London - Harrow Research Ethics Committee

Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

01 September 2016 (Revised 05.09.2016)

[redacted]

Dear [redacted]

Study title:	**EVALUATING THE NET EFFECTS OF EXTENDING THE AGE RANGE FOR BREAST SCREENING IN THE NHS BREAST SCREENING PROGRAMME IN ENGLAND FROM 50-70 YEARS TO 47-73 YEARS**
REC reference:	**10/H0710/9**
EudraCT number:	**N/A**
Amendment number:	**4**
Amendment date:	**01 July 2016**
IRAS project ID:	**29856**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee reviewed the following amendment;
Amendment to protocol so that instead of women who are allocated additional screening after age
70 being offered only 1 extra triennial screening invitation (at ages 71-73), these same women will be offered up to 3 triennial invitations (the first at ages 71-73, and where feasible others at ages 74-76, or both at ages 74-76 and at 77-79); the actual number of extra screens after age 73 will depend on the resources currently available at each clinic.

The trial protocol (now version 4), participant information sheet and GP poster have been amended accordingly, and have also been modified with the intent of making them read more smoothly and explaining more clearly what the study involves. No change is proposed

in who is randomised to screening in either age range and who is not (or in any aspect of the screening offered before age 50), and no change is proposed in information sought from government records.

In addition to the amendment noted above, the trial protocol now includes:
• reference to the trial as “AgeX” in the protocol’s title, text, and descriptive material
• revision of the Introduction and Background to bring them up to date
• changes that were given ethical approval in November 2014 (and are in version 3 of the protocol) eg, stating that linkage to NHS hospital records had now been approved
• clarification of the role of Public Health England (PHE) in the breast screening programme since PHE became responsible for it in 2013 (eg, the NHSBSP is now called the BSP)
• updated membership of the Trial Management Group
The trial participant information sheet and the GP poster (information sheet version 4.0; GP poster version 2.0) have been amended to clarify their meaning (with no information removed), and now:
• include changes to reflect possibly inviting women for screening throughout their 70s
• ask women to let their screening office know if they are unable to attend their appointment
• mention that record linkage to routinely collected NHS data will use data from NHS Digital (previously HSCIC), following a request from NHS Digital that this be mentioned.
As women who did not accept their last screening invitation prior to joining the AgeX trial are unlikely to accept their trial invitations, they will be excluded from the primary analyses. This was already stated in previous versions, but is now given somewhat greater prominence in version 4.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [AgeX_GP Poster_Amendment _v2.3_August_2016]	2.3	01 August 2016
Notice of Substantial Amendment (non-CTIMP)	4	01 July 2016
Participant information sheet (PIS) [AgeX_Participant_Info_v4.4_September 2016]	4.4	04 September 2016
Research protocol or project proposal [AgeX Protocol_Amendment4.1-August2016]	4.1	01 August 2016

Membership of the Committee

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

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

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

10/H0710/9:	**Please quote this number on all correspondence**

Yours sincerely

pp.

Dr Jan Downer
Chair

E-mail: nrescommittee.london-harrow@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: [redacted]

London - Harrow Research Ethics Committee

Attendance at Sub-Committee of the REC meeting in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Jan Downer	Consultant Anaesthetist	Yes	
Ms Monika Temple	Retired	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Lucy Roberts	REC Assistant