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22 September 2010

Dear Mark

### **ECC 6-06 (g) /2009 - Survival Analysis of a cohort of Clostridium difficile infected and non infected patients admitted to Addenbrooke's Hospital between 2005 - 2007**

Thank you for applying for support under section 251 of the NHS Act 2006 to process patient identifiable information without consent. This application was originally considered by the Ethics and Confidentiality Committee at its meeting on 25 November 2009.

#### **Context**

This application requested patient information to compare patients with C-difficile between 2005 and 2007 with a control group in order to determine survival rates. Support under section 251 was requested to permit access to MRIS data to undertake linkage and provision of mortality data, including death registration.

#### **Outcome**

At this meeting, Members agreed to provide support under section 251 via the Health Service (Control of Patient Information) Regulations 2002. The view was that it could fall under section 3 (1) of 'Communicable Disease and other risks to public health', namely:

- (b) recognising trends in such diseases and risks.

Members had been concerned by the implication that no user involvement had been undertaken due to potential detriment to the reputation of the hospital, and did not consider this to be an appropriate justification for not undertaking service user involvement in this important area. As such, this approval was provisional upon carrying out appropriate user involvement and provision of a system level security policy so as to maintain the security and confidentiality of the requested information.

User engagement was subsequently carried out and details provided to the NIGB Office; such information was welcomed. It is also understood that communication had taken place between the applicant and the security review team in relation to completion of the system level security policy. Confirmation of satisfactory security arrangements has now been received from the security review team. As such, this letter constitutes formal confirmation of final approval under section 251, and our Register of approved applications (<http://www.nigb.nhs.uk/ecc/reg>) will shortly be updated to include this activity.

### Annual Review

Please note that your approval is subject to submission of an annual review report to show how you have met the conditions or report plans, and action towards meeting them. It is also your responsibility to submit this report prior to the anniversary of your final approval and to report any changes such as to the purpose or design of the proposed activity, or to security and confidentiality arrangements.

If you have any queries regarding this letter please do not hesitate to contact the NIGB Office on 020 7633 7052. Email queries should be sent to [eccapplications@nhs.net](mailto:eccapplications@nhs.net). Please quote the above reference number, in full, in any future correspondence.

Yours sincerely

Natasha Dunkley  
NIGB Approvals Manager

### **Ethics and Confidentiality Committee Standard Conditions of Approval**

The support provided under section 251 is subject to the following standard conditions.

The applicant will ensure that:

1. The requested patient identifiable information is only used for the purpose(s) set out in the application.
2. Confidentiality is preserved and that there is no disclosure of information in aggregate or patient level form that may inferentially identify a person, nor will any attempt be made to identify individuals, households or organisations in the data.
3. Requirements of the Statistics and Registration Services Act 2007 are adhered to regarding publication where relevant.
4. All staff with access to patient identifiable information have contractual obligations of confidentiality, enforceable through disciplinary procedures.
5. All staff with access to patient identifiable information have received appropriate ongoing training to ensure they are aware of their responsibilities.
6. Activities are consistent with the Data Protection Act 1998.
7. Audit of data processing by a designated agent of the Secretary of State is facilitated and supported.
8. The wishes of people who have withheld or withdrawn their consent are respected.
9. The NIGB Office is notified of any significant changes which impact on the approval of the application.