

## Broughton, Erin

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**From:** Buckle Rob  
**Sent:** 01 June 2011 17:35  
**To:** 'jc'  
**Cc:** Potter Caroline; Cooper Frank; Moody Catherine; Potter Christine  
**Subject:** vCJD blood test - approval for additional support

Dear John

I am pleased to confirm that your request for supplementary funding for further investigating the specificity of the prion blood assay has been approved, albeit capped at £200k. Under the costings submitted in your case for support, this will entail the Unit absorbing the full costs of improving assay robustness and development of a confirmatory test.

This award is contingent on the submission of a full project plan for implementation of the award, with an associated timeline. The office will also require 3-monthly updates on progress, once initiated. Please could you ensure this information is provided to Catherine Moody.

Lastly, our finance section will be in touch in due course to confirm how the award will be administered.

I look forward to hearing about the progress with this component of your work, which hopefully will help your discussions with commercial partners as you seek to move this forward to the next developmental stage.

With best wishes

Rob

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**From:** jc  
**Sent:** 12 April 2011 14:03  
**To:** 'Buckle Rob'  
**Cc:** Caroline Potter (Prion); Frank Cooper (Prion); Moody Catherine  
**Subject:** RE: vCJD blood test - process for considering a case for additional support

Dear Rob

Apologies for the delay. I was awaiting the formal letter from Professor Turner on behalf of the National Blood Service and their Prion Working Group before responding. I have also had to attend to a family illness which produced a further delay.

I now enclose a document covering the issues you list and also append the letter from Marc Turner. Issues of assay sensitivity and robustness are also raised by Marc and so we have costed for evaluation of these in addition so the total is higher than the rough estimate of circa £400k I suggested to John Savill and yourself when we met to discuss this.

Please do not hesitate to let me know if you need any further information.

All best wishes

John

Professor John Collinge FRS  
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**From:** Buckle Rob [mailto:Robin.Buckle@GRO-C]  
**Sent:** 01 April 2011 14:25  
**To:** jc  
**Cc:** Caroline Potter (Prion); Frank Cooper (Prion); Moody Catherine  
**Subject:** RE: vCJD blood test - process for considering a case for additional support

Dear John

I have not heard from you in relation to the proposal below. Could you please confirm with Catherine Moody how you wish to proceed, as we do need to agree a timeline if a funding request is to be considered by Strategy Board.

Regards

Rob

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**From:** Buckle Rob  
**Sent:** 09 March 2011 18:25  
**To:** 'jc'  
**Cc:** Potter Caroline; Cooper Frank; Moody Catherine  
**Subject:** vCJD blood test - process for considering a case for additional support

Dear John

As discussed at our meeting with John Savill, MRC would be pleased to consider the case for supporting the additional costs involved in developing the prion blood test further, namely to provide reassurance as to the specificity of the test by assessing the false negative rate using 5000 blood samples from a non-exposed US population. I understand that these have already been acquired.

To progress this, could you please provide a brief case for support (2-3 sides) that covers the following issues:

- An overview of your plans for developing the test for i) screening and ii) diagnosis
- The scale of resource required for progressing this next stage, coupled to the timeline required (ie. are there different options re. resource v. speed of delivery?)
- The rationale for the numbers (5000) selected for this specificity testing
- The IP arrangements and business model envisaged in moving forward - ie. the role of D-Gen and how the use of public funding to develop a screening assay can best deliver a test for UK public health benefit. For example, could the screen ultimately be offered to the NHSBTS at cost-price, with potential commercial return to be accrued in overseas markets?
- The likely requirements for next stage funding, both in terms of the nature of the developmental steps and the likely cost.

In terms of the funding envelope you will identify for this, the proposal is that this would be funded 50:50 between an MRC supplementary award and redirection of existing Unit resource.

For the decision points ahead, this case will be assessed by MRC Strategy Board. The next meetings are next week, on the 15th March, and 5<sup>th</sup> May. Whilst consideration of your case for support would ideally be through one of these meetings, I can also offer the possibility of a decision through a virtual process during April, given that there isn't an SB meeting at that time due to the Easter break.

Please let me know how you wish to proceed.

Regards

Rob

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**From:** jc [mailto:jc@] **GRO-C**  
**Sent:** 09 March 2011 09:13  
**To:** Buckle Rob  
**Cc:** Potter Caroline; Cooper Frank  
**Subject:** RE: vCJD blood test - specificity study on US blood donors

Dear Rob

I would be most grateful for an update.

Best

John

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**From:** jc  
**Sent:** 03 March 2011 09:48  
**To:** 'rob.buckle@' **GRO-C**  
**Cc:** Caroline Potter (Prion)  
**Subject:** vCJD blood test - specificity study on US blood donors

Dear Rob

You were kindly going to get back to on the way ahead for funding this following our meeting with John Savill. Given John's clear steer to proceed we have ordered 5500 samples from the US which are expected soon. I wondered how you wanted us to proceed?

Just to keep Head Office updated, on the clinical side we now have governance approval from UCLH Trust R&D and Clinical Director to proceed with diagnostic testing using our blood assay.

Best wishes

John

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