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***UK Biobank* gets unanimous backing from international experts after piloting phase**

Multi-million pound project to go national from end of 2006

UK Biobank – the multi-million pound visionary medical project aimed at improving the prevention, diagnosis and treatment of a wide range of diseases that kill, disable or cause widespread misery (such as cancer, heart disease, diabetes, dementia, mental illness, joint disease and many other debilitating conditions) – announced today (Tuesday 22 August) that it has received the go-ahead to roll out its programme nationwide.

Following a three-month piloting phase in the Manchester area, the final protocol received unanimous backing from a team of international scientific and medical experts, and from the project's funders.

The success of the 3,800-participant piloting phase means that, around the end of this year, letters will start going out to men and women aged 40 to 69, who will be invited to attend one of a network of assessment centres¹ to be set up in locations all around the UK. The aim is to recruit half a million people – nearly one percent of the British population – over the next four years.

UK Biobank will gather, store and protect a vast bank of medical data and material that will allow researchers to study in depth, in decades to come, how the complex interplay of genes, lifestyle and environment affects our risk of disease. It is the first time that such a project has been attempted in such fine detail on such a vast scale.

The final protocol for the £61m project, which is being funded by the Medical Research Council (MRC), the Wellcome Trust, the Department of Health, the Scottish Executive and the Northwest Regional Development Agency has been subjected to rigorous and detailed scrutiny by an independent International Review Panel set up by the funders.

In its report, the panel concluded that: "*UK Biobank* has the potential, in ways that are not currently available elsewhere, to support a wide range of research, particularly investigations into complex interactions of various exposures, including genetic and lifestyle factors in the pathways to disease and health." The panel were impressed with the level of detailed planning and piloting that had gone into the development of the protocol, and considered it to be one of the most fully developed protocols they had seen. *UK Biobank* was also found to have set new standards for automated blood sample processing and storage, supplemented by a sophisticated computerised system to track samples. The panel said the approach to ethical oversight and governance of the resource was "exemplary and would be held up as a gold standard across the world".

The panel's overall view was that "*UK Biobank* is a unique opportunity to build an amazingly rich resource with a range of endpoints for future research that justified the initial establishment costs."

Professor Rory Collins, *UK Biobank*'s Principal Investigator said: "Clearly, everyone at *UK Biobank* is delighted with the support and enthusiasm that this unique public health project has received from the funders and, in particular, from the eminent independent experts who scrutinised every detail of our protocol and plans. We are also grateful for their ideas for adding value to the resource, which we are already starting to implement and will be exploring further with the many scientists already involved in *UK Biobank*, as well as with other international experts. In addition, we have established an independent International Scientific Advisory Board to help us develop the resource during the years to come. We will constantly review everything we do so as to maximise recruitment of the widest possible cross-section of the population, to improve the quality of the health-related information that is obtained, to inform participants and the public about our progress, and to uphold the highest scientific and ethical standards throughout. For decades to come, the *UK Biobank* resource should provide researchers around the world with vital insights into some of the most distressing diseases of middle and old age."

The chairman of the International Review Panel, Professor Thorkild Sørensen, from the Institute of Preventive Medicine in Copenhagen, Denmark, said: "It was a great honour to chair the panel for this exciting and very important project. Comprehensive and impressive plans, based on valuable pilot studies, were presented to the panel, who unanimously endorsed the protocol and put forward a number of suggestions that would enhance the long-term value of this unique project."

Dr Adrian Mercer, Chief Executive of South Manchester NHS Primary Care Trust – the first PCT to participate in the piloting phase – said: "The project was successfully launched in Manchester, being well received by those invited to take part and supported by PCTs and clinicians. I am sure the roll-out nationally will be equally successful."

Professor Colin Blakemore, Chief Executive of the Medical Research Council said: "*UK Biobank* offers enormous potential to find out more about the complex links between our genes, the lives we lead and our health. The Medical Research Council is delighted to continue to fund this project, which will provide scientists with extraordinary information and will offer unprecedented opportunities to improve people's lives. The project, under the leadership of Rory Collins, is already helping researchers by pioneering new ways to gather and collate large quantities of information. Over the coming years the data from this study will grow into a unique resource for future generations."

Dr. Mark Walport, Director of the Wellcome Trust said: "The piloting of *UK Biobank* has gone extremely well. The funders, advised by international peer reviewers, were very impressed by the leadership of Rory Collins and his team and by their plans for the future implementation of *UK Biobank*. I am delighted that we have agreed full funding for the programme and that large-scale recruitment will start shortly. *UK Biobank*, already watched with envy by researchers across the world, will provide a remarkable resource, allowing us to answer important questions about health and disease. This study has the opportunity to make a real difference to the health of future generations."

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¹ The idea of establishing a large national blood-based cohort was first proposed in 1999, with a provisional decision to support it made by the funders in 2002. So, there had been nearly seven years of consultation and meticulous planning for *UK Biobank* before an initial start-up phase in the Manchester area got underway in March this year. This three-month 'pilot' to refine procedures led to the now-approved final protocol, which will be further enhanced as the project proceeds. Recruitment into the first assessment centre for the main phase of *UK Biobank* will start at the end of this year. Over the course of the 3-4 year recruitment period, there will be around 35 centres in England, Scotland and Wales, each open for about six months. The centres will be located in areas where there are about 150,000 men and women aged 40-69 living within about 10 miles' radius. Each centre will be optimally located for public transport links, easy parking and access, including for disabled people. They will be staffed by trained nurses and other healthcare professionals. People in the target population will be mailed invitations to participate. Further information will be available from *UK Biobank's* website www.ukbiobank.ac.uk, and there will be a freephone number that invitees (and other interested people, such as GPs) can ring to discuss any questions with a study team member. No one will be pressured to take part and participants will be free to withdraw at any time. All of these procedures have been carefully tested in the pilot phase, and found to be very acceptable by participants. The single baseline assessment visit takes about 90 minutes and involves a computer touch-screen questionnaire, a short interview, some standard measurements, and small samples of blood and urine. The samples – totalling around 10 million – are going to be stored for decades at ultra-low temperatures, with a purpose-designed robotic system handling samples from about 1,000 people every day. Information about participants' subsequent health will be obtained, with their permission, from medical and other health-related records. Stringent security systems will be in place to protect participants' privacy. The entire project, which complies completely with the Data Protection Act and other relevant legislation, is subject to ongoing review by an independent Ethics & Governance Council and an International Scientific Advisory Board, as well as by a multicentre research ethics committee. Researchers from around the world will be able to apply to *UK Biobank* for access to the resource, which will be subject to appropriate approval procedures.

² For more information on *UK Biobank*, including the names of the International Review Panel, see www.ukbiobank.ac.uk

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