HRCDC
Health Research Consent Declaration Committee

Date: 22nd June 2021
Location: Videoconference by Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Alyson Bailey
Kevin Clarke
Aideen Hartney
Claire Colins
Kathy Brickell
Evelyn Mahon
John Ferguson
Zubair Kabir
Dan Rea
Barry O'Sullivan
Cornelius Cooney
John Woods
Barry Lyons
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions ☒YES

Returning Applications – For Consideration

Applicant	Ref No.	Title
Patrick Sheahan	21-001-AF1	Determination of HPV status of Oropharynx cancer using p16 immunohistochemistry, morphology, and RNAscope (RNA ISH)

New Applications - For Consideration

Applicant	Ref No.	Title
Carla Perrotta	21-006-AF1/CSO	SARS-CoV-2 clusters and superspreading events in workplaces in Ireland: a retrospective analysis
Deirdre Murray	19-020-AF2	BASELINE Study
Fergus McCarthy	19-070-AF2	SCOPE study

Meeting Items

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

2. Apologies
Simon Furney, Sheelah Connolly and Mary Tumelty

3. Disclosure of Interest
Applications 19-020-AF2 & 19-070-AF2: Barry O'Sullivan (BOS) disclosed that he has collaborated with UCC's INFANT centre who manage the BASELINE and SCOPE studies. It was noted that BOS is not directly involved in either of these studies, however data from these studies may be included in future collaborations that BOS maybe involved with. BOS was absent for the discussions on both applications.

4. Minutes of the last meeting
Draft minutes of the 18th May 2021 meeting were circulated in advance of the meeting and were agreed by the HRCDC.

5. Matters arising
The Secretariat provided updates on the responses that have been received from the following Applicants, which were noted at the 18th May 2021 HRCDC meeting:

- Ref ID 20-027-AF1 '*Immune Dysfunction in Acute Brain Injury'*: further to the Chair's correspondence to the Applicant regarding the progress made to meet Condition 1 of the consent declaration, the Applicant responded by outlining the reasons for the delayed response and provided a comprehensive update on the public and patient involvement (PPI) activities that had commenced to date. The PPI activities included partnerships with relevant PPI representative groups and the inclusion of a PPI representative as an advisor to the study. The Applicant also confirmed that participants have not yet been recruited to the study. Based on the information provided it was noted that Condition 1 is met and remains valid for the duration of the study.

- Application 19-027-AF3 *'Identification of predictive and prognostic biomarkers in triple negative breast cancer'*: the HRCDC were informed that Condition 4 and all other conditions attached to the consent declaration made for this study are now in progress or have been met by the Applicant.

6. Returning Applications

Reference ID:	21-001-AF1
Lead Applicant:	Patrick Sheahan
Lead Data Controller:	South Infirmary Victoria University Hospital (SIVUH) (NOTE: St. James's Hospital is no longer involved in this study)
Title:	Determination of HPV status of Oropharynx cancer using p16 immunohistochemistry, morphology, and RNAscope (RNA ISH)
Research Objective:	See HRCDC meeting minutes of 2nd March 2021
Reason for Declaration:	See HRCDC meeting minutes of 2nd March 2021
HRCDC Comments:	The Chair introduced the agenda item and reminded the members of the additional information that was requested from the Applicant. The Chair referred to the discussion on this application at the previous meeting and summarised the outstanding matters and the responses provided by the Applicant. The consensus of the HRCDC was that a consent declaration should be made. The decision was based on the

	following discussion points: **Public Interest** • Based on the responses provided, the HRCDC was of the view that there is a strong public interest case for undertaking this study. The HRCDC further discussed that participant consent should be obtained where possible, in particular, for those who are attending follow-up clinic visits. • The consent declaration will therefore cover the processing of data of participants where consent cannot be obtained. **Consent and Transparency measures** • The HRCDC discussed the Applicant's response that prior to the commencement of the study, explicit consent could be obtained from patients who are attending follow-up clinics. It was noted that for patient's not attending follow-up clinics consent could be obtained by posting out consenting documentation and obtaining verbal consent by phone. • With regards transparency measures, the Applicant stated that posters and information leaflets specific to this study would be developed and made available in clinics and hospital websites. **Public and Patient Involvement (PPI)** • The HRCDC acknowledged the Applicant's response to the HRCDC's query outlining how PPI activities will be enhanced. The Applicant briefly outlined that a local PPI committee has been formed for head and neck cancer related research. In addition, a PPI network consisting of public and patient representatives is to be established and consulted on the study design, consent process and transparency measures prior to the commencement of this study. • Noting the Applicant's previous response that PPI activities would be undertaken in Q2 of 2021, the HRCDC commented that the PPI committee and network should be established and consulted as soon as possible so that they may inform the design and implementation of a consent process and transparency in a timely manner prior to the commencement of the study. • Considering that PPI, consent and transparency activities have yet to commence, the HRCDC was of the view that the Applicant should provide a midterm report on the progress they have made in these areas within 6 months of the consent declaration being made. **Other** • It was noted that, of the 400 bio-samples included in this study, that all 400 are p16 positive. It was further noted that participants whose HPV status changes from positive to negative as a result of testing performed in this study, will be informed of this change of status.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 22nd June 2021 and shall be valid until 31st March 2024 (24 months from the start of the study in Q1 2022)

	at which point the data will be irrevocably anonymised, or upon confirmation that the personal data have been rendered anonymised or destroyed sooner.
Conditions Attached:	**Condition 1.** The Applicant is required to submit a midterm report detailing the progress that has been made with regards (i) undertaking PPI activities, (ii) designing and implementing a consenting process and (iii) enhancing transparency measures. This midterm report must be submitted 6 months from the date of the consent declaration being made.
HRCDC Recommendations:	**Recommendation.** The Applicant is recommended to bring forward (i) the establishment of the PPI network and (ii) the consultations with PPI representatives as early as possible so that the consent process and transparency measures can be explored in a timely manner in advance of the study commencing in 2022.

7. New Applications

Reference ID:	21-006-AF1/CSO
Lead Applicant:	Carla Perrotta & Fionn Cléirgh Büttner
Lead Data Controller:	University College Dublin
Title:	SARS-CoV-2 clusters and superspreading events in workplaces in Ireland: a retrospective analysis
Research Objective:	The COVID-19 pandemic has infected more than 220,000 people in Ireland, and killed more than 4,000, in one year. It has become clear that infected individuals do not transmit COVID-19 equally, and relatively few infectious individuals (~10%) are responsible for most (~80%) of local transmission. Environmental factors likely contribute COVID-19 clusters, or 'superspreading' events. Cramped and/or crowded indoor settings, with poor ventilation, and long contact exposures create high-risk environments for COVID-19 clusters and associated superspreading events. Familiar workplaces such as meat-processing plants and retail outlets possess such environmental features that facilitate explosive COVID-19 clusters. Consequently, this retrospective, longitudinal study aims to (i) identify the characteristics of workplace settings that experience COVID-19 clusters, and (ii) investigate the relationship between COVID-19 clusters in workplace settings and community transmission/epidemic trajectory. Study findings will inform targeted control efforts that can mitigate the risk of COVID-19 and future infectious disease outbreaks in workplace settings.
Reason for Declaration:	The Applicant is seeking to access and process pseudonymised data (research microdata files) from the COVID-19 Data Research Hub, hosted by the Central Statistics Office (CSO). As the data being accessed is pseudonymised data and that it is not feasible to seek consent from individuals whose data is held by the CSO within the COVID-19 data hub, a consent declaration is required.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee (REC) for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval or

	provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Secretariat reminded the HRCDC of the approval process for accessing data from the CSO COVID-19 Data Research Hub including the requirement to have obtained approval from the Research Data Governance Board (RDGB), the CSO and for the researcher to be designated an Officer of Statistics in accordance with the Statistics Act 1993. The HRCDC was further reminded by the Secretariat that the HRCDC application had been adapted specifically for researchers accessing the COVID19 Data Research Hub. Specifically, sections of the application form relating to data protection security measures, have been pre-populated based on the security measures that are in place by the CSO for accessing the COVID-19 Data Research Hub. These sections were populated in consultation with the CSO to ensure accuracy of information. 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. The decision was based on the following discussion points: **Public Interest** • The HRCDC was of the view that the study was of strong public interest. **Public and Patient Involvement (PPI)** • The HRCDC discussed the matter of PPI engagement with regards to the secondary use of COVID19 datasets for health research purposes. It was considered that PPI activity should be much broader, beyond a single, specific study. It was therefore queried what PPI engagement could have been undertaken to inform and engage patients and the public on the secondary use of COVID-19 datasets for health research. • The Secretariat commented that it engages with the planning group that has oversight of the implementation of the COVID-19 Data Research Hub and would discuss the matter of more wider PPI engagement with this group. **Transparency measures** • The HRCDC was of the view that enhanced transparency measures should be implemented by the Applicant to inform participants and the public about this study, the study findings and the use of the CSO COVID-19 Research Data Hub. • It was discussed that information could be provided on the data controller's and/or CSO websites. The HRCDC also noted the comment from the RDGB recommending wider public engagement and the dissemination of research findings.

	Data Security • The HRCDC queried the use of emails as the method of forwarding the researcher's outputs from the Data Research Hub. It was noted that the data outputs extracted from the hub are checked by the CSO before its release and would be considered fully anonymised data, to the researcher. • The HRCDC commented that the CSO's data security controls provided strong additional safeguarding measures. **Other** • The HRCDC noted and agreed with the observations of the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee, specifically in relation to transparency measures. • It was discussed that the consent declaration will not be effective until final approval to access the COVID-19 Data Research Hub has been granted by the CSO.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 22nd June 2021 and is valid for one year, until 22nd June 2022, in line with the duration of the Officer of Statistics appointment made to the Applicant by the Central Statistics Office (CSO). *NOTE 1*: The consent declaration will not come into effect until Condition 1 is met. *NOTE 2:* The Applicant may submit an amendment request to the consent declaration if an extension to the duration of the consent declaration is required, subject to the Applicant's reappointment as an Officer of Statistics and approval by the CSO.
Conditions Attached:	**Condition 1.** It is a condition that this consent declaration is not effective until final approval to access the COVID-19 Data Research Hub has been granted by the CSO. Confirmation of final CSO approval must be provided to the HRCDC as soon as possible. **Condition 2.** Aligned with the recommendations of the RDGB with regards wider public engagement and dissemination, the Applicant is requested to implement transparency measures so that participants, the public and other relevant stakeholders, can be made aware of this study, the study findings and the use of the CSO COVID-19 Data Research Hub. Consideration should be given to providing information on the data controller's website, the CSO website and other relevant platforms. The Applicant is required to report on the efforts made to implement transparency measures as part of the Annual Review.

Reference ID:	19-020-AF2
Lead Applicant:	Deirdre Murray
Lead Data Controller:	University College Cork
Title:	BASELINE Study

Research Objective:	The BASELINE study commenced in 2008 with an aim to establish a prospective paediatric birth cohort, which will have access to detailed information on maternal health, fetal growth and childhood nutrition, growth and development in the first 2 years of life. The longitudinal monitoring of these infants has allowed direct investigation of several research areas in a way which had not previously been possible in Ireland. Three main research themes/aims were focused on (i) fetal and early life growth trajectories which foretell later disability and metabolic disorder, (ii) food allergy and eczema in early childhood and (iii) vitamin D deficiency. Although the initial proposal focused on these important areas, the formation of this birth cohort offers opportunities for further research as the cohort grows older. Building on these aims, the BASELINE study has since followed up with the children at 5 years of age and collected data on their growth and development. The BASELINE study hopes to continue to follow-up at 12 and 15 years and to follow their progress until they are 16. More recently, funding has been received to study specific areas of development in these children. These areas include but are not limited to: maternal cytokine profiles during pregnancy in mothers who progress to have children with a diagnosis of autistic spectrum disorder; maternal cortisol levels in mothers with a subsequent diagnosis of cognitive and behavioural abnormalities; and lipid profiles in children with obesity at 5 years.
Reason for Declaration:	A consent declaration is sought for the continued processing of personal data specifically for the BASELINE where explicit consent from participants cannot be obtained. The processing activities involved are: (i) Specifically for the purpose of the BASELINE study: the continued processing (pseudonymisation, retention and analysis) of personal data already collected from participants from gestation until the 5-year follow-up assessment and the processing of personal data from pregnant Mothers that was initially collected as part of the SCOPE study (Ref ID 19-070-AF2, considered at this meeting), (ii) the sharing of data with external collaborators; the Lifecycle/MOCO consortium, (iii) the continued storage, only, of the BASELINE data for 25 years after the BASLINE study concludes, for unspecified future research.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee (REC) for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair reminded the members that this study had been submitted to the HRCDC for consideration under the 'AF2' category of applications which sought a declaration for studies that commenced prior to the Health Research Regulations. It was highlighted that AF2 Applicants considered that consent obtained was compliant with the

previous data protection legislation. Recent amendments[1] to the Health Research Regulations subsequently provided a derogation to have explicit consent for studies that had obtained consent compliant with previous data protection legislation. However, further to the amendments being made, some Applicants have now reviewed the consent obtained, and considered it not in line with the previous data protection legislation and still require a consent declaration. Therefore, the HRCDC must consider these studies and balance the public interest case for the study.

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. The decision was based on the following discussion points:

Public Interest

- While the HRCDC commented that the application was complex and challenging to consider, it was of the view that there is a strong degree of public interest in the study.
- The HRCDC further commented that while it is up to the data controller to determine if a consent declaration is required, it was noted that participants did provide consent for the BASELINE study upon their enrolment to the study.

Scope of the consent declaration

- With regards the scope of the declaration, it was noted and agreed that the declaration will cover data processing activities for the BASELINE study that has research ethics committee (REC) approval. The HRCDC discussed and agreed that a declaration cannot be made to cover data processing for future, unknown research activities.
- In addition, it was noted that while DNA is currently being stored, genetic analysis has not been carried out yet. Correspondingly it was agreed that genetic analysis would not be covered by this consent declaration.
- The HRCDC also queried the duration of the declaration that was requested. It was noted that the BASELINE study wishes to follow-up children until 16 years of age, until 2027 with the personal data stored for a further 25 years. The HRCDC discussed and agreed that it would be appropriate to make a declaration for an initial period of 15 years which will include data storage, after such time a request for an extension could be requested by way of submitting a declaration amendment request to the HRCDC for consideration.
- It was commented that future BASELINE activities including genetic analysis and other activities requiring future REC approval can submit a declaration amendment request or separate consent declaration application, as is appropriate.

[1] http://www.irishstatutebook.ie/eli/2021/si/18/made/en/pdf

Data Transfers and Collaborators

- The HRCDC discussed the information provided by the Applicant regarding the sharing of data with collaborators. The Applicant's response noted that data shared with internal collaborators or co-investigators is considered pseudonymised while data shared with external collaborators, consortiums or co-investigators is anonymised. In addition, the Applicant outlined that contractual arrangements are or will be in place when data is transferred, including the use of Standard Contractual Clauses if data is transferred outside of the European Economic Area (EEA).
- The HRCDC noted that a collaboration with Quest Diagnostics, USA, to assess the lipid profiles of children, relied on the Privacy Shield Framework which has since been deemed invalid. The Applicant's response confirmed that the results of the analysis undertaken with Quest Diagnostics have been received, the remnant bio-samples have been destroyed and that the agreement with Quest is no longer valid. The HRCDC queried if the data associated with the bio-samples has also been destroyed by Quest.
- From the information provided, it was noted that the collaboration with the Lifecycle/MOCO consortium is ongoing. No other external collaborations as part of BASELINE were noted by the Applicant. It was discussed that future collaborations under the BASELINE study, including with external partners, will require the submission of an amendment request or a new HRCDC application, whichever is most appropriate.

Re-consenting and the withdrawal of consent

- Although the HRCDC commented that the information on the re-consenting process was difficult to follow, it was acknowledged that the study has made considerable efforts to obtain re-consent from participants, as well as obtaining assent from the children who were enrolled in the study as infants.
- It was noted that all participants who enrolled in the study have been contacted to obtain their re-consent. The latest response from the Applicant confirmed that 659 participants have returned their consent forms, of which 11 wish to withdraw their consent.
- The Applicant stated that the data and samples of those who have withdrawn after the re-consenting process will be destroyed simultaneously by the end of Q3 2021 to ensure that the destruction is undertaken in a controlled manner. While the HRCDC noted the reasons why data and bio-samples will not be destroyed until this timepoint, even though consent has now been withdrawn, it was of the view that data and samples should be destroyed as soon as possible.
- The HRCDC also noted that the number of participants who remained eligible at each of the study's follow-up assessments, up to and including the 5-year assessment, had reduced from the number who enrolled at the beginning of the BASELINE study. The Applicant provided some information on the number of participants who were lost to follow-up or left the study between each assessment stage.

	• The HRCDC queried the status of the participants who did not participate in the follow-up assessments and were still contacted to obtain their re-consent. It was noted that the Applicant stated that no participants formally withdrew from the study or officially expressed a wish to have their data and samples destroyed prior to the re-consenting process commencing. The Applicant outlined that the participants where either lost to follow-up or non-contactable at the time of their appointments. • The HRCDC commented that the Applicant should have robust procedures in place with regards participant withdrawal from the study. It was discussed that clear information should be provided to participants on what will happen their personal data in such circumstances, including whether there is a time point at which the data cannot be destroyed. It was also commented that a consent declaration cannot be made to override a participant's wish to withdraw their consent. **Non-responses** • Notwithstanding the efforts made to obtain re-consent, the HRCDC noted that, as part of the re-consenting process, participants may not have been informed that their data and bio-samples will continued to be stored and processed should they not provide a response to the request for re-consent. The HRCDC therefore discussed if further information should be provided to the non-responding participants. On balance and given the nature and extent of the data collected for BASELINE, including genetic data, the HRCDC was of the view that it would be appropriate to provide further information to this cohort. **Child participants and future consent** • The HRCDC noted the nature and extent of the data collected for BASELINE, including genetic data and was of the view that the children recruited to BASLINE should be requested to provide their explicit consent for the processing and storage of their personal data when they turn 18 years old. **Public and Patient Involvement** • The HRCDC noted the Applicant's response with regarding previous PPI activities and that no further engagement with PPI groups is planned. The HRCDC discussed that PPI is an important data protection safeguard, in addition to enriching the health research study. It was also commented that the development and undertaking of research should involve multiple stakeholders. • The HRCDC was therefore of the view that PPI engagement should be undertaken going forward, including for example by engaging with the working PPI group located at UCC's INFANT centre. **Transparency** • The HRCDC commented that the study and participants would benefit from continued communication activities, including via the

	BASELINE and INFANT study website, within the hospital and through PPI engagement. **Other** • It was discussed that the Applicant should be requested to consider anonymising the personal data as soon as possible, in line with the data protection principle of data minimisation. • The HRCDC noted and agreed with the observations of the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee.
HRCDC Decision:	The consensus of the HRCDC was that that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 22nd June 2021 and shall be valid for 15 years, until 31st June 2036, or upon confirmation that the data has been irrevocably rendered anonymised or destroyed, or whichever occurs sooner. *NOTE:* The Applicant may seek an extension of the consent declaration towards the end of the 15yr period by way of an amendment request should this be required.
Conditions Attached:	**Condition 1.** It is a condition of this declaration that the personal data and associated bio-samples of participants who have withdrawn their consent following the re-consenting process, must be destroyed as soon as possible. For the avoidance of doubt this consent declaration does not cover the further processing of this cohort's data, only the storage of their data until it has been destroyed. The Applicant is required to report on the deletion of personal data and destruction of bio-samples of participants who have withdrawn from the study as part of the Annual Review. **Condition 2.** It is a condition of this declaration that this study has a clear protocol in place regarding what will happen to a participant's personal data if they wish to withdraw from the study. This includes providing clear information to the participant on what will happen their personal data in such circumstances, including if there is a time point at which their data cannot be destroyed. *NOTE:* a consent declaration cannot be made to override a participant's wish to withdraw their consent. Data controllers who wish to continue to process the personal data of participants who have withdrawn their consent, are responsible for ensuring they are compliant with data protection legislation. The Data Protection Officer should be consulted where necessary. **Condition 3.** For participants who have not responded to the re-consenting process, the Applicant is requested to write out and inform them that their personal data and bio-samples will continue to be processed for the purpose of the BASELINE study and further stored for future research. Information should be provided on who to contact if they wish to receive more information or to discuss their options. The Applicant should highlight that a consent declaration was made by the

	HRCDC to permit the processing of their data specifically for the BASELINE study in the absence of reconsenting participants. The Applicant is required to report on the progress made to fulfil this condition as part of the first Annual Review. **Condition 4**. The Applicant must ensure that a re-consent protocol is designed and implemented so that children recruited to BASELINE are given the opportunity to provide their explicit consent for data processing when they turn 18 years of age. Attempts to obtain their consent must be made within one year of the participant turning 18. The Applicant must report on this activity as part of each Annual Review, including where attempts to seek consent are unsuccessful. **Condition 5.** The Applicant is requested to enhance the transparency measures that are undertaken for the BASELINE study. Transparency measures should inform participants about a number of areas including the ongoing use of their data as part of the BASELINE study, the dissemination of research findings, their data protection rights and withdrawal from the study. Consideration should be given to enhancing transparency via updates to the BASELINE and INFANT centre websites as well as through PPI engagement. **Condition 6.** The Applicant is requested to undertake public and patient involvement (PPI) activities as part of the BASELINE study, in areas such as informing future BASELINE research, the dissemination of findings, transparency measures and future consent protocols. The Applicant should consider utilising the working PPI group at the UCC INFANT centre. **Condition 7.** It is a condition of this consent declaration that the Applicant confirm that the data shared with Quest Diagnostics has also been deleted by Quest Diagnostics. A response should be provided as soon as possible to the HRCDC.
HRCDC Recommendations:	**Recommendation.** In line with the data protection principle of data minimisation, the Applicant is requested to consider whether the personal data from the BASELINE study can be irrevocably anonymised sooner than the intended 25-year duration.

Reference ID:	19-070-AF2
Lead Applicant:	Fergus McCarthy
Lead Data Controller:	University College Cork
Title:	SCOPE study
Research Objective:	Over 48 million babies are born to first time mothers worldwide each year. Almost one in five pregnancies are complicated either by pre-eclampsia, spontaneous preterm birth (PTB) and/or a small for gestational age (SGA) baby. In approximately half the affected pregnancies, the disease necessitates hospital admission for the mother and/or the baby, or results in maternal or perinatal mortality. All three conditions have life-long consequences for the child.

	There are a number of known clinical risk factors and biomarkers for these diseases. Although none are useful predictors in isolation, combinations of markers are likely to prove to be effective predictors of adverse pregnancy outcomes. The prerequisite to effective prevention is accurate predication of high-risk women who would benefit from preventative therapy. Currently there is no screening method to accurately predict which first-time mothers will develop pre-eclampsia, SGA or spontaneous PTB. Development of a reliable and valid screening test would enable first time mothers to be stratified according to obstetric risk. The primary objective of SCOPE is to produce clinically useful screening tests to detect first time mothers at risk of pre-eclampsia, spontaneous PTB and/or growth restricted babies, allowing intervention to prevent these conditions.
Reason for Declaration:	The Applicant outlines that it is not possible to re-consent participants due to the age and nature of the study, with participants recruited more than 10 years ago. The consent declaration is requested for: (i) the purpose of the SCOPE study only: the continued processing (pseudonymisation, retention and analysis) of personal data already collected from all participants (mothers, fathers, babies) in the SCOPE study, including the sharing of data with SCOPE consortium members, (ii) the continued storage only of the SCOPE personal data, for unspecified future research studies (iii) the processing of the SCOPE study data for the purposes of the IDEA study.
HRCDC Comments:	The HRCDC noted that ethics approval had been granted by the Research Ethics Committee (REC) for the study where the design, methodology and ethical aspects of the study, including consent protocols are considered. Only studies that have ethical approval or provisional ethical approval, can be considered by the HRCDC to consider if the public interest outweighs the requirement for explicit consent. The Chair and Secretariat provided an overview the SCOPE study, how it forms part of a wider international consortium of collaborators and how it links to the previously discussed BASELINE study, where participants of the BASELINE study were recruited from the SCOPE study. It was highlighted that the SCOPE study under consideration, also fell into the category of 'AF2' applications as discussed earlier and therefore, the HRCDC must consider the SCOPE study and balance the public interest case for the study. The Chair requested each HRCDC member to indicate whether a consent declaration should be made. After discussing the application, and based on the information provided by the Applicant, it was the consensus of the HRCDC that that a consent declaration should be made. This decision was made based on the following discussion points: **Public Interest**

	• The HRCDC was of the view that there is a strong degree of public interest in the study. **Scope of the declaration - data sharing** • The HRCDC discussed the scope of the declaration that was requested, based on the information that was provided by the Applicant. • The HRCDC noted from the Applicant responses, that collaborators wish to access the SCOPE study datasets for three further studies. Specifically, for an internal UCC study (the IDEA study) and two other studies external to UCC. • It was discussed that the two external studies outlined by the Applicant had not yet obtained Irish REC approval, and it was therefore agreed that these studies seeking access to the SCOPE dataset cannot be covered by this declaration. • The HRCDC further discussed the Applicant's request for the declaration to cover the use and processing of the SCOPE dataset for the internal UCC 'IDEA' study. It was noted from the Applicant's responses that the remit of the IDEA study was aligned with the remit of original research question of the SCOPE study and REC approval has been obtained for the IDEA study. It discussed that the HRCDC application however, related to the SCOPE study and processing of SCOPE study data. It was noted that the IDEA study involved the processing of data collected from other UCC INFANT centre studies, not just the SCOPE study. In addition, the HRCDC discussed that more information could have provided about the IDEA study to help determine the public interest case. • In considering these points, the HRCDC was of the view that the consent declaration would not include the provision and processing of SCOPE data for the purpose of the IDEA study as sufficient information was not available to assess the public interest of the IDEA study. • It was discussed that future collaborations under the SCOPE study, with collaborative parties not part of the SCOPE consortium, will require the submission of an amendment request or a separate application, whichever is most appropriate. This would include for the IDEA study and the two other external collaborations noted in their responses. **Scope of declaration - general** • The HRCDC noted the reference to the fathers participating in the SCOPE study. The HRCDC acknowledged the Applicant's response and agreed that the processing of the data obtained from the mother's partner could fall under the scope of the declaration. • It was further noted and agreed that the declaration will cover data processing activities for the purpose of the SCOPE study that are covered by current research ethics committee (REC) approval. The HRCDC commented that a declaration cannot be made to cover data processing for future, unknown research activities.

- In addition, it was noted that while genetic samples (placental blood and saliva samples) are currently being stored, no genetic analysis has been performed and will require REC approval. Correspondingly genetic analysis is also not covered by this consent declaration.
- The HRCDC discussed that future SCOPE study activities including genetic analysis, external collaborations and other activities requiring future REC approval, can also submit a declaration amendment request or separate consent declaration application, as is appropriate.

Reconsent

- The HRCDC noted the reasons why efforts had not been made to reconsent participants, namely the significant size of the participant cohort, the unknown circumstances of pregnancy outcomes and other personal circumstances.
- It was further noted from patient information leaflets used initially, that participants were informed that they would be contacted in the future to seek permission for other studies. The HRCDC was unclear if participants had been recontacted or could be contacted further in this regard.
- Notwithstanding the reasons outlined for not seeking consent, the HRCDC discussed and agreed that efforts could have been made to reconsent participants for the SCOPE study. It was further agreed that opportunities may still arise to enable the researchers to reconsent, such as when participants attend follow up clinics and therefore efforts should be made to reconsent participants where practicably possible and appropriate.
- It was discussed that efforts made to reconsent should be reported to the HRCDC as part of the annual review. It was agreed that the declaration would continue to cover the processing of data where reconsent could not be obtained, but not however, where participants withdraw their participation and data from the SCOPE study.
- The HRCDC was also of the view that, regarding the neonate cohort that was recruited to the SCOPE study, explicit consent for the processing and storage of this cohort's personal data should be obtained when they turn 18 years old.

Public and Patient Involvement (PPI)

- The HRCDC noted the Applicant's response with regarding previous PPI activities and that no further engagement with PPI groups is planned. The HRCDC discussed that PPI is an important data protection safeguard, in addition to enhancing the quality of the health research study. It was also commented that the development and undertaking of research should involve multiple stakeholders.
- The HRCDC was therefore of the view that PPI engagement should be undertaken going forward, including for example by engaging with the working PPI group located at UCC's INFANT centre.

Transparency

	• The HRCDC commented that the study and participants would benefit from continued communication activities, including via the SCOPE and INFANT study website, within the hospital and through PPI engagement. **Data minimisation and Declaration Duration** • The HRCDC also queried the duration of the declaration that was requested, until 2036. The HRCDC discussed and agreed that the Applicant should be requested to consider anonymising the personal data as soon as possible, in line with the data protection principle of data minimisation. **Other** • The HRCDC noted and agreed with the observations of the Secretariat regarding technical and more standard safeguards that may need to be considered by the Committee.
HRCDC Decision:	The consensus of the HRCDC was that that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 22nd June 2021 and shall be valid for 15 years, until 31st June 2036, or upon confirmation that the data has been irrevocably rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1.** It is a condition of the declaration that the scope of the consent declaration *does not cover* the sharing and use of the SCOPE data for the IDEA study. The Applicant may submit an amendment request or a new consent declaration application to the HRCDC in relation to the IDEA study. **Condition 2.** The HRCDC requests the Applicant to make efforts to reconsent the SCOPE study participants where practicably possible and appropriate, particularly where opportunities to do so arise, such as when participants attend follow up clinics. This is a reporting requirement as part of the Annual Review which should include numbers of participants reconsented and those that may withdraw from the study. *Note:* The declaration will continue to cover the processing of data where reconsent cannot be obtained. Where participants withdraw their participation and data from the SCOPE study further to making attempts to reconsent, the declaration will not cover the processing of data where consent has been withdrawn. A consent declaration cannot override a participants wish to have their data withdrawn from a study. Clear protocols must also be in place should a participant wish to withdraw their data from the SCOPE study. **Condition 3** The Applicant must ensure that a re-consent protocol is designed and implemented so that the neonate cohort recruited to SCOPE are given the opportunity to provide their explicit consent for data processing when they turn 18 years of age. Attempts to obtain their consent must be made within one year of the participant turning

	18. The Applicant must report on this activity as part of each Annual Review, including where attempts to seek consent are unsuccessful. **Condition 4.** The Applicant is requested to enhance the transparency measures that are undertaken for the SCOPE study. Transparency measures should inform participants about a number of areas including the ongoing use of their data as part of the SCOPE study, the dissemination of research findings, their data protection rights and withdrawal from the study. Consideration should be given to enhancing transparency via updates to the SCOPE and INFANT centre websites as well as through PPI engagement. **Condition 5.** The Applicant is requested to undertake public and patient involvement (PPI) activities as part of the SCOPE study, in areas such as informing future SCOPE research, the dissemination of findings, transparency measures and future consent protocols. The Applicant should consider utilising the working PPI group at the UCC INFANT centre.
HRCDC Recommendations:	**Recommendation 1.** In line with the data protection principle of data minimisation, the Applicant is requested to consider whether the personal data from the SCOPE study can be irrevocably anonymised sooner than the 2036.

8. Annual Reviews of Declarations

The Secretariat has received 5 Annual Reviews in advance of the meeting all of which were deemed to be satisfactory:

- Ref ID: 19-021-AF3 (Eve Griffin - National Self Harm Registry)
- Ref ID: 19-041-AF3-COV (John Laffey - Regulatory Sepsis)
- Ref ID: 20-010-AF1/COV (Linda Coate - COVID-IYON Study)
- Ref ID: 19-009-AF3 (Aideen Hartney - Moving In Study)
- Ref ID: 19-025-AF2 (Gerry McElvaney - Alpha1)

9. Activities report and Upcoming events

The Secretariat (EV) provided an overview of the Activities Report which was provided to the HRCDC in advance of the meeting. Upcoming events of interest where also noted:

- **14th June:** GDPR and biobanking book review (https://www.bbmri-eric.eu/news-events/elsi-webinar-gdpr-and-biobanking-book-review-meet-the-authors/)
- **23rd June:** HDR UK Scientific Conference: Data Insights in a Pandemic (https://www.hdruk.ac.uk/events/scientific-conference-data-insights-in-a-pandemic/?utm_source=SciConEmail&utm_medium=email&utm_campaign=SciConfinalagenda10June21)
- **24th-25th June:** PPI Summer School (https://www.eventbrite.com/e/6th-public-and-patient-involvement-ppi-summer-school-tickets-148722156975)

- **30th June:** Integration & IT Challenges in Healthcare (https://www.eventbrite.ie/e/integration-it-challenges-in-healthcare-tickets-158635889215)
- **Article of Interest:** https://www.theguardian.com/commentisfree/2021/jun/06/tell-me-how-youll-use-my-medical-data-then-i-might-sign-up?CMP=Share_iOSApp_Other

10. Any Other Business

The HRCDC were informed that a presentation on the topic of Biobanking, which was to follow the meeting, has been postponed to a later date.

*** The Chair closed the meeting***