



Children's Health Ireland

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DPO 001 Rev.1

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13/06/22

Dr Susan Byrne
CHI at Crumlin
Dublin

Research Study Admendment

The EpiFUN study: Correlations between phenotype, genotype and functional analysis in the neurological disorders of childhood

Dear Susan,

We have now reviewed the amendments to your study, and associated changes to the study documentation with regard to ascertaining whether these specific amendments raise any data protection concerns:

The following documentation formed part of the review process:

- **REC Standard Application** [1 EpiFun V4 REC CHI at Crumlin track changes]
- **Parent/Guardian consent form** [2 DPO update EpiFUN Parent Guardian Consent Form V4 track changes]
- **Over 18 consent** form [8 DPO update EpiFun Participant consent 18 years and above V3 tracked]
- **Parent/Legal Guardian Information Leaflet** [9 DPO update EpiFUN ParentGuardian InformationLeaflet V5 track changes]
- **Patient Information Sheet 12-14** [12 EpiFUN Patient Information Leaflet 12-14 V4 tracked]
- **Patient Information Sheet 14-16** [13 EpiFUN Patient Information Leaflet 14-16 V4 tracked]
- **Patient Information Leaflet 16-17** [14 DPO update EpiFUN Patient Information Leaflet 16-17 V4 track changes]
- **Information Sheet over 18** [15 EpiFUN Over 18 InformationLeaflet V1]
- **Process for material transfer** [16 EpiFUN Process for transfer of material V2 track]
- **Amendment Form** [17 CHI STUDY AMENDMENT FORM_EpiFUN 202204121]
- **DPIA** [17a EpiFUN updated DPO DPIA CHI at Crumlin for ethics ammendment 2022 track changes]

Based on our review we can confirm that these specific amendments to the study do not raise any data protection concerns, with the changes communicated appropriately in the study documentation.

Please note – this document is limited to affirming that the amendments to the study have been reviewed from a data protection perspective.

Yours sincerely,

Alan Mac Kenna

ALAN MAC KENNA on behalf of Trilateral Research
Data Protection Officer - CHI at Crumlin

p.p. Ciaran Greaney
Data Protection Advisor