



Office for National Statistics - 1 Drummond Gate - London SW1V 2QQ
Tel: 020 7533 5888 - Fax: 01633 652747 - E-mail: info@ons.gov.uk
www.statistics.gov.uk

**Medical Research Unit
Room B6/08**

Telephone: 020 7533 5233

Fax: 020 7533 5635

Professor Richard Baker
Director
Clinical Governance Research & Development Unit
Department of General Practice & Primary Health Care
University of Leicester
Leicester General Hospital
Leicester LE5 4PW

21st October 2002

Our reference: 107/048/02

Dear

Ms J Martin has now given her conditional approval for your study to proceed. Since your study involves the processing of patient data without informed consent Section 60 support will be required. ONS is currently in discussions with the Secretariat of the Patient Information Advisory Group (based at the Department of Health). We are planning to submit a class action to PIAG to cover the passing of patient information to NHSCR and the passing of information from NHSCR back to the researcher without informed consent. This application is intended to cover most historical medical research studies and studies which submitted their application to ONS before September 2002. Since this process is expected to take some time the Department of Health have agreed that we can continue to supply researchers with data in the meantime.

However we do not know if our application will be successful and, even if it is, PIAG may decide that specific individual research studies do not meet the conditions attached to the class support. In this case researchers may be requested to submit an individual application for Section 60 support. Although Ms Martin has approved your study, she may in future withdraw this approval to access data from NHSCR if PIAG decides that your study should not receive Section 60 support.

This approval will be valid for 18 months. If you are unlikely to submit the work to NHSCR within this time please contact me.

Would you please complete and sign the attached Confidentiality Declaration which sets out the conditions under which ONS can release the data. One copy should be returned to me, the other is for you to keep. I need to receive one signed copy before any data can be provided to you.

Dr Goldblatt is on annual leave until 4th November 2002. We will contact you after that date as to how ONS can progress your study.



Please contact me if you require any further information.

Yours sincerely

Code A

Gloria Brackett



CONFIDENTIALITY DECLARATION 1 NOTIFICATION OF DEATH FOR RESEARCH PROJECTS
ONS reference: 107/0048/02

**Research Project: Clinical Audit of Deaths in Gosport War Memorial Hospital
 And a local General Practice**

Head of Research Unit: Professor RH Baker
Qualifications: MBBS MD FRCGP

Status: Director, Clinical Governance R&R Unit

**Address: Department of General Practice & Primary Health Care
 University of Leicester, Leicester General Hospital
 Gwendolen Road, Leicester
 LE5 4PW.**

Telephone number: 0116 258 4873

I acknowledge the following conditions under which information is supplied by ONS:

1. the information released to me will be used for the purposes of the approved research project identified above;
2. no contact will be made with any individual(s) identified in the information supplied, except as agreed in the protocol and associated letters;
3. the information supplied by ONS will not be released to any other individual(s) or organisation(s) not directly connected with the project, except in the form of statistical tables or conclusions;
4. while in my keeping, the information supplied by ONS will be stored with proper safeguards to ensure confidentiality;
5. the prior agreement of ONS will be sought for any extension of this project beyond what was originally made known to ONS, if it involves the use of records supplied or derived from the records supplied by ONS;
6. any reports, papers etc published will not identify individuals or enable individuals to be identified;
7. all records supplied by ONS and any copies will be destroyed on completion of the project;
8. anyone replacing me and becoming responsible for this project will complete an ONS confidentiality declaration before receiving any further records from ONS.

Name in capitals:

Signed:

Date:

Please send the completed form to: Mrs G Brackett
Medical Research Unit, Room B6/08, ONS, 1 Drummond Gate, London SW1V 2QQ
