

**BIOMEDICAL RESEARCH UNIT ANNUAL REPORT  
2014/15 Financial Year**

**Note:** The accompanying *NIHR Biomedical Research Units – Guidance on Completion of Annual Reports for 2014/15 Financial Year* contains essential guidance on the information you need to provide when completing this proforma. **Please complete the form using a font size no smaller than 10 point (Arial).**

**1. UNIT DETAILS**

**Name of the NIHR Biomedical Research Unit:**

The NIHR Biomedical Research Unit in Nutrition, Diet and Lifestyle at the University Hospitals Bristol NHS Foundation Trust and the University of Bristol.

**Contact details of the individual to whom any queries on this Annual Report will be referred, and to whom feedback on the annual report will be sent:**

**Name:** Dr Vanessa Marshall

**Job Title:** Bristol Nutrition BRU Manager

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**Tel:** 0117 342 1750

**2. DECLARATIONS AND SIGNATURES**

**Contact details of the NHS Organisation administering the NIHR Biomedical Research Unit award:**

**Name:** University Hospitals Bristol NHS Foundation Trust

**Address:** Trust Headquarters, Marlborough Street, Bristol BS1 3NU

**Name of the Chief Executive of the NHS organisation:**

Robert Woolley

I hereby confirm, as Chief Executive of the NHS organisation administering the NIHR Biomedical Research Unit award, that this Annual Report and the Financial Report have been completed in accordance with the guidance issued by the Department of Health and provides an accurate representation of the activities of the NIHR Biomedical Research Unit:

**Signature** .....  
(Chief Executive)

**Date:** .....

### 3. OVERVIEW OF ACTIVITIES (no more than two pages)

#### **Progress against objectives:**

The Bristol Nutrition BRU has been open for three years. We have made significant progress with our short term objectives and have also made progress with our medium term objectives which we have outlined in the sections below. We continue to expand our staff numbers and budget savings across year two has allowed us to appoint a new Research Assistant in statistics to work on the increasing volume of information being generated from BRU projects. We also plan to employ two additional Research Assistant field workers and an additional Administration Assistant in the final two years.

We now have over 70 approved projects across all our five research themes, and recruited nearly 1000 participants across these studies. The details of these are listed in the Finance and Activity Report submitted with this report and on our website, <http://www.bristolnutritionbru.org.uk>. We have published 37 papers over the last three years and have a number of manuscripts in preparation.

#### **Progress with leadership, governance and management arrangements:**

The management and reporting structure of the Bristol Nutrition BRU are firmly established, adhering to the executive group terms of reference. Our executive group comprises the director (Andy Ness), deputy director (Julian Hamilton-Shield), two other theme leads (Richard Martin and Ashley Cooper), and the unit manager (Dr Vanessa Marshall). It meets every two weeks. We have also introduced Deputy Theme leads- Dr Charlotte Atkinson (Peri-operative theme), Dr Athene Lane (Sedentary/Diabetes theme) and Dr Angie Page (Prostate cancer theme) who attend larger quarterly meetings of the executive. The executive group receives advice from our scientific advisory board which last met on 19<sup>th</sup> September 2014.

Research themes provide formal reports to the unit's executive group. These are then collated into a quarterly update report that is tabled at meetings of the NHS trust's research group and at equivalent research groups in the two university faculties across which the unit operates.

#### **Top Three Achievements**

##### **Public Engagement**

Bristol Nutrition BRU has an agreed Engagement Policy based on University of Bristol guidelines and an Engagement Lead (Rachel Perry). All staff members have specific training and we arrange our own in house Engagement activities. We also participate in University and Hospital Trust Engagement activities, including the National Clinical Trial Days, incorporating the NIHR "It's OK to Ask" campaign. Two of our most successful Engagement activities have been our "How'd You like Them Apples" game (first trialed at the Green Man Festival in August 2014) and Dr Elanor Hinton inviting Year 13 students from Redland Green School to visit the Clinical Research and Imaging Centre - University of Bristol (CRIC). Dr Hinton ran workshops on MRI and the brain. Both of these initiatives have had extremely good feedback. We plan to expand our Engagement work with a schools project involving collecting real-time data in a school setting, around the theme of asthma. We are also discussing collaboration with the Ideal Community Project to support the delivery of a new health-related module in their peer-mentoring scheme. Ideal is a development organisation focused on creating and delivering projects that build confidence, awareness, skills and new opportunities young people and adults affected by issues such as drugs and offending.

##### **Training**

We have a formal training policy, Training Lead (Dr Charlotte Atkinson) and training budget. The BRU has four PhD students (three non-clinical and one clinical) The BRU also hosts and part funds an MD student, hosts one other MD student and one MRes student and has had a successful research administration intern in the past year. The BRU has a designated dietitian liaison (Laura Birch). All staff have the opportunity to participate in internal, University, Trust and NIHR training and all staff benefit from regular staff review to review their training needs.

We have continued to meet and share ideas with the training leads at BRU/Cs with an interest in nutrition and physical activity (Leicester/Loughborough and Southampton) through joint meetings held approximately twice a year. In addition, we have established contact with the training lead at the CLAHRC West. We ran a course on the analysis of dietary data and offered free places to the Leicester/Loughborough BRU and Southampton BRC.

## Grant Funding

The Bristol Nutrition BRU has supported several successful applications for grant funding across all themes.

We have also secured major awards in three of our four substantive themes. This significant level of funding in these themes will enable us to extend our research and produce definitive findings that will inform clinical practice and ultimately result in patient benefit. We also have a large grant under development in immune-nutrition.

1. Cancer prevention in hard to reach groups - £15,000 - CRUK/BUPA Foundation
2. NIHR Clinical Academic Training Internship- £10,000
3. NIHR Research Capability Funding award for NIHR grant application for Cystic Fibrosis-Related Diabetes- £20,000
4. NIHR Rare Diseases TRC Fellowship PhD Grant of £228,362
5. NIHR Rare Disease proposal. Type 2 diabetes in children. 2013-2015 £195,000 + £199,885 costs (£15,783 to BRU Bristol)
6. NIHR Efficacy and Mechanism Evaluation (EME) Programme Award (Treatment of Barth syndrome by CARDIOlipin MANipulation (CARDIOMAN): A randomised placebo-controlled pilot trial conducted by the nationally commissioned Barth Syndrome Service). £440,000 awarded.
7. NIHR Research Capability Funding award-Dietary intake & PA in men on ADT- £12,000
8. Elizabeth Blackwell Institute – Prehabilitation in Cancer- £8,207
9. NIHR Programme Development Grant with University of Sheffield- £24,554
10. Elizabeth Blackwell Institute Catalyst fund "Crowd-sourcing of dietary data for nutritional assessment" - £42, 883
11. Elizabeth Blackwell Clinical Primer: Dr Kate Hawton. Effects of change in rate of eating on neural food responses and memory for food. £56,595
12. Cancer Research UK Population Research Committee - Programme Award. C18281/A19169. 1st June 2015 to 31st May 2020. £4,154,270.00: Reducing the burden of cancer: causal risk factors, mechanistic targets and predictive biomarkers Richard Martin & Caroline Relton (PIs).
13. NIHR Public Health Research grant 13/117/01 "The effectiveness and cost effectiveness of an employer-led intervention to increase walking during the daily commute: Cluster randomised controlled trial". 33 months from 1<sup>st</sup> November 2014. £1,272,395. PI Suzanne Audrey (SSCM).
14. NIHR Public Health Research grant "Does active design increase walking and cycling? Evaluation of a natural experiment examining whether moving into housing in East Village increases family levels of physical activity, particularly walking and cycling." £618,065. 1st April 2014-31st March 2017. Owen C (St George's; PI), Rudnicka A (St George's), Cook D (St George's), Whincup P (St George's), Page AS (University of Bristol), Cooper AR (University of Bristol), Lewis D (LSHTM), Cummins S (LSHTM)

#### 4. PROGRESS MADE IN EACH RESEARCH THEME (no more than one page per theme)

##### Childhood Theme

The Childhood theme has 13 studies ongoing and four planned pending ethical approval

##### Progress with leadership of the theme

The research area is led by Professor Julian Hamilton Shield, and supported by Miss Laura Birch (Research Associate), Dr Elanor Hinton (PT Research Associate) and Dr Georgina Williams (Clinical PhD Student). Georgina Williams (Clinical PhD Student) has come back from maternity leave February 2015. Dr Kate Hawton will be joining the team in September 2015 for a six month clinical primer.

##### Details of the progress of the theme's strategy

- (1) Broaden remit beyond obesity, diabetes and cystic fibrosis (original fields of suggested study in application). We now have studies in asthma and the rare diseases (including Barth syndrome and urea cycle defects). We envisage extending our work into further chronic diseases of childhood.
- (2) Engage other departments in the university in research related to our core work. We have a number of collaborations with the Nutrition Behaviour Unit (NBU) in Experimental Psychology, the Sensor Platform for HEalthcare in a Residential Environment (SPHERE) in the Department of Electrical and Electronic Engineering and the MRC Integrative Epidemiology Unit.
- (3) Enable researchers/industry to successfully apply for NIHR grants in diseases related to childhood
  - a. EME (Treatment of Barth syndrome by CARDIOlipin MANipulation (CARDIOMAN): A randomised placebo-controlled pilot trial conducted by the nationally commissioned Barth Syndrome Service). £440,000 awarded. This is a randomised trial with qualitative and clinical input from BRU.
  - b. i4i Award. Feasibility study of breath ammonia device to manage children with urea cycle defects (AmBeR). Industry collaboration with Breath UK. Outline short-listed – final decision June 2015 £660,701
- (4) Collaboration with other relevant NIHR BRCs/BRUs: Active collaborative work with Great Ormond Street Biomedical Research Centre on childhood obesity (Viner) and Urea Cycle Defects/device development (Abulhoul).

##### Examples of effective translation, or significant progress along the translational pathway, as a result of NIHR BRU funding.

At this stage, projects within the childhood theme are ongoing. Therefore there is limited progress along the translational pathway at this time.

##### Examples of effective translation, or significant progress along the translational pathway, as a result of NIHR BRU funding :

No projects as yet have had significant impact on translation of on translation pathway.

##### Examples of the creation and development of intellectual assets through the work of the research theme

Abstracts presented at national meetings from work within BRU

- (1) Incidence and clinical associations of acute pancreatitis in children aged 0–14 years in the United Kingdom. Royal College of Paediatrics and Child Health, Annual Meeting April 2015 (Majbar AA)
- (2) Diagnosis, clinical management, acute and short-term comorbidities and outcome of acute pancreatitis in children aged 0-14 years in United Kingdom. British association of Paediatric Surgeons, Annual meeting May 2015 (Majbar AA)
- (3) Objective Measurement of Feeding Behaviour and Natural Variation in Feeding Characteristics by Adiposity and Genotypic Variation. Physiol Society. Harrogate 2014 (Shihab)
- (4) Using fMRI to assess the impact of Mandolean training on the neural control of obesity in young people. Association for the Study of Obesity Annual Meeting (Birmingham 2014) (Hinton)
- (5) Attitudes to exercise in young people with type 1 diabetes. Diabetes UK Annual Meeting London 2015 (Rynicks)

## **Perioperative Theme**

### **Progress against specific objectives detailed in the original application.**

- We have completed a Cochrane review on gum chewing (sham feeding) and postoperative recovery and the review has now been published. In addition, an associated podcast has been recorded and is available on the Cochrane website. The early post-operative feeding Cochrane review has been updated and the revised manuscript will be submitted during the next review period. As noted in the last report, we have not undertaken a Cochrane review of pre-operative feeding as it is being conducted by others.
- Two qualitative interview studies are being conducted to address our objectives. The first aims to explore the experiences of perioperative nutrition in people undergoing colorectal surgery. The second aims to gain an understanding of the experiences, practices and contexts of healthcare providers (HCP) towards the enhanced recovery programme, with a focused enquiry on nutritional elements of the programme.
- The qualitative study that recruited HCP aims to understand the experiences of healthcare professionals in three different surgery contexts: colorectal, head and neck, thoracic. This will provide an understanding of the culture and networks of these three differing settings and any shared values, expectations and norms.
- Exploratory work has begun on the potential to use Hospital Episode Statistics (HES) data to look at length of hospital stay as a proxy for Enhance Recovery After Surgery (ERAS) implementation across hospitals. This work will be developed during the next reporting period.
- Members of this theme are also collaborating on the development of studies in the area of nutrition in people undergoing surgery for head and neck cancer (see below for more information).

### **Progress with leadership of the theme**

The research area continues to be led by Dr Charlotte Atkinson (deputy theme lead), under the guidance of Professor Andy Ness.

### **Details of the progress of the theme's strategy**

- As noted last year, we are using data from an NIHR RfPB funded trial (on the effect of chewing gum on paralytic ileus) to look at potential predictors of when a person begins eating again after colorectal surgery. We are also using the data to look at eating as a predictor of outcome (e.g., length of hospital stay, complications, etc.). A total of 411 patients were recruited to the trial and this secondary data analysis is currently underway as part of a PhD project. We anticipate that a manuscript from this work will be submitted for publication by the end of this year.
- Work within the theme has been expanded to include studies of immunonutrition. Members of the theme are leading a systematic review and meta-analysis of trials of immunonutrition in people undergoing surgery for head and neck cancer. To date, all searches have been done, data have been extracted and analysed, and the manuscript is currently in preparation. The need for a well conducted and sufficiently powered trial has been identified, and members of the theme are designing a randomised controlled trial to look at the effects of immunonutrition in people undergoing surgery for head and neck cancer. We plan to apply for funding for this trial through the NIHR HTA funding mechanism.
- Another new collaboration that has stemmed from work within this theme is with colleagues at the Clinical Trials and Evaluation Unit and the NIHR Cardiac BRU in Bristol on studies of prehabilitation. The ultimate goal of the work is to develop a multi-component prehabilitation intervention (which will include a dietary component) to be used before surgery in people undergoing major surgery for cancer, with the aim of improving patient outcomes post operatively and supporting enhanced recovery pathways.

### **Examples of effective translation, or significant progress along the translational pathway, as a result of NIHR BRU funding.**

At this stage, most of the projects within the perioperative theme are ongoing; therefore, there is limited progress along the translational pathway at this time. Nevertheless, the planned submission of an application for funding from the NIHR for a trial of immunonutrition in people undergoing surgery for head and neck cancer has stemmed from work and collaborations that have developed within this theme.

### **Examples of the creation and development of intellectual assets through the work of the research theme**

A Cochrane review was completed in February 2015 by PhD student, Vaneesha Short, bringing together the evidence on whether chewing gum helps the digestive system recover following surgery (<http://www.cochrane.org/podcasts/10.1002/14651858.CD006506.pub3>). Poster presentation at ESPEN (The European Society for Clinical Nutrition and Metabolism) Congress, Geneva, Switzerland.

## **Prostate Cancer Theme**

### **Progress against specific objectives detailed in the original application**

The aim of this theme is to provide a robust evidence-base for the development of definitive lifestyle and nutritional interventions in men diagnosed with prostate cancer. We have made excellent progress against all our pre-specified objectives including Systematic reviews, Mendelian randomization analyses, Observational data analysis, Qualitative studies Feasibility studies and Translational and biomarker studies. Data was presented at the World Cancer Congress, 2014, Melbourne Australia and several papers have been published in this reporting period as well as a Cancer Research UK Population Research Committee - Programme Award and a CRUK/BUPA Foundation Award (see earlier).

### **Progress with leadership of the theme**

The research area is led by Professor Richard Martin and Dr Athene Lane from the School of Social and Community Medicine, supported by Dr Lucy Hackshaw-McGeagh (Research Associate). Professor Richard Martin is Theme Lead; in March 2015 Dr Athene Lane became Deputy Theme Lead. We have convened and maintained a steering committee of clinicians (urology, oncology), laboratory and population scientists, and qualitative researchers for the prostate cancer theme. The steering committee meets on a quarterly basis and contributes to the ongoing development of the research. We have convened a prostate cancer Patient and Public Involvement (PPI) group, involving four prostate cancer survivors; new members to the PPI group are currently being recruited.

### **Details of the progress of research area strategy, including any changes (eg, discontinuation of originally planned work, or new areas of research)**

There are no changes to the originally planned work but we have expanded our work to include work in the new areas.

Other work in new cancer areas includes:

- Head and neck cancer: Professor Richard Martin and Andy Ness awarded a Wellcome Trust 4 year PhD studentship for Rhona Benyon to investigate modifiable exposures, mechanisms and biomarkers in the prognosis of head and neck cancer
- Colorectal cancer: Professor Richard Martin is developing collaborations with Professors Chris Paraskeva and Anne Williams through a joint PhD student (Hannah Carr) who is investigating lifestyle modifications in colorectal cancer
- Breast cancer: Professor Richard Martin, Dr Mona Jeffreys and Dr Emma Turner have been awarded a University Cancer Research Fund grant (£5000) to undertake qualitative research into the barriers and facilitators of implementing lifestyle interventions

### **Examples of effective translation, or significant progress along the translational pathway**

Most of our studies are now underway, we have started collecting data, and some are complete. Several studies are translational (see above). We have presented preliminary findings at conferences, have had articles published and we are currently drafting further papers. The research to date has informed the development of the feasibility trial which is underway.

Within the wider context, members of the prostate cancer theme have been involved in translation and engagement activities around healthy diet and physical activity to men with prostate cancer, clinicians, school children and members of the public at a number of events:

- 'Healthy Living' workshops in local schools
- 'Bristol Bright Night' at @Bristol Science Centre
- 'British Science Week'
- Prospect, a Bristol and District Prostate Cancer Support Group (presenting to the group, working with individual members and discussing ongoing research at the BRU)
- 'A Week In Your Life Project' (working with local communities within areas of deprivation and discussing diet, physical activity, lifestyle and cancer)
- Meetings with clinicians and researchers from Penny Brohn Cancer Care

### **Examples of the creation and development of intellectual assets**

Data was presented at the World Cancer Congress, 2014, Melbourne Australia and several papers have been published in this reporting period (See Publications section of Finance and Activity report).

## Type 2 Diabetes/Sedentary Theme

Progress with the strategy to achieve the specific objectives of this theme is described below.

- **Systematic review.**

We have conducted a systematic review of the evidence for the association between objectively measured sedentary time and metabolic outcomes. This is the first systematic review on this topic and shows that the strongest association between time spent sedentary and metabolic outcomes is with insulin sensitivity. The manuscript was published in Preventive Medicine in May 2015.

- **Efficacy of modifying sedentary time on change in metabolic outcomes.**

We have conducted a small (n=18) randomised crossover trial to investigate the effect of interrupting sedentary time by standing and walking on the blood glucose level of office workers. Interstitial glucose levels were measured using a continuous blood glucose monitor, allowing us to look both at glucose level and variability. Unfortunately we could find no effect of interrupting prolonged sedentary time by either standing or a short bout of walking. A manuscript is currently in preparation.

- **Qualitative investigation of sedentary behaviour.**

We have conducted an in depth analysis of transcripts from the The Early ACTivity In Diabetes (Early ACTID) RCT to explore the barriers and facilitators of physical activity behaviour change in that study. This work gives insights into the factors influencing motivation of people with type 2 diabetes to both take part in a research study and for initial and continued lifestyle behaviour change. Two manuscripts are in preparation.

In the past year we have been conducting an observational study (STAMP-2) in people with newly diagnosed type 2 diabetes to investigate three main issues (see below). To date we have recruited approximately 160 patients from three sites. Recruitment to STAMP-2 will end in May 2015.

- **Accuracy of objective measurement of sedentary time**

We are measuring sedentary time with both a waist worn accelerometer and an activPAL inclinometer to determine the accuracy of the accelerometer, and associations with metabolic outcomes will be explored. Analyses of the final dataset will commence in August 2015.

- **Spatial mobility of people with type 2 diabetes**

We are measuring time spent and physical activity outdoors by integrating accelerometers with global positioning system (GPS) data to describe the spatial mobility of people with type 2 diabetes. These data will be used to determine the volume and intensity of physical activity outdoors, and association with metabolic health. Analyses of the final dataset will commence in August 2015.

- **Co-existing behaviours**

We have collected detailed 3 day food diaries that will allow us to explore the interaction between sedentary time/behaviour and eating pattern/diet and metabolic outcomes. To date, approximately 60 diaries have been coded. It is anticipated that a dataset will be available by the end of 2015.

- **Feasibility of intervention to target sedentary time.**

We are developing feasibility studies focussing on active travel since it may both displace sedentary time (traveling in a car) and increase physical activity, may be behaviourally sustainable, and has been shown to be associated with lower risk of disease and improved metabolic health in healthy adults. Two studies are in the early stage of development.

### Progress with leadership of the theme

The research area is led by Professor Ashley Cooper and Dr Angela Page from the Centre for Exercise, Nutrition and Health Sciences, School for Policy Studies (Deputy Theme Lead), and is supported by Dr Catherine Falconer (Research Associate).

### Details of the progress of research area strategy, including any changes (eg, discontinuation of originally planned work, or new areas of research)

There are no changes to the originally planned work.

### Examples of effective translation, or significant progress along the translational pathway, as a result of NIHR BRU funding.

At this stage, projects within the diabetes theme are ongoing; therefore, there is limited progress along the translational pathway at this time.

### Examples of the creation and development of intellectual assets through the work of the research theme

The theme has published widely and our PhD student, Laura Brocklebank's systematic review "Accelerometer-measured sedentary time and cardiometabolic biomarkers" in Preventive Medicine is the first systematic review on this topic and shows that the strongest association between time spent sedentary and metabolic outcomes is with insulin sensitivity.

## **Core Theme**

### **Progress against specific objectives detailed in the original application**

*Objective 1 - Training in nutritional research methods for clinicians and non-clinical scientists to strengthen research in nutrition in clinical populations*

We have a designated training lead (Dr Charlotte Atkinson), a dedicated training budget, a training policy and a comprehensive and innovative training programme for our staff (See Section 6. Training)

*Objective 2: Identify further interventions for clinical populations translated from observational studies and transferred from trials in primary care and the general population*

Our core theme is carrying out experimental research projects not included in any of the specific themes to help identify further interventions for clinical populations.

- Folic acid in pregnancy and all cause and cause-specific mortality: further follow up of the Aberdeen folate trial. These results have been published.
- Aberdeen Folic Acid Supplementation Trial: Follow up of offspring – We are working with the MRC Integrative Epidemiology Unit to assess the feasibility of following up the offspring born to mothers in this trial and measuring their epigenetic profile on saliva samples. 194 samples have now been returned.
- An ethnographic study of food choices in public areas of a sample of UK NHS hospitals – this project assessed the feasibility of collecting information of the quality and price of food available in the foyers of NHS hospitals in the south west of England. We have completed this project.
- Omega-3 fatty acids and depression in adults: a Cochrane review – in this review we focussed on people with clinical depression. The review has been submitted.
- Systematic review of animal and human studies of low energy sweeteners on appetite and obesity – we are working with academic and industry partners under the auspices of the International Life Sciences Institute (ILSI) Europe to systematically review animal and human studies have reported on energy sweeteners. This review has been resubmitted to the International Journal of Obesity.
- Effects of nicotine challenge on eating topography – we are planning to examine the effect of nicotine on eating in collaboration with the MRC Integrative Epidemiology Unit and the Nutrition Behaviour Unit in the School of Experimental Psychology.
- The Association between Adiposity and the Presentation and Clinical Course of Crohn's disease- this is an MD project.
- Pilot Study using Wellpoint healthcheck Kiosk in the Education Centre at United Hospitals Bristol for staff and visitors - a NOCRI introduced collaboration with industry carried out in conjunction with Leicester/Loughborough BRU
- Evaluation of urinary chloride dipsticks for the rapid estimation of hydration status in patients- a BRU supported study which won Gus Hamilton, the lead research clinician, an Innovations Challenge Award.
- Pulsed glucocorticoid replacement therapy for patients with adrenocortical insufficiency secondary to Addison's disease and congenital adrenal hyperplasia (Pulses Study). We are carrying out qualitative work to support this trial.

*Objective 3: Multidisciplinary research capacity for each of the areas*

Our core team provides co-ordinated methodological support across all themes. Our core team offers mentorship and practical support in data management, systematic reviewing, statistics and qualitative methodology. Our core team is also supporting patient and public involvement and public engagement and is described in the relevant sections below.

### **Progress with leadership of the theme**

Professor Andy Ness leads this theme. He is supported by members of his Lifecourse Epidemiology and Population Oral Health Group (Dr Vanessa Marshall, Dr Charlotte Atkinson (Training), Dr Sam Leary and Dr Andrea Waylan). The methodological team comprises Dr Chris Penfold (statistics), Dr Rachel Perry (systematic reviews), Dr Aidan Searle and Dr Eileen Sutton (qualitative methods) and Mr Stu Toms (data management). The team report on a monthly basis to the executive group.

### **Details of the progress of research area strategy, including any changes (e.g., discontinuation of originally planned work, or new areas of research)**

We have continued our work as planned and run the projects described above.

### **Examples of effective translation, or significant progress along the translational pathway**

None to date

### **Examples of the creation and development of intellectual assets**

Publications including "Folic acid in pregnancy and mortality from cancer and cardiovascular disease: further follow up of the Aberdeen folic acid supplementation trial". Journal of Epidemiology & Community Health



## 5. PATIENT AND PUBLIC INVOLVEMENT AND ENGAGEMENT (no more than one page)

### Patient and public involvement:

The Bristol Nutrition BRU's PPI strategy has been reviewed and updated, with changes to the strategy approved by the Executive in January 2015. The PPI lead, Dr Eileen Sutton, is working with a newly appointed Research Dietitian to set up a Diabetes PPI group. The established Prostate Cancer and Perioperative Health PPI groups continue to provide support to the Unit. Both groups have four active members each and their activities have included commenting and advising on the development of research materials for individual research projects, providing input on a research bid and reviewing preoperative patient materials provided to patients in the Trust. BRU researchers continue to liaise with existing local PPI groups for research in the Childhood Theme. Within the wider University members of the Prostate Cancer group have also visited a house set up as part of the SPHERE project (Engineering) to provide feedback to the project researchers. PPI input was also sought by the PPI Lead for collaborative projects: members of the Addison's Disease Self Help Group and the Congenital Adrenal Hyperplasia Support Group were consulted in the development of patient materials for the PULSES study (Centre for Synaptic Plasticity) and the chair of the Barth Syndrome Society for the CARDIOMAN study. The PPI lead regularly attends NIHR PPI Leads meetings and liaises with local PPI contacts in the CLAHRC and the WEAHSN. The PPI Lead presented a poster on setting up PPI in the BRU at the NIHR INVOLVE conference in Birmingham in November 2014. In addition to the above activities our PPI groups we are moving forward in involving members in determining the future strategy of the BRU. We will look for volunteers from our current group members and hope that two will agree to become part of the Strategy Group. The PPI Lead submits a quarterly report on PPI activities for approval by the Executive.

### **Public Engagement**

The Bristol Nutrition Biomedical Research Unit is committed to public engagement. We have a Public Engagement Lead, Rachel Perry, and a Unit Engagement Policy to guide engagement activity within the unit. It was developed with support from the University of Bristol Centre for Public Engagement, discussed with BRU staff and agreed by the BRU Executive. All Unit staff are all committed to engagement training and contributing to public engagement activities. The BRU Engagement Policy outlines work in four key areas

**Supporting University strategy and engagement activities** – we will continue to work with the University and Trust to support their strategy and centrally organised engagement activities (we have run a stall at the Clinical Trials Day for the past two years).

**Staff training** – all BRU unit staff were trained in Engagement by Kate Miller from the Centre of Public Engagement. She ran a half day workshop on engaging with the public. Media training was also offered to all staff by the press office training centre. Several members of the team have now received this training.

**Leading engagement activities** – We continue to run a seminar series open to the public and advertised on the BRU website. Much of the engagement work we have done this year has been with school-aged children. The "How'd You like Them Apples" game was first trialled at the Green Man Festival in August 2014 and then run again at the Bristol Bright Nights festival in September 2014. It has since been expanded into a 45 minute workshop that has been taken into local schools and community events including The Galleries shopping centre. Dr Elanor Hinton invited Year 13 students from Redland Green School to visit Clinical Research and Imaging Centre (CRIC), Bristol for workshops on MRI and the brain. Students had the opportunity to see the MRI scanner and learn about how it works, and Dr Hinton gave examples of what imaging has taught us about the brain in health and disease.

**Future Engagement Activities:** Following from the success of the above two initiatives, we plan to expand our Engagement work with school-aged children which will involve collecting real-time data in a school setting at Hanham Wood Academy around the theme of asthma. Another new venture planned is to work with the Ideal Community Project to support the delivery of a new health-related module in their peer-mentoring scheme for people. [IDEAL is a development organisation focused on creating and delivering projects that build confidence, awareness, skills and new opportunities for young people and adults](#) affected by issues such as drugs and offending

**Monitoring and reviewing engagement activities** – the policy will continue to be reviewed and updated annually. The engagement lead regularly updates the team with Engagers' Digest which enables them to find engagement activities that they are interested in. Engagement progress is written in a quarterly report and sent to the Executive team.

**Please also describe how you make patients and the public aware of the research being undertaken within your Unit, and signpost them towards appropriate information about participating in research.** PPI and Engagement Policies are both available on the Bristol Nutrition BRU website and all activities are regularly reported on the News section of the website. Our monthly seminars are advertised and open to the public. We represent the Nutrition BRU at University of Bristol and UH Bristol events such as the Postgraduate Festival of Science and International Clinical Trials Day where posters and flyers are available.

## 6. TRAINING (no more than two page)

We have a formal training policy (see <http://www.uhbristol.nhs.uk/research-innovation/our-research/bristol-nutrition-bru/training/>) and a Training Lead (Dr Charlotte Atkinson). Our policy describes training activity and opportunities in five areas which are described below along with highlights of some of the training in the past year. Since the last report, the policy has been updated based on the outcome of a staff and student questionnaire and a 'Present and Discuss' session on training within the BRU. Guidelines for funding towards travel, subsistence and attendance costs at scientific conferences and training courses for BRU staff, students and affiliates have also been produced.

### 1. Students and placements

- *Studentships*: The BRU has four PhD students (three non-clinical and one clinical) but also hosts and part funds an MD student and hosts another MD student and an MRes student. The BRU hosted a third year undergraduate student studying Animal and Veterinary Bioscience at the University of Sydney to spend January and February 2015 with the BRU on a work placement with Elanor Hinton at CRIC using Functional MRIs to study eating behaviours in childhood obesity.

- *Internships*: These are aimed at post-graduates looking to obtain experience in the areas of scientific research administration or clinical trial management. The BRU has had one intern since February 2014 (whose initial 12 month contract was extended by 6 months). She is due to start a PhD at the University of Bristol (UoB) in September 2015. We are planning to have another intern at the BRU for 12 months from April 2016.

- *Dietetic research training*: The BRU has a designated dietitian liaison (Laura Birch). Activities in the past year include a 'Getting Started in Research' workshop that Laura delivered to the paediatric dietetics team at the Bristol Royal Infirmary (BRI), and the provision of individualised advice to local dietitians looking to set up research studies. Laura attends dietetic departmental meetings and invites dietitians to the BRU seminar series as well as notifying them of any other relevant training opportunities. She will deliver a workshop on Research Methods and Study Design at the British Dietetics Association Paediatric Special Interest Group in London in May 2015.

### 2. NHS and University Training

- *Generic / core training*: All BRU staff and students have been encouraged to attend generic and core training courses offered by the Trust and UoB. In the past year, staff and students have attended courses in areas such as Endnote, budget related training (e.g., FEC, Profin), and how to manage research groups.

- *Good Clinical Practice (GCP) and other mandatory training*: All BRU staff and students have access to mandatory training such as GCP training courses.

- *Short Courses*: These courses are run by the School of Social and Community Medicine at the UoB, and cover a range of health services research and epidemiological methods, as well as generic research skills. In the past year, 13 places on these courses have been funded by the BRU.

### 3. NIHR Training

- *NIHR training opportunities*: All BRU staff and students who are part or fully funded by the NIHR have the opportunity to take advantage of the various courses and training meetings offered by the NIHR. One of our PhD students has been allocated a place at the NIHR summer school residential course in July 2015.

### 4. BRU Internal Training and Staff Review

- *Reading Group*: The BRU runs a reading group which all staff and students within the Unit may attend. Key basic methodological texts or specific articles / book chapters are covered over several weeks and provide a platform for learning and discussion away from day to day tasks. In the past year we have read and discussed a series of papers related to systematic reviews and meta-analyses, and the BRU theme leads have taken us through a series of papers relevant to their work.

- *Present and Discuss*: The BRU holds regular Present and Discuss meetings. These provide an informal platform to talk about current work or previous work, lessons learned from prior work, or to practice a conference / other presentation. BRU staff, students, affiliates, and visiting fellows, in addition to other UoB and UHBristol staff and students have presented at and attended these meetings.

- *Research Methods course*: All BRU staff and students have access to training on research methods, which

consists of a series of e-lectures that have been developed by Dr Sam Leary (Senior Lecturer in Statistics, and member of the NIHR statistics group). Three associated 2-hour tutorials have also been developed, and can be used in conjunction with the e-lectures to augment / reiterate information presented in the e-lectures.

- *Training Days*: Training workshops / seminars have been run with support and input from additional UoB and Trust groups and the NIHR, including the Research Design Service Southwest, Research and Innovation, and the UoB Press Relations team.
- *Team Building and Away Days*: The BRU from time to time runs Team Building Events and Away Days to further encourage cross-Unit interactions and to allow a more strategic discussion of topics related to the Unit. In the past year we have held a series of away days to facilitate strategic discussions including away days for BRU executive group members, BRU theme leads and affiliates, and BRU staff and students. An example of a team building event was when we went to a local charity (The Square Food Foundation) to cook our Christmas dinner.
- *Travel and Conferences*: BRU staff and students are encouraged to attend relevant national and international scientific meetings, and individualised training budgets fund or part fund these meetings.
- *Staff Review*: All staff are encouraged to meet regularly with their line manager / key colleague, and to undergo formal staff review once a year.
- *Co peer review*: Senior staff will be encouraged to co peer review manuscripts with junior staff.

## 5. BRU Open Training

- *Seminar Programme*: The BRU runs a formal CPD accreditable seminar programme. Seminar speakers include both internal and external people, and attract a varied audience.
- *Workshops*: The BRU developed and ran a workshop entitled 'Nutritional Epidemiology - An introduction to issues in analysis and interpretation of dietary data'. This was a three day course run as a pilot in 2015, and provided free of charge to attendees. The course covered areas such as nutrition research methods and the analysis of nutrition data. Staff and students from the BRU and other schools within the UoB attended, as well as external researchers from both within and outside the UK. Protected places on the course were offered to the Leicester / Loughborough BRU (from which three people attended) and the Southampton BRC. Feedback on the course was very positive, and we are currently refining the course to be run again (as a fee-paying course) in 2016. Protected free places will again be offered to the Leicester / Loughborough BRU and the Southampton BRC.
- *Sabbaticals and visiting fellows*: An agreement has been reached between the BRU and the Institute for Advanced Studies (IAS) at the UoB regarding support for BRU Sabbaticals. These are run through the IAS, with one of a proposed two annual sabbaticals being funded by the IAS subject to them being competitive. In the past year two fellows have been hosted at the BRU, and we are currently hosting Dr Sorrel Burden on a three month sabbatical from the University of Manchester.

### Summary

As shown above, the training within the Bristol Nutrition BRU covers a broad range of areas and, as such, aims to develop staff in all clinical and non-clinical professions. We have a named Training Lead (Charlotte Atkinson) along with a dedicated training budget, and we encourage all staff and students to take advantage of the opportunities available to them.

#### • Specific training plans for the BRU

In the next year we plan to continue to facilitate access for staff, students, and affiliates to a wide range of training opportunities both in house and elsewhere.

#### • Ongoing or planned collaborative training, secondment or networking with other parts of the infrastructure.

We have continued to meet and share ideas with the training leads at BRU/Cs with an interest in nutrition and physical activity (Leicester/Loughborough and Southampton) through joint meetings held approximately twice a year. In addition, we have established contact with the training lead at the CLAHRC West. We ran a course on the analysis of dietary data (see above for details), and offered free places to the Leicester/Loughborough BRU and Southampton BRC. Southampton provided us with two free places on the week-long, residential Intercollegiate Course in Human Nutrition run by the Academy of Medical Royal Colleges and taught by Southampton BRC investigators.

#### • Overall amount of expenditure on training for this year

The total expenditure on training and conferences during 2014-2015 was £14,994. (This does not include staff time costs).

## 7. LINKS WITH INDUSTRY (no more than two pages)

The Bristol Nutrition BRU has limited scope, due to its research areas in engaging with pharma, *in vitro* diagnostics, CRO's and non-life sciences companies but has made significant progress in engaging with biotech and medtech/devices:

- (1) Breath Dx UK: Evaluation and validation of a breath ammonia measurement technology for the improved management of patients with urea cycle defects. Assisted in qualitative work relating to PPI. Initiated application and submitted outline to NIHR i4i product development award 2015. Short-listed, interviews on June 17<sup>th</sup> (London).
- (2) Cambridge Temperature Concepts: Development and testing of a cutaneous device to recognise hypoglycaemia in children with diabetes whilst asleep. Final aim would be to produce a device that alerts parents to episodes of hypoglycaemia. Version 2 of device currently under evaluation. Delays in testing second device related to IP/patent ownership negotiations between company and venture enterprise company: unrelated to BRU activities.
- (3) Genotek- Pilot study to evaluate the performance of the DNA Genotek Stool Collection Kit compared to a standard stool self-collection kit for microbiome analysis.
- (4) Maltron: BIOSCAN 920 – II: Evaluation of bio-impedance device for evaluation fluid shifts (extra cellular/intracellular fluid) in diabetic ketoacidosis in children with type 1 diabetes to ensure safer resuscitation. Ethics approval received 27<sup>th</sup> March 2015.
- (5) Wellpoint health kiosks: Study of user decision making subsequent to using health kiosk within United Bristol Hospitals NHS Foundation Trust: analysis of study data currently underway.
- (6) Nutricia: Our intern completed her placement at Nutricia and following the success of this, we plan to explore the option of future placements and are investigating the possibility of a jointly funded PhD opportunity.

Our strategic plan for increasing engagement with industry included utilising our links with secondary care (in particular Bristol Children's Hospital) to identify groups of patients with particular needs for improved disease monitoring to be used in proof of concept device testing and to feed back patient experience to device manufacturers. We also have access to patient groups from the Bristol Urological Institute, the Bristol Dental Hospital, and the Bristol Royal Infirmary. In addition, we have links to Bristol Robotics Laboratory and SPHERE- a Sensor Platform for Healthcare in a Residential Environment (University of Bristol EPSRC funded).

**7.2 Please indicate the total number of UK Small and Medium Enterprises (SMEs) you have worked with during financial year 2014/15 and provide brief details of key examples. Please list ALL UK SMEs that you have worked with during 2014/15 in the Finance & Activity Report (*BRU Finance & Activity Report 2014-15.xls*).**

We have worked with a total of six UK Small and Medium Enterprises, with brief details described above and noted on the Finance and Activity Report.

**7.3 Please provide details of; i) any new strategic partnerships between your Unit and industry during financial year 2014/15 ii) the progress of ongoing strategic partnerships between your Unit and industry during financial year 2014/15. Please list all new strategic partnerships between your Unit and industry during 2014/15 in the Finance & Activity Report (*BRU Finance & Activity Report 2014-15.xls*).**

We have no formal strategic partnerships to report but a series of project based collaborations as described above. We are hoping to form a strategic partnership with Nutricia following a successful intern placement and the development of a joint PhD opportunity.

**7.4 Please provide brief details of key examples of studies active in financial year 2014/15, as follows:**

- **Contract commercial trials**
- **Industry collaborative research studies**
- **Other academic commercial research**

We do not have any Contract Commercial Trials at present. In the financial year 2015 the four Industry Collaborative studies are:

(1) Breath Dx UK: Evaluation and validation of a breath ammonia measurement technology for the improved management of patients with urea cycle defects (Breath Dx UK)

(2) Evaluation of bio-impedance device for evaluation fluid shifts (extra cellular/intracellular fluid) in diabetic ketoacidosis in children with type 1 diabetes to ensure safer resuscitation. Ethics approval received 27<sup>th</sup> March 2015 (Maltron)

(3) Study of user decision making subsequent to using health kiosk within United Bristol Hospitals NHS Foundation Trust: analysis of study data currently underway (Wellpoint)

(4) Pilot study to evaluate the performance of the DNA Genotek Stool Collection Kit compared to a standard stool self-collection kit for microbiome analysis (Genotek).

We are still planning a study to develop and test a cutaneous device to recognised hypoglycaemia in children with diabetes whilst asleep with Cambridge Temperature Concepts. The final aim would be to produce a device that alerts parents to episodes of hypoglycaemia.

**7.5 Please provide the number and key examples (including name of funder/grant scheme) of any partnerships or studies with industry which have led to further industry, public or charity research funding, including as part of consortia.**

Within the Childhood theme, an industry collaboration with Breath UK has submitted an outline for a feasibility study of breath ammonia device to manage children with urea cycle defects (AmBeR) for an i4i (Innovation for Invention (i4i) Programme award (£660,701). The final decision is expected in June 2015

**7.6 Please provide the number of Agreements signed with industry during financial year 2014/15 and provide brief details of key examples, as follows:**

- **Non-Disclosure Agreements**
- **Model Trial Agreements including mICRA and mCTAs**

Number of agreements signed with industry:	
Non-Disclosure Agreements	1
Model Trial Agreements including mICRA and mCTAs	0

## 8. LINKS WITH OTHER NIHR INFRASTRUCTURE (no more than one page)

**Please specify the type and the number of other NIHR infrastructure collaborations (e.g. with other BRUs and BRCs, Clinical Research Facilities (CRFs), Healthcare Technology Co-operatives (HTCs), Collaboration for Leadership in Applied Health Research Centres (CLAHRCs), Diagnostic Evidence Co-operatives (DECs), Translational Research Partnerships (TRPs), NIHR BioResource, NIHR National Biosample Centre, MRC/NIHR Phenome Centre, Experimental Cancer Medicine Centres (ECMCs), Clinical Research Networks (CRNs), Dementia Translational Research Collaboration (D-TRC), Rare Disease Translational Research Collaboration (RD-TRC) and the Patient Safety Translational Research Centres.**

The Bristol Nutrition BRU has built up a network of UK Collaborations, including Aberdeen, Birmingham Bournemouth, Cambridge, Leicester, Leeds, Manchester, Plymouth, Southampton and Taunton.

Professor Andy Ness meets regularly with Professor Gianni Angelini (Bristol Cardiac BRU) and Professor Andrew Dick (NIHR Biomedical Research Centre -Ophthalmology) to discuss strategic plans for collaboration to share good practice in management, training, statistics, systematic reviews, qualitative research, data management, bio-storage and potential joint projects. For example, Dr Sam Leary, with Dr Jessica Harris set up a joint statistics group in 2013 with the NIHR Bristol NIHR Biomedical Research Unit for Cardiovascular Disease. The group meets quarterly.

In December 2014, Professor Andy Ness and Professor Julian Hamilton-Shield visited David Goldblatt, Director of the NIHR Biomedical Research Centre at Great Ormond Street Hospital for Children NHS Foundation Trust and University College London to discuss increased collaboration (See Childhood theme Section on collaborative work with Great Ormond Street Biomedical Research Centre on childhood obesity and Urea Cycle Defects/device development).

The Bristol Nutrition BRU is working together with the Leicester Loughborough Nutrition BRU and the Southampton BRC to explore opportunities for joint training programmes. We meet three times a year, rotating the location between the three groups to share plans, progress and policies. This gives managers, training and PPI leads the opportunity to exchange ideas. Southampton BRC funded Dr Vanessa Marshall and Ms Vaneesha Short to attend the week-long, residential Intercollegiate Course in Human Nutrition run by the Academy of Medical Royal Colleges and taught by Southampton BRC investigators; We ran a three day course on the analysis of dietary data and offered free places to the Leicester/Loughborough BRU and Southampton BRC.

We continue to host an NIHR Rare Disease Translational Research Collaboration research fellow - Ethan Sen – who is working on nephrotic syndrome. His supervisor Professor Moin Saleem is now a BRU affiliate. Bristol is also a collaborator in another NIHR Rare Disease consortium proposal in Type 2 diabetes in children.

Rachel Perry, Dr Charlotte Atkinson and Professor Andy Ness are working with Dr Maria Pufulete in the Bristol Cardiac BRU regarding a potential joint BRU project in pre-surgical care.

Dr Sam Leary is a member of the NIHR Statistics Group. She attended the Feasibility and Pilot Studies Workshop in April 2015 hosted by the group, and will feedback the relevant information to the BRU staff in a "Present and Discuss" session. She has now become the Membership Secretary for the group, and will attend the next Steering Group meeting to discuss plans for taking this role forward. She has also volunteered to host an NIHR Statistics Group event such as a workshop in Bristol in the future.

One of our Core studies (Evaluation of the Wellpoint Healthcheck kiosks) is the result of NOCRI introduced collaboration with industry, carried out in conjunction with Leicester/Loughborough BRU.

**Please also outline any strategic plans for increasing engagement with these NIHR Infrastructure schemes.**

We will continue to meeting with our local BRU and BRC and with the nutrition BRU and BRC to further develop collaboration. We will also aim to work closely with CLAHRC West, hosted by University Hospitals Bristol NHS Foundation Trust. This opened on January 1<sup>st</sup> 2014 and offers opportunities to strengthen our link to ongoing and new applied research.

## 9. IMPACT IN HEALTHCARE PROVISION (no more than one page)

**Please list any significant new work showing how your Unit is translating its work into practice for the benefit of patients within your Trust and influencing its translation further afield; you may also summarise significant developments in examples reported previously.**

As Progress made in each theme section, all of our studies are still at an early stage and too early for translating into practice for direct patient benefit.

**Please also describe examples of work which has significant potential to improve patient outcomes or experiences in the future, setting out how the Unit plans to ensure that these potential benefits are realised.**

### 1. Cambridge Temperature Concept study

The aim of this study, now planned to start is to develop and test a cutaneous device to recognise hypoglycaemia in children with diabetes whilst asleep – a major concern for parents of children with diabetes. We will work with the company to refine a new device developed directly from our work with the company in a phase one study. The final aim would be to produce a device that alerts parents to episodes of hypoglycaemia which has the potential of great benefit for children and parents.

### 2. Dietary manipulation to improve glycaemic control in young people with cystic fibrosis related diabetes.

Our research dietitian, Laura Birch, has secured funding from the Research Funding Committee at United Hospitals Bristol Foundation Trust, to work on a pilot project with the aim to improve diabetic control by dietary manipulation in a population of young people who have both cystic fibrosis and diabetes. If successful, it would lead to a further trial, the outcome of which has the potential to have direct patient benefit.

### 3. Cycling Intervention for people with diabetes

Our Type 2 diabetes theme have been working closely with the third sector group Life Cycle UK, to provide training and guided bicycle rides as an intervention for people with type 2 diabetes. We are starting to develop feasibility studies based upon the data, and involving the participants, from STAMP-2. Active travel presents a suitable target for such intervention since it may both displace sedentary time (e.g. travelling in a car) and increase physical activity, may be behaviourally sustainable (i.e. people develop a “habit” of travelling actively), and has been shown to be associated with lower risk of disease and improved metabolic health in healthy adults. We wish to test whether cycling also has the potential to be both acceptable and effective in people with type 2 diabetes. Life Cycle UK is a Bristol charity that has 18-years’ experience of supporting people to cycle. Participants will initially receive 1 to 1 training in cycling, and will progress towards regular group rides. They will be offered the opportunity to participate either on conventional bicycles, or on electric bicycles. Electric bicycles will be chosen to make cycling easier, but not to remove all effort, and anecdotally have been suggested as an effective way to get larger or less healthy people cycling. We aim to conduct this study over 1 year from September 2015 in order to evaluate whether participants drop out of cycling over the winter, but then start cycling again in the spring, to give an indicator of potential maintenance of the behaviour. To ensure the study achieves its potential, the BRU is supporting a 1 year research assistant post to work on this study, is funding the purchase of bicycles and will fund Life Cycle UK to deliver the intervention.

In addition to these specific examples of future planned directions, three of the four substantive themes have secured funding to take forward research to larger patient outcome focussed trials, and some of our qualitative work across themes can be considered for taking forward as proposals, particularly from the Peri-operative theme to CLARHC West for implementation studies.

## 10. OTHER COMMENTS (no more than one page)

Please use this space to provide us with any other information you would like to highlight, or comments you would like to make.

Professor Andy Ness is a UK NIHR Senior Investigator and a Fellow of the UK Association for Nutrition.

This form, together with the BRU Financial & Activity Report and an Added Value pro forma (using the structured template provided) must be submitted, by email, no later than **1pm on Monday 18 May 2015** to Sonja Tesanovic ([sonja.tesanovic@nihr-ccf.org.uk](mailto:sonja.tesanovic@nihr-ccf.org.uk)).

A signed copy of this report should be sent no later than **Tuesday 26 May 2015** to:

Dr Sonja Tesanovic  
NIHR Central Commissioning Facility  
Grange House  
15 Church Street  
Twickenham, TW1 3NL