AGREED BY TRENT MREC SUB-COMMITTEE 14 SEPTEMBER 2005

USE OF TISSUE/DATA IN ESTABLISHED BANKS WITHOUT ADDITIONAL MREC APPROVAL

General Requirements:

- The purposes for which banked tissue/data can be used without additional MREC approval, will be agreed between the MREC and the CI when the application to establish the bank is approved.
- The CI will be responsible for ensuring that tissue/data is only released for MREC approved purposes. If there is a change of CI, the new CI will have to agree to the same conditions of approval.
- The purposes may be changed by a substantial amendment to the original application to establish the bank, subject to MREC approval.
- Individual studies that fall outside the agreed purposes must be the subject of a separate application to the MREC.
- Each 'bank' should have a scientific review committee to assess each application for its use. The composition of this committee should be agreed with the MREC when the application to establish the 'bank' is approved.
- 6. An annual report must be submitted to the MREC listing studies for which tissue/data has been released, including the title and a short summary. This will enable the MREC to see that tissue/data has only been released for the purposes it has approved. For the first year the committee will require real time reports as and when a new use of data occurs.
- There must be no patient contact, no effect on individual patient care now or in the future and no plans to feed back results to individual patients.

Specific Requirements:

(agreed on 4 August 2005 with Prof Julia Hippisley-Cox, Chief Investigator for main QRESEARCH databank study MREC/03/4/021)

Amended 14 October 2005 to include real time reporting for the first year.

QRESEARCH

- The purposes, that include research and audit, are limited to studies on disease surveillance and health inequalities; aetiology, natural history, prevention, detection, diagnosis, management and outcome of illness based on data held in primary care and the organisation and activity of primary care services.
- Only uses data routinely collected in a primary care setting and that strong personal identifiers (including name, address, date of birth or death, and post code) are removed before inclusion in the database.
- 3. Studies must be approved by a scientific committee, CI studies excepted if they have already been independently reviewed.
- 4. The CI for all studies must be based in the UK and 'raw' data should not be transferred out of UK without specific REC approval.

Robert Bing Chairman, Trent MREC 14 September 2005 Amended 14 October 2005