

**Northumberland, Tyne and Wear NHS Foundation Trust (NTW),
The Newcastle upon Tyne Hospital NHS Foundation Trust (NuTH) and
Faculty of Medical Sciences, Newcastle University (FMS)**

NEWCASTLE ACADEMIC HEALTH PARTNERS' EXECUTIVE

**Thursday 19th May 2016
at 08.00 in Boardroom, Medical School Boardroom**

MINUTES

Present:	Dr Alan Bagnall	Interim Clinical Director of R&D, NuTH
	Professor Chris Day	Pro-Vice Chancellor, FMS
	Professor John Kirby	Dean of Postgraduate Studies, FMS
	Mr John Lawlor	CEO, NTW
	Dr Rajesh Nadkarni	Medical Director, NTW
	Professor Julia Newton (Chair)	Director of Newcastle Academic Health Partners
	Professor John Simpson	Dean of Research & Innovation (Clinical), FMS
In Attendance:	Dr Séamus O'Neill	CEO, Academic Health Science Network
Secretary:	Amanda Tortice	Head of Newcastle Joint Research Office

15/57 Apologies for Absence

Professor David Burn, Director of the Biomedical Research Unit
Sir Leonard Fenwick, CEO, NuTH
Dr Bruce Owen, Director of Medical Education, NTW
Mr Andrew Welch, Medical Director, NuTH
Professor Avan Sayer, Director of the Biomedical Research Centre
Emma Shipley, Head of Training and Development, NuTH
Professor Paula Whitty, Clinical Director of Research, NTW

15/58 Minutes/Actions from the previous meeting (31st March 2016)

Resolved:
The minutes were agreed as an accurate record.

15/59 Matters arising: all covered under the main agenda items.

15/60 NEWCASTLE ACADEMIC HEALTH PARTNER'S STRATEGY (Min ref. 15/46)

Received:
An update from Professor Newton regarding the further development of the strategy following the meetings with the theme and domain leaders.

Reported that:

- a) The theme leaders had produced brief vision statements across all their individual areas, namely Ageing and Long-Term conditions; Cancer; Brain and the Nervous System; and Children and Young Persons.
- b) The next step was for the cross-cutting Research Domain Leaders to define how their areas would/could interact with all the medical themes: Genomics; Diagnostics & Precision Medicine; Novel Therapeutics; Lifestyle, Devices and Digital; and Interaction between Mental and Physical Health. This was to be completed by the end of May 2016.
- c) The NAHP Research Day (16th June 2016) will include presentations focusing on each theme together with the top five posters that have been submitted. The event had received external sponsorship and the intention was to pull together the submission as a book.

Agreed that:

- d) The strategy should be published on the NAHP website. Additionally, the slides presenting the visions of the themes/domains should be published, noting the required change in personnel noted for NTW

Action:

Professor Newton to upload the strategy/amended slides to the NAHP website.

15/61 NEWCASTLE OFFERING: "BEING JOINED UP" (Min ref. 15/49)

Noted that:

- a) The draft document drawn together across NuTH and FMS was circulated throughout NTW by Professor Whitty for additional inserts, which are in the process of being written.
- b) A consistency check will be made across the entries to ensure a uniform style/approach.
- c) It was acknowledged that the starting point of this work was a query from the UKTI – the primary audience for the brochure was to raise awareness of the range of services available across Newcastle, both internally and externally.

Agreed:

It was fully anticipated that funding for this promotional work could be secured from company sponsorship, but should the development of the brochure or associated promotional material require additional financial support, the CEOs of NTW and NuTH, together with the Pro-Vice Chancellor of FMS should be approached for a funding stream

Action:

Professor Newton to continue the development of the brochure and other associated promotional materials.

15/62 JOINT RESEARCH EXECUTIVE (JEE)

Received:

The JEE Constitution and Terms of Reference and the JEE minutes from the meeting held on 3rd November 2015

Considered:

Documents for the further competition under the HENE tender that were issued on 9th May 2015, including the 'Questions and bidder responses for completion and return'

Reported that:

- a) Newcastle University was leading a consortium bid with NuTH for the above tender, with NTW also identified as a partner organisation. Newcastle was one of six consortia that been successful at the initial bidding stage.
- b) The tender documentation had been released on 9th May 2016 with a submission deadline of 6th June 2016 (together with an interview date already identified as 8th June 2016).
- c) Professor Newton had discussed the bid already with Professor Kirby (FMS), Dr Owen (NTW) and also Mr Turnbull (NuTH) – given the timescales involved, it was acknowledged that all that could be commissioned for at this stage would be existing modules/programmes that could be rebadged appropriately.
- d) There were also financial constraints which made the provision potentially difficult – for example, for credited courses, the fee charged would be £35/credit and, of this £31.42 would be passed to the central University. There was more flexibility with the mentorship scheme but, whilst NuTH could deliver this, HENE required that this also be accredited – this would have to be identified as

an aim for the future. The costs associated with the majority of the modules/programmes were fixed and so any cost recovery was highly dependent on number students enrolled.

- e) The Newcastle offering could be tiered, with very large master classes offered together with smaller, high level accredited training opportunities.
- f) Deadline for the required central sign-off within the University was **27th May 2016**. Helen Kelt in the FMS Enterprise Team was coordinating the documentation for submission.

Agreed:

The business plan developed should be fully costed and would include a profit/loss-sharing element across the NAHP Partners, which could be formalised through a specific Memorandum of Agreement.

Actions:

Professor Newton to send Dr Nadkarni the list of requirements for the submission.

15/63 MHRA INSPECTIONS

Received:

An update from Professor Newton regarding the MHRA inspections that have recently taken place across the University and Newcastle upon Tyne Hospitals NHS Foundation Trust, namely:

- Cellular Therapies Facility (CTF)
- Newcastle Clinical Trials Unit (NCTU)
- Good Clinical Practice (GCP) – site inspection

Reported in relation to CTF inspection that:

- a) This is a university-managed facility, with the Medicines and Healthcare products Regulatory Authority (MHRA) and Human Tissue Authority (HTA) licences held by NuTH, which is also responsible for the quality assurance aspects.
- b) The inspection took place in late 2015, with issues identified relating to the organisational structure and associated reporting lines, with the potential for blurring across organisations.
- c) Professor Newton had met with the Faculty Accountant and Director of the CTF (Professor Dickinson) together with Neil Watson, MHRA licence holder, and Anne Black, QA Manager.
- d) A paper will be developed to consider the principle of moving the facility to NuTH for increased clarity.
- e) Professor Newton would ensure NAHP Executive was updated with this document's progress.

Reported in relation to NCTU inspection that:

- f) The inspection took place in January 2016 across the NCTU, which is an FMS facility.
- g) The University received one critical finding relating to pharmacovigilance in a specific trial for which NuTH was acting as sponsor. The final report has not yet been received as there was one individual site inspection required to be undertaken – it was understood that this had now taken place and had been satisfactory.

Reported in relation to the GCP site inspection that:

- h) This inspection took place w/c 9th May 2016 across all of NuTH's research portfolio. As expected, the study considered in the NCTU inspection which resulted in the critical finding was picked as one specifically for review in the NuTH site inspection. Also one of the inspectors who went to NCTU's inspection was also part of the review team for NuTH.
- i) The Trust received one critical finding, relating to sponsor oversight, plus four other major findings. In relation to the critical finding, the MHRA inspection report will be available within 15 days of the inspection and the Trust will have 15 days to respond. The full report will not be available until 25 days after one additional site visit in relation to one of the individual studies review, after which a response will be required within 25 days.

Noted that:

- j) The MHRA inspections were becoming notably more stringent in their approach, and this view had been calibrated with colleagues across the UK.
- k) Whilst the critical received in relation to the NCTU inspection did have a bearing on the NuTH GCP inspection, it was thought not to be entirely responsible for the outcome.
- l) There was much to do across both NuTH and FMS, specifically in relation to the working relationships between the Newcastle Joint Research Office and NCTU. Historically, this had been a 'comfortable' working relationship and needed to be explicitly built on more formal foundations.
- m) The changes in relation to the Health Research Authority processes would also need to be built into the structures moving forward.

Actions:

- i) **Amanda Tortice** was to meet with Susan Ridge, Trust Research Governance Manager to plan a response to the critical finding.
- ii) **Professors Newton and Bagnall** to meet with Amanda Tortice/Susan Ridge to plan the longer term preventative actions

15/64 THE FUTURE OF THE MRC PATHOLOGY NODE AND BIOBANKING IN NEWCASTLE

Reported that:

- a) Professor Andy Hall currently is the Principal Investigator for the Pathology Node, as well as the Principal Investigator of the generic consent form for the NAHP Biobank. He is also the Designated Individual for the University's Human Tissue Authority Research (HTA) Research Licence.
- b) Professor Hall had recently submitted notice of his resignation.
- c) In relation to the Pathology Node, Professor Day and Professor Newton had a meeting organised with a potential candidate who may take over this role.
- d) There was a separate, relatively wide meeting already arranged in June to consider the next steps for the NAHP Biobank.
- e) In relation to the HTA Research Licence held by the University, again an individual had been identified as a potential candidate to pick up this role.

15/65 PROGRESS ON NIHR INFRASTRUCTURE RENEWALS

Received:

Updates on the NIHR infrastructure renewals as follows:

- Biomedical Research Centre (BRC)
- Clinical Research Facilities (CRF)
- Diagnostic Evidence Cooperative (DEC)

Reported that:

- a) The submission deadlines for the BRC and CRF were identical.
- b) In relation to the BRC pre-qualifying questionnaire, it had been confirmed that all the identified themes had been retained, allowing Newcastle to bid for a potential maximum of £27m. All aspects of the bid were progressing well, although the cross cutting area of 'informatics' could be further strengthened.
- c) The DEC renewal had been postponed although no deadline had been released; discussions at the national level were considering if the DECs could nest more neatly with Healthcare Technology Cooperatives moving forward.

Action:

Professor Simpson/Professor Sayer to include Professor Wipat (re Bioinformatics) and Professor Goodship (re Health informatics) in further discussions surrounding the BRC bid development.

15/66 PRESS COVERAGE

Reported that:

- a) The internal processes within NTW had been clarified and support would be available for NAHP press releases.
- b) The FMS process whereby all press released from the medical faculty would be checked by either Professor Day or Professor Newton, to ensure appropriate representation of partner trusts, appeared to have stalled recently.

Action:

Professor Newton to clarify the FMS procedure for press releases again with the University Corporate Affairs team.

15/67 AOB

A Durham

Reported that:

- a) An email had now been sent to all staff in Durham University about the potential options relating to the School of Medicine, Pharmacy and Health.
- b) One of the options being considered was to transfer the School to FMS as part of Newcastle University. This was supported by FMS – the Medicine students currently only to their pre-clinical at Durham before transferring to Newcastle for their clinical component; in relation to the 'Health' strand, this involved a smaller number of staff (eg those who support the Research Design Services activities led by Newcastle); and in relation to the Pharmacy strand, this would have a major, positive impact on FMS and, more broadly, the NAHP.
- c) Professor Day will continue to keep the NAHP Executive updated as plans were explored.

B Invitation to Tender: Dept of Health – Policy Research Units

Reported that:

An invitation to tender had been released by the Department of Health Policy Research Programme for the development of 'Policy Research Units' – the deadline for stage 1 applications was 1.00 pm on 21st June 2016. One of the research briefs identified was Mental Health.

Action:

Professor Nadkarni and Professor Whitty to consider a potential bid, given how closely this fits with the NTW's strategy.

PART TWO (ITEMS FOR INFORMATION)

15/68 JOINT RESEARCH EXECUTIVE (JRE)

Received:

Minutes from the JRE meeting held on 16th March 2016

15/69 DATE OF FUTURE MEETING

***All meetings are held from 08:00 – 10:00**

21st July 2016 – Conference room 3, Walkergate, Benfield Road

22nd September 2016 – Freeman Boardroom

17th November 2016 – Conference room 3, Walkergate, Benfield Road