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Mr Ghulam Nabi
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Date: 20 November 2014
Your Ref:
Our Ref: **DL/14/ES/1070**
Enquiries to: Mrs Diane Leonard
Direct Line: 01382 383871
Email: eosres.tayside@nhs.net

Dear Mr Nabi

Study title:	**Multiparametric Magnetic Resonance Imaging characterization and guided biopsy of the prostate in men suspected of having prostate cancer**
REC reference:	**14/ES/1070**
Protocol number:	**CSO-PG13-005**
IRAS project ID:	**152473**

Thank you for your letter of 16 November 2014, 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.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the Assistant Co-ordinator, Mrs Diane Leonard, eosres.tayside@nhs.net.

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, subject to the conditions specified 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

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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).

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).

Approved documents

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

Document	Version	Date
GP/consultant information sheets or letters	v 1.0	04 July 2014
IRAS Checklist XML [Checklist_17112014]		17 November 2014
Letter from sponsor [Letter from sponsor MULTIPROS]		30 July 2014
Other		

Document	Version	Date
Other [Email requesting e-submission available on HARP]		16 November 2014
Other [Copy of insurance certificate]		17 June 2014
Other [Response to request]		16 November 2014
Participant consent form	1.4	10 November 2014
Participant information sheet (PIS)	1.4	10 November 2014
REC Application Form [REC_Form_17112014]		17 November 2014
Research protocol or project proposal [MUTLIPROS study PROTOCOL v1.1 31st July 2014]	v 1.1	31 July 2014
Summary CV for Chief Investigator (CI) [CI CV Ghulam Nabi]		
Summary CV for student [Szewczyk-Bieda]		
Summary CV for supervisor (student research) [Academic Supervisor CV G Nabi]		

Statement of compliance

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

After ethical review

Reporting requirements

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
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

14/ES/1070	Please quote this number on all correspondence

Yours sincerely

for Dr Carol Macmillan
Chair

Email:eosres.tayside@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: NHS Tayside R&D Office
TASC