Strategy for ensuring independence of research conducted by members of the Nuffield Department of Population Health

Research funding

The Nuffield Department of Population Health (NDPH) is a medical research and teaching department within the University of Oxford's Medical Sciences Division, with a focus on the causes, prevention and treatment of premature death and disability worldwide. It employs around 600 people, including clinicians, statisticians, social scientists, other researchers, IT and other research support staff. Many of its scientists are world-leading experts in their field and collaborate extensively with other researchers around the world.

Research at NDPH is funded in a number of ways. Much of the funding is peer-reviewed, which involves other experts independently assessing the Department's planned research. Such support is provided by a number of government institutions and charities, including the Medical Research Council, National Institute for Health Research, Department of Health, British Heart Foundation, Cancer Research UK and Wellcome Trust. In addition, funding is obtained from healthcare companies, particularly for large studies of the treatment and prevention of disease. NDPH's research is conducted independently of the funding sources.

After completion of NDPH's studies, reports of their results are written (without restrictions by the funders) and submitted to general or specialist journals, where they typically undergo peer-review before publication. NDPH staff publish nearly 1000 papers per year. Every 5 years or so, the Higher Education Funding Council for England conducts an assessment of University-based research that is used to determine the distribution of government research funding to universities. The most recent assessment in 2014 found that NDPH's research is world-leading in terms of its quality and impact on population health.

Maintaining NDPH's independence from industry funding

NDPH aims to address important health questions which can sometimes require very large studies to produce reliable findings. In the case of common life-threatening illnesses (such as heart disease, stroke and cancer), even small advances in prevention and treatment can help to avoid thousands of premature deaths and much disability worldwide.

The conduct of clinical trials that involve many thousands of participants, often in multiple countries around the world, requires a substantial research effort and can be very expensive. Given the costs involved, industry funding and provision of study drugs help to ensure that clinical trials can be of sufficient size and scope to assess the safety and efficacy of treatments reliably. Likewise, large-scale observational studies of the associations of risk factors with disease may well require substantial investment in genetic and other assays by industry in order to unlock scientifically important data for population health research.

NDPH staff decide what studies in which to be involved for scientific reasons and then seek government, charity and/or industry research funding to cover the costs. For example, NDPH

researchers have taken a lead in clarifying the relevance of cholesterol to the risk of cardiovascular disease, and then assessing the impact of lowering cholesterol levels with statin therapy. In the case of NDPH's Heart Protection Study, it took several years to obtain the funding, with half coming from the Medical Research Council (government) and the British Heart Foundation (charity), one quarter from Merck (manufacturer of simvastatin) and one quarter from Roche (manufacturer of vitamins E, C and beta-carotene). That trial showed statin therapy reduces the risk of heart attacks and strokes safely for a wide range of patients at high risk of such events, but the vitamins produced no benefit. Both results were reported prominently by NDPH researchers independently of all of the funders.

All of NDPH's research that receives industry funding is governed by University of Oxford contracts which protect the independence of study design, conduct, analysis, interpretation and reporting. NDPH (not the funders) controls the databases, and controls the analyses and interpretation of its studies, with no restrictions from funders on what is reported.

The Department does not engage in activities that pose or appear to pose a conflict of interest. In particular, NDPH would not accept funding for research from tobacco or alcohol companies, and has carefully limited engagement with food and nutrition companies.

A list of current NDPH grants from industry can be found in the attached annex.

NDPH policy on consultancies, honoraria or other personal benefits

Acceptance of Honoraria Payments and Participation in Industry Meetings

Honoraria are payments made for activities notionally provided without charge. NDPH staff may accept honoraria payments, but care should be taken to ensure that the source of the funding does not raise conflict of interest issues. (For example, funding from a potentially conflicted source may be made to appear legitimate by channelling it through a University.)

NDPH has an explicit policy of not accepting any personal honoraria payments directly or indirectly from the pharmaceutical and food industries. It only seeks reimbursement to the University of Oxford for the costs of travel and accommodation to participate in scientific meetings. This approach is intended to help ensure that decisions to give lectures or advice are determined by the scientific value of doing so, and not by personal financial gain.

Invitations from pharmaceutical or food companies to participate in meetings should be considered carefully to ensure they are scientifically legitimate, or that a specific scientific interest of NDPH would be served by acceptance. If not, such invitations should be declined.

Consultancy agreements

The University's view is that consultancy can be an important means by which staff make their knowledge and expertise available to government, public sector organisations, community

groups and business. Any consultancy activity by NDPH staff must be approved by both the Head of Group and the Head of Department. It must fulfil the following criteria:

- The purpose of the consultancy should be clearly stated.
- It should not pose or appear to cause a conflict of interest.
- No payments directly or indirectly from pharmaceutical or food companies.
- It should be limited to provision of advice and assistance, and not include undertaking of substantial research for external bodies (which should be funded by a research grant).

Anyone considering any paid activity outside of the Department should first discuss it with their line manager and Head of Group. In addition, any external activities leading to consultancies, should be reviewed by Oxford University Consulting, which will carry out due diligence checks to ensure compliance with relevant University ethics and funding policies.

Please see the relevant <u>University guidance on Outside Appointments</u>, including Consultancy agreements.

Investments

It is recognised that pensions are based on investments in companies over which staff have no control. However, it is recommended that NDPH staff not hold shares directly in tobacco companies, or in pharmaceutical, biotechnology or food companies that might be affected by research or publications in which they are involved or by their public statements.

If in doubt about any of these issues, staff are encourage to discuss them with their line manager or with members of the Department's HR team.

Related Policies

All NDPH staff are also required to comply with University policies, including:

- University policy on bribery & fraud
- University policy on research integrity
- University policy on gifts and hospitality

Annex: Commercial funding received by the Nuffield Department of Population Health, University of Oxford, since 2003

ACE trial of acarbose (2008-2017)

Bayer: £135K *

ASCEND trial of aspirin and fish oils (2004-ongoing)
Abbott/Solvay/Mylan: £2.1M plus drug supply

Bayer: £1.8M plus drug supply

Assessing the potential for SenseCam to fight the current global health

crises of increasing obesity and physical inactivity (2010-2013)

Microsoft: £69K

ATLAS trial of tamoxifen duration (1997-ongoing)

AstraZeneca: £1.0M plus drug supply BEST-D pilot trial of vitamin D (2012-2014)

Tishcon: free drug supply only

Big Data Institute (2018-2019)

Novartis Pharma AG Switzerland: £4K

CCS-2 trial of metoprolol and clopidogrel (1999-2005)

AstraZeneca: £1.1M plus drug supply Sanofi: £1.1M plus drug supply

China Kadoorie Biobank (2002-ongoing)

AstraZeneca: \$300K Bayer AG: £300K GlaxoSmithKline: £3.6M

Merck: £200K

Development of digital biomarkers for dementia (2016-ongoing)

Eli Lilly and Company USA: £600K

Development of digital biomarkers for dementia (2016-ongoing)

Roche: £600K

Diabetic Peripheral Neuropathy Treatment with Dorsal Root Ganglion Stimulation a Randomised Controlled Trial (2018-2020)

St Jude Medical Europe Inc: £52K

Doctor Referral of Overweight People to Low Energy Treatments (2015-2020)

Cambridge Weight Plan Ltd: £35K

Economic burden of malignant neoplasms in the EU (2011-2012)

Pfizer: £36.5K

Elinogrel feasibility trial (2010-2011)

Novartis: £500K

Establishing Fuwai-Oxford research centre (2010-ongoing)

Merck: £1.1M

EXSCEL trial of exenatide (2009-2017)

Amylin: £473K *

FOXFIRE trial of chemotherapy with or without radioembolisation for bowel cancer that has spread to the liver (2009-2017)

Sirtex: £228K *

Genomic Data Working Group (2020-2025)

Regeneron Pharmaceuticals Inc: £107K

Heart Protection Study (1993-2002) Merck: £5.5M plus drug supply Roche: £5.5M plus drug supply

Annex updated May 2020

Heart Protection Study follow-up studies (2003-2010)

Merck: £1.2M

GlaxoSmithKline: \$400K Liposcience: £50K

HPS2-THRIVE trial of niacin/laropiprant (2005-2015)

Merck: £53M plus drug supply

HPS3/TIMI55-REVEAL trial of anacetrapib (2010-ongoing)

Merck: £108M plus drug supply HPS 4/TIMI 65 – ORION-4 (2017-ongoing)

MEDCO: £54M

HPS 5/ORION-17 (2020-ongoing)

MEDCO: £1M

MaatHRI Project (Ultromics) (2018-2022)

Ultromics Limited: £79K

NAVIGATOR trial health economics analysis (2013-2014)

Novartis: £15K *

Next generation sequencing analysis - a clinical study (2011-2014)

Life Technologies: £125K *

Non-invasive rapid assessment of liver disease using magnetic resonance (2016-2019)

Perspectum Diagnostics: £273K *

Oxford Participation & Activities Questionnaire (Ox-PAQ) Phase 2 Study (2014-ongoing)

Actelion: £58K

Pfizer Innovation Award (2004)

Pfizer: £50K to CTSU for unrestricted research

PROCARDIS genetic study (1998-2011)

AstraZeneca: £1.7M

SEARCH trial of simvastatin dose (1997-2010)

Merck: £22.7M plus drug supply

SHARP trial of simvasatin/ezetimibe (2002-2013)

Merck/Schering: £40M plus drug supply

SHARP-2 EMPRESS (2017-ongoing)
Boehringer Ingelheim: £91M
STICS trial of rosuvastatin (2011-2014)

AstraZeneca: \$100K

TECOS Trial Evaluating Cardiovascular Outcomes with Sitagliptin (2008–ongoing)

Merck & Co Inc: £140k *

The Transthyretin (ATTR) Amyloidosis Questionnaire (ATTRAQ) (2020-ongoing)

Pfizer: £147K

UK-HARP-III pilot study of LCZ696 (2013-ongoing)

Novartis: £2.6M

3-C trial of transplant rejection (2009-ongoing)

Pfizer: £530K Novartis: £350K

* Funds received by NDPH's Health Economics Research Centre for trials led by other Oxford University departments or Institutions.