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*
Bridget Doyle, bridgetdoyle@rcsi.ie

6th April 2023

Dear Prof. Delanty,

RE: **Application:** "Development and Establishment of the Epilepsy-Associated Ready Register (EAGER) – A Register of Patients with Epilepsy caused by Pathogenic Mutations."
Reference ID: **23-002-AF1**
Data Controller(s): Royal College of Surgeons Ireland
Decision: Conditional Declaration

Thank you for your application to the HRCDC seeking a consent declaration on behalf of Royal College of Surgeons Ireland. The HRCDC convened on 29th March 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 **Conditional Declaration** 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 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). Further to the collection, transfer and storage of data, 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.

Not in scope: Please note that the declaration for the EAGER Register cannot extend beyond the above scope, including to allow the sharing/disclosure of personal data with other parties outside of RCSI (e.g., personal data cannot be shared with another university or company doing the future trial). The declaration is for RCSI conducting the pre-screening using the Register and contacting the participant about the study. To share personal data with a third party, the participant's consent will be required for such sharing, or if this cannot be provided then a separate consent declaration will be required.

Note:
- The consent declaration for data processing as described above is valid for a period of 1-year.

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- While the HRCDC was of the view that there is a public interest case in developing this type of Register for pre-screening purposes, the HRCDC also queried the practicalities and feasibility on how the Register would operate and be used effectively for pre-screening for potential future studies in Ireland, and correspondingly for contacting participants, in the context that it is an excel spreadsheet that will be accessed and processed only one data controller, RCSI, and by a small number of personnel assigned to work on the Register. It was also not clear to the HRCDC if there are plans to promote the Register so that it can be fully utilised for pre-screening for future studies and how the Register, which captures 3 hospital sites, will develop over time into a more formalised 'national' register.
- The consent declaration is made for 1- year to allow the HRCDC to see how the Register develops and operates over this time, and to consider the progress that is made to meet the attached conditions, including with regards enhanced transparency, PPI and capacity to consent. Before the expiration of the declaration in 1- year, the Applicant can request an extension to the duration of the consent declaration and provide updates on the above.

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

  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.

  Note for context: 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 there should be opportunities for further engagement including with those living with epilepsy, and not just their family.

  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.

  Note for context:
  - 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 necessity test, among others.
  - However, it was 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 and if the collection of

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data in the Register without contacting the participant for future trials was necessary in the context of the 'necessity test' for legitimate intertest and the principle of data minimisation.

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

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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).

- 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 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)*

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

- 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

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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,
- 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.

HRCDC note: Lastly, 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 is up to the data controller to determine if these amendments can apply in the context of this Register i.e., RCSI conducting pre-screening using the EAGER Register. In any case, the scope of the consent declaration made, as described above, covers RCSI undertaking pre-screening activities using the EAGER Register.

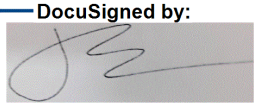
Please confirm acceptance of the Declaration and that the conditions are understood and accepted, within 30 working days of receipt of this letter, or the Conditional Declaration will lapse. Any clarifications required with respect to the decision made must be requested within the 30 day timeline.

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.

Kind regards,

DocuSigned by:

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06 April 2023

Jonny Barrett
Programme Officer, Secretariat
Health Research Consent Declaration Committee

[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.