



Health Research Authority

Skipton House
80 London Road
London SE1 6LH
Tel: 020 797 22545
Fax: 020 797 22546
Email: hra.comms@nhs.net

To: R&D Director

Please reply to: Joan Kirkbride, Director of Operations
Email: joan.kirkbride@nhs.net
c/o HRA Manchester Centre, Barlow House,
4 Minshull Street, Manchester M1 3DZ
(Office: 02071048023 Sharon Melbourne)

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Dear R&D Director

Beyond Compliance

The HRA has been advised that some NHS organisations are requiring NHS REC review for Beyond Compliance follow up and x rays. This is not the case and this has been the situation since its implementation in 2012. At that time, the HRA's predecessor organisation the National Research Ethics Service (NRES) working with the MHRA agreed that work undertaken as part of the Beyond Compliance Initiative was considered to be service evaluation.

Those setting up this initiative wished to ensure that their work was conducted to high ethical standards and the NRES agreed to organise a review of their patient information and consent documentation. Beyond Compliance is an effective and efficient system designed to improve patient safety following implantation of medical devices where the follow up arrangements for patients is at the discretion of the Consultant Surgeon. It is recognised good practice, endorsed by the British Orthopaedic Association that all hip and knee replacements require follow up and where a novel device is used that the follow up should be more frequent. It is accepted that this will include the use of radiation. Additionally, at a recent Royal College of Surgeons conference the overwhelming view of the audience was that follow up for all implants was necessary, with particular emphasis on novel devices, those with known problems and procedures carried out by less experienced surgeons.

If you would wish to have any further discussions about this matter, please contact Mr Will Bowen, HRA Collaboration and Development Manager at:
w.bowen@nhs.net | T. 02079728923 | M. 07768 555 483

Yours sincerely

Joan Kirkbride
Director of Operations
T. 07979806425

