

Bwrdd Iechyd Prifysgol Caerdydd a'r Fro Cardiff and Vale University Health Board

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From:

Professor JI Bisson

R&D Director

R&D Office, 2<sup>nd</sup> Floor TB2 University Hospital of Wales

Cardiff CF14 4XW

08 April 2011

Dr Ceri Hoddell
Community Dental Service
Room 136
Dental Hospital
Heath Park
Cardiff
CF14 4XY

Dear Dr Hoddell

Re: 11/DEN/5058E: A Randomised Trial To Determine The Relative Cost And Effectiveness Of Pit And Fissure Sealants and Fluoride Varnish in Preventing Dental Decay (Seal or Varnish)

Thank you for your recent communication regarding the above project, which was reviewed on 25 March 2011 by the Cardiff and Vale Research Review Service (CaRRS).

Documents submitted for review were:

Document	Version	Date
Favourable Opinion Letter from Research		15 February 2011
Ethics Committee		
NHS RD Form	3.1	Received 4 March 2011
SSI Form	3.1	Received 4 March 2011
Protocol and supporting documentation	1.0	11 January 2011
Information Sheet: Parent	1.0	12 January 2011
Information Sheet: Child	1.0	12 January 2011
Patient Consent Form	1.0	12 January 2011
Medical History Form	1.0	12 January 2011
GP Letter of Invitation	1.0	12 January 2011
Invitation Letter for Pare/Guardian	1.1	11 February 2011







I am pleased to inform you that the Panel has no objection to your proposal.

R&D approval from Cardiff and Vale UHB is now subject to:

- Receipt of an approved study agreement signed by all parties
- Receipt of a signed copy of the document "Standard Conditions of Management Approval for Clinical Trials of Investigational Medicinal Products"

Once the above are in place, an R&D approval letter will be issued. You should not begin your project before receiving this written confirmation from the R&D Office.

If you require any further information or assistance, please do not hesitate to contact staff in the R&D Office.

Yours sincerely,

Professor Jonathan I Bisson
Chair of the Cardiff and Vale Research Review Service (CaRRS)

CC Prof Barbara Chadwick, R&D Lead
Sponsor contact, Chris Shaw
Kathryn Bethune, Clinical Trials Pharmacist
Anthony Williams, Finance
Trial Manager, Simon Hutchings