisable to discuss this with the relevant Institution's legal office and Data Protection Officer, as appropriate. **Condition 2.** The HRCDC has requested confirmation that the research ethics committee approval is up-to-date and valid, and any subsequent changes that may have made to the study since the previous REC approval, have been reviewed and approved by the REC. Any subsequent REC approval letters should be provided to the HRCDC.

7. Annual Reviews

The Secretariat has received 1 Annual Review in advance of the meeting and was deemed to be complete subject to the Applicant making continued efforts to engage with PPIs and advocacy groups for the duration of the study.

8. Any other Business

- The Secretariat provided an update on the proposed amendments to the Health Research Regulations, including amendments to the Appeal process. It is understood from the Department of Health that these amendments are at an advanced stage.
- The Secretariat provided a brief summary of the HRCDC's activities from Q1 to Q3 2020, including progress made with pending applications. It was noted that a significant volume of work has been carried out by both the Secretariat and HRCDC in response to the COVID-19 pandemic and its impact on health research. As of the date of the meeting, the HRCDC convened an additional 5 times between April and June specifically to expediate consideration of COVID-19 research applications for studies seeking a consent declaration. The HRCDC has received 18 COVID-19 focused

applications to date, 11 of which were submitted through the NREC COVID-19. The HRCDC have made 8 consent declarations for COVID19 research studies to date.

- It was confirmed that an additional dedicated COVID-19 HRCDC meeting will be held on Wednesday 23rd September to consider remaining NREC-HRCDC COVID-19 applications.

******The Chair closed the meeting******