

Bwrdd lechyd Prifysgol Caerdydd a'r Fro Cardiff and Vale

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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

03 May 2012

Dr Alastair Sloan Cardiff University School of Dentistry Heath Park Cardiff CF14 4XY

Dear Dr Sloan

Cardiff and Vale UHB Ref: 12/DEN/5348: Harnessing Dental Pulp Cells To Enhance Dental Tissue Regeneration

NISCHR PCU Ref: 80343

The above project was forwarded to Cardiff and Vale University Health Board R&D Office by the NISCHR Permissions Coordinating Unit. A Governance Review has now been completed on the project.

Documents approved for use in this study are:

Document	Version	Date
NHS R&D Form	3.4	Received 5 April 2012
NHS SSI Form	3.4	Received 5 April 2012
Protocol	0.6	27 February 2012
Study Flow Chart	0.4	14 February 2012
Participant Information Sheet	0.4	16 April 2012
Participant Information Sheet: Questionnaire	0.47	16 April 2012
Reminder Letter	0.3	16 April 2012
Interview Confirmation Letter	0.2	16 April 2012
Introductory Letter – Questionnaire	0.2	16 April 2012
Questionnaire: Pre-procedure	0.7	16 April 2012
Questionnaire: Post-procedure	0.5	16 April 2012

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Interview Topic Guide	1.0	03 April 2012	
Consent Form: Questionnaire	0.5	16 April 2012	
Consent Form: Interview	0.3	16 April 2012	-

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

You have informed us that Cardiff University is willing to act as Sponsor under the Research Governance Framework for Health and Social Care.

Your study may be eligible for adoption by the NISCHR Portfolio. You must now apply to have this trial adopted in order for the UHB to receive funding to support this study. If your study is adopted onto the NISCHR Clinical Research Portfolio (CRP), it will be a condition of this NHS research permission, that you will be required to regularly upload recruitment data onto the portfolio database.

To apply for adoption onto the NISCHR CRP, please go to: <a href="http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=31979">http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=31979</a>. Once adopted, NISCHR CRP studies may be eligible for additional support through the NISCHR Clinical Research Centre. Further information can be found at: <a href="http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=28571">http://www.wales.nhs.uk/sites3/page.cfm?orgid=580&pid=28571</a>

To upload recruitment data, please follow this link: <a href="http://www.crncc.nihr.ac.uk/about\_us/processes/portfolio/p\_recruitment">http://www.crncc.nihr.ac.uk/about\_us/processes/portfolio/p\_recruitment</a> Uploading recruitment data will enable NISCHR to monitor research activity within NHS organizations, leading to NHS R&D allocations which are activity driven. Uploading of recruitment data will be monitored by your colleagues in the R&D office. If you need any support in uploading this data, please contact <a href="mailto:CAV\_research.development@wales.nhs.uk">CAV\_research.development@wales.nhs.uk</a>

Please accept this letter as confirmation of permission for the project to begin within this UHB.

May I take this opportunity to wish you success with the project and remind you that as Principal Investigator you are required to:

- Inform NISCHR PCU and the UHB R&D Office if any external or additional funding is awarded for this project in the future
- Submit any substantial amendments relating to the study to NISCHR PCU in order that they can be reviewed and approved prior to implementation
- · Ensure NISCHR PCU is notified of the study's closure
- Ensure that the study is conducted in accordance with all relevant policies, procedures and legislation
- Provide information on the project to the UHB R&D Office as requested from time to time, to include participant recruitment figures

Yours sincerely,

Professor Jonathan I Bisson R&D Director

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- R&D Lead Prof Vaseekaran Sivarajasingam Sponsor contact, Chris Shaw, RACD Data Manager / Study Coordinator, Kathleen Withers, CEDAR CC