WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 4
Ground Floor, Tennent Building
Western Infirmary
38 Church Street
Glasgow
G11 6NT
www.nhsggc.org.uk

Miss Megan J Austin
Wolfston Centre
106 Rottenrow
Glasgow
G4 0NW

Date 31 May 2011
Direct line 0141-211-1722
Fax 0141-211-1847
e-mail evelyn.jackson@ggc.scot.nhs.uk

Dear Miss Austin

Study title:	**Nanoindentation and Atomic Force Microscopy of healthy and osteoarthritic articular cartilage**
REC reference:	**11/AL/0343**

The Proportionate Review Sub-committee of the West of Scotland REC 4 Research Ethics Committee reviewed the above application on 31 May 2011.

Ethical opinion

The Sub-Committee decided that:

1. The study is suitable for proportionate review since it involves residual tissue that is fully anonymised and for which individual informed consent has been attained through the general consenting mechanisms now in place in the West of Scotland.
2. The Chair asked for justification regarding the sample size of 50 which will yield 200 samples for analysis. The Researcher explained that they have nanoindenting bovine articular cartilage to assess the variability in healthy tissue and to fine tune the m ethodology s o as no t t o w aste h uman t issue. H owever, bo vine ar ticular cartilage is not pathological tissue and so the main research question cannot be powered by such a study. To get a spread of data across individuals, they suggest that they initially request 16 femoral heads. If data suggest further heads would significantly add to the study, they will request an amendment to the application.
3. The answer given in QA17-2 to be changed to omit "Consider" in second statement to read "Add information on bone donation."
4. It is assumed that each piece of tissue released will be approved by a relevant pathologist.
5. It is assumed that each piece of tissue will come with a copy of the confirmation of consent for use.

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

The documents reviewed and approved were:

Document	Version	Date
Investigator CV	-	17 May 2011
Other: Dr P E Riches's CV	-	-
Protocol	1	17 May 2011
REC application		28 April 2011

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

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.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/AL/0343	**Please quote this number on all correspondence**

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

Yours sincerely

Evelyn Jackson

for **Dr Brian Neilly**
Chair

Enclosures: List of names and professions of members who took part in the review
"After ethical review – guidance for researchers"

Copy to: Louise McKean, University of Strathclyde