HRCDC
Health Research Consent Declaration Committee

Date: 20th July 2021
Location: Videoconference by Zoom

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Kevin Clarke
Sheelah Connolly
Simon Furney
Dan Rea
Cornelius Cooney
Mary Tumelty
Emily Vereker (Secretariat)
Jonny Barrett (Secretariat)

Observer

Name
Caitriona Creely (Health Research Board)

Quorum for Decisions
☒**YES**

New Amendments - For Consideration

Applicant	Ref No.	Title
Alistair Nichol	20-022-AF1/AMD1	PHIND Study
Shona Pfeiffer	19-085-AF1-AMD1	Blood Biomarkers to Predict Recovery from Ischaemic Stroke
Prof. Deirdre Murray, Fergus McCarthy – with Dr Elaine McCarthy	19-020-AF2 19-070-AF2	IDEA Study (Joint amendment to BASELINE and SCOPE)

New Applications - For Consideration

Applicant	Ref No.	Title
Norman Delanty	21-008-AF1	Evaluation of the EEG SubQ system for epilepsy
Mary McCarron	21-009-AF1	Developing post-diagnostic support guidelines for dementia
Mark Little	19-044-AF2	Rare Kidney Disease (RKD Registry and Bioresource

Meeting Items

1. Opening

The Chair opened the meeting and welcomed the members. The Chair also welcomed Dr Caitriona Creely from the Health Research Board, as an observer to the meeting.

2. Apologies

Kathy Brickell, Barry Lyons, John Ferguson, Aideen Hartney, Claire Colins, Zubair Kabir, John Woods, Barry O'Sullivan, Caroline Byrne (Secretariat).

3. Disclosure of Interest

There were no disclosures of interest for this meeting.

4. Minutes of previous HRCDC meeting (22.06.2021)

Draft minutes of the 22nd June 2021 meeting were circulated in advance of the meeting and were agreed by the HRCDC.

5. Matters arising

Emily Vereker (EV) informed the HRCDC of the Research Data Governance Board planning group meeting of 22nd June 2021 where the matter of broader public and patient involvement (PPI) activity regarding researcher access to the COVID-19 Data Research Hub, was discussed. The upcoming HIQA report on a national public engagement survey was also highlighted as a potentially useful resource (https://www.hiqa.ie/hiqa-news-updates/national-public-engagement-survey-future-health-information-ireland-commences).

6. Amendments

Reference ID:	20-022-AF1/AMD1
Lead Applicant:	Alistair Nichol
Lead Data Controller:	Queens University Belfast St Vincent's University Hospital Belfast Health and Social Care Trust
Title:	PHIND Study
Research Objective:	See minutes of 4th September 2020
Purpose of Amendment:	The amendment is to reflect a change to the study's consent model. Some participants will lack decision-making capacity to consent due to the nature of their illness; assent is obtained from their next-of-kin/proxy in a face-to-face encounter, and they provide written assent. During a pandemic, family members are placed under severe visiting restrictions as per hospital policy, rendering a face-to-face discussion challenging. The study proposes to contact the next-of-kin by telephone and seek to obtain their assent over the phone. The assent form will also be sent to the relative to be signed and returned.
HRCDC Comments:	It was the consensus of the HRCDC that the amendment to the consent declaration could be made. **Telephone assent** • The HRCDC noted that the use of telephone assent has become a common and standard approach to obtain proxy assent during the COVID-19 pandemic.

	• The HRCDC noted the Applicant's response that a copy of the assent form will be sent to the next-of-kin, however, no reference was made to providing the corresponding study information leaflet to the next-of-kin in the HRCDC application form or the telephone assent form. • The HRCDC further noted that the telephone assent form does not ask the next-of-kin to confirm that they have had the opportunity to ask questions about the study. • It was also commented that the telephone assent form should provide contact information if the proxy wishes to request further information or if they have any further queries.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Amendment Duration	The Amendment is made commencing 20th July 2021 and shall be valid until 31st December 2026 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).
HRCDC Recommendations:	**Recommendation.** The HRCDC recommends the following actions for consideration regarding the telephone assent form: (i) a copy of the associated study information leaflet should be forwarded to the individual who is providing proxy assent on behalf of the study participant, prior to obtaining assent where possible. (ii) the assent form should request the proxy to confirm that they have had the opportunity to ask further questions about the study, (iii) contact information should be provided on the assent form should the proxy wish to discuss the study further.

Reference ID:	19-085-AF1/AMD1
Lead Applicant:	Shona Pfeiffer
Lead Data Controller:	Royal College of Surgeons in Ireland (RCSI)
Title:	Blood Biomarkers to Predict Recovery from Ischaemic Stroke
Research Objective:	See minutes of 2nd March 2020
Purpose of Amendment:	The scope of the consent declaration made was to process personal data where participants lack decision-making capacity, specifically recording and storing the participant's name and medical record number (MRN) prior to obtaining deferred consent. The scope of the amendment request is for the following additional data processing activities for participants who lack decision-making capacity: (i) The collection and analysis of additional personal data, including clinical data from the medical records, data associated with the bio-samples and follow-up data collected up to day 90 for the purpose of this research study, (ii) The sharing of data with the study collaborator, National University of Ireland Galway, for the purpose of this study, (iii) The ongoing storage of the data for 7 years. Proxy assent will be obtained where the participant lacks decision-making capacity.
HRCDC Comments:	The Chair reminded the HRCDC of the scope of the declaration that was made for this study and outlined the amendment sought by the

	Applicant. It was also highlighted that a public interest case was required. The Chair requested each member to indicate whether the request for the amendment should be approved. Based on the information provided, it was the consensus of the HRCDC that the amendment to the consent declaration could be made. **Public Interest** • It was noted that the amendment request was quite extensive in nature. The HRCDC also discussed that the amendment form was challenging to read, and that further information and clarity could have been provided on the additional clinical data to be collected and further processed. • The HRCDC accepted the Applicant's reasons why it was important to process the personal data of participants who lack-decision making capacity in this study, and that the exclusion of these participants would have a significant impact on the generalisability of the study results. The HRCDC was of the view that there was a strong public interest case for this amendment. **Assent process** • The HRCDC noted the proxy assent protocol outlined by the Applicant. It was discussed that no reference was made to the timeline for obtaining proxy assent or whether telephone assent would be sought should it not be possible to obtain face-to-face assent. However, it was noted that if assent cannot be obtained, then data and associated bio-samples are destroyed and not included in the study. • The HRCDC commented that no further personal data, beyond participant name and MRN, should be collected and processed until proxy assent is obtained and that proxy assent should be obtained as soon as possible. • It was discussed that a further amendment to the consent declaration would be required, including research ethics committee approval, if a telephone assent model was later introduced in this study. • The HRCDC was also of the view that proxy assent should be re-affirmed at an appropriate point in time should the participant continue to lack decision-making capacity for a prolonged period. **Study information leaflets** • It was noted that the proxy assent study information leaflet states that blood sampling is undertaken as part of standard clinical management. The HRCDC discussed that the study information leaflet should make it clear to the proxy that the blood samples taken are not limited to those taken for care and treatment, but also collected for the purpose of this research study. • The HRCDC also noted that the proxy assent form provides different options with regards the use of the personal data and associated bio-samples for future research. It was discussed that the number of

	options provided could be confusing for the individual who is providing proxy assent. The HRCDC further discussed that consideration should be given to removing these options as proxy assent is not lawful valid consent for processing personal data. Furthermore, the scope of the consent declaration and amendment is limited to data processing for the purpose of the '*Blood Biomarkers to Predict Recovery from Ischaemic Stroke'* study only. The consent declaration cannot cover the processing of personal data for future, unspecified research studies. **Research Ethics Committee (REC) Approval** • It was noted that RCSI REC approval for the study expires in December 2024 and an extension to the approval will be requested.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declaration could be amended.
Amendment Duration	The Amendment is made commencing 20th July 2021 and shall be valid until 31st April 2031 or upon confirmation that the data has been rendered anonymised or destroyed, or whichever occurs sooner (This timeline is an extension to the original duration of the consent declaration that was made previously).
Conditions Attached:	**Condition 1.** Proxy assent on behalf of the participant must be obtained as soon as possible following the participant's admission to the hospital. For the avoidance of doubt, no further personal data, beyond the participant's name and medical record number (MRN), can be collected and processed prior to obtaining proxy assent; this aligns with the scope of the declaration previously made. **Condition 2**. 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 be taken as an additional safeguard: - 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. - 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 the proxy assent, the Applicant should ensure that the participant has not regained decision making capacity such that deferred participant consent could not be sought. **Condition 3.** An extension of the RCSI Research Ethics Committee (REC) approval must be obtained prior to its expiration on 10th December 2024. When made, confirmation of this extended approval must be provided to the HRCDC.
HRCDC Recommendations:	**Recommendation.** The Applicant is requested to consider reviewing and amending the assent form and associated study information leaflet as follows: (i) It should be clear to the individual providing proxy assent, that blood samples are taken for care and treatment *and* for the purpose of this

	specific research study. In this context consideration should be given to amending the statement '*Blood sampling is part of the normal clinical management*' to ensure clarity and consistency of information. (ii) As the scope of the consent declaration is limited to data processing for the purpose of the '*Blood Biomarkers to Predict Recovery from Ischaemic Stroke*' study only, and proxy assent has no lawful basis, the Applicant is requested to consider amending or deleting the options provided in the assent form with regards the future use of personal data for research.
Other Comments:	The HRCDC noted that a telephone assent protocol was not outlined in the amendment request form. If a telephone assent model is introduced into the study, a further amendment to the consent declaration would be required, including research ethics committee approval.

Reference ID:	19-020-AF2/AMD1 (BASELINE study) 19-070-AF2/AMD1 (SCOPE study)
Lead Applicant:	Elaine McCarthy Deirdre Murray Fergus McCarthy
Lead Data Controller:	University College Cork
Title:	The IDEA Study (A joint amendment for the BASELINE and SCOPE studies)
Research Objective:	See minutes of 22nd June 2021
Purpose of Amendment:	Conditional consent declarations have been made for the SCOPE Pregnancy study and the BASELINE Birth Cohort study. These longitudinal, prospective studies provide a unique opportunity to investigate pregnancy and early-life determinants of later health in women and their children. Iron deficiency is the most common micronutrient deficiency in the world, with pregnant women and infants the most vulnerable. Iron deficiency has lasting health consequences for both the mother and her child, but particularly for the development of the child's brain. The IDEA study aims to tackle this global public health challenge by constructing and validating two screening tools, one for pregnant women and their infants and a second for preterm infants, to identify individuals at an increased risk of iron deficiency. As the objectives of the IDEA project align with the original research objectives of both the SCOPE and BASELINE studies, an amendment to the SCOPE and BASELINE consent declarations is sought to allow the processing of personal data from these studies for the IDEA study being carried out by UCC, the data controller.
HRCDC Comments:	The Chair reminded the HRCDC of the Applicant's initial request for the consent declaration for the SCOPE study to cover the processing of the SCOPE data for the IDEA study. It was noted that the consent declaration made for the SCOPE study did not extend to the IDEA study. It was further highlighted that the IDEA study would process data collected under both the SCOPE and BASELINE studies, that received consent declarations. The Applicant had been advised by the Secretariat that an amendment to the consent declarations could be

	requested to cover the IDEA study, and as part of this the Applicant should provide further information on the IDEA study to determine the public interest case. The HRCDC were reminded that the IDEA study was an internal UCC study with a separate study protocol, different Principal Investigator and had separate REC approvals from the BASELINE and SCOPE studies. The Chair requested each HRCDC member to indicate whether the request for the amendment should be approved. Based on the information provided, it was the consensus of the HRCDC that the amendment to the consent declarations for the BASELINE and SCOPE studies could be made. **Public Interest** • From the information provided by the Applicant, the HRCDC noted that the IDEA study was closely aligned with the objectives of the BASELINE and SCOPE studies and that the further use of these datasets for research was important. • The consensus of the HRCDC was that there was a strong public interest case in further processing the BASELINE and SCOPE data for the purpose of the IDEA study. **Existing consent declaration conditions** • The HRCDC discussed that all standard conditions of the consent declarations made for the BASELINE and SCOPE studies are applicable to the IDEA study, including some more specific conditions attached and recommendations made. It was commented that public and patient involvement which was a condition previously attached to the consent declaration for the BASELINE and SCOPE studies, should also be carried out for the IDEA study. **Future amendments** • The HRCDC discussed the consent obtained for the SCOPE and BASELINE studies, which was not considered by the Applicant to be compliant under the previous data protection legislation. It was commented that further amendment requests may be submitted by the data controller for the use of these data sets, by the data controller. • It was discussed whether a consent declaration could be made to more broadly cover the processing of the SCOPE/BASELINE personal data, for future related research studies, subject to UCC remaining the data controller of those studies and other safeguards including research ethics committee approval. The Secretariat is examining if this would be permitted under the regulations and will consult the Department of Health about the interpretation of the regulations. **Other** • The HRCDC noted the Applicant's response that the data protection impact assessment (DPIA) for both the BASELINE and SCOPE

	studies will be updated to reflect the additional data processing activities for the IDEA study. It was commented that the DPIA should be treated as a live document and therefore updated by the Applicant. • From the information provided it was noted and commended that updated information on the IDEA study will be provided on the BASELINE and SCOPE study websites.
HRCDC Decision:	The consensus of the HRCDC was that the conditional declarations made for both the BASELINE and SCOPE studies, could be amended.
Amendment Duration	The Amendment is made commencing 20th July 2021 and shall be valid until 31st June 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 declarations made for both the BASELINE and SCOPE studies).
Conditions Attached	**Condition 1.** The Applicant is required to update the data protection impact assessment (DPIA) for the BASELINE and SCOPE studies to reflect the additional data processing activities, data protection risks and mitigating actions associated with the IDEA study. **Condition 2.** All standard and specific conditions attached to the consent declarations made to the BASELINE and SCOPE studies also apply to the IDEA Study. As part of this the Applicant is requested to ensure that the public and patient involvement activities to be undertaken for the BASELINE and SCOPE studies, a condition attached to the consent declarations made, should also extend to the IDEA study, where appropriate. ***Note:*** Condition 1 of the consent declaration for the SCOPE study (i.e., that the declaration does not cover the IDEA study) is no longer applicable.

7. New Applications

Reference ID:	21-008-AF1
Lead Applicant:	Norman Delanty
Lead Data Controller:	The Royal College of Surgeons in Ireland (RCSI)
Title:	Evaluation of the 24/7 EEGTM SubQ system in subjects with uncontrolled epilepsy across two important common epilepsy syndromes
Research Objective:	The purpose of this study is to evaluate the performance of a portable brainwave (Electroencephalogram 'EEG') recording system for home monitoring of epileptic seizures - 24/7 EEG SubQ System device. People with epilepsy (idiopathic or symptomatic generalised epilepsy) who are still experiencing seizures despite receiving treatment will be invited to participate in the study. At present there is no other minimally invasive system or device available for ultra-long-term (weeks to months) EEG recording in the home environment. This study investigates the performance of such portable device for the better detection and monitoring of epilepsy seizures. The study will take place in the epilepsy monitoring unit (EMU) at Beaumont hospital and throughout 3 months of home recording.

Reason for Declaration:	A consent declaration is sought for the purposes of processing personal data of individuals who lack decision-making capacity. Specifically patient records will be reviewed, data collected, integrated and analysed with study data to be collected prospectively. Approximately 50% of patients in this study will have been diagnosed with symptomatic generalised epilepsy who almost always have significant intellectual disability.
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 formal decision should be deferred pending receipt of further information. **Public Interest** • The HRCDC discussed the degree of the public interest. It was noted that the study would involve a relatively small number of participants, 10 in total, of whom approximately 50% would lack decision-making capacity to provide consent. The HRCDC queried the extent to which a study involving this number of participants will help to achieve the research objectives and, correspondingly, if there is a sufficiently strong public interest case. • The HRCDC also queried the extent and type of data outputs that would be produced from the 24/7 EEG SubQ System portable device and processed as part of this study. • It was also discussed that it would be useful to request further information on what international studies using this device have been undertaken, how this specific RCSI study will help to build on previous studies and the potential impact it will have. **Capacity to consent** • Given the small number of participants, the HRCDC queried whether it would be possible for the study to only recruit participants who had decision-making capacity. • The HRCDC noted that the REC had a condition on its approval that the research should only be carried out on individuals that lack decision-making capacity, if the required knowledge cannot be obtained otherwise, in line with the HSE National Consent Policy. The HRCDC was not clear what the response of the Applicant was to this REC condition. • It was noted that two types of epilepsy are the subject of this research, one of which is symptomatic generalised epilepsy which is prevalent in individuals with intellectual disabilities who may lack decision-making capacity to provide consent. It was commented that it is

important not to exclude participant cohorts who may lack decision-making capacity.

- The HRCDC also queried how the participant's decision-making capacity is assessed and how individuals with diminished capacity, who are unable to provide consent, can complete the study questionnaire and seizure logbook, or whether this is completed on their behalf. The extent to which the participant who lacks decision making capacity is included in the decision-making process, was also queried.

Research Ethics Committee (REC) approval

- The HRCDC noted that conditional REC approval has been obtained. It was discussed that the matters raised by the REC must be addressed, including the REC point with regards the HSE National Consent Policy. Correspondingly confirmation of full REC approval will also be required.

Public and Patient Involvement (PPI)

- The HRCDC discussed the Applicant's response with regards PPI. It was noted that while future PPI activities are planned as part of the wider RCSI-hosted FutureNeuro Center PPI strategy, no PPI activity for the research study itself appears to be planned in the near future.
- The HRCDC commented that the level of PPI engagement should be greatly strengthened and enhanced, given the nature of the study and participants involved. In particular, the HRCDC discussed that there are opportunities to engage with PPI representative groups, such as Epilepsy Ireland.

Study Information leaflet & Assent/Consent forms

- The HRCDC noted that the proxy assent form provides several different options with regards the storage and future use of the personal data, which could be confusing for the individual who is providing proxy assent. The HRCDC discussed that consideration should be given to removing these options as proxy assent is not lawful valid consent for processing personal data and that the scope of the consent declaration, if made, would be limited to data processing for the purpose of this study only.
- The HRCDC also discussed the Applicant's response with regards the role of Beaumont Hospital and the device manufacture, UNEEG and T&W Engineering A/S (TWE) in this study. It was commented that the study information leaflets, and assent/consent forms, would be updated to clarify and accurately reflect the specific roles and responsibilities of these parties within this study.
- It was noted that the study information leaflet states that data cannot be erased when anonymised. From the information provided, the Applicant also outlined that if a patient withdraws from the study that their data will be erased. The HRCDC commented that it should be clear to the participant and the individual providing proxy assent that the data will be erased prior to anonymisation, if they wish to withdraw from the study.

	Other • The HRCDC noted that a system will be designed to help link the data collected from the various data sources. It was discussed that more information could be requested on this system.
HRCDC Decision:	The consensus of the HRCDC was that a formal decision would be deferred pending receipt of further information.
Further Information Requested:	**Query 1.** To fully understand the significance of the public interest case for the study, the Applicant is requested provide the HRCDC with further information as follows: (i) elaborate on how the data to be collected and analysed from the small number of participants, would impact and contribute meaningfully the objectives of the study, (ii) what other comparable studies, including international studies, have also examined the performance of the 24/7 EEG SubQ System device, and correspondingly how this specific RCSI study builds on and contributes to this research area, (iii) provide more specific information on the extent and type of data outputs that would be produced from the 24/7 EEG SubQ portable device and processed for the purpose of this study. **Query 2.** The HRCDC requests the Applicant to consider and respond to the HRCDC as to whether the study can be conducted only with participants who have the decision-making capacity to provide consent. Linked to this, please confirm that condition 1 (adherence to the HSE National Consent Policy) set out in the conditional REC approval from Beaumont Hospital, have been implemented. **Query 3.** The HRCDC requests more information on: (i) how the decision-making capacity of participants is assessed and determined, and (ii) the extent to which participants who lack decision-making capacity are involved in the decision-making process, and (iii) what supports are provided to them during this process. **Query 4.** Please clarify who completes the study data logs and questionnaires: the participant, carer/next-of-kin/proxy or both? Will participants who lack decision-making capacity complete these documents alone or with assistance? **Query 5.** The HRCDC requests further information on what more in-depth public and patient involvement (PPI) activities can be undertaken sooner then Q4 2021, such as engagement with relevant representative groups, for example Epilepsy Ireland. **Query 6.** Please confirm that the study information leaflets and assent/consent forms have been updated to accurately reflect the roles and responsibilities of the parties within the study, specifically that they have been updated to clarify the role of Beaumont Hospital, UNEEG and TWE. Linked to Query 5, please also confirm: (i) if the study information leaflets and assent/consent forms have been, or will be, reviewed by PPI representatives to ensure

	readability for the participants and the proxy individual providing assent. (ii) if the following observations noted by the HRCDC can be addressed and study information leaflets and assent/consent forms amended accordingly: - the proxy assent forms provide options for the future unspecified use of data. Please note that proxy assent on behalf of a participant is not considered valid consent for data processing. The scope of the declaration, if made, will also be limited to data processing for the purpose of the 21-008-AF1 study only and will not cover future, unknown research. - the study information leaflets should clearly outline that data will be deleted if a participant withdraws from the study, prior to data anonymisation. The Applicant is requested to provide a copy of the amended versions of these documents if available. **Query 7.** It is noted that data linkage system will be designed for this study. Please provide further information on this system, including data security measures and when it is expected to be operationalised for use in this study.

Reference ID:	21-009-AF1
Lead Applicant:	Mary McCarron
Lead Data Controller:	Trinity College Dublin
Title:	Including best practices and the voices of experience in developing post-diagnostic dementia support guidelines for people with an intellectual disability
Research Objective:	People with an intellectual disability are at greater risk of developing dementia than the general population, but services are ill prepared to provide post-diagnostic support to people with an intellectual disability and dementia and their carers. This study aims to advance such efforts by examining post-diagnostic supports for people with an intellectual disability and dementia through the development of accessible best practice guidelines for post-diagnostic dementia supports for people with an intellectual disability in Ireland. This will be achieved through: (1) examining the current landscape of post-diagnostic care; (2) considering barriers to access; (3) incorporating existing best practices; and (4) giving due consideration of the experiences and recommendations of people with an intellectual disability living with dementia and their families/carers. A consent declaration is required as the study will be recruiting people with an intellectual disability and dementia, who may have limited capacity to consent to taking part in the research.
Reason for Declaration:	The declaration is requested to process the personal data of participants who lack decision-making capacity to provide explicit consent (specifically study work packages 3 & 4). Data processing for the purpose of undertaking this research study includes collection, pseudonymisation, transfer, analysis and storage of personal data.
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 conditional declaration should be made. **Public Interest** • The HRCDC discussed the objectives of the study and noted the appropriate use of qualitative research methods to collect the required data as well as the anticipated sample size. • The HRCDC commented that this was an important research area. It was further commented that the inclusion of participants who lack-decision making capacity in this type of research was also important. • Based on the information provided it was the consensus of the HRCDC that there was a strong public interest case for undertaking this study. **Proxy Assent/Consent process** • It was noted that a key worker or support worker who knows the participant may provide proxy assent on their behalf. It was also noted that where the participant is able to confirm their consent but unable to sign, their affirmation will be witnessed by the support person on the day. • The HRCDC noted the Applicant's response that the individual providing assent must have known the participant for at least 6 months. The HRCDC commented that the process for obtaining proxy assent must be suitably robust to ensure that the individual who provides proxy assent, including a key/support worker, has had sufficient contact during that period in order to have sufficient knowledge of the person to understand the participant's will and preferences. • It was also noted that the key/support worker, who may be providing proxy assent, may also be a participant in the study interviews themselves. It was further noted that interviews will be conducted with the family member/carer, where it is not possible to interview both the individual with an intellectual disability and the family member/carer. • As the objectives of the research study aim to determine the quality of the services provided to individuals with an intellectual disability and dementia, the HRCDC discussed that it was important to have sufficient processes in place to mitigate against potential data biasness and conflict of interests that may arise, and ensure the confidentiality of information provided by the participant. • The HRCDC also commented that it is important that participants who lack decision-making capacity are involved in the decision-making process to the greatest extent possible and their opinions considered.

	Research Ethics Committee (REC) approval • In addition to the REC approval from Trinity College Dublin, the Applicant stated that REC approval will also be sought from the St. James's Hospital / Tallaght University Hospital joint REC. It was discussed that confirmation of this REC approval must be provided to the HRCDC once obtained. **Additional research sites** • From the information provided, the HRCDC noted that participants with an intellectual disability and dementia may be recruited from other service providers outside the National Intellectual Disability Memory Service (NIDMS) in Tallaght University Hospital, which could include the Daughters of Charity and other sites. • The HRCDC queried how participants would be recruited from other service providers and what safeguards will be in place. It was noted that local ethics approval will be sought where relevant. • It was discussed that the Applicant will be required to seek an amendment to the consent declaration to process the personal data of participants who lack decision-making capacity form other service sites besides the NIDMS, subject to obtaining the required REC approval. **Assent/Consent forms** • It was discussed that the signature page of the accessible consent form provided to the participant with an intellectual disability should specifically name the study that they are consenting to. • Furthermore, the HRCDC was of the view that the 'family member/guardian agreement form' should clearly request assent for the processing of the participants personal data. The information provided should also clearly outline that the study involves multiple service sites. **Other** • The HRCDC noted the query from the data protection officer (DPO) with regards the encryption and security of individual devices. The HRCDC discussed that the DPOs feedback on this matter should be considered and addressed by the Applicant, where relevant. • 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 *a* Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 20th July 2021 and shall be valid until 31st December 2022 or upon confirmation that explicit consent has been obtained or the personal data have been rendered anonymised or destroyed, or whichever occurs sooner.
Conditions Attached:	**Condition 1.** The scope of this declaration is limited to participants recruited via the National Intellectual Disability Memory Service (NIDMS).

	Condition 2. When obtained, confirmation of research ethics committee (REC) approval from the St. James's Hospital / Tallaght University Hospital Joint REC must be provided to the HRCDC. No data processing can commence from service sites that will be covered by this REC approval, until such approval is confirmed. **Condition 3.** The Applicant is required to ensure that the protocol for obtaining proxy assent on behalf of the participant must ensure that the individual who provides proxy assent sufficiently understands the will and preferences of the participant, in particular where proxy assent is obtained from a key worker or support worker. **Condition 4.** Given the nature and objectives of the study, and that support/key workers involved in supporting the participants that lack decision-making capacity, may also be participants themselves in the qualitative interviews, the Applicant must ensure that sufficient processes are in place to ensure potential conflict of interests are managing accordingly if they arise. The confidentiality of information provided by the participant should also be safeguarded where possible.
HRCDC Recommendations:	**Recommendation 1.** To provide clarity and consistency of information, the Applicant is requested to review and amend the study information leaflet and assent/consent forms as follows: (i) it should be made clear to the participants and the individual providing proxy assent that individuals will be recruited from other services besides the NIDMS. (ii) the signature page of the accessible consent form should specifically name the study to clearly outline to the participants that they are consenting for this study. (iii) ensure that the 'Family member/guardian agreement form' clearly outlines that their assent is requested to process the personal data of the participant who lacks decision-making capacity. **Recommendation 2.** The Applicant is requested to ensure that feedback from the data protection officer with regards the security and encryption of study devices, is addressed if not addressed already.

Reference ID:	19-044-AF2
Lead Applicant:	Mark Little
Lead Data Controllers:	Trinity College Dublin & Firalis SAS
Title:	Rare Kidney Disease (RKD) Registry and Bioresource *(collaborative study with Firalis SAS – the HELICAL Study)*
Research Objective:	The purpose of this study was to set up a central repository (bio-samples and linked data) to support research aimed at improving the prevention, diagnosis and treatment of the rare auto-immune condition vasculitis. The intention is to understand more about causes and progression with the long-term goal of research into better diagnostic tests and treatments.
Reason for Declaration:	The scope of the declaration is for a data processing being carried out in connection with an industry collaborator. Collaboration with industry was not detailed in the original consent forms for the registry and

	bioresource. Specifically, the declaration is for the continued sharing and use of data and associated samples from the RKD Registry/Bioresource with an industry collaborator, Firalis SAS, for the purpose of the HELICAL study.
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 'AF2' applications sought a declaration for studies that commenced prior to the Health Research Regulations. AF2 Applicants considered that consent obtained was compliant with the 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 for all or part of the study. Therefore, the HRCDC must consider these studies and balance the public interest case for the study. The Secretariat highlighted that a consent declaration was not required for the RKD Registry/Bioresource itself but limited to the processing of personal data from the RKD Registry/Bioresource in a specific industry collaboration, which was not detailed in the original consent forms. It was further highlighted that confirmation was pending on whether the industry collaborator, Firalis SAS, was a joint data controller. Should a consent declaration be made it was discussed that the declaration would not be effective until confirmation was provided on the data controllership and that specific conditions would be attached in this regard. 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** • It was noted that the HRCDC application form submitted primarily related to the RKD Registry/Bioresource rather than the specific industry collaboration with Firalis SAS. The HRCDC discussed whether further information should be sought from the Applicant on this specific collaboration and the role of Firalis SAS to help determine the public interest case. • On balance, and considering the additional information provided by the Applicant, the HRCDC agreed that more information was not required. It was the view of the HRCDC that there was a public interest case for processing the personal data already collected from participants for the purpose of the collaboration with Firalis SAS. **Scope of the declaration**

	• The HRCDC noted that the application form requested a declaration to enable the processing of the RKD Registry/Bioresource data for future industry collaborations. • It was discussed that the scope of the declaration will be limited to the specific collaboration with Firalis SAS only, which was the only industry collaboration outlined by the Applicant. If required, an amendment request or new HRCDC application, as appropriate, can be submitted for future industry collaborations. **Re-consenting process** • It was noted that since the submission of the application form, re-consent for RKD Registry/Bioresource has been obtained from 235 participants. This re-consent was obtained through face-to-face interaction as participants attended the clinics. The Applicant outlined that none of the participants refused to provide updated consent. The HRCDC commended the efforts made by the Applicant to obtain re-consent. • Of these 235 participants that re-consented, the HRCDC noted that 11 are included in the Firalis SAS collaboration. The consent declaration subsequently applies to the processing of data from 101 participants where reconsent has not yet been obtained. • The HRCDC also discussed the Applicant's response with regards obtaining re-consent by alternative means, including by post. It was noted that ethical approval was pending across all the study sites to allow postal re-consent. • The HRCDC commented that efforts should be made, where possible and approved by the research ethics committee, to obtain re-consent for participants who may not be attending the clinics. **Public and Patient Involvement (PPI)** • The HRCDC commented on the relatively strong level of PPI that has been undertaken as part of the RKD Registry/Bioresource. **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 a Conditional Consent Declaration should be made.
Duration of Declaration:	The Declaration is made commencing 8th August 2018 and shall be valid until re-consent can be obtained, or if reconsent is not achievable, until the end of the Firalis SAS collaboration, at which point all samples and data will be irrevocably anonymised by 31st December 2022. *(The Applicant can request an extension to the consent declaration by way of submitting an amendment request to the HRCDC for consideration)*
Conditions Attached:	**Condition 1.** Firalis SAS is confirmed as a joint-data controller[1] with TCD for the collaborative HELICAL study accessing data from the RKD

[1] Following the HRCDC meeting, the Secretariat received written confirmation from the Applicant that Firalis SAS was noted as a joint-data controller for the data processing for the HELICAL study

	Registry/Bioresource. The consent declaration will not become effective until the following actions are completed, and this condition is fully met: (i) an authorised signatory on behalf of Firalis SAS must be provided on the HRCDC application form and submitted to the HRCDC. This is in line with the HRCDC processes where joint-data controllers apply for a consent declaration. (ii) feedback from the Firalis SAS data protection officer (DPO), or equivalent, must be provided to the HRCDC on the RKD Registry/Bioresource data protection impact assessment (DPIA), to ensure any data protection risks to data being processed by Firalis SAS is assessed, and risks mitigated against where necessary. (iii) confirmation that Firalis SAS shall support the implementation and compliance of the consent declaration jointly with Trinity College Dublin, where required. **Condition 2.** The scope of this consent declaration is limited to the processing of personal data from the RKD Registry/Bioresource specifically for the purpose collaboration with Firalis SAS only. For the avoidance of doubt, the consent declaration does not extend to the processing of data for other industry collaborations. If required, an amendment request or new consent declaration application, as appropriate, can be submitted to the HRCDC for consideration. **Condition 3.** The Applicant is required to confirm to the HRCDC that the contractual agreement/arrangement in place with Firalis SAS, has adequate terms and conditions with regards a joint-data controller arrangement, as required under Article 26 of GDPR. Where existing arrangements require updating, this should be carried out as soon as possible and no later than 3 months of receipt of the decision letter, with notification provided to the HRCDC. **Condition 4.** The Applicant is required to continue efforts to re-consent participants. This includes efforts to obtain re-consent via the hospital/clinical visits as well as by alternative means, such as telephone or post, where participants are not attending the clinics. The efforts made to obtain re-consent from participants via clinics and other approaches, as well as the numbers who have re-consented is a reporting requirement of the Annual Review.
HRCDC Comment	The HRCDC notes that re-consent has been obtained from 235 participants and further notes the Applicant's statement that '*None of the participants refused to provide updated consent'*. The HRCDC therefore understands that the participants that re-consented to date have all actively affirmed re-consent for data processing and are not 'non-responders'. If this understanding is incorrect, the Applicant must provide clarification to the HRCDC.

8. Annual Review of Declarations

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

- Ref ID: 20-001-AF1 (Jack Laffan - A retrospective analysis of the Irish national Acute Coronary Syndrome (ACS) programme database)
- Ref ID: 20-003-AF1 (Gerard Curley - Blood Brain Barrier (BBB) Disruption and Dynamic Contrast Enhanced Magnetic Resonance Imaging (DCE-MRI) Changes In Severe Traumatic Brain Injury (TBI))
- Ref ID: 20-013-AF1/COV (Joe Eustace - Solidarity Trial)

The HRCDC discussed that where Annual Reviews have not been submitted and there has been no engagement from the Applicant or significant delays on this matter, the HRCDC agreed that the matter could be raised with the Chair, who may correspond directly with the Applicant. It was also proposed that the HRCDC decision letter will include a statement outlining that failure to meet an attached condition, including the condition to submit an Annual Review, may result in the HRCDC considering revoking a consent declaration.

9. Activities Report & Upcoming Events

The Secretariat (EV) provided an overview of the Activities Report which was provided to the HRCDC in advance of the meeting. EV highlighted the recent submission by the Health Research Board (HRB) on the public consultation on the Data Protection Commission's new Regulatory Strategy, which the Secretariat contributed to.

Other activity included the Secretariat's participation in the HRB's cross organisation meeting on PPI activity and shared learning's in this area

The HRCDC were informed of the Joint Action Towards the European Health Data Space (TEHDAS) https://tehdas.eu/ which involves 25 countries, where Ireland is represented by the DOH and HRB. Within the HRB, the Secretariat will be involved peripherally in relevant work packages of TEHDAS.

Articles of interest where also noted:

- EU-UK: Commission adopts positive UK adequacy decisions - EU-UK: Commission adopts positive UK adequacy decisions | News post | DataGuidance.
- EOLAS magazine, which targets key decision makers in government and business, is carrying a feature on HRBs role in Ireland's response to COVID-19 - https://issuu.com/agendani/docs/eolas_issue_46?fr=sMGJhMDE5NTY0NzE

10. Any Other Business

- Following confirmation of a quorum, it was confirmed that the HRCDC will convene for an additional meeting on 17th August 2021.
- The Biobank Speaker has been confirmed for the HRCDC meeting on 7th September 2021.

*** The Chair closed the meeting***