

**Performance & Operating Framework**  
**2018-2019 Review of the Renal Services [directorate application for Academic status](#)**

**Please try to limit your response to a total of four pages (the page limit does not include appendices)**

### **1. Executive Summary**

The Renal Services Directorate has had a successful 2018/19 as we continue to grow our research portfolio and are on course to achieve the majority of our targets.

We have increased our number of active studies to 56, and have recruited significantly more participants into our studies compared to 2017/18 – 249 at the end of Q2 2018/19 compared to 95 at the end of Q2 2017/18. This is largely due to the success of our SYRS Clinical Trials Assistant to support our portfolio of studies.

We continue to build on our collaborations with SchARR and Y&H CLAHRC, in addition to building a collaborative network with national and international colleagues. There continues to be a focus on patient centred research, with Sheffield being at the forefront of the Standardised Outcomes in Nephrology (SONG) Initiative, covering the following key areas: Peritoneal Dialysis (PD), Polycystic Kidney Disease (PKD), Glomerular Disease (GD), Fatigue and Vascular Access. This work is done in collaboration with the University of Sydney, Australia, with the aim of developing standardised endpoints for renal trials of the future. We continue to work with device companies in the areas of near patient testing for PD related peritonitis and a wearable PD system.

Final data analysis is now being undertaken on the UK Catheter Study (STH18334) and SHAREHD Study (STH18999), with the results of these analyses being presented at upcoming national and international conferences. Dr James Fotheringham continues to develop work on the impact of the two day dialysis gap on patient outcomes and is about to lead a national multi-centre study. Dr Roslyn Simms has been appointed as a consultant nephrologist with strong academic interest in cystic disease. Dr Simms will spend 1 day per week at the University of Sheffield to as part of the renal genetics group.

## **2. Commentary on your Directorate's Performance against your 2018/2019 Targets (See Appendix 1 spreadsheet for your Directorate's 2018-2019 POF table)**

- The team have submitted 2 NIHR grants and a KRUK grant so far throughout 2018/19. One has been unsuccessful and we are awaiting the outcome of two. We also support our national colleagues and have been co-applicants on grant applications.
- In 2018/19 we are involved in 51 portfolio studies which is much greater than our target of 33. This includes 9 commercial studies and 6 studies where STH is sponsoring and leading.
- There has been a significant increase to recruitment to portfolio studies – 365 up to the end of Q3, compared to 302 throughout the whole of 2017/18. This has been driven largely by the successful appointment of a Clinical Trials Assistant across SYRS who has had a major impact on recruitment for the directorate. We continue to work with the CRF although recruitment into CRF studies continues to be challenging, largely as a result of staff absences within the nursing team. We meet with the CRF team regularly at our research executive meetings to troubleshoot operational problems with ongoing studies. In addition, Louese Dunn meets with the nursing team monthly to discuss the progress of each study.
- We are currently under target for our 70 day benchmark and recruitment to time and target metrics. This is due to issues with the equipment provided for STH19730; patients not presenting within the recruitment period with a rare disease (STH20065); and not recruiting patients within a very short recruitment period (STH20232).
- We are above target for all our staffing metrics and continue to encourage all our trainees to participate in clinical trials. We continue to support and encourage grant applications from all members of our multi-disciplinary team. This is highlighted in our number of studies with a local CI metric where we are above target and continue to increase year on year.

## **3. Commentary on your Directorate's Performance against your 2018/2019 Annual Plan (See Appendix 3 for your Directorate's Annual Plan)**

Objective 1 – Ongoing. We continue to monitor the performance of our studies at our monthly research executive meetings. Accrual is reviewed in detail and potential solutions to any identified problems are discussed.

Objective 2 – Ongoing. Our research administrator, Megan Bennett, is currently on maternity leave, therefore part-time cover has been appointed in the interim. When Megan returns, the employment of her temporary cover will be reviewed. We aim to seek permanent funding for the research administrator role by using funds from within the directorate's research account.

Objective 3 – Ongoing. Due to the success of the role we have now appointed 2 CTAs across SYRS. Subject to performance review, these posts will be made permanent after one year.

Objective 4 – Achieved. Due to a collective effort and the hard work of clinical staff, the CTA and CRF our recruitment has increased substantially throughout 2018/19.

**4. Please provide a commentary of your directorate's research performance against your research income listed within Appendix 2.**

*You should comment here on your directorate's research performance against the financial information contained within Appendix 2, highlighting any areas of excellence and impact or challenges you may have.*

There has been a significant fall in grant and commercial activity in 2018/19 which has reduced from £378,512 to £190,657, a difference of £187,855; and our funding from other sources has dropped from £176,652 to £150,606, a difference of £26,046. We were disappointed in the income received from our NIHR Annual Allocation due to our funding based on a projected recruitment of 13 throughout 2018/19. It is unclear where this figure was calculated from as we have always recruited a minimum of 300 participants in previous years.

Despite this fall in funding we have significantly increased our recruitment by 61% at the end of Q3 compared to Q3 in 2017/18, and have increased the number of studies we participate in. Although there has been a large reduction in funding we understand we are currently forecast to end the year with a balanced research account.

We continue to submit feasibility forms to express our interest in commercial trials to contribute further to the income of the directorate, if successfully selected.

**5. Are there any changes or addendums that you have made to your research strategy. What are your intentions on delivering on the new Trust Innovation Strategy?**

Our core research strategy remains unchanged.

We have had discussions with Prof Tindale to develop ideas on possible areas of innovation. These are currently focused on wearable dialysis machines and the development of biomarkers for kidney disease.

As an interim measure, Dr Khwaja will act as innovation lead for the directorate as our innovation strategy is developed. We will be liaising with colleagues who may be interested to take on this role in the future.

**6. Do you have any other comments you would like to add to your 2018-2019 Review of your POF performance?**

We continue to increase the number of portfolio studies we participate in and achieve all our strategic targets, whilst continually developing and promoting research within the directorate. We will continue to apply for and secure funding to continue to increase our portfolio, and encourage more locally led grant applications.

With the increase of studies being led by the renal directorate the success of the CTA role has been critical. We continue to increase capacity with the recruitment of two CTAs to increase our number of studies and recruitment; we aim to secure our administrative staff to support the set-up and delivery of more renal led studies.

Our two large multi-centre studies (STH18999 & STH18334) are now closing down; however we continue to manage multi-centre studies within the UK (STH19857 & STH20488), and Internationally (STH20201). We have developed close links with the University of Sydney research team leading the SONG initiative and are continually approached to bring further SONG projects into the UK due to the successful delivery of previous projects.

The Renal SHCT fundraiser has had a huge impact on our fundraising activity, therefore providing additional funding to corn-feed smaller projects from within the directorate. Her activity also increases the awareness of research and PPI both within the directorate and within the wider community.

**7. Please justify here why your directorate should attain/retain Academic status?**

We have successfully delivered on all of the 2018/19 key targets we are able to manage. We continue to develop an environment that promotes and supports clinical research, which is reflected in our increase in activity. With the support that comes from being an academic directorate, we aim to continue to develop our research team and continue to increase our activity in 2019/20.

**Appendix 1- Directorate 2018-2019 POF table – *Attached. Please update as described in the guidance.***

**Appendix 2 – Directorate 2018-2019 Financial Information up to Quarter 3 -**

*Data supplied by finance, please contact your allocated Directorate Research Accountant if you have any queries regarding this information.*

Grant and Commercial Income Received to STH				Other Funding Sources Supporting Delivery							
Grant Income	Commercial Income	Other Research Income	Total (Grant & Commercial)	LCRN Infrastructure Support (A)	Research Lead (D)	CRF & CCTC LCN Infrastructure Support (A)	Experimental Medicine Support (A & D)	LCRN Service Support (D)	RCF (A & D)	Total Other Funding	Grand Total Funding
£152,626	£37,799	£232	<b>£190,657</b>	£44,556	£7,200	£51,205	£110	£31,604	£15,932	<b>£150,606</b>	<b>£341,263</b>

**Appendix 3 - Directorate 2018-2019 Annual plan (current years)**

Objective	Actions Required	Resources required	Evidence of success	Lead & Completion date
1. Management of current research activity	<p>Full engagement from all team members</p> <p>Studies are discussed at monthly executive meetings</p> <p>Failing studies (e.g. recruitment, data completeness) are identified and plans are discussed to support the delivery of these projects</p>	<ul style="list-style-type: none"> <li>Clinical time to support research projects</li> <li>CRF nursing and data co-ordinator time to manage the projects</li> </ul>	Recruitment to studies is on target	<p>All research active staff</p> <p>CRF</p> <p>Ongoing</p>
2. Role of the renal research administrator is protected	Funding is secured to support the role	<ul style="list-style-type: none"> <li>Permanent funding source</li> </ul>	Research administrator post becomes permanent	<p>LD</p> <p>June 2019</p>
3. Role of the Clinical Trials Assistant is protected	Funding is secured to support the role following its initial 12 month term	<ul style="list-style-type: none"> <li>Permanent funding source</li> </ul>	Clinical Trials Assistant post becomes permanent	<p>LD</p> <p>December 2018</p>
4. Reverse the decline of participants recruited into renal studies	<p>Ensure studies are approved in a timely manner to allow for the maximum recruitment period</p> <p>Potential recruitment barriers are identified quickly and solutions are implemented</p>	<ul style="list-style-type: none"> <li>Sufficient clinical time</li> <li>Sufficient space available to meet with participants i.e. clinic rooms</li> <li>SYRS CTA post is continued</li> </ul>	Recruitment figures stabilise throughout 2018/19	<p>All research active staff</p> <p>LD</p> <p>March 2019</p>

**Appendix 4 - Directorate 2019-2020 Annual plan. Please provide a NEW annual plan for 2019-20 using the template provide below.**

**Over the next 12 months we will:** *line one is just an example and can be deleted*

Objective	Actions Required	Resources required	Evidence of success	Lead & Completion date
1. Management of current research activity	<p>Full engagement from all team members</p> <p>Studies are discussed at monthly executive meetings</p> <p>Failing studies (e.g. recruitment, data completeness) are identified and plans are discussed and implemented to support the delivery of these projects</p>	<ul style="list-style-type: none"> <li>Clinical time to support research projects</li> <li>CRF nursing and data co-ordinator time to manage the projects</li> </ul>	Recruitment to studies is on target	<p>All research active staff</p> <p>CRF</p> <p>Ongoing</p>
2. Role of the renal research administrator is protected	Funding is secured to support the role	<ul style="list-style-type: none"> <li>Permanent funding source</li> </ul>	Research administrator post becomes permanent	<p>LD</p> <p>August 2019</p>
3. Role of the Clinical Trials Assistant is protected	Funding is secured to support the role following its initial 12 month term	<ul style="list-style-type: none"> <li>Permanent funding source</li> </ul>	Clinical Trials Assistant post becomes permanent	<p>LD</p> <p>February 2020</p>
4. Continue to increase the number of participants recruited into renal studies	<p>Ensure studies are approved in a timely manner to allow for the maximum recruitment period</p> <p>Potential recruitment barriers are identified quickly and solutions are implemented</p>	<ul style="list-style-type: none"> <li>Sufficient clinical time</li> <li>Sufficient space available to meet with participants i.e. clinic rooms</li> <li>SYRS CTA post is continued</li> </ul>	Recruitment figures increase in 2019/20	<p>All research active staff</p> <p>LD</p> <p>March 2020</p>