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**From:** MA Birchall, [REDACTED]  
**Sent:** 26 November 2008 11:22  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: HTA Licence  
**Attachments:** letter to HTA 26nov08.doc

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Dear [REDACTED]  
Please find attached letter as requested. A hard copy will be in the post to you shortly.  
Best wishes  
Martin

-----Original Message-----

> From: MA Birchall, [REDACTED]  
> Sent: 21 November 2008 23:33  
> To: [REDACTED]  
> Cc: [REDACTED]  
> Subject: Re: HTA Licence  
>  
> Dear [REDACTED]  
> Letter finally opened.  
> I can confirm that NO licensable activities whatsoever have occurred >  
> since 16th June 2008, and that there is no intention to commence them  
> in the future.  
> I am moving to [REDACTED] in January and will be working solely through  
> [REDACTED], and through official regulatory procedures and channels, >  
> including those overseen by the HTA.  
> Would you like a formal, signed letter stating all this also?  
> All best wishes  
> Martin Birchall

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**From:** MA Birchall, [REDACTED]  
**Sent:** 21 November 2008 23:14  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** Re: HTA Licence

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Hi [REDACTED]  
The letter wont open!  
We are conducting NO further research at Langford, and are talking actively to [REDACTED] so that we can have a solid regulatory base for any future work. Does this answer your question?  
Best wishes and thanks again.  
Martin

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**From:** MA Birchall, [REDACTED]  
**Sent:** 10 June 2008 14:43  
**To:** [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** Re: Letter re ceasing HTA licensable activities

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

[REDACTED]  
Your work on our behalf has been excellent. I will consider the implications of withdrawal of licensable activities immediately.

We do a fair amount of analysis of human tissue analysis here under appropriate ethical approvals (frozen tissue and cell cultures) and hope this is still okay. We will not of course perform any more work where tissue is destined for human trials of course. Please confirm that the former (simple analysis of tissue, appropriately recorded and under ethical approval) remains okay.

Best wishes

Martin



University of  
**BRISTOL**

**Professor Martin Birchall, MD(Cantab), FRCS,  
FRCS(Otol), FRCS(ORL)**  
*John Farndon Professor of Surgery and Laryngology*

**NHS**



26 November 2008

Laryngeal Research Group,  
Churchill Building,  
Langford House,  
Langford  
Bristol BS40 5DU, U.K.



The Human Tissue Authority  
Finlaison House  
15-17 Furnival Street  
London EC4A 1AB

Dear [REDACTED]

**Re: Your letters 9 June 2008 (“Establishment of epithelial cell lines...”) & 21  
November 2008**

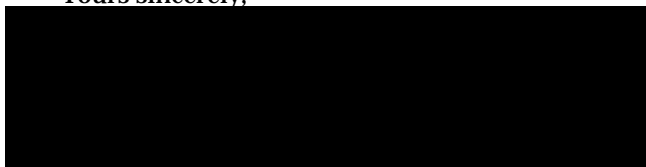
Many thanks for the above correspondence. The contents have been extremely helpful in advising us of our regulatory responsibilities and application routes necessary to support the present research.

Firstly, I can confirm that no licensable activity has taken place at the University of Bristol Langford since before 16<sup>th</sup> June (as per my letter to you dated 16<sup>th</sup> June), and that there are absolutely no plans to perform any in the future at this site.

For the information of the HTA, please note that we are presently talking to [REDACTED] with a view to collaborative human cell work in their dedicated GLP/GMP cell culture laboratories, and that any moves in this direction will commence with applications for licensing by the HTA and/or any other necessary regulatory bodies in accordance with UK and EU law.

Please don't hesitate to get in touch by e-mail or telephone if you want to discuss this further. As previously stated, I should like to go on record as thanking the HTA for their proportionate approach to our singular case in June 2008, without which this major breakthrough for surgery, science and human health would not have been possible.

Yours sincerely,



**Martin Birchall, MB B.Chir., MA (Hons, Cantab.), MD (Cantab.),  
FRCS (Eng, Gen), FRCS (Eng, Otol), FRCS (ORL)  
Consultant in Otorhinolaryngology, [REDACTED]  
Professor of Laryngology, University of Bristol**