HRCDC
Health Research Consent Declaration Committee

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PRIVATE AND CONFIDENTIAL

Professor Norman Delanty
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By email only: normandelanty@beaumont.ie
Cc by email only: Karina Halley, karinahalley@rcsi.ie
Gianpiero Cavalleri, gcavalleri@rcsi.ie

19th December 2023

Dear Professor Delanty,

RE:	**Application:**	"Research Use of Diagnostic Genomic Testing Data for Epilepsy"
	Reference ID:	23-012-AF1
	Data Controller(s):	Beaumont Hospital Royal College of Surgeons in Ireland
	Decision:	Consent Declaration subject to attached conditions

Thank you for your application to the HRCDC seeking a consent declaration on behalf of Beaumont Hospital and Royal College of Surgeons in Ireland. The HRCDC convened on 12th December 2023 and reviewed the above referenced application, accompanying documents and responses to the Secretariat queries. After careful consideration, we are pleased to inform you that the following decision was made by the HRCDC:

- The HRCDC has exercised its right under Regulation (8)(4)(b) and has made a **Consent Declaration**, **subject to attached conditions**, that the public interest in carrying out the health research significantly outweighs the requirement of the Applicant(s) to seek explicit consent of the data subject, whose personal data is being processed for the above referenced health research study.

- The scope of the Conditional Declaration is for the following data processing activities specifically related to the above referenced health research study:

Scope of Declaration:
The scope of the consent declaration covers the processing of the personal data of those who lack decision-making capacity for this specific study and by the parties specifically named only (RCSI, Beaumont Hospital and CeGaT Laboratories), from the 100 individual sample size outlined in the HRCDC application (i.e., sample size to determine the effectiveness of the data collection model).

The data processing includes collecting, analysing, and storing data, including follow-up data. The personal data to be processed includes demographic and clinical data, including images, and already generated genetic data. In this context, please note the following important points:

- The consent declaration covers data processing activities within the scope of the specific 'Research Use of Diagnostic Genomic Testing Data for Epilepsy' study that is covered by the REC approvals granted on 17th October 2023.
- With regards the genetic data to be processed (i.e., re-analysed) the scope covers the processing of the data that will already be generated from the clinically indicated DNA tests only, as ordered by the patient's clinician.

- Changes that may occur to this study (e.g. the addition of new parties/collaborators, increase in 100 participants outlined, further activities that require additional/new REC approval etc.) are not covered and will require the submission of an amendment request form for consideration.
- The consent declaration does not cover the further processing of personal data (including pseudonymised data) of the participants who lack decision-making capacity for other future separate studies and/or the sharing of such data with other parties (note: based on the information provided, the data of those who lack decision-making capacity is considered pseudonymised. Further, it is noted that the DPO and REC comments outline that genetic data is 'identifiable data'.)
- Data on family history/family of participants and the merging of individual level personal data with other datasets is not covered; the Applicant confirmed that personal data on family is not processed in this study and only results, not individual personal data, will be merged.

Note: when undertaking this study, it is important that the principle of data minimisation is adhered to.

- The following specific conditions have been attached to the Conditional Declaration as follows:

  Condition 1. As part of the Annual Review, the Applicant is requested to report on the number of participants recruited to this study who lack-decision making capacity.

  Condition 2. The study should employ separate and specific proxy information leaflets and proxy assent forms aimed at the relative/friend providing proxy assent who may not be in a legal role such as a 'Decision Making Representative' or 'Legal Representative'. These separate, specific documents should use the term '*participant representative'* when referring to the proxy individual and make it clear that the study is seeking the suitable individual's 'proxy assent' (rather than their 'consent') for data processing.
  In addition, the wording of this sperate proxy documentation should be clearly aimed at the proxy; accordingly, the document should not be written in the first-person that refers to 'your data', 'your samples', 'your healthcare' etc.

  Note for context: It was noted that a single information leaflet and 'consent/assent' form are employed, with the titles and content referring to proxy permission from a 'Decision-Making Representative', Legal Representative' and/or 'Decision Supporter'.
  A '*decision-making representative'* is a formal and legal support structure provided for in the 2015 Assisted Decision Making Act. It was further discussed that the current documentation and its use of terms such as '*legal representative' and 'I am the legal representative for…'* do not accurately reflect the process where a relative/friend provides proxy permission on behalf of a participant who lacks capacity as an additional safeguard rather than legally valid consent; therefore the use of the term 'Legal Representative' to describe the relative/friend is likely to be inaccurate in most scenarios and in the context of health research. It was further discussed that the term 'Decision Supporter' is not appropriate.
  Lastly, it was noted by the HRCDC that the wording of this study documentation was not directed at the proxy; for example, much of the content appears to be written in the first-person that refers to 'your data', 'your samples', 'your routine healthcare'.
  For the reasons noted above, when seeking proxy assent from a relative/friend on behalf of the participant who lacks decision-making capacity, the HRCDC was of the view that study should employ and use separate and specific proxy information leaflets and proxy assent forms for the

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relative/friend that does not use terms such as 'Decision Making Representative', 'Legal Representative' and 'Decision Supporter', and whose language is tailored to the proxy,.

Condition 3. The required data agreements and arrangements must be in place between the parties for this study prior to data being transferred.

Condition 4. Feedback from the RCSI data protection officer on the study DPIA, and the outstanding signature from Beaumont Hospital on the HRCDC application form should be submitted as soon as practicable and within 2 months. Data processing cannot commence until these are submitted.

Condition 5. Confirmation of full REC approval should be submitted as soon as practicable and within 2 months.

- The Declaration is made solely to the Applicant(s) who is the Data Controller and not to any other third party.

- The Declaration is made commencing 12th December 2023 and shall be valid until 31st December 2028, or until the personal data is deleted or fully anonymised or participant consent is obtained, whichever occurs first.

In addition to the decision made by the HRCDC, the following standard conditions of the Declaration shall apply:

- Where the data controller(s) of the study covered by the consent declaration is located outside of Ireland, the local Irish sites involved in the study (e.g., hospital site) must be jointly responsible with the data controller(s) for implementation of, and compliance with, the consent declaration.

- the Applicant must complete an Annual Review to the HRCDC on the anniversary date of this decision letter and for every year, or part year, the Declaration is valid,

NOTE: Failure to submit an Annual Review to the HRCDC, a statutory requirement under the Health Research Regulations (Regulation 13(1)), may lead to a revocation of the consent declaration.

- the Applicant must have any necessary contractual obligations in place,
- all activities being carried out are in compliance with the General Data Protection Regulations, the Data Protection Act 2018 and Health Research Regulations 2018, for the duration of the Declaration,
- any amendments to the health research as approved by an ethics committee, and/or changes that relate to, or may impact the data processing activities and consent declaration and conditions attached, must be approved by the HRCDC via a formal amendment request, prior to changes coming into effect[1],
- any breaches that occur that affect the integrity of the Declaration and the protection of data subjects, must be reported to the HRCDC,

[1] The amendment request application form and accompanying guidance (including examples when an amendment should be submitted) can be found at: https://hrcdc.ie/apply/#b-3. Applicants are also encouraged to contact the Secretariat prior to submitting an amendment request for HRCDC consideration.

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- the health research must be conducted lawfully and ethically. Accordingly, the requisite research ethics committee (REC) approval must be in date for the declaration to be operational; the consent declaration made is not valid where the requisite REC approval is not, or is no longer, in place. It is the responsibility of the Applicant to ensure that the requisite REC approval is and continues to remain in place.

Lastly, the HRCDC have made further recommendation(s) to the Applicant on the following areas of the application that should be considered by the Applicant. Note, these/this recommendation(s) are not conditions attached, but nonetheless should be considered:

Recommendation 1. Based on the information provided, it was not fully clear to the HRCDC whether the PPI engagement to date included dialogue to capture the views of those who have reduced decision-making capacity. The Applicant/data controllers are requested to undertake PPI engagement to capture the views and perspectives of those with reduced capacity.

Recommendation 2. It should be ensured that the documents provided to the proxy and/or participants, include clear transparent information on how the biosamples and data are transferred, including how the bio samples are sent to the external laboratory for the purpose of the clinically indicated DNA testing. It should also be clear that CeGaT Laboratories are the only external laboratory where samples/data are sent; therefore, the broad references to 'outside laboratories' should be amended.

Recommendation 3. The participants/proxy should be provided with an explicit option in the consent/assent form on whether they wish to be notified of incidental findings.

Note: The data controller should be mindful of checking for typos/errors in the study documents: for example, it is noted that Options 5 and Options 6 in the 'legal representative' consent/assent form are duplicates

Please confirm acceptance of the Declaration and that the conditions are understood and accepted, within 30 working days of receipt of this letter, or the Conditional Declaration will lapse. Any clarifications required with respect to the decision made must be requested within the 30 day timeline.

As per the Regulation (11)(1), you, the Data Controller are entitled to appeal the decision of the HRCDC by giving notice in writing to the Minister of Health (HRCDCappeals@health.gov.ie) of your intention to appeal the decision and request the establishment of an appeals panel. The HRCDC should also be informed if an appeal has been requested (via secretariat@hrcdc.ie). Written notice must be provided within 30 working days of receipt of this letter.

Please notify your Data Protection Officer or equivalent authority within your organisation of this decision.

On behalf of the HRCDC and Secretariat, we wish you the very best of luck with the research study.

******SIGNATURE PAGE TO FOLLOW******

Kind regards,

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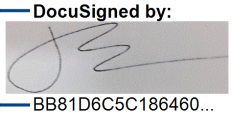
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19 December 2023

Jonny Barrett,
Project Officer, Secretariat
Health Research Consent Declaration Committee