Research involving the NHS: retention of records

The following legislation, policies and common-practice guidance apply to the retention of records relating to research carried out in the NHS.

Data Protection Act 1998 (DPA) - Schedule 1, Part 1, Principle 5.

Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.

(Data Protection Act 1998 (DPA) - Schedule 1, Part 1)

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006[1] - sections 18 and 28.

The sponsor and the chief investigator shall ensure that the documents contained, or which have been contained, in the trial master file are retained for 5 years after the conclusion of the trial …..

The sponsor and the chief investigator shall ensure that the medical files of trial subjects are retained for at least 5 years after the conclusion of the trial.

An ethics committee shall retain all the documents relating to a clinical trial on which it gives an opinion for:

(a) where the trial proceeds, at least three years from the conclusion of the trial: or
(b) where the trial does not proceed, at least three years from the date of the opinion.

(The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006)

[1] These regulations amend The Medicines for Human Use (Clinical Trials) Regulations 2004.

COMMISSION DIRECTIVE 2003/63/EC (brought into UK law by inclusion in The Medicines for Human Use (Fees and Miscellaneous Amendments) Regulations 2003) – section 5.2(c). As a list of technical requirements, the Directive was simply added to a list of Community provisions that had to be complied with.

Marketing authorisation holders must arrange for essential clinical trial documents (including case report forms) other than subject's medical files, to be kept by the owners of the data:

— for at least 15 years after completion or discontinuation of the trial,

— or for at least two years after the granting of the last marketing authorisation in the European Community and when there are no pending or contemplated marketing applications in the European Community,

— or for at least two years after formal discontinuation of clinical development of the investigational product.

Subject's medical files should be retained in accordance with applicable legislation and in accordance with the maximum period of time permitted by the hospital, institution or private practice.

The documents can be retained for a longer period, however, if required by the applicable regulatory requirements or by agreement with the sponsor. It is the responsibility of the sponsor to inform the hospital, institution or practice as to when these documents no longer need to be retained.

The sponsor or other owner of the data shall retain all other documentation pertaining to the trial as long as the product is authorised.

The final report shall be retained by the sponsor or subsequent owner, for five years after the medicinal product is no longer authorised.

(COMMISSION DIRECTIVE 2003/63/EC)

Research Governance Framework for Health and Social Care – paragraph 2.3.5.

Data collected in the course of research must be retained for an appropriate period, to allow further analysis by the original or other research teams subject to consent, and to support monitoring by regulatory and other authorities.

(Research Governance Framework for Health and Social Care)

Governance Arrangements for NHS Research Ethics Committees (GAfREC) – paragraph 7.8.

A REC should retain all relevant records for a period of at least three years after completion of a research project……

(Governance Arrangements for NHS Research Ethics Committees (GAfREC))

Good Research Practice (MRC Ethics Series, 2000, updated 2005) – paragraph 5.2.

Personal Information in Medical Research (MRC Ethics Series, 2000, updated 2003) – chapter 7.

Data Protection Act 1998 – Part IV, Section 33 (3).

MRC

The guidance on storage and reuse of research data suggests keeping research records for between 20 and 30 years (see guidance for full details).

DPA

Personal data which are processed only for research purposes in compliance with the relevant conditions may, notwithstanding the fifth data protection principle, be kept indefinitely. However, the view of the Patient Information Advisory Group (PIAG) is that Principle 5 should be adhered to where personal data are used with support under Section 60 of the Health and Social Care Act 2001, and that the proposed retention period should be made explicit where the basis for access is consent.[2]

(Good Research Practice)

(Personal Information in Medical Research)

(Data Protection Act 1998 - Part IV, Section 33)

Other considerations

It is common practice for records to be kept for various lengths of time, eg seven, eight or fifteen years. However, Principle 5 of the DPA should be born in mind.

It is not legitimate to archive health records for historical purposes. If such records are no longer required for the purposes of providing care, then they should not be retained in identifiable form or used for other purposes, without patient consent or without support under Section 60 of the Health and Social Care Act 2001.

[2] PIAG will be giving further consideration during 2007 to the issue of data retention, with a view to issuing revised guidance if appropriate.

Various organisations, eg sponsors, funders, regulatory bodies, ethics committees, trusts, universities, may stipulate how long records should be kept. However, meeting any of these requirements in relation to research involving the NHS must be consistent with UK law and DH guidance.

Additional information

For aspects of records and research involving the NHS not covered above, please refer to DH's Records Management: NHS Code of Practice.

In case of any query, please email stella.barclay@dh.gsi.gov.uk

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