HRCDC
Health Research Consent Declaration Committee

Date: 12th October 2021
Location: Videoconference by Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Alyson Bailey
Kevin Clarke
Claire Collins
Sheelah Connolly
John Ferguson
Aideen Hartney
Zubair Kabir
Barry O' Sullivan
Dan Rea
Cornelius Cooney
Mary Tumelty
John Woods
Barry Lyons
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)

Quorum for Decisions ☒ YES

New Applications - For Consideration

Applicant	Ref No.	Title
Patrick Mallon	20-005-AF1/COV	The All-Ireland Infectious Diseases Cohort Project (AIID Cohort Project)
Elaine Walsh	21-016-AF1	Medication review for frail older adults in primary care: use of the STOPPFrail (version 2) tool in nursing home populations'
Michael O'Callaghan	21-017-AF1/CSO	COVID-19 in Ireland: A retrospective analysis of general practice's contribution to assessment and testing

Meeting Items

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

2. **Apologies**
   Evelyn Mahon, Simon Furney, Kathy Brickell, Caroline Byrne (Secretariat)

3. **Disclosure of Interest**

Application 21-017-AF1/CSO: Claire Colins (CC) declared her interest in this application and was absent during the meeting when this application was considered.

4. Minutes of the last meeting

Draft meeting minutes of 7th September 2021 were circulated in advance of the meeting and were approved by the HRCDC subject to minor corrections.

5. Matters arising

- 21-008-AF1(Evaluation of the 24/7 EEGTM SubQ system in subjects with uncontrolled epilepsy across two important common epilepsy syndromes): The HRCDC where informed that the Applicant no longer wishes to have the application considered by the HRCDC and therefore the application is formally withdrawn.

6. New Applications

Reference ID:	20-005-AF1/COV
Lead Applicant:	Patrick Mallon
Data Controllers:	University College Dublin St. Vincent's University Hospital Dublin Mater Misericordiae University Hospital Cork University Hospital Beaumont Hospital Wexford General Hospital Children's Health Ireland
Title:	The All-Ireland Infectious Diseases Cohort Project (AIID Cohort Project)
Research Objective:	The All-Ireland Infectious Diseases (AIID) Cohort study aims to create a data-rich prospective dataset derived from patients attending hospitals across Ireland, including Cork University Hospital, Mater Misericordiae University Hospital, St Vincent's University Hospital (incorporating St Michael's Hospital, Dun Laoghaire and St Columcille's Hospital, Loughlinstown), Beaumont Hospital and Wexford General Hospital who present with suspected Infectious Diseases including COVID-19. Patients with suspected infection including COVID-19 will be identified on admission to hospital. If the patient is willing to participate after an informed consent process, their clinical data will be collected, and samples will be taken for bio banking. This will provide a platform to answer questions related to infectious diseases including COVID-19 that may arise in the future.
Reason for Declaration:	A consent declaration is requested to process personal data of participants where it is impractical to obtain written informed consent due to COVID-19 infection control restrictions and/or where the participants lack decision making capacity. A deferred consent model is therefore proposed. In addition, deferred proxy assent from the next-of-kin will be obtained. The data processing activities covered by the declaration, if made, is limited to (i) the collection and storage of personal data, including systematic follow-up data and personal data linked to collected, associated bio-samples and (ii) the pseudonymisation of this personal data for ongoing storage, for data security purposes.

	The scope of the consent declaration, if made, will not cover the further processing of the personal data prior to obtaining participant consent (i.e., accessing, transferring, scientific analysis, including genetic analysis for ethically approved studies)
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 Secretariat provided an overview of the study, informing the HRCDC that the application was originally submitted and pre-reviewed in 2020 but that a revised application was submitted in 2021. The Secretariat stated that the resubmitted application has been provided for the HRCDC's consideration. 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 discussed the public interest case. It was noted that the purpose of the AIID cohort study was broad in nature, focusing on the collection and maintenance of a rich data and biological sample set obtained from participants with Tuberculosis, HIV, Hepatitis C and COVID-19, to be further used for future research relating to infectious diseases. • The HRCDC discussed that more information could have been provided by the Applicant on proposed research questions and anticipated deliverables that maybe explored in future research studies. • Notwithstanding the absence of more defined research questions and given the limited scope of the consent declaration and that deferred proxy assent and participant consent will be obtained, on balance, it was the view of the HRCDC that there was a public interest case in the AIID Cohort study for the collection and storage of personal data for future defined and ethically approved research studies. **Scope of consent declaration** • The HRCDC discussed the extent of personal data that will be collected and stored for future research prior to obtaining deferred consent, and if this was appropriate. • It was also discussed if the personal data would be further processed beyond collection and storage for future research purposes, without deferred consent being obtained. • The HRCDC queried the number of participants that may not be able to provide consent and whether deferred consent will be obtained

	from most of these participants. It was further discussed that participants who lack decision-making capacity, and therefore covered by this consent declaration, would likely be COVID-19 patients. • The Secretariat noted and agreed that the scope of the consent declaration, if made, would be limited to the collection, pseudonymisation and storage of personal data only, until deferred participant consent can be provided for the continued collection, storage, and subsequent future use of the data. • It was discussed that the scope would not cover any further processing activities, including transfer or analysis, and would require than a consent declaration amendment request or new application will be required, subject to ethics approval. • It was also commented that deferred proxy assent provided an additional safeguard. • Based on the information provided, the HRCDC also discussed and was of the view that it would not be appropriate to collect and store personal data for future research purposes for a prolonged period, if deferred consent from the majority of participants is not obtained. The HRCDC noted that it would review the consent declaration if it transpires that deferred consent is not obtained from a high number of participants. Correspondingly the Applicant must report on the number of, participants where deferred consent is and is not obtained. **Duration of the consent declaration** • The HRCDC noted that an indefinite consent declaration was requested, whilst the data will be retained for 15 years after the completion of the study. However, it was discussed that no end date was provided for the AIID Cohort study or timeframe for future research studies accessing and using this data. • In line with previous decisions, the HRCDC considered it appropriate to make a time-limited declaration for the AIID Cohort study, which can be extended by the Applicant by way of an amendment request for HRCDC consideration. **Deferred assent/consent** • The HRCDC noted that a consent declaration was requested to include participants who could not be consented due to infection control measures. The HRCDC discussed and was of the view that it should be possible to implement a process for obtaining participant consent in an infection control environment and in advance of data collection, where the participant has decision-making capacity. It was further commented that a verbal consent process had been implemented by researchers over the course of the COVID-19 pandemic. The HRCDC was therefore of the view that the consent declaration will only cover the personal data of those who lack decision-making capacity to provide consent.

	• The HRCDC discussed how and when deferred assent will be obtained in light on ongoing COVID-19 restrictions, for example whether assent is obtained over the phone or in-person. It was noted from the information provided that deferred proxy assent will be obtained as soon as is practicable. • Should the participant continue to lack decision-making capacity for a prolonged period of time, the HRCDC discussed that proxy assent should be reaffirmed as an additional data protection safeguard. • It was also noted that a process must be implemented to ensure the deletion of personal data and biological samples collected, if deferred assent or consent is not provided or withdrawn. **Study information leaflets & assent/consent forms** • The HRCDC discussed if participants and their proxy are provided with copies of the consent/assent forms that they have completed and signed. It was commented that such copies should be provided as a record of the assent/consent that has been granted. • It was noted that the consent and assent forms provide differing information and options on the future use and storage of the personal data and biological samples, and lack of clarity on the data retention period. • The HRCDC discussed that the study information leaflet and assent form provided to the proxy should primarily focus on the collection and storage of the participant's personal data, in line with the scope of the declaration being made. It was considered that should a data controller wish to further process personal data for specific and defined research studies, where the participants continue to lack decision-making capacity, then the Applicant can revert to the proxy with additional information at the point of this future research. Correspondingly, it was also discussed that this could be tied into the process for re-affirming assent. • Although outside the scope of the declaration made, it was discussed that the participant information leaflet should provide as clear and consistent information as possible on the future research that maybe undertaken with the personal data and biological samples. • It was noted that it is up to the data controller to ensure that the consent, including broad explicit consent, obtained for future is sufficient and complies with the Health Research Regulations. • It was also observed that the proxy information leaflet and assent forms should be tailored specifically for the individual providing assent and avoid references such as for example 'your' samples. **Research Ethics Committee (REC) approval** • The HRCDC queried if the required REC approvals where in place and noted that REC approval was received from St. Vincent's University Hospital and the Mater Misericordiae University Hospital and that other sites where granted approval from the National Research Ethics Committee.

	• The Secretariat commented that the clinical sites who have not yet joined the study will not be covered within the current scope of the consent declaration. Where new clinical sites join the study, then a consent declaration amendment request must be submitted to the HRCDC for consideration, accompanied by confirmation of the required REC approval. **Public and Patient Involvement (PPI)** • The Applicant's response to PPI engagement was noted. It was discussed that while PPI engagement has previously been undertaken and specific to representative groups/individuals for HIV infectious disease cohorts, it does not involve engagement with other representative groups or individuals for other infectious diseases. Given that this study relates to other infectious diseases such as Tuberculosis and Hepatitis C and COVID-19, the HRCDC was therefore of the view that broader PPI engagement should be undertaken to seek wider views and perspectives representative of all infectious disease cohorts included in the study. **Data minimisation** • The HRCDC further commented that the Applicant should give consideration to ensuring that only the minimal amount of data is collected and stored for the purpose of the AIID Cohort study. However, it was also acknowledged that it may be challenging for the Applicant to determine what data is needed for future research. **Other** • The Secretariat highlighted that data protection officer feedback and authorised signatures on behalf of Children's Health Ireland remained outstanding. • It was discussed that where personal data is transferred outside the EEA then the required arrangements, such as Standard Contractual Clauses, must be in place. • The HRCDC also noted and agreed with the observations made by 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 a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 12th October 2021 and is valid for 5 years until 12th October 2026, or until participant explicit consent has been obtained or the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner. The Applicant may submit an amendment request for HRCDC consideration, to extend the duration of the consent declaration if required.
Conditions Attached:	**Condition 1.** It is a condition of the consent declaration that the scope only covers the processing of personal data (i.e. collection,

	pseudonymisation and storage only) of participants who lack the decision-making capacity, until deferred consent is obtained. **Condition 2.** For the avoidance of doubt the consent declaration only covers data processing at the hospital sites that have already joined the AIID Cohort study and that have received research ethics committee approval. If additional hospital sites join the study at a later date, then a consent declaration amendment request must be submitted to the HRCDC for consideration, with confirmation of REC approval. *Note*: Any future amendments requests should be submitted by the lead Data controller and new joint data controller. **Condition 3.** Authorised signatures on the HRCDC application form and data protection officer feedback on the data protection impact assessment (DPIA) must be provided to the HRCDC on behalf of the joint data controller, Children's Health Ireland (Crumlin Hospital and Temple Street Children's Hospital). The consent declaration will not cover these hospital sites until this condition is met. **Condition 4.** Where a participant continues to lack decision-making capacity for a prolonged period of time and where proxy assent remains in place, the HRCDC requests that the following action should also be taken as an additional safeguard: (i) the Applicant should seek confirmation from the individual who provided proxy assent, that they wish for the participant's personal data to continue to be processed as part of this research study, with this process appropriately documented for record purposes, (ii) confirmation should be obtained at an appropriate stage of the study that does not cause undue distress or harm to the individuals concerned. This is a reporting requirement as part of the Annual Review. *Note:* Prior to confirming proxy assent, the Applicant should ascertain if that the participant has regained decision-making capacity such that deferred participant consent could be sought. **Condition 5.** The HRCDC reserves the right to review the consent declaration should it transpire that deferred consent cannot be obtained from a significant number of participants due to continued and prolonged lack of decision-making capacity. The Applicant is therefore required to report on the number of participants whose deferred consent is and is not obtained due to their continued lack of decision-making capacity, as part of the Annual Review. **Condition 6.** A transparent and specific process for destroying the personal data and biological samples must be implemented if deferred assent or deferred consent is not provided or is withdrawn. **Condition 7.** In line with the data protection principle of data minimisation, the Applicant is required to ensure that only the

	minimum amount of personal data is collected for the purpose of the AIID Cohort study. **Condition 8.** The Applicant is required to further strengthen Patient and Public Involvement (PPI) activities to include engagement with PPI groups representative of the wider AIID Cohort study participants, such as participants with COVID-19, Tuberculosis, Hepatitis C and other relevant co-infectious diseases.
HRCDC Recommendations:	**Recommendation 1:** The HRCDC recommends the following actions to be considered by the Applicant: (i) review and amend the proxy study information leaflet and assent form to focus and emphasise that their assent is requested to only collect, pseudonymise and store the participant's data for future research purpose. This is aligned with the scope of the consent declaration for participants who lack decision-making capacity, which is limited to the collection and storage of personal data only. (ii) if the personal data is to be further processed for more defined research purposes at a future point in time, it is also recommended to consider reverting to the proxy individual to provide more detailed information on the future research that will be undertaken. Correspondingly, this recommendation is linked to Condition 3 and should be considered when reaffirming proxy assent. (iii) it is recommended to address the following observations made by the HRCDC with regards the information provided to the proxy: - inaccurate use of the term '*your*' data or sample in the proxy study documents, - the statement '*If there is no known objection by your relative to be included*' should be reframed more positively to ask the proxy individual if they believe their relative would wish to participate in this study, - the statement '*may have rights'* should be amended to clarify that participants do have data protection rights. It is acknowledged that there may be derogations to such rights, therefore these should be clearly outlined, where relevant. - clarify potentially inconsistent information on the storage of the data and biological samples. **Recommendation 2.** The HRCDC recommends that the participant information leaflet (PIL) and consent form are reviewed and amended to ensure clarity, transparency and consistency of information for participants. In this context the following observations were made by the HRCDC and should be addressed: (i) the Applicant should ensure that the participant consent form clearly requests their permission for both the storage and the future use of personal data and biological samples, with the consent options on future use appropriately layered and clear to the participant, avoiding the use of 'bundled' consent.

	(ii) it is noted that the participant consent form and proxy assent forms does not include the same 'Yes/No' options and should be cross referenced. Specifically reference to genetic analysis, data transfers outside the EEA, and engagement with commercial companies are inconsistent across forms. (iii) the PIL should provide as much information as possible to ensure the participants are fully informed, about the future research that maybe undertaken with their data and biological samples, including who and what organisations the data may be shared with and nature of genetic analysis. (iv) Points (iii) in Recommendation 1 should also be addressed, where relevant in the participant study documents *Note:* It is the responsibility of the data controller to ensure that the consent obtained, including broad explicit consent, for future use of data complies with the Health Research Regulations. **Recommendation 3.** If not being implemented already, it is recommended to provide the individual providing proxy assent and the participant providing consent, with a copy of the study information leaflet and assent/consent form that they have completed and signed, for their records.

Reference ID:	21-016-AF1
Lead Applicant:	Elaine Walsh
Lead Data Controller:	University College Cork (UCC)
Title:	Medication review for frail older adults in primary care: use of the STOPPFrail (version 2) tool in nursing home populations.
Research Objective:	This study is being undertaken to learn more about medication safety and appropriate medication prescribing in older residents in nursing home settings. The purpose of this study is to apply an evidence-based tool called STOPPFrail (Screening Tool of Older Persons Prescriptions in frail adults with limited life expectancy) to the medications of patients residing in a nursing home setting. STOPPFrail (version 2) is a set of 25 statements which highlight medication classes that may be inappropriate in a frail older adult with limited life expectancy. This tool has been developed to reduce inappropriate prescribing. It is intended to be used as an aid when reviewing the medications of frail older adults. This study is looking at the practical issues surrounding using the STOPPFrail tool in nursing homes. Potential participants for the study in this setting often lack the mental capacity to provide informed consent and therefore a consent declaration is being sought.
Reason for Declaration:	Due to the population of frailer older nursing home residents that will be included in this study, some may have cognitive impairment and it may not be possible to always get explicit consent from the participants themselves. Therefore, a consent declaration is sought to process the personal data of participants who lack decision-making capacity.
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 decision of the HRCDC that a conditional declaration should be made. **Public interest** • The HRCDC discussed the public interest case for the study in conjunction with the study design and the objectives and outcomes it aims to achieve. It was noted that a control group to benchmark against the research findings was not highlighted by the Applicant. • It was discussed that while the study's objectives and deliverables where ambitious given the study design, the greatest benefit would most likely be for the study participants directly. The HRCDC commented that it was important research to undertake in this area and to include this cohort of participants. It was also commented that useful feasibility findings could be produced. • The HRCDC was therefore of the view that, on balance, there was a public interest case in this study. **Pre-screening** • The HRCDC noted that pre-screening only of medical records may be undertaken by the UCC researcher to establish whether an individual was eligible for inclusion in the study, if pre-screening cannot be done by the General Practitioner (GP) practice or nursing home. It was noted from the information provided by the Applicant that an 'authorised persons' agreement for this activity would be in place between UCC, on behalf of the researcher and the data controllers of the personal data being reviewed. • It was discussed that an amendment to the Health Research Regulations provides for pre-screening activities to be undertaken by an 'authorised person' without explicit consent or a consent declaration, subject to suitable safeguards being met, including an 'authorised person' agreement[1]. • It was therefore noted that pre-screening of the GP and nursing home medical records by the UCC researcher, does not fall under the scope of this consent declaration. **Data access** • The HRCDC noted that, further to the pre-screening activity, access to the GP practice and nursing home medical records, will be provided to the UCC researcher to collect and further process the relevant data for the research study.

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

	• It was queried the extent to which the researcher will be given access to GP and nursing home medical records, or if access would be limited to the data that is specifically required for the study. The HRCDC discussed that it may be difficult for a GP or nursing home to limit researcher access to data within medical records that is strictly necessary for this study. • It was also queried if it would be appropriate and feasible for the GP or nursing home staff to extract the required data such that non-relevant data could not be accessed by the researcher. • Considering the proportionality of the data that can be accessed from the medical records for collection and further processing, on balance with the study's proposed objectives and outcomes, the HRCDC was of the view that the consent declaration should be limited. It discussed that scope of the declaration would not cover the further access and collection of data from the GP and nursing home the medical records by the UCC researcher, which is additional to pre-screening activity. Instead, an alternative process should be implemented whereby only personal data strictly required for the study is extracted by the GP or nursing home staff and then shared with the research team. The HRCDC discussed that such an alternative method should be feasible and is appropriate in the context of this study. **Data sharing** • The HRCDC discussed whether the 'authorised person' agreement between UCC and the GP practices, would be sufficient to cover data transfer between the parties. • It was noted that the 'authorised person' agreement relates to pre-screening only and not collection, pseudonymisation and subsequent sharing of data. Therefore appropriate data sharing agreements or arrangements, with relevant data protection terms and conditions, must also be in place between the GP practice/nursing home and the data controller UCC for the study. • The method of data sharing between the research team and data storage was also discussed. While this process was considered to be reasonably secure, it was commented that the Applicant should consider if there are alternative offline encrypted methods that could be used to minimise potential data risks, including risks that may result from human error. **Decision-making capacity to consent** • The HRCDC discussed how participant decision-making capacity will be assessed within this study. Specifically, it was noted that the Mini-Mental Status Examination or a GP assessment will be performed. It was further noted that deferred participant consent will not be sought during the study. • The HRCDC was of the view that capacity should be considered from a functional perspective. In addition, while it is acknowledged that

	many participants may not have or never regain decision-making capacity, the Applicant should not assume that this is the default position as capacity can fluctuate over time. Correspondingly the HRCDC commented that capacity to consent should be reviewed at appropriate points in the study's lifetime and, where possible, deferred participant consent should be obtained. **Proxy assent** • The HRCDC was also of the view that the proxy assent process must be robust and ensure that assent is obtained from a suitable proxy who understands the will and preferences of the individual, if the participant lacks decision-making capacity. • The HRCDC discussed that the Applicant should report on the number of participants where proxy assent has been obtained and the number of participants who provided consent, as part of the Annual Review. **Study information leaflets and assent/consent forms** • It was noted from the information provided that the GP will be provided with a consent form to complete. to request the GP's permission for their own participation in the study and not to request assent for data processing on behalf of the participant from the GP. The HRCDC further noted that this consent form will be amended to ensure the purpose of this document is clear. • It was noted that the study information leaflets should be revised to ensure clarity and transparency regarding what will happen to the personal data if participant consent or proxy assent is withdrawn and should be tailored specifically for the reader/individual providing consent or assent. • It was also commented that there is no statement referencing the participant's will and preferences in the assent/consent documentation. • It was noted that a consent declaration was cited as the legal basis for data processing in the proxy information leaflet. • It was also commented that it could be clearer from the documents where personal data will be sourced from. **Public and Patient Involvement (PPI)** • The HRCDC noted that the Applicant had undertaken some engagement with stakeholders on the matter of consent and study procedures. These stakeholders included GPs, nursing home management and staff. • However, it was not clear to the HRCDC whether engagement had been undertaken with older people or other participant representative groups and if engagement with 'carers', as reference by the Applicant, meant nursing home carers or the participant/patient's relatives. The HRCDC was therefore of the view

	that PPI engagement should be strengthened to include representatives of the participants and their relatives. **Other** • In line with the principle of data minimisation, it was noted that the Applicant could consider anonymising or destroying the personal data in a shorter timeframe. • It was commented that the Applicant should consider further transparency measures to share the study findings with a wider audience. • The HRCDC also noted and agreed with the observations made by the Secretariat regarding technical and more standard safeguards.
HRCDC Decision:	The decision of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 12th October 2021 and is valid for 2 years and a further 10-year retention period until 12thOctober 2033, or until participant explicit consent has been obtained or the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner.
Conditions Attached:	**Condition 1.** The scope of this consent declaration does not cover further access and collection of personal data from GP and/or nursing home medical records by the UCC researcher, that is additional to pre-screening. An alternative process should be implemented whereby only the relevant and strictly required personal data from the medical record is extracted by GP or nursing home staff and subsequently securely transferred to the research team for the purpose of this study. **Condition 2.** The data controller must ensure that appropriate data sharing arrangements are in place between UCC as the data controller of the study, and the GPs and nursing homes, as data controllers of the personal data being accessed, prior to the sharing of personal data between the parties. Personal data cannot be disclosed, shared/transferred until such arrangements are in place. *Note:* Reference to an 'authorised persons' agreement is noted and correspondingly, from the information provided by the Applicant, pre-screening is not covered by this consent declaration. However, such an agreement relates to pre-screening activities only. Therefore, the Applicant must ensure that appropriate data sharing arrangements, with appropriate data protection terms and conditions, are in place between the relevant parties for the purpose of this study. It is the responsibility of each party to ensure that the required agreements/arrangements are in place. **Condition 3.** Full assistance must be provided by the research team to support participants and ensure their inclusive engagement in the consenting process. Where participants have decision-making capacity, their consent must be obtained. When determining decision-making capacity, consideration must be given to assessing capacity from a functional perspective rather than a determining capacity from a

	primarily medical perspective. This aligns with the principles of the Assisted Decision-Making Act 2015. Further consideration should also be given as how deferred consent could be sought in some cases where functional capacity may fluctuate, such that there is decision-making capacity. **Condition 4.** As part of the assent/consent process the Applicant is requested to ensure that suitable robust processes are in place to identify the most appropriate individual who can provide proxy assent on behalf of the participant who lacks decision-making capacity, and who understands the will and preferences of the participant. In this regard proxy assent should be obtained from the next-of-kin/relative and not from the nursing home. The Applicant is requested to report on the number of participants where proxy assent has been obtained. Note: The use of 'your relative/resident' is noted throughout the proxy information leaflet and assent form and it is unclear who specifically is providing proxy assent. Assent should be obtained from the next-of-kin or relative as opposed to the nursing home itself. **Condition 5.** Public and patient involvement (PPI) is considered an important activity by the HRCDC and is viewed as a key data protection safeguard in situations where the participant cannot provide consent. PPI also provides a valuable way of enhancing the level of transparency, which itself is an important data protection principle. It is a condition of this declaration that PPI or engagement activities are undertaken with relevant individuals and/or representative groups of the study participants and/or their relatives for the reasons outlined above as soon as possible. Areas of consideration for PPI activity could include the development of the research, wider public transparency measures and the dissemination of research findings. Progress on meeting this condition is a reporting requirement as part of the Annual Review. **Condition 6.** Confirmation must be provided to the HRCDC that the GP specific information leaflet and consent form has been amended and approved by the research ethics committee to clarify that the intention of these documents relates to the GP's own participation study and are not aimed at requesting proxy assent from the GP on behalf of the study participant. **Condition 7.** The HRCDC requests that the study information leaflets, and assent/consent forms are further reviewed and amended to ensure clarity, transparency and consistency of information for participants and/or individuals providing assent. The following observations were made by the HRCDC and should be addressed prior to the commencement of the study:

	(i) it should be clearly outlined what will happen the personal data if participant consent or proxy assent is withdrawn and where the personal data is sourced from, (ii) references to '*their data'* as opposed to '*your data'* in the participant information leaflet, and the heading '*Do you have to take part'* in the proxy information leaflet should be amended (iii) aligned with Condition 4, references to *'resident'*, for example *'we would like to invite your relative/resident'* should be amended (iv) a consent declaration is not a legal basis for data processing, but a data protection safeguard. Correspondingly the Article 6 legal basis/Article 9 relevant condition noted in the study information leaflets should be reviewed and amended. This matter should be discussed with your data protection officer. (v) a statement should be included in both the proxy and participant information leaflets and assent/consent forms to request positive confirmation that the participant wishes or would wish to participate in this study.
HRCDC Recommendations:	**Recommendation 1.** The HRCDC notes the use of secure online methods to share and store personal data amongst the research team. To further reduce data protection risks, the Applicant is requested to consider if there are alternative offline, encrypted methods that could be used to further minimise potential data risks, including those that may result from human error. **Recommendation 2.** The HRCDC recommends that the Applicant explores how the findings from this study can be disseminated to a wider audience than may benefit from the study findings, other than to academic audiences. **Recommendation 3.** In line with the principle of data minimisation the Applicant is requested to consider whether the personal data can be anonymised or destroyed sooner than the referenced data retention period of 10 years.

Reference ID:	21-017-AF1/CSO
Lead Applicant:	Michael O'Callaghan
Lead Data Controller:	Irish College of General Practitioners (ICGP)
Title:	COVID-19 in Ireland: A retrospective analysis of general practice's contribution to assessment and testing.
Research Objective:	General practice in Ireland plays an important role in screening services and is often the first point of contact with the health service for those with new, potentially serious complaints. This project aims to determine the number of GP electronic referrals ('eReferrals') for COVID-19 PCR testing and community hub assessments. Time spent on testing eReferrals and community hub assessments means that other areas of care may have been impacted by reduced availability of GP staff. Accurately describing general practice's contribution to the national COVID-19 testing efforts and hub assessments will allow us to estimate

	how much time GPs and practice staff dedicated to these activities. This may help inform how general practice services are best utilised, during this ongoing health crisis and in future
Reason for Declaration:	The Applicant is seeking to access and obtained pseudonymised data (research microdata files) from the COVID-19 Data Research Hub, hosted by the Central Statistics Office. 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 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. As the application related to the CSO COVID-19 Research Data Hub and considering that the same data protection safeguards will be implemented as in previous CSO applications, the consensus of the HRCDC was that a conditional declaration should be made. **Public Interest** • The HRCDC was of the view that there is a public interest case in this study. **CSO Approval** • Aligned with previous consent declaration applications to process personal data from the COVID-19 Data Research Hub, confirmation of final Central Statistics Office approval must be provided to the HRCDC. **Transparency measures** • It was commented that appropriate transparency measures to inform the public about this study, including via the ICGP website, should be developed and implemented in an appropriate timeframe. **Additional Data** • The HRCDC noted that the study may wish to access vaccination data via the COVID-19 Data Research Hub, however this data is not yet available. It was highlighted by the Secretariat that a consent declaration amendment request will be required to use this data if it becomes available. **Other** • The HRCDC noted inaccurate references to a consent declaration from the Health Research Board are made in the data protection impact assessment (DPIA). It discussed noted that such references should be amended.

HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made on 12th October 2021 and is valid for one year, until 12th October 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.** 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 COVID-19 Data Research Hub. Consideration should be given to providing information on the data controller's 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.
HRCDC Recommendations:	**Recommendation 1.** The scope of this consent declaration does not cover the access to vaccination data for this study. Should this data become available within the COVID-19 Data Research Hub, it is recommended that the ICGP/Data controller, apply for an amendment to the consent declaration for the processing of this data, for HRCDC consideration. A new application should not be required. **Recommendation 1.** The Data Protection Impact Assessment form (pg5) states '*A consent declaration from the HRB must be in place before any access to CSO RMFs will be allowed*'. It is recommended that the Applicant revise to state 'from the Health Research Consent Declaration Committee' and correct other references to the HRB throughout. For clarity this should be amended to reflect that a consent declaration is made by the HRCDC.

7. Annual Review of Declarations

The Secretariat has received 3 Annual Reviews in advance of the meeting which were deemed satisfactory:

- Ref ID: 19-006-AF3 (Michael Farrell - The Contribution of Whole Genome Sequencing to Brain Tumour Biology)
- Ref ID: 19-086-AF1 (Ignacio Martin-Loeches - Sepsis Immunosuppression in Critically Ill Patients)
- Ref ID: 20-024-AF1-COV (Alistair Nichol – GenOMICC study)

8. Activities Report & Upcoming Events

Past and upcoming events and an article of interest were noted to the HRCDC:

- PPPOSI: Learning from the Pandemic Response: Implications for Health Information in Ireland; 10th September (Event recording: https://www.youtube.com/watch?v=WMidlWZ6AvI; Summary Report: https://www.ipposi.ie/wp-content/uploads/2020/07/Summary-Report-13-July-Final-Version-.pdf)
- Health Research Board: Creating our Future: Help us shape future health and care; 9th November 2021 (https://www.hrb.ie/news/events/upcoming-events/creating-our-future-help-us-shape-future-health-and-care/)
- Irish Health Research Forum: Health research – how to be responsive and resilient in the face of crises; 17th November, 10am-12.30pm (https://www.eventbrite.ie/e/health-research-how-to-be-responsive-and-resilient-in-the-face-of-crises-registration-186963120727)

9. AOB

- The Secretariat informed the HRCDC that the HRCDC's Standard Operating Procedures (SOPs) are currently under review. A draft of the updated SOPs will be shared with members for discussion.
- The Conflict-of-Interest (COI) Policy and accompanying COI log are in the process of being updated and will be shared with the Committee.
- It was discussed and agreed that an additional standard consent declaration condition will be added to the HRCDC decision letters to clarify when an amendment to a consent declaration maybe necessary.
- The Chair noted that some HRCDC members are approaching the end of their first term on the Committee in Q1 2022. Members were asked to begin to give consideration on whether they wish to remain on the HRCDC for a 2nd term which is provided for in the Health Research Regulations. It was discussed that the Chair and Secretariat will be in touch again in due course on this matter.

*** The Chair closed the meeting***