## Protocol for the release of confidential abortion data for bona fide research purposes

### Document Purpose
Best Practice Guidance

### Gateway Reference
16348

### Title
Protocol for the release of confidential abortions data for bona fide research purposes

### Author
Department of Health, Abortion Statistics Team

### Publication Date
September 2011

### Target Audience
PCT CEs, PCT Chairs, academic institutions

### Description
This document is intended as a guide for academic researchers requiring access to abortion data for scientific research purposes.

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SE1 6LH  
-  
www.dh.gsi.gov.uk

### For Recipient's Use
Protocol for the release of confidential abortions data for bona fide research purposes

This document is intended as a guide for academic researchers requiring access to abortion data for scientific research purposes.

Contact details

For further information, or to discuss your requirements, please contact the Abortion Statistics Manager, Department of Health on 020 7972 5537 or email abortion.statistics@dh.gsi.gov.uk

Background to release of abortion data

Registered medical practitioners are legally required to notify the Chief Medical Officer (CMO) of every abortion performed. The Department of Health receives these notifications on form HSA4 and undertakes statistical processing and analysis. A statistical bulletin is published around May each year, containing tables of information derived from the notifications.

The Data Protection Act 1998 places a statutory obligation on the Department of Health to ensure that the statistics we release on abortion do not relate to a living individual who can be identified from those data alone or in conjunction with other available information, unless the conditions laid out in the Act are met. In recent years, the Department has attempted to meet this obligation by following the disclosure guidance for abortion statistics developed by the Office for National Statistics in July 2005. A judgment handed down in 2011 by the High Court in a case relating to the release of information on principal medical condition for abortions performed under Ground E, showed that the disclosure controls set out in the guidance were overly cautious in some circumstances. The format of the tables in the annual report have therefore been revised, with a more limited degree of suppression applied, where still necessary to avoid the disclosure of personal data. The Department intends to publish more details about the new arrangements for assessing and dealing with the risk of disclosure in the coming months.
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Further tables are released into the public domain in response to ad hoc enquiries, where doing so is in line with legislation.

In addition, under regulation 5(e) of the Abortion Regulations 1991, patient level data may be released in a controlled manner "for the purposes of bona fide scientific research", subject to the Chief Medical Officer's agreement and the receipt of a completed and signed confidentiality agreement. See below and appendices A & B.

(a) Disclosure of confidential patient information:

The NHS Care Record Guarantee for England sets out the rules that govern how patient information is used in the NHS and what control the patient can have over this. It is based on professional guidelines, best practice and the law and applies to both paper and electronic records. More information can be found at:

http://www.nigb.nhs.uk/guarantee

(b) Subsequent processing by CMO:

The public interest in research which improves health and health care must be weighed against the public interest in the confidentiality of patient information. By custom and practice, the National Information Governance Board for Health and Social Care (NIGB) has become the independent body which advises Secretary of State on this balance of public interest.

Additional requirements for release of data

As noted above, patient level data may be released "for the purposes of bona fide scientific research", subject to the Chief Medical Officer's(s) agreement and a confidentiality agreement. See link below and appendices A & B for further details.


Before data are released, approval must be gained from a research ethics committee appointed in accordance with UK Health Departments' policy. Proof of approval from such a body is required before an application for abortion data will be considered by the Chief Medical Officer. The Chief Medical Officer will then assess whether the information can be disclosed under the regulations of the Abortion Act 1991 and under the conditions set out in the confidentiality agreement. See appendix B.

Applications for approval can be made at the following website:
http://www.nres.nhs.uk/applications/

In many cases, research designs can be revised so that patient identifiable data is not required and the request can be accommodated within the restrictions on data release and so avoid the need for REC and CMO approval. For example, it might be possible to use age in place of date of birth, and PCT of residence rather than postcode. Suppressions and aggregations can also be used where small numbers of cases would otherwise prevent release.

Revised October 2012
Appendix A


Notice of termination of pregnancy and information relating to the termination

4. – (1) Any practitioner who terminates a pregnancy in England or Wales shall give to the appropriate Chief Medical Officer –
   (a) notice of the termination, and
   (b) such other information relating to the termination as is specified in Schedule 2 to these Regulations,
and shall do so by sending them to him within 14 days of the termination either in a sealed envelope or by an electronic communication transmitted by an electronic communications system used solely for the transfer of confidential information to him.

(2) The appropriate Chief Medical Officer is –
   (a) where the pregnancy was terminated in England, the Chief Medical Officer of the Department of Health, Richmond House, 79 Whitehall, London, SW1A 2NS; or
   (b) where the pregnancy was terminated in Wales, the Chief Medical Officer of the Welsh Government, Cathays Park, Cardiff, CF1 3NQ.

Restriction on disclosure of information

5. A notice given or any information furnished to a Chief Medical Officer in pursuance of these Regulations shall not be disclosed except that disclosure may be made –

   (a) for the purposes of carrying out their duties –
      (i) to an officer of the Department of Health authorised by the Chief Medical Officer of that Department, or to an officer of the Welsh Government authorised by the Chief Medical Officer of that Office, as the case may be; or
      (ii) to the National Statistician duly appointed under Section 5 of the Statistics and Registration Service Act 2007 or an employee of the Statistics Board (established under section 1 of that Act) authorised by the National Statistician; or
      (iii) to an individual authorised by the Chief Medical Officer who is engaged in setting up, maintaining and supporting a
computer system used for the purpose of recording, processing and holding such notice or information; or

(b) for the purposes of carrying out his duties in relation to offences under the
Act or the law relating to abortion, to the Director of Public Prosecutions or a member of his staff authorised by him; or

(c) for the purposes of investigating whether an offence has been committed under the Act or the law relating to abortion, to a police officer not below the rank of superintendent or a person authorised by him; or

(d) pursuant to a court order, for the purposes of proceedings which have begun; or

(e) for the purposes of bona fide scientific research; or

(f) to the practitioner who terminated the pregnancy; or

(g) to a practitioner, with the consent in writing of the woman whose pregnancy was terminated; or

(h) when requested by the President of the General Medical Council for the purpose of investigating whether the fitness to practise of the practitioner is impaired, to the President of the General Medical Council or a member of its staff authorised by him.

(i) to the woman whose pregnancy was terminated, on her supplying to the Chief Medical Officer written details of her date of birth, the date and place of the termination and a copy of the certificate of registration of her birth certified as a true copy of the original by a solicitor or a practitioner.
## Appendix B

**DEPARTMENT OF HEALTH CONFIDENTIALITY DECLARATION AND NON-DISCLOSURE AGREEMENT FORM**

**ABORTION STATISTICS**

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<th>Research/Project Title:</th>
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### (A) Details of Data Custodian:

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<th>Address:</th>
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**Declaration:**

I, the Data Custodian named above, understand that the information is released to me with permission from the Chief Medical Officer under regulation 5(e) of the Abortion Regulations 1991 (bona fide scientific research) and will be used only for the purposes of the approved research or project identified above. I will ensure that the publication of any results using these abortion data are agreed by the Department of Health. I have read, understood, and will follow the guidelines listed at the end of this document.

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(B) Please sign and date for confirmation of REC approval. (A copy of the confirmation documentation should be attached to this form)

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(C) Details of Contact Person (if not Data Custodian)

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<th>Name:</th>
<th>Address (if different)</th>
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(D) Names of additional assistants

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(E) How long do you wish to retain the data? **If longer than 12 months**, please justify your reasons below (the maximum data retention period is **3 years and then a review** is required).

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<th>......Months/years</th>
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(F) The data supplied will be used only for the following purpose(s) – **Please include details of your research/work:**

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Notes and Guidelines

1. Please keep a copy of all the documents for your own records.

2. A copy of the documentation confirming approval from the Research Ethics Committee (REC) and the Ethics and Confidentiality Committee of the National Information Governance Board for Health and Social Care (NIGB) (formerly the Patient Information Advisory Group, PIAG) using the arrangements created under S251 of the NHS Act 2006 should be attached when submitting this form.

3. Assistants of the Data Custodian who wish to access the abortion data supplied must sign and date box C/D to acknowledge acceptance of the terms and conditions prior to being allowed access to the data. The Department of Health may request a copy of the up-to-date list at any time. The Data Custodian should take disciplinary action against any assistant breaching the common law duty of confidence with regard to this data.

4. After the work outlined in box F has been completed, the data must be destroyed. You will be sent a letter approximately one month before the end of the data retention period. This letter will give you the opportunity to either extend the data retention period or confirm that the data is destroyed.

5. The data must not be copied or transferred to any third party. If requested under the Freedom of Information Act the data are protected by the Exemptions in sections 40 and 44 of the FOI Act and must not be released.

6. Prior notice of intention to publish abortion data should be given to the Department of Health and where feasible, a copy of the published work should be provided.

7. All outputs resulting from access to these data must meet the guarantee contained in the principles of the National Statistics Code of Practice and the Protocol on Data Access and Confidentiality.

8. The Department of Health has the right to refuse permission to publish information arising from abortion data.

9. The data must be stored with proper safeguards to prevent unauthorised access. Please note; This condition is subject to unannounced site inspections by Department of Health staff to ensure that measures are satisfactory.

10. The Department of Health must be informed as soon as possible if custodianship of the data should change. The new Data Custodian must give assurances in writing that the terms of this document will continue to be followed. The Data Custodian must also report to the Department of Health any changes in the organisation, personnel having access to the data, or systems on which the data would be held.

11. The Data Custodian must report immediately to the Department of Health any instances of breach of any of the terms of this agreement.
12. Low Cell Values. Values between 0 and 9 must be suppressed. Note that zeros must also be suppressed. If only one cell requires cell suppression, at least one other component cell (the next smallest) must be suppressed so as to avoid calculation of suppressed value from the totals. In addition, DH must agree any tables of data published so that small numbers cannot inadvertently be derived by using a combination of published data.

13. No contact will be made with any individual(s) identified in the information supplied except as agreed in the protocol and associated letters.

Enquiries regarding completion of this form can be made on

Tel. 020 7972 5537 or by email to Abortion.Statistics@dh.gsi.gov.uk

Please return this form signed and completed to:
Abortion Statistics,
Room 5A Skipton House,
80 London Road,
London SE1 6LH