Charity funding bid - Renal

Author: Tim Diggle Head of FR Sponsor: Mark Wightman Dir. of Mktg & Communications Date: 2 July 2015

Executive Summary

Trust Board paper V

Context

UHL's renal department are in the middle of ground-breaking research into kidney disease. Due to a change in funding, two researchers and a PHD student are about to lose their funding. Leicester Hospitals Charity has received legacies specifically to support kidney research which would cover the cost of supporting the researchers and PHD student whilst they secure further funding. UHL and Univ. of Leicester are currently in discussions about future funding for this type of research.

Questions

1. How will UHL patients benefit?
2. How does this fit with the UHL strategic direction?
3. What is the exit strategy, should the Charity choose to support this project?

Conclusion

1. Patients from Leicestershire will have access to ground-breaking treatments for kidney disease (some have already have been placed on an international trial thanks to one of the research strands - see Appendix).
2. UHL is at the forefront of kidney research internationally. The research undertaken could have huge benefits for our patients, and our reputation as a teaching and research hospital.
3. A detailed, high level process is taking place between the Finance teams at University of Leicester and UHL around the funding support for UHL researchers working at Univ. of Leicester and vice versa. We hope that this will resolve the problem.

Input Sought

Decision: We would welcome the board's decision regarding whether the Charity should fund this research for the next year, using legacy bequests given to us to support research into kidney disease. This bid is fully supported by Nigel Brunskill, Professor of Renal Medicine and Director of Research & Development.

For Reference

Edit as appropriate:

1. The following objectives were considered when preparing this report:

Safe, high quality, patient centred healthcare	[Yes]
Effective, integrated emergency care	[Not applicable]
Consistently meeting national access standards	[Not applicable]
Integrated care in partnership with others	[Not applicable]
Enhanced delivery in research, innovation & ed'	[Yes]
A caring, professional, engaged workforce	[Not applicable]
Clinically sustainable services with excellent facilities	[Not applicable]
Financially sustainable NHS organisation	[Yes]
Enabled by excellent IM&T	[Yes]

2. This matter relates to the following governance initiatives:

Organisational Risk Register	[Not applicable]
Board Assurance Framework	[Not applicable]

3. Related Patient and Public Involvement actions taken, or to be taken: [IGA nephropathy patient day took place on 8th March 2014, supported by Kidney Research UK and British Kidney Patients Assoc. Patients have also been recruited into relevant drug trials]

4. Results of any Equality Impact Assessment, relating to this matter: [not known]

5. Scheduled date for the next paper on this topic: [TBC]

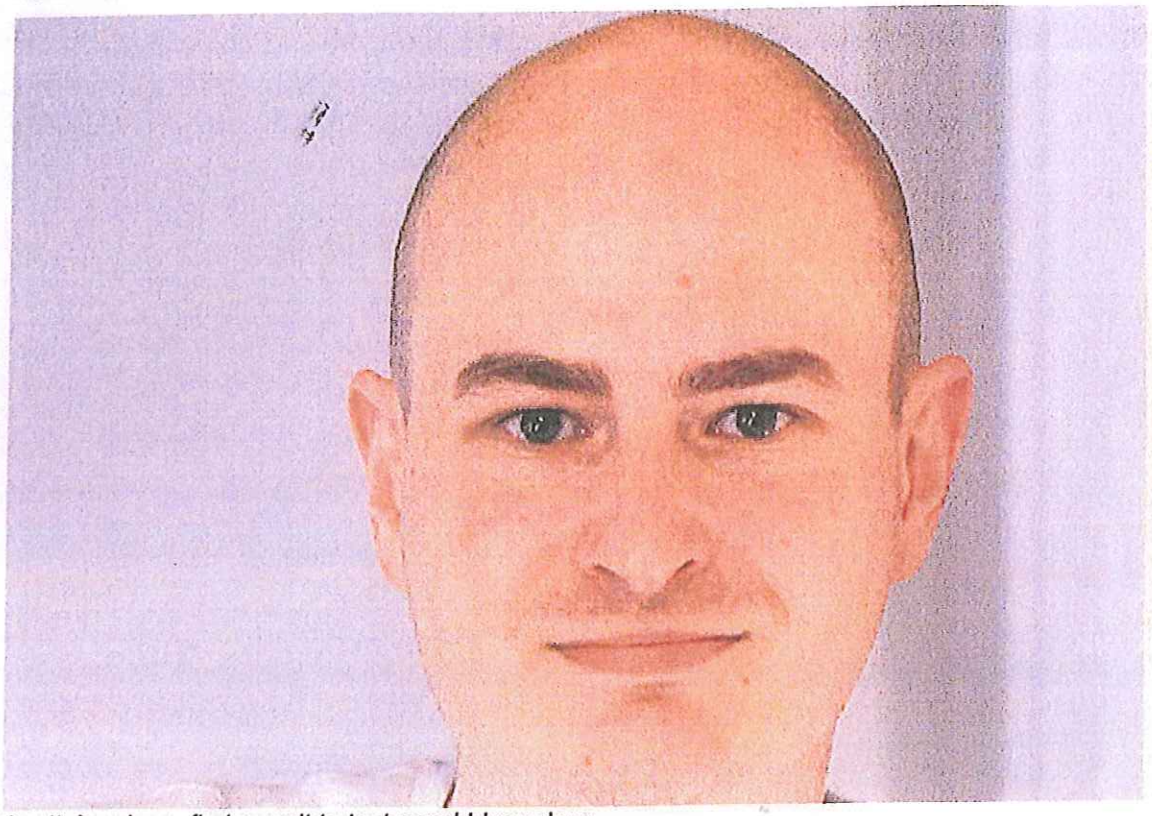
6. Executive Summaries should not exceed 1 page. [My paper does comply]

7. Papers should not exceed 7 pages. [My paper does comply]

First recruit to world trial of new kidney disease drug

By Merc_Reporter Posted: January 12, 2015

By Cathy Buss



Scott Jennings, first recruit to test new kidney drug

A 33-year-old man has become the first person to be recruited to a global trial of a new medication for a chronic kidney disease.

Scott Jennings, from Earl Shilton, was diagnosed with IgA nephropathy a few months ago.

The condition commonly affects young people and can lead to kidney failure and the need for dialysis or a kidney transplant.

It happens when antibodies called IgA1 settle on the kidney and cause inflammation and scarring.

Scott, who works for a printing company in Earl Shilton, said: "It is very exciting to be involved in this research study.

"I am only 33 and I have been healthy my whole life so to get my diagnosis from a routine blood test was a shock. There had been no sign of the disease.

"At the moment it is a case of managing the condition such as keeping my blood pressure at the right level and I watch what I eat."

He added: "I have to have a few more tests but the trial is scheduled to begin in March.

"I can't quite believe that I have been asked to take part in this ground-breaking research."

The trial will look at the effectiveness of a drug, fostamatinib, as a new treatment.

It will involve up to 75 adult patients from 25 research centres across Europe, America and the Far East.

The research team is Leicester is led by Dr Jonathan Barratt, reader and honorary consultant nephrologist at Leicester's hospitals and the University of Leicester.

He said: "It is very satisfying for Leicester to be the first centre in the world to recruit to this study.

"We were involved in the laboratory studies that showed for the first time that fostamatinib might be a new treatment for IgA nephropathy."

The proposed study was first presented to patients and families at an event hosted by the Leicester IgA nephropathy research group last year.

Dr Barratt said: "We found it invaluable to listen to everyone's experiences, concerns and suggestions and we will continue to incorporate that perspective in our work."

Read more: http://www.leicestermercury.co.uk/recruit-world-trial-new-kidney-disease-drug/story-25842579-detail/story.html#ixzz3ZuePTrmc
Follow us: @Leicester_Merc on Twitter | leicestermercury on Facebook

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

REPORT TO: CHARITABLE FUNDS COMMITTEE

DATE: 21.01.2015

REPORT FROM: Jonathan Barratt

SUBJECT: SUPPORTING INFORMATION FOR GRANT APPLICATION: 5426

APPLICATION DETAILS

Amount:		AAA £57,853 (over 1 year) BBB £52,632 (over 1 year) PhD stipend £60,000 (over 3 years)
	TOTAL	£170,485.00
Fund number and type:		LRE4 Renal Research fund
Available fund balance:		£180,852.69
Equipment panel approval received?		Not applicable

1. BRIEF DESCRIPTION OF THE GOODS/SERVICES TO BE FUNDED

1.1 This bid will augment a programme of research investigating potential new therapies for kidney disease by supporting the salaries of two current members of staff who are at risk due to discontinuation of current funding streams. **AAA** is an accomplished laboratory scientist who has, until recently, been working in the Transplant Research team. With the imminent departure of Professor Nicholson, AAA is redirecting their research and as such is not yet in a position to apply for their own funding. This additional year of funding will provide AAA with the opportunity to integrate their research programme into those of Professor Brunskill, Dr Barratt & Dr Burton who lead the Renal Research programme in Leicester. By aligning the research with Leicester's core strengths AAA will be in a competitive position to apply for their own funding in 12 months time. **BBB** is a key member of the laboratory team and has extensive *in vitro* and *in vivo* skills that are core to a number of highly successful research programmes within Leicester. The aim of this additional 1 year funding is to provide sufficient time to identify external grant funding to support BBB's salary going forward. The **PhD stipend** will support the development of a promising young biomedical scientist who is currently working on an NIHR award but is due to finish in April 2015.

2. WHY IS FUNDING THROUGH THE TRUST REVENUE/CAPITAL BUDGETS NOT APPROPRIATE

2.1 There is no trust funding stream for this research expenditure.

3. WHAT ADDITIONALITY DOES THIS PROVIDE TO PATIENTS/STAFF OVER AND ABOVE THE TRUST'S CORE ACTIVITY

3.1 The continuation of high quality research focussed on understanding why disease develops, and identifying novel therapeutic targets that will ultimately improve the care we give to patients is core to UHL's function. This funding will allow the retention of key members of research staff who perform high quality clinical research and support the development of a promising science undergraduate into a renal research scientist. This activity is at risk of being lost without this salary support and, if lost, will diminish the ability of the Renal Research Unit to obtain competitively awarded research funding from organisations such as Kidney Research UK.

4. VALUE FOR MONEY CONSIDERATIONS

4.1 The maintenance of research activity will facilitate the ability of the Renal Research Unit to apply for external funding to continue support of these individuals beyond the 1 year of funding requested.

5. WHAT ARE THE IMPLICATIONS IF THE APPLICATION IS UNSUCCESSFUL?

5.1 Key individuals with specific laboratory skills will be lost from the Renal Research Laboratories. This will significantly limit the scope of our laboratory research programme and our national and international competitiveness in obtaining external peer reviewed funding.

6. DOES THIS ISSUE FEATURE ON YOUR CBU RISK REGISTER?

6.1 N/A

7. IS THIS APPLICATION SUPPORTED BY YOUR DIVISIONAL MANAGER AND/OR DIRECTOR?

7.1 Yes

8. IS THIS APPLICATION FOR STANDARD EQUIPMENT WHICH WOULD NORMALLY BE IN USE WITHIN THE TRUST?

8.1 No

9. ANY OTHER SUPPORTING INFORMATION

9.1 The aim of the work to be undertaken by the individuals included in this application is to develop new treatments for kidney disease that could convert quickly to novel interventions for patients across the UK and worldwide.

10. BACKGROUND

10.1 In the UK more than 3 million adults exhibit some degree of chronic kidney disease (CKD). These patients are at risk of cardiovascular disease and/or needing dialysis in the future. CKD is particularly common in diabetes, but the mechanisms whereby established kidney disease worsens are common to nearly all kidney

disease. Therefore there are two potential strategies for treatment: target the underlying cause (e.g. diabetes); or target the common mechanisms driving worsening of already established kidney disease. Unfortunately there has been little progress in developing new therapeutic agents for kidney diseases in the last 20 years.

11. THE RESEARCH

11.1 The individuals supported in this application will lead and deliver a programme of research to test new potential therapies for kidney disease. These include: those directed against the underlying cause - C-peptide and sialic acid as treatments for diabetic kidney disease; and those directed at common mechanisms of progression - inhibitors of the lectin pathway of complement activation and the anti-kidney scarring agent TRAM 34. Evidence from studies in the laboratory or in other, non-kidney, diseases, suggests that these agents may be very promising candidates to treat CKD. The next challenge is to evaluate these treatments in relevant animal kidney models in order to determine whether either; there is sufficient justification to further develop them to use in human patients; conversely they should be abandoned in order to focus on different areas. This programme of work will use a range of laboratory models to quickly test these new treatments for kidney disease, already established as potential therapeutic candidates through pioneering research work in Leicester.

12. Note on Renal Research Fund – LRE4

12.1 The available fund balance has been received from two legacies which total £165k. £106k received in 2011/12 from one estate and £58k from another estate in 2015. Both of the wills specifically say the money is to be used for the purpose of research into kidney disease. This application does therefore fit within this remit.

13. Additional comments from Dr Barratt:

13.1 “The research staff concerned are working on projects that will identify new treatments for common kidney diseases. Kidney disease is the area of medicine with the lowest number of new treatments and clinical trials. Specifically these researchers are looking at novel approaches to blocking complement activation that will lead to new treatments for patients with protein uric renal disease or who have acute kidney injury. The treatment of acute kidney injury is a UHL priority area and an NHS England pathfinder project. The researchers are also looking at an exciting new treatment for diabetes complications – another major health problem for Leicester’s patients. This research is unique to Leicester, only Leicester has the specific tools to do this work. The research places Leicester researchers at the international forefront with all the reputational enhancement that this brings, as well as offering the promise of new treatments for patients.

13.2 One example of the impact this research can generate and how it can benefit patients both in Leicester and beyond is from our IgA nephropathy research programme. Laboratory work undertaken in Leicester and London demonstrated a potential beneficial effect of a new drug- fostamatnib for the treatment of IgA nephropathy-a kidney disease that affects young people in their 20s and 30s and can cause kidney failure:

Spleen tyrosine kinase is important in the production of proinflammatory cytokines and cell proliferation in human mesangial cells following stimulation with IgA1 isolated from IgA

nephropathy patients. Kim MJ, McDaid JP, McAdoo SP, Barratt J, Molyneux K, Masuda ES, Pusey CD, Tam FW. J Immunol. 2012 Oct 1;189(7):3751-8. Epub 2012 Sep 5.

13.3 This has led to the first worldwide trial of this drug in patients with IgAN. UHL is participating in this study and recruited the first global patient and has the highest global recruitment for this study (see appendix)"

14. Additional comments from Nigel Brunskill:

14.1 "There is a detailed, high level process occurring between the Finance teams at University of Leicester and UHL around the funding support for UHL researchers working at Univ. of Leicester and vice versa. I am hopeful that this will resolve this problem.
However, using these researchers to perform this work funded from this charitable fund would be much better value than losing them and then having to appoint someone new to do it, even if it were only for a year."

15. Conclusion:
15.1 The Charitable Funds Committee is asked to approve the use of these legacy funds to support this research project.