HRCDC
Health Research Consent Declaration Committee

Date: 29th March 2023
Location: Zoom videoconferencing

Minutes of the Meeting

HRCDC Attendance

Name
Brigid McManus
Evelyn Mahon
Alyson Bailey
Aideen Hartney
Dan Rea
Cornelius Cooney
Mary Tumelty
John Woods
Barry Lyons
Jonny Barrett (Secretariat)
Caroline Byrne (Secretariat)

Quorum for Decisions
☒YES

New Applications – For consideration

Applicant	Ref No.	Title
Professor Norman Delanty	23-002-AF1	Development and Establishment of the Epilepsy-Associated Gene-Ready Register (EAGER) – A Register of Patients with Epilepsy caused by Pathogenic Mutations.
Prof Ray McDermott	23-003-AF1	CADY Sub-study 1: Biomarker and Major Adverse Cardiovascular Events (MACE) data Analysis

Meeting Items

1. **Opening**
   The Chair opened the meeting and welcomed the members. The Chairperson informed the HRCDC that she had been re-appointed by the Minster for Health to a second term as Chairperson. The HRCDC were also informed that Evelyn Mahon has been appointed to a second term as Deputy Chairperson and that Aideen Hartney has been appointed as a second Deputy Chairperson.
   It was further noted that the newly appointed Secretariat Programme Manager, Ms Brid Burke, would be commencing her role the following week. The HRCDC welcomed Brid to the Secretariat and looks forward to meeting her at the next meeting.

2. **Apologies**
   Sheelah Connolly, Claire Collins, Kathy Brickell, Simon Furney, Zubair Kabir, Barry O'Sullivan.

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

4. Minutes of the last meeting

Draft minutes of 28th February 2023 were circulated in advance of the meeting and were approved by the HRCDC.

5. New Applications

Reference ID:	23-002-AF1
Lead Applicant:	Professor Norman Delanty
Data Controllers:	Royal College of Surgeons Ireland
Title:	Development and Establishment of the Epilepsy-Associated Gene-Ready Register (EAGER) – A Register of Patients with Epilepsy caused by Pathogenic Mutations.
Research Objective:	The aim of this study is to set up an Irish register of patients with epilepsy due to known genetic mutations. This will allow researchers to identify patients who may be suitable for new treatments or clinical trials developed in the future to target particular types of genetic epilepsies (known as precision or targeted therapies). The patient will only ever be contacted by the Consultant, or the Research Nurse assigned to work on this register and will never be contacted by a third party.
Reason for Declaration:	Consent will be obtained from participants who have decision-making capacity. The consent declaration is requested to process the personal data of those who lack decision-making capacity to provide explicit consent; for this cohort, proxy assent will be obtained on their behalf. The scope of the consent declaration is for the collection, transfer and storage of data to and by the data controller RCSI - personal data for the register will be collected from participating hospital medical records. The declaration also covers the processing of the personal data in the register for pre-screening purposes by the data controller of the Register, RCSI, for future studies, including RCSI informing participants about future trials. The declaration would not cover the further processing of the personal data beyond this scope, including the sharing or disclosure of personal data with any third parties.
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 Chairperson introduced the application, and the Secretariat informed the HRCDC of the scope of the consent declaration that can be made. The Chairperson 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 case.**

	• The HRCDC discussed the purpose of the Register and the type and extent of data that is to be collected. There was extensive discussion on the public interest case and why the Register was necessary, as the personal data to be collected and processed for pre-screening purposes by the Register staff is already available for pre-screening via the hospital medical records, including the electronic epilepsy patient record. The public interest case was also considered in the context that the Register is to be held, accessed and used for pre-screening purposes in an excel spreadsheet by only one data controller, RCSI, and by a small number of personnel assigned to work on the Register; the HRCDC questioned whether having just two RCSI personnel responsible for conducting pre-screening via an excel format and contacting participants about future studies would limit the use of the Register, and therefore the public interest case and extent to which all potential clinical trials would be able to utilise the Register. • It was also queried if there are plans to promote or otherwise inform researchers about the existence of the Register so that it can be fully utilised for pre-screening purposes, and if there are plans to expand who can access the Register data for pre-screening in the future. It was commented that the Register should be promoted and that expanding access to data in the Register for pre-screening, subject to the required approvals being in place, could further enhance the public interest case. The Register was also described by the Applicant as aiming to be a 'national' register. In this context the HRCDC also questioned how the register may develop and be formalised from an excel spreadsheet that includes 3 hospital sites, to a sustainable 'national' register. • On balance, the HRCDC was of the view that there is a public interest case in this type of register which could provide a potentially useful tool for pre-screening for future studies in what is an important area of research. It was also commented that the Register has the potential to expedite how relevant clinical trials can be made known to patients. However, while there is a public interest case, it was unclear to the HRCDC how the Register would practically operate in the real-world and how it would develop over time. Therefore, it was the view of the HRCDC that a consent declaration would be made for 1- year to allow the HRCDC to see how the Register develops and operates, as well as the progress that is made to meet the attached conditions. The data controller can seek an extension of the declaration beyond the 1-year duration. **Determining decision making capacity** • It was commented that the Applicant should ensure that decision-making capacity is determined from a functional perspective, which aligns with the principles of the Assisted Decision-Making Act (ADMA). The HRCDC was of the view that it cannot be assumed that participants would automatically lack decision-

making capacity based only on their epilepsy diagnosis or if they are considered 'vulnerable', as was referenced in by the Applicant. It was also commented that decision-making capacity can fluctuate over time and therefore the study should re-visit a participant's decision-making capacity over time.

- Where a participant lacks decision-making capacity, the Applicant describes obtaining proxy assent from a 'legal representative', however the HRCDC was concerned on what was meant by a legal representative in the context of this study as there is no concept of a legal representative being able to provide permission for data processing purposes, although noting that the term is used in context of clinical trials. The HRCDC regards obtaining proxy assent from someone who understand the participant's will and preferences as a suitable safeguard. It was noted that the applicant refers to obtaining proxy assent from a family member such as a parent or sibling who acts as a carer or guardian.

Research ethics and data agreements

- It was commented that no data should be collected and transferred from the hospital sites prior to the requisite research ethics approvals and data agreements being in place.

Information leaflets.

- The HRCDC discussed the Applicant's response to the research ethics committee on whether it is possible to give a time interval when seeking consent or proxy assent to allow the individual to consider whether to participate in the Register. The Applicant's response was that consent can be obtained on the day it was requested or rearranged for a future date. It was commented that study information leaflets don't reflect this response and should be updated.
- It was also highlighted that the information leaflets use the terms 'research' and 'study' to describe the Register; as the data is being processed for the purpose of a pre-screening Register and will not be shared with third parties or processed as part of specific study analysis, it was discussed that the information leaflets should be amended to remove references to 'research' and 'study' and make it fully clear that this is a Register for pre-screening, and how the data will be used now and how it maybe used in the future.
- The HRCDC further commented that the study information leaflets refers to approaching both the 'legal representative' and the epilepsy patient about this Register, which may create confusion on who is being requested to provide consent/proxy assent. The study information also asks the 'legal representative' to provide permission for the researcher to access the patient's records. For clarity the information leaflets should make it clear that the 'legal representative' is being asked to provide proxy assent on behalf of the patient and the reasons why. It was further discussed that information leaflets should outline what will

	happen the data in the Register if a participant or the person providing proxy assent on their behalf withdraws, including whether the data will be deleted from the Register. • In the interest of transparency, the HRCDC was also of the view that the study information leaflets should outline all the hospital sites that will be included in the Register and that there is a risk of data breach rather than no study risks. It was also discussed that the leaflets should outline whether the consultant who is managing the Register, and would be doing the pre-screening activities for future studies, has a relationship with commercial organisations who may be involved in such future studies. **PPI engagement and Transparency** • The Applicant outlined that the information leaflets and consent forms were discussed with the 'legal representative' of people living with epilepsy, for their input on the design of the documents. The HRCDC discussed that further engagement should occur including with those living with epilepsy, and not just their family members, on issues including the consent/proxy assent process and transparency measures. The HRCDC was of the view that there would likely be opportunities for the Applicant to enhance such PPI engagement. • The HRCDC was also of the view that transparency measures should be enhanced so that researchers can be informed about the Register and its purpose. **Legal basis and data minimisation** • It was noted that the Applicant had outlined Article 6(1)(f) 'legitimate interest' as the legal basis for processing personal data and outlined why, in their view, it met the purpose, necessity and balance tests. • It was also noted that the study information leaflets refer to two options for the participant and the person providing proxy assent: (A) permission to being included in the register and to being contacted to find out information about trials and studies or (B) permission to being included in the Register but to not receiving further information about future trials and studies. The HRCDC questioned why a participant would be recruited to the Register but not contacted about future trials given the purpose of the Register; it was discussed whether Option B related to the use of the Register data for other purposes beyond pre-screening. The HRCDC also questioned if the collection of data in the Register without contacting the participant for future trials was necessary both in the context of the necessity tests for legitimate intertest and the principle of data minimisation. • It was discussed that the Applicant should review and ensure the Register will only collect the data that is necessary for the purpose of the Register both for the reasons of data minimisation and to ensure the legitimate purpose legal basis can apply. It was further emphasised that the scope of the consent declaration

	would not go beyond the use of the Register data for pre-screening for future studies by RCSI. **Other** • It was further noted that amendments made to the Health Research Regulations provide that pre-screening activities do not require consent or a consent declaration subject to certain conditions and criteria being met. It was discussed that the amendments may apply with regards using the register data for pre-screening purposes, however there is ambiguity on this matter, and it is up to the data controller to determine if the amendments can apply. • It was discussed how future clinical trials that may be interest are identified by clinicians; it was highlighted that professional networks are important. • The HRCDC queried if the Register can utilise other software beyond an excel spreadsheet to securely store the data. It was also commented that the data should be securely encrypted when transferred between the parties. • 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, that were similar to conditions made in previous consent declarations. These observations included involving the participants in the decision-making process to the best extent possible and amending use of the term proxy assent in the study documents for the legal representative.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration, should be made.
Duration of Declaration:	The Declaration is made commencing 29th March 2023 and shall be valid for 1 year until 31st March 2024 (*The Applicant can request an extension of the duration of the declaration by submitting an amendment request form for consideration)*
Conditions Attached:	**Condition 1.** The Applicant is requested to enhance the transparency measures so that researchers may be informed about the Register, it's purpose and how it can be utilised for pre-screening. Enhanced transparency measures should consider the data controller and hospital websites as well as considering if information can be provided on other appropriate third-party sites. **Condition 2**: It is a condition of this declaration that public and patient engagement activities are strengthened, including engagement with patients with epilepsy and/or other representative groups such as Epilepsy Ireland. Matters for PPI discussions could include the consent/proxy assent process and information leaflets, transparency measures and the overall development of the Register. **Condition 3.** The Applicant should review the data to be collected for the Register and ensure that it will only collect the data that is necessary for the purpose of the Register, considering both the

	principle of data minimisation and to ensure the 'legitimate purpose' legal basis that the data controller is relying on can apply. **Condition 4.** - The Applicant is requested to ensure that it is not automatically assumed that patients with epilepsy – who the Applicant describes as 'vulnerable' - would lack decision-making capacity to consent to this register and that decision-making capacity is therefore always determined from a functional perspective, which aligns with the principles of the Assisted Decision-Making Act. - The patient with epilepsy should also be involved, to the best extent possible, in the decision-making process with regards inclusion in the Register and for their views to be taken on board. Where a participant who lacks decision-making capacity is enrolled in the Register, then the Applicant is further requested to revisit if they can provide consent at a later date as capacity can fluctuate over time. - It was also not fully clear to the HRCDC what was meant by obtaining permission from a 'legal representative' in the context of this study as there is no concept of a 'legal representative' being able to provide permission for data processing purposes – however it is noted that the term is used in the context of clinical trials. The HRCDC regards obtaining proxy assent from someone who understands the participant's will and preferences as a suitable safeguard and therefore the Applicant should ensure that the person providing proxy assent on behalf of the participant who lacks decision making capacity, understands the participant's will and preferences. - The Applicant is requested to report on determining capacity from a functional perspective and who provides proxy assent on the participant's behalf as part of the Annual Report. **Condition 5**. Confirmation of full, research ethics committee approvals from all three hospital sites must be submitted to the HRCDC as soon as possible and within 3 months of receipt of this letter. A consent declaration cannot cover data processing where the required REC approval is not in place. **Condition 6.** The required data agreements and arrangements must be in place between the parties prior to data being transferred. Data cannot be transferred before such agreements and arrangements are in place. **Condition 7.** The Applicant is requested to explore and consider if an alternative platform to an excel database can be used by the Register, in the context of both data security and the practical and effective use of the data for the purpose of pre-screening. The Applicant is also requested to ensure that the data is securely encrypted when transferred from the hospital sites. **Condition 8**. To ensure clarity and consistency of information for the participants and those providing proxy assent on their behalf,

	the study information leaflets and consent/assent forms should be reviewed and amended as follows prior to recruiting participants: (i) Aligned with the responses provided to one of the research ethics committees, the study information leaflets should outline that consent/proxy assent can be provided on the day of request or that a time interval can be provided to consider the study documents and provide consent/proxy assent at a later date. (ii) As the data is being processed for the purpose of a pre-screening Register and will not be shared with third parties or processed as part of specific study analysis, the documents should be amended to remove references to '*research*' and '*study'* and make it fully clear that this is a '*Register for pre-screening'* and on how the data will be used now and how it may be used in the future. (iii) the study information leaflets for the legal representative refers to approaching both the legal representative and the epilepsy patient about this Register, while the legal representative is also asked to provide permission for the researcher to access the patient's records. For clarity the information leaflets should make it clear that the legal representative is being asked to provide '*proxy assent'* on behalf of the patient who lacks decision-making capacity. (iv) Further to point (iii) the term '*proxy assent'*, not '*consent*' should be used when referring to seeking permission from a suitable individual to process the personal data of a patient with epilepsy who lacks decision-making capacity. (v) The study information should make it clear what will happen the participant's personal data in the Register if consent or proxy assent is withdrawn i.e., the personal data will be deleted. (vi) The names of all the hospital sites and that a data breach is a potential risk should be outlined in the information leaflets. (vii) The leaflets should outline whether the Principal Investigator of the Register, Prof Delanty, who is managing the Register and would be doing the pre-screening activities for future studies, has a relationship with commercial organisations who may be involved in such future studies. (viii) Further to Condition 4, the term 'legal representative' should be amended, with reference instead made to 'a person who understands the participant's will and preference' and/or family member, carer, guardian. **Condition 9.** Please submit written signatures on the HRCDC application form from the PI of the Register within 3 months of receipt of this decision letter (only typed signatures have been submitted to date).

Reference ID:	23-003-AF1

HRCDC
Health Research Consent
Declaration Committee

Lead Applicant:	Prof Ray McDermott
Data Controllers:	Cancer Trials Ireland Abbott Laboratories
Title:	CADY Sub-study 1: Biomarker and Major Adverse Cardiovascular Events (MACE) data Analysis.
Research Objective:	Between 2008 and 2014, 483 patients enrolled in the CADY study to test if cardiac blood biomarkers could predict heart problems in women treated with Trastuzumab (Herceptin) for breast cancer. They were at greater risk from death from cardiovascular causes. If those at higher risk were identified earlier and treated, such adverse outcomes may be preventable. Cardiac biomarkers are produced and released into the blood when the heart is under strain. Blood samples from enrolled patients have been tested and results are available. This sub-study includes a repetition of the biomarker testing on leftover blood samples including an additional biomarker and the collection of survival and major adverse cardiovascular events data. Through a collaboration with Abbott Laboratories these data together with already available data will be used to develop a predictive tool for cardiotoxicity using a Machine Learning approach.
Reason for Declaration:	The Applicant states that while consent was obtained from participants for the main, original CADY study, the consent obtained does not cover this new sub-study. The Applicant also outlines why it is not considered feasible to seek participant re-consent for this new sub-study. The scope of the consent declaration is for the purpose of this new CADY sub-study only, involving the further processing of personal data that was obtained from the original main CADY study and the collection and further processing of new patient data obtained from a chart review (i.e., updated survival and major adverse cardiovascular event data). Data processing includes collection, transfer, analysis, storage etc of the personal data. Data and associated samples will be transferred between the joint data controllers and named data processors; the Applicant stated that the data received by the US based joint controller, Abbott Labs, is considered to have been anonymised.
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 case.**

	• On balance the HRCDC was of the view that there is a public interest case for this study. **Reconsenting participants.** • The HRCDC discussed the reasons highlighted by the Applicant on why it wouldn't be practicable or appropriate to seek the reconsent of participants for this sub-study, including references that seeking re-consent could cause harm or distress to the participant. It was commented that the potential for causing distress would not, on its own, be a reason to justify not seeking reconsent. • The HRCDC noted and discussed that the aims and objectives of this new sub-study were closely aligned with the objectives of the original main study and queried, whether participants who have consented to the main CADY study, would be surprised if their personal data was to be processed for this sub-study. • On the practicalities of seeking reconsent, it was commented that the number of participants per hospital site was relatively small and that the hospital records would be accessed for the sub-study to collect follow-up data; the HRCDC queried if accessing the hospital records could also help to determine if the participant was still attending the hospital and accordingly if reconsent could be obtained in such a scenario. The HRCDC was therefore of the view that efforts should be made to seek participant consent where this is possible and practicable, in particular, to seek reconsent where the participant maybe currently attending the hospital. Where re-consent cannot be obtained it was also discussed that the participant should be contacted to inform them about the study and the processing of their personal data. **Transparency and PPI engagement.** • The HRCDC was of the view that making study information available via the Cancer Trials Ireland website and on clinicatrials.gov was insufficient. It was discussed that transparency measures should be enhanced with information about the sub-study, the processing of personal data and the participant's data protection rights provided on other channels and platforms that are more likely to be seen or frequented by participants and the public, for example providing information via relevant cancer patient groups websites as well as via social media. • The response from the Applicant regarding public and patient engagement was also discussed. It was noted that the study has been highlighted to Cancer Trials Ireland's Patient Consultant Committee (PCC) but that no engagement or discussions have occurred yet with this group. The HRCDC commented that PPI engagement should commence with the PCC prior to the beginning of the study, and that such engagement should examine the matters of obtaining participant reconsent and enhancing transparency measures.

	Scope of the consent declaration • It was highlighted that the consent declaration will not cover data processing for the original main CADY study and that it is up to the data controller to ensure data protection compliance with regards the main study. • On the further processing of personal data for the purpose of this sub-study, it was discussed that the declaration will not cover the processing of personal data where a participant has already withdrawn from the CADY study, as a declaration cannot override the decision of a participant to withdraw. • It was further noted that the research ethics committee had raised questions on whether the consent originally obtained from participants allowed for the use of biosamples and data for future research. The Applicant's response was that the original consent allowed patients to consent for future research. The HRCDC commented that the consent declaration for the CADY sub-study will not cover the processing of data of those who did not agree to provide consent for future research. **Data sharing agreement.** • The HRCDC queried whether the designation of the hospital sites as data processors in this study is correct. It was discussed that the relationship between the hospital sites and the joint data controllers of the study seemed more related to a data controller to data controller transfer of data. It was commented that the Applicant should be asked to revisit the designation of each party to ensure it is correct and that the most appropriate data agreements are in place. **Other** • The HRCDC queried the type of data protection training that will be completed by personnel from the Joint Data Controller, Abbott Laboratories. • The importance of a participants data protection rights, including the right to withdraw was re-emphasised by the HRCDC. • The decision of the Applicant to choose Article 6(1)(f) 'Legitimate Interest' as the legal basis for processing data was discussed by the HRCDC. It was commented that Art 6(1)(e) 'public interest' while relevant to public authorities can apply to any organisation that carries out tasks in the public interest. • It was commented that the data to be processed is pseudonymised, with the risk of re-identification of the participant relatively low and the data to be transferred to Abbott Laboratories considered to be anonymised. It was further discussed that the transfer of data between the parties should be securely encrypted. • 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, that were similar to conditions made in previous consent declarations. These observations included confirmation of full

	REC approval, the withdrawal of data and submitting outstanding DPO feedback.
HRCDC Decision:	The consensus of the HRCDC was that a Conditional Consent Declaration, should be made.
Duration of Declaration:	The Declaration is made commencing 29th March 2023 and shall be valid until May 2025 and for 5 years archiving thereafter, or until the personal data has been destroyed or irrevocably anonymised, whichever occurs sooner.
Conditions Attached:	**Condition 1.** The consent declaration covers the processing of personal data for the purpose of this CADY sub-study only; it does not cover the processing of personal data with regards the original, main CADY study. In addition, the consent declaration does not cover the processing of personal data (i) where the participant has already withdrawn their consent and (ii) where consent for future research was not provided by the participant. **Condition 2.** A consent declaration cannot cover data processing where research ethics committee approval is not in place. The consent declaration therefore does not come into effect for St Vincent's University Hospital and St James's Hospital & Tallaght University Hospital, until confirmation of full research ethics committee approvals for these sites is in place and evidence of such has been submitted to the HRCDC. Further, for the other additional sites that were named in the HRCDC application form for which REC approval had yet to be sought, the declaration also does not cover these hospitals until confirmation of full and final approval for these sites is in place and submitted to the HRCDC. **Condition 3.** The Applicant is requested to enhance the level of transparency for this study. Information on this sub-study, the processing of personal data and data protection rights, including the right to withdraw, how to exercise such rights and any derogations to such rights, should be provided on other appropriate communication channels and platforms that are likely to be frequented or seen by participants and the public; examples include providing information via cancer patient group websites and appropriate social media channels. The Applicant is requested to report on this condition as part of the Annual Review. **Condition 4.** The Applicant is requested to undertake public and patient involvement (PPI) activities prior to the study commencing; the consent declaration will not come into operation until PPI engagement has occurred with Cancer Trials Ireland's Patient Consultant Committee (PCC) as was outlined in the HRCDC application form and that the project has taken account of this feedback The Applicant is requested to report to the HRCDC on the PPI engagement that has occurred within 3 months of receipt of this decision. Engagement with PPI representatives should consider the

	important topics of reconsenting participants and enhancing transparency measures *(please see Condition 3 and Recommendation 1).* **Condition 5.** It is a condition of this declaration that the required data agreements and arrangements are in place between the relevant parties for the purpose of this sub-study, including agreements between the joint data controllers, the hospital sites, data processors and the transfer of data outside of the EEA. In this regard, the Applicant is also requested to revisit the roles and responsibilities that have been designated to each of the parties to ensure they are correct and that the correct agreements/ arrangements are put in place (i.e., data controllership, data processors, third party data controller etc.). The transfer of data should not occur prior to this condition being met. **Condition 6.** Where a participant wishes to withdraw from the sub-study then this wish should be respected, and their data removed from the study where possible to do so, taking into consideration any GDPR derogations that may apply. It this context, it is noted that the Applicant states that a participant's data cannot be deleted or removed from the study once it has been anonymised for transfer to Abbott Laboratories; the Applicant should ensure that it is not reasonably possible to have the participant's data deleted or removed from the study if they withdraw post-anonymisation (i.e., ensure that reasonable steps are taken to determine if their data can be identified and removed from the study post-anonymisation and transfer to Abbott Laboratories). ***Note:*** the HRCDC re-emphasises the importance that the participant's data protection rights are respected, including where a participant wishes to withdraw their data from the study; in such a situation the data controller should respect their decision and remove their data from the study where this is reasonably practicable, taking into consideration any GDPR derogations that may apply. **Condition 7.** It must be ensured that the data transferred between the parties is securely encrypted. **Condition 8.** Data protection officer feedback from Abbott Laboratories on the data protection impact assessment must be submitted to the HRCDC as soon as practicable and within 2 months of receipt of this letter. No transfer of data to Abbott Laboratories can occur until this condition is met.
HRCDC Recommendations:	**Recommendation 1.** The Applicant is strongly recommended to make reasonable efforts to obtain the reconsent of living participants where such opportunities arise and where this is practicable, in particular where the participant maybe attending the hospital during the study's lifetime. Where reconsenting a participant is not practicable, then the Applicant is also strongly recommended to make efforts to provide the participant with direct information about the study, the processing of personal data and

	their data protection rights, for example via sending them an information leaflet or requesting that their GP informs them about the study.

6. HRCDC Annual Activities Report 2022

The Secretariat circulated the proof-read and designed version of the Annual Activities Report to the HRCDC in advance of the meeting. The HRCDC approved the report for submission to the Minster for Health.

7. Annual Reviews

The Secretariat has received 3 annual reviews in advance of the meeting which were deemed satisfactory:

- **Ref ID:** 19-045-AF2; Sharon O'Toole, DISCOVARY Bioresource Study.
- **Ref ID:** 19-006-AF3; Michael Farrell, Contribution of Whole Genome Sequencing to Brain Tumour Biology.
- **Ref ID:** 21-016-AF1; Elaine Walsh, Medication review for frail older adults in primary care: use of the STOPPFrail (version 2) tool in nursing home populations

8. Activities report and events of interest

The following upcoming event of interest was noted by the Secretariat:

- **IPPOSI conference, 'Building a Data-Sharing Enabled Health Sector in Ireland.'** Wednesday 3rd May (https://www.eventbrite.ie/e/2023-ipposi-conference-tickets-569174886407)

9. Any Other Business

- The Secretariat informed the HRCDC that the updated SOPs are now uploaded to the HRCDC website.
- The Chairperson invited the members to suggest any future topics of interest they would find beneficial for presentations or talks at future meetings.
- The HRCDC were informed of the latest update from HRCDC Application 19-021-AF3/AMD1 (National Self-harm Registry) with regards progressing their attached conditions.

****The Chair closed the meeting. Following the meeting the HRCDC attended a presentation by the Decision Support Service****