Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
EVALUATING THE AGE EXTENSION OF THE NHS BREAST SCREENING PROGRAMME

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

(●) Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? (●) Yes ( ) No

• Does the study involve exposure to radioactive materials? ( ) Yes (●) No

b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No

c) Will you be using existing human tissue samples (or other human biological samples)? ○ Yes ◉ No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ◉ England
- ○ Scotland
- ○ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- [ ] IRAS Form
- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [x] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

4a. Will you be seeking data from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS)?

◉ Yes ○ No

4b. Will you only be seeking non-identifiable HES/SUS data?

○ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Do you want your NHS R&D application(s) to be processed through the NIHR Coordinated System for gaining NHS Permission?

○ Yes ◉ No

If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

◉ Yes ○ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

◉ Yes ○ No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	[redacted]		[redacted]
Work Address	[redacted]		
	[redacted]		
	[redacted]		
PostCode	[redacted]		
Email	[redacted]		
Telephone	[redacted]		
Fax			

Full title of study:	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
Lead sponsor:	Oxford University
Name of REC:	Ealing and West London Research Ethics Committee
REC reference number:	10/H0710/9
Name of lead R&D office:	Clinical Trials & Reserach Governance
Date study commenced:	June 2010
Protocol reference (if applicable), current version and date:	Version 4 dated July 2016
Amendment number and date:	Amendment 4 dated July 2016

Type of amendment

(a) Amendment to information previously given in IRAS

○ Yes ◉ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

◉ Yes ○ No

If yes, please submit <u>either</u> the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

◉ Yes ○ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

○ Yes ◉ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

Summary of the amendments that now yield Version 4 of the AgeX trial protocol

Explanatory background notes: The national Breast Screening Programme (BSP) routinely invites women of age 50-70 every 3 years to attend a screening clinic, and about 70% accept. The aim of the AgeX trial is still, as before, to assess reliably the risks and benefits of additional triennial breast screening before age 50 and, separately, after age 70. It still, as before, uses a cluster-randomised design to determine which women will and will not be sent additional invitations, and then uses routinely collected government statistics to monitor the effects on patterns of hospital treatment and on health outcomes (including breast cancer incidence and breast cancer mortality).

Substantial amendment
The only substantial protocol amendment is 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.

This change was recognised as desirable from a research perspective ever since the study began, because if substantial numbers of the women who are allocated additional screening after age 70 do get more than one triennial screening in their 70s, then the AgeX trial will assess both the risks and the benefits of additional screening after age 70 more clearly and reliably than if these women had received only one such invitation in their 70s.

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. Note that 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.

Other amendments
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.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

We have slightly changed the information sheet and GP poster to clarify the meaning of sentences and laid them out in ways to make them more readable, but no information has been deleted. We would value the advice of the MREC on these improvements.

List of enclosed documents

Document	*Version*	*Date*
Protocol	4.0	18/07/2016
GP Poster	2.0	19/07/2016
Participant Information Sheet	4.0	19/07/2016

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by [redacted] on 22/07/2016 13:37.

Job Title/Post: Visiting Professor

Organisation: University of Oxford

Email: [redacted]

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by [redacted] on 22/07/2016 14:01.

Job Title/Post:

Organisation:

Email: