



Joint Research Office

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Information Processing Unit, Area 6
Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road
Victoria
London SW1W 9SZ

23rd October 2015

Dear MHRA,

EudraCT number: 2009-015533-79

Full title: An assessment of the effects of pressors on graft blood flow after free tissue transfer surgery: A randomised study – Part II
A single site study investigating the effects of noradrenaline, dobutamine and metaraminol on blood flow in free tissue transfer completed in patients following head & neck cancer resection.

Sponsor protocol number: 14/0022

I would be grateful if the MHRA would approve the change in sponsorship for the above trial, from Oxford University Hospital NHS Trust to University College London. The study is an open label study in which transfer of 24/7 emergency contact details is not required. Furthermore, two patients have previously been recruited at Oxford University Hospital NHS Trust in 2011; however the patients have finished the study in 2011, and are receiving no further care.

Whilst the study was conducted at Oxford University NHS Trust there was not a DSUR submitted since 2012, the MHRA were called regarding this and upon speaking to a safety assessor it was suggested that a DSUR will be submitted covering the period from 2012 onwards on the next DIBD.

Furthermore, it was noted that the trial had not been put on hold whilst the CI had been transferring job roles to UCL, this was also discussed with the MHRA clinical trials helpline and it was advised to just notify you on submission of the changes in sponsorship.

Director UCL SLMS Research Support Centre, Director R&D UCLH – Professor Monty Mythen
Managing Director UCL SLMS Research Support Centre – Dr Nick McNally
Co Director of R&D (RFH) – Dr Emma Morris
Co Director of R&D (RFH) – Dr Adele Fielding



File Name	Document
Covering-letter	Covering letter dated 23-Oct-2015 (OCR copy)
Signed-cover-letter	Cover Letter dated 23-Oct-2015 (Signed)
Substantial-amendment-notification-signed	Substantial amendment form signed by sponsor dated 23-Oct-2015
Updated-CTA	Updated CTA signed by UCL as the new sponsor dated 23.10.2015
XML updated CTA	EudraCT XML file 23-Oct-2015
Letter-Oxford-Sponsorship-Transfer	Letter from Oxford (previous sponsor) confirming the transfer of sponsorship to UCL dated 26-Aug-2014
UCL-Sponsorship-Confirmation	Letter from UCL confirming sponsorship of the Free4Flow study 17-Dec-2014

Please send all correspondence to our postal address.

Yours sincerely



Anne Marie Downey
Sponsor Regulatory Advisor