Great North Biobank Protocol for Access

The Chief Investigator, Dr Sophie Hambleton (sophie.hambleton@ncl.ac.uk), will be responsible for chairing a governance committee to assess requests to use samples taken from the Biobank. Specifically, this committee will be responsible for ensuring that projects are scientifically sound, clinically relevant and adequately funded. Studies that involve animal research, or research into termination of pregnancy or reproductive medicine are explicitly excluded from ethical approval and will not therefore be considered. The committee will include Professor John Loughlin (Professor of Musculoskeletal Research), Dr Andrew Gennery (Reader in Paediatric Immunology), Dr Michael Wright (Consultant in Clinical Genetics) and at least one designated and appropriately experienced consultant (or appropriate nominee) from the Great North Children's Hospital. A lay member will be nominated by the Bubble Appeal (a local charity that supports research into primary immunodeficiency and stem cell transplantation). Applications will first be filtered by at least 2 committee members by applying the following criteria:

(a) scientific merits of the proposed research
(b) whether the proposed study addresses an unmet need in paediatric research
(c) whether the proposed research is feasible and timely in the proposed setting
(d) whether appropriate samples are available within the biobank.

All applications will be considered using the same criteria, regardless of the type or location of the research organization. The full committee will then consider the application on its merits. Where there may be a conflict of interest, the committee member will not form part of that governance committee to ensure impartiality. A summary of samples released will be included in the annual report to the Newcastle and North Tyneside 1 Research Ethics Committee. This report will be submitted annually.

For samples to be released to other centres, Dr Hambleton will ensure that she has received written evidence of sufficient funding support, research sponsorship and approvals from relevant regulatory bodies locally. This will also require the consent of the NHS Trust Research and Development Dept who will ensure that appropriate procedures for material transfer and indemnity are adhered to for those applications deemed acceptable by the Governance Committee. A service level agreement (SLA) between the NHS Trust and Newcastle University provides that for all tissues donated with consent under ethical approval, Newcastle University will be the "custodian" of such tissues. A Materials Transfer Agreement (MTA) will be established between Newcastle University and the host institution, including the associated indemnity. Newcastle University's Public Liability insurance indemnifies the University for any damages it is held legally liable to pay to a third party if such materials were lost and the third party suffered a loss or injury (including stress and anxiety) because of it.

Request to perform research in Newcastle University using samples collected as part of the Great North Biobank

Approval has been obtained from the Newcastle & North Tyneside 1 Research Ethics Committee to perform research on samples collected as part of the Great North Biobank by groups based in Newcastle University without the need to obtain specific consent for individual projects. However, it is a condition of this approval that details of the projects included are submitted to the LREC as part of an annual report when they will be reviewed to ensure that they fall within the remit described in the accompanying protocol.

In order to dothis **please complete the sections below and send this form by e-mail to Dr Sophie Hambleton** (sophie.hambleton@ncl.ac.uk). Applications will be considered by the governance committee of the Great North Biobank, consisting of clinicians, scientists and a lay representative. The purpose of the review is to ensure that the work proposed does not duplicate ongoing studies in Newcastle, is adequately funded and has a reasonable prospect of producing meaningful results. Every effort will made to decide on the suitability of projects within 4-6 weeks. If access to samples is denied the reasons for this will be explained in writing.

Please note that results of laboratory investigations covered by this protocol specifically exclude any that would be used to influence the treatment of individual patients.

Pro forma for submitting a request to use samples in the Biobank by research groups in Newcastle University

(Electronic versions of this form may be obtained from sophie.hambleton@ncl.ac.uk)

Contact details

Name of Principal Investigator
e-mail
Telephone
Address

Project details

Title of project
Source and amount of funding
Place where research will be conducted
Sponsor (eg NHS Trust)
Details of peer review (eg through funding peer review or local research committee).

Abstract (no more than 500 words). Please attach copy of full application and /or research protocol if available Is the proposed project a pilot study or a more substantive project? Are the results likely to contribute to a publication in the near future? If so, please give brief details.

Sample details

Number and type required (eg bone marrow, blood, CSF, other)	
Minimum size of sample (eg cell number or quantity of RNA, DNA or protein)	
Please justify, including details of power equations where performed	

To be completed by biobank manager Sample availability - How many samples are available of the type requested? Are you aware of other projects which are likely to benefit form the use of samples of this nature?	
Date application received	
Date sent for approval	
Date of approval decision	
Outcome	