



National Research Ethics Service
Thames Valley Multi-Centre Research Ethics Committee

Building L27
University of Reading
London Road
Reading
RG1 5AQ

25 April 2007

Telephone: 0118 918 0556
Facsimile: 0118 918 0559

Professor John Gregory
Professor of Paediatric Endocrinology & Honorary Consultant
Cardiff University
Department of Child Health
Heath Park
Cardiff
CF14 4XN

Dear Professor Gregory

Full title of study: Development and Evaluation of a Psychosocial
Intervention for Children and Teenagers Experiencing
Diabetes (the DEPICTED) Study
REC reference number: 07/MRE12/9

Thank you for your letter of 18 April 2007, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application	5.3	25 January 2007
Investigator CV	#46, v1.2	21 March 2007
Protocol	#8, v1.6	24 January 2007
Covering Letter		26 January 2007
Letter from Sponsor	#1	05 April 2005

This Research Ethics Committee is an advisory committee to South Central Strategic Health Authority
*The National Research Ethics Service (NRES) represents the NRES Directorate within
the National Patient Safety Agency and Research Ethics Committees in England*

Peer Review	#2	23 July 2004
Statistician Comments	#6	25 January 2007
Questionnaire: Talking diabetes parent 5-11yrs	#39, v3	25 January 2007
Questionnaire: Talking diabetes parent 11-16yrs	#40, v3	25 January 2007
Questionnaire: Talking diabetes patients 11-16yrs	#40, v3	24 January 2007
Questionnaire: Talking Diabetes 7-10 yrs	#41, V4	14 March 2007
GP/Consultant Information Sheets	#22, v1.0	14 March 2007
Participant Information Sheet: Patient trial PIS 11-15 yrs	#9, v1.3	14 March 2007
Participant Information Sheet: Parent trial	#11, v1.3	14 March 2007
Participant Information Sheet: Information for clinical teams	#20, v1.1	27 February 2007
Participant Information Sheet: Patient trial 6-10 yrs	#10, v1.3	14 March 2007
Participant Information Sheet: Family PIS audio recording	#27, v1.0	25 January 2007
Participant Information Sheet: Pilot	#19, v1.0	25 January 2007
Participant Consent Form: patient - pilot 6-10yrs	#24, v1.1	25 January 2007
Participant Consent Form: Patient - pilot 11-15yrs	#23, v1.1	25 January 2007
Participant Consent Form: Parent - pilot	#25, v1.1	25 January 2007
Participant Consent Form: Patient trial 11-15 yrs	#12, v1.1	14 March 2007
Participant Consent Form: Parent	#14, v1.1	14 March 2007
Participant Consent Form: Patient audio recording 6-10yrs	#31, v1.0	25 January 2007
Participant Consent Form: Patient audio recording 11-15 yrs	#30, v1.0	25 January 2007
Participant Consent Form: Parent - audio recording	#32, v1.0	25 January 2007
Participant Consent Form: Patient 6-10yrs	#13, v1.0	22 January 2007
Response to Request for Further Information		18 April 2007
Letter from funding body	#5	05 January 2005
Trial Steering Committee members	#7	
Glamorgan University indemnity arrangements	#4	25 January 2007
Cardiff University Indemnity arrangements 01/08/06 - 31/07/07	#3	01 August 2006
Patient approach letter 11-15yrs	#18, v1.0	22 January 2007
Case Record Form - Visit 1	#43(2), v4	24 January 2007
Baseline patient information	#42, v2	24 January 2007
Audio recording log	#44, v1	25 January 2007
Flowchart parent	#35, v1.0	25 January 2007
Parent trial approach letter 6-10 yrs	#17, v1.0	22 January 2007
Parent trial approach letter 11-15 yrs	#16, v1.0	22 January 2007
Flowchart young person	#36, v1.0	25 January 2007
Notepad & Instructions	#37(2) 3T	25 January 2007
Folder design	#37(1) 3T	25 January 2007
Case record form - visits 2,3,4	#43(1), v3	24 January 2007
Assent form for children - audio recording	#33, V1.1	14 March 2007
Assent form for children - pilot	#26, v1.2	14 March 2007
Assent form for children - trial	#15, v1.2	14 March 2007
Clinician consent - trial	#21, V1.0	14 March 2007
Clinic recruitment proforma	#29, v1.0	27 February 2007
Letter of invitation to participate - clinical teams	#28, v1.0	27 February 2007
The Talking Diabetes Learning Programme	#34, v1.0	17 March 2007

R&D approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final approval from the R&D office for the relevant NHS care organisation.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

07/MRE12/9

Please quote this number on all
correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

pp 
Dr Christopher Cheetham
Chair

Email: scsha.TVREC@nhs.net

Enclosures: Standard approval conditions
 Site approval form

Copy to: Sponsor - Ms Sheila Greener
 Department of Health
 Quarry House
 Quarry Hill
 Leeds
 LS2 7UE