COISTE EITICE UM THAIGHDE CLINICIÚIL

Clinical Research Ethics Committee of the Cork Teaching Hospitals

Tel: +353-21-4901901

Email: crec@ucc.ie

Cork

Ireland

ECM 6 (f) 22/10/2024 & ECM 3 (qq) 22/10/2024

Date: 10th October 2024

Dr Louise Gibson Consultant Paediatrician Cork University Hospital Wilton Cork

Study Title: The Experiences of Hospital and Health Care visits for Young Autistic People.

Dear Dr Gibson

The following documents have been approved:

Submission Document	Approved	Version	Date
Revised Application Form	Yes	2	1 st October 2024
CV for Chief Investigator	Yes	1	24 th April 2024
Parent/Guardian Participant Information Leaflet	Yes	2	1 st October 2024
Child Participant Information Leaflet	Yes	1	1st October 2024: Change to Version 1 prior to use
Participant Invitation Letter	Yes	1	24 th April 2024
Questionnaire to Autistic Young Person	Yes	1	24 th April 2024
Questionnaire to Parent/Guardian of Autistic Child	Yes	1	24 th April 2024.

Full approval is now granted to carry out the above study. The date of this letter is the date of authorization of the study.

Please keep a copy of this signed approval letter in your study master file for audit purposes. The study must be carried out in accordance with General Data Protection Regulation and Health Research Regulation 2018/2021.

You should note that ethical approval will lapse if you do not adhere to the following conditions:

- 1. Submission of an Annual Progress Report/Annual Renewal Survey (due annually from the date of this approval letter). We would encourage you to keep note of this date as the CREC will not issue a reminder.
- 2. Report unexpected adverse events, serious adverse events or any event that may affect ethical acceptability of the study
- Submit any change to study documentation (minor or major) to CREC for review and approval. Amendments must be submitted on an amendment application form and revised study documents must clearly highlight the changes and contain a new version number and date. Amendments cannot be implemented without written approval from CREC.
- 4. Notify CREC of discontinuation of the study
- 5. Submit an End of Trial Declaration Form and Final Study Report/Study Synopsis when the study has been completed.

Yours sincerely

Professor David Kerins

Chairman

Clinical Research Ethics Committee

Of the Cork Teaching Hospitals