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Professor Susan Bewley MA MD FRCOG
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11 December 2015

Dear Professor Bewley

Evaluating the age extension of the NHS breast screening programme

Further to your email of 2 November, I take your requests in the order in which you made them:

a) The Research Governance Framework to which I referred is the one issued by the Department of Health, which can be found at: https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition.

b) I enclose a copy of Professor Parker's letter to me. The enclosures mentioned in his letter were HRA documents which have been superseded by the HRA's response to you of 20 March 2015, and are therefore not enclosed with this letter.

c) I do not know to which meeting and minutes the HRA is referring. You may wish to seek further clarification from the HRA.

d) Professor Patnick continues to be the Principal Investigator of the Age Extension Trial and continues to be a Visiting Professor in the Nuffield Department of Population Heath, University of Oxford

Yours sincerely

Ewan G McKendrick

Professor Ewan McKendrick

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Professor Ewan McKendrick
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10th March 2015

Dear Ewan,

You recently asked me to review the documentation relating to a complaint made to the University of Oxford about a trial entitled, '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). I am writing now to report on my findings. My comments below are informed by a review of the various documents you provided me with, by discussion with the Health Research Authority and the National Research Ethics Advisors' Panel, and by a conversation with Heather House.

The communications from the complainant to the University cover a diverse range of issues and approach the trial from a number of different but interconnected directions. My reading of these documents is that the complaint against the University is grounded in the following four related claims:

1. That the scientific rationale and justification for the study are flawed
2. That the process of ethics review and approval was inadequate
3. That the approach taken to consent in the study is not conducive to the achievement of valid consent
4. That the Principal Investigator has a conflict of interest and is insufficiently experienced to lead the trial

Having clarified these claims, an important consideration in beginning to address them is to delineate the nature and extent of the University's responsibilities in these four areas. My initial reading of this was that whilst the University and the researchers employed by it do have important relevant responsibilities these are limited. My assessment was that the researchers have responsibilities to: propose a research question and methodology they consider scientifically important and robust, to complement this with an approach to consent they have good reason to believe appropriate, to build a research team they judge able to conduct the research to a high standard, and to submit the proposal to appropriate and timely independent ethical review. The responsibility for formally reviewing and approving these aspects of the proposed research, however, including the approach to consent and the appropriateness of the research team lies with the research ethics committee tasked with this role.

What this suggested to me was that the four key elements of the complaint listed above might be more appropriately addressed by the research ethics committee or by the Health Research Authority than by the University. I have had conversations with representatives of the Health Research Authority and the National Research Ethics Advisors' Panel with the intention of checking that my assessment of the relevant responsibilities was accurate. In the course of these conversations it became apparent that the Health Research Authority had also received a complaint about the same trial and that their consideration of the complaint had also included discussion of the relationship between the complementary but different responsibilities of the REC and of the sponsor. We agreed that a coherent, comprehensive and appropriate response to the complainant would need to reflect these responsibilities. To this end, the HRA provided me with copies of their consideration of these questions. I am

attaching these documents here. For ease of reading, in each of the documents I have highlighted the sentences relating to the responsibilities of the sponsor in yellow.

It is clear from these documents that the HRA's assessment of the nature and scope of the responsibilities of the University as sponsor and those of the research ethics committee/HRA is very much in accord with my initial assessment above. It is also clear from these documents that the HRA is addressing all of the issues listed above i.e. the four primary elements of the complaint made to the University, in its response to the complaint made to them.

It is important to note that the HRA/NREAP documents mention the following additional sponsor responsibilities, which are not an explicit part of the complaint against the University but are related to it. These responsibilities are to:

- Establish a Data Monitoring and Ethics Committee with appropriate expertise that meets at least once a year
- Monitor conduct of the trial and ensure compliance

Bearing in mind the various considerations I have outlined in this letter as a whole, my suggestion is that in its response to the complaint the University does the following:

- Sets out clearly the nature and scope of its responsibilities as a sponsor and the fact that these are in accord with the views of the HRA
- Indicates how these responsibilities have been or are going to be met
- Acknowledges the fact that the HRA is the relevant authority with regard to the core elements of the complaint and that the University is committed to complying with their requirements

Finally, one thing that was striking from my reading of the correspondence between the complainant and the University was that communication has been with several different members of the University staff. I would suggest that a process is put in place to ensure that all future correspondence relating to this complaint is conducted through a single, inclusive process to ensure consistency and inclusiveness. I would also recommend that the University's response to the complaint be shared with the HRA and with the researchers conducting the trial.

I hope that my comments and suggestions are helpful. If you would like any further input from me please do let me know.

Kind Regards

Michael Parker
Professor of Bioethics and Director of the Ethox Centre