

Guidance Notes

Section 60 of the Health and Social Care Act 2001

This guidance is intended for:

- Those wishing to obtain identifiable patient information;
- Data controllers who are asked to supply identifiable patient information;
- Research Ethics Committees who are asked to advise on the ethical disclosure and use of identifiable patient information.

in circumstances where:

- Patient consent has not been obtained, and
- There is no other reliable basis in law to permit the disclosure and use of identifiable patient information

N.B. Section 60 exemption applies only for England and Wales, there is no equivalent for Scotland or Northern Ireland

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Overview

Section 60 of the Health and Social Care Act 2001 (H&SCA)¹ permits the temporary setting aside of the Common Law duty of Confidentiality (see *Detailed Guidance: Section 1* for more detail) for the use of medical records for specific purposes. It does not set aside the requirements of the Data Protection Act 1998 (DPA98)^{2,3}.

The appropriate use of medical records to support direct patient care would not be considered a breach of confidentiality⁴.

Who should apply

Applicants will either be data providers who wish to ensure that they are not at risk under the Common Law when providing extracted information from medical records to other organisations or individuals, or such organisations or individuals seeking to gather information from one or more NHS organisations. S60 exemption protects the provider of the information – the recipient of the information would still be expected to treat the information received appropriately and in accordance with agreed protocols⁵.

How to apply

Application is made through the PIAG Secretariat⁶ by completing the Application Form in Annex C and providing the required documentation to support the Application (see Annex D - Application Checklist). Your application will be vetted by the Secretariat, who may respond with questions and/or may advise you that your application is unlikely to be accepted by PIAG based on previous experience. You will need to address any questions and possibly update or add to your application. Once complete, your application will go before the Patient Information Advisory Group at one of their quarterly meetings (currently early in March, June, September, and December). Your application should be submitted at least one month before the next PIAG meeting and it is worth notifying the PIAG Secretariat well in advance that you intend to apply.

¹ <http://www.hmsa.gov.uk/acts/acts2001/20010015.htm>

² <http://www.hmsa.gov.uk/acts/acts1998/19980029.htm>

³ Use and Disclosure of Health Data: Guidance on the Application of the Data Protection Act 1998, Office of the Information Commissioner, <http://www.dataprotection.gov.uk/dpr/dpdoc.nsf>

⁴ See the NHS Confidentiality Code of Practice for details concerning appropriate use of medical records to support direct patient care.

⁵ Such as MRC Guidelines, etc.

⁶ PIAG Secretariat, Confidentiality Issues Section, Department of Health, Room 1N35A, Quarry House, Quarry Hill, Leeds

If your application is accepted at such a meeting, then you should receive a response within two weeks of the meeting. You may only be given a conditional acceptance, subject to your providing further information to resolve points concerning your application, in which case the relevant information will need to be provided and accepted before the approval would be endorsed – generally this would not have to wait for a further PIAG quarterly meeting.

If you have been granted ‘class support’ then you may proceed once your approval is complete and any conditions satisfied.

If your application requires ‘specific support’, then appropriate regulations will need to be drafted and submitted to Parliament. This may take some months, perhaps between 3 and 6 months, and may be delayed awaiting a suitable ‘slot’ in the Parliamentary calendar. There is, of course, no guarantee that Parliament will adopt the Regulations as presented, and you may need to be involved in the process of considering changes as the Bill works its way through the Parliamentary process.

Next Steps

- 1) Read this Guidance document – particularly appreciate the PIAG Principles (see page 4) so that you understand what is needed, both in terms of the application and in terms of what your organisation needs to have in place. You may even find that Section 60 support is inappropriate for your needs.
- 2) Read through the Application Form, the section ‘How to Complete the Application Form’, and the Application Checklist to identify additional materials that are required. You may need to track these down within your organisation, or you may need to instigate actions to develop them and get any missing processes and procedures implemented.
- 3) Make informal contact with the PIAG Secretariat, ideally by sending in (via post, fax, or e-mail) a brief outline of your project or requirement to aid any telephone discussions. This may help avoid a lot of work on both sides. You can also check out the likely timetable for your application and the precise deadlines involved. Missing a deadline for an application will mean at least a three-month wait until the next PIAG meeting.
- 4) Complete the Application Form, following the guidance in ‘How to Complete the Application Form’ and drawing up a list of all the documents referenced so that you can make sure that they are all included with your submission.
- 5) Ensure that a knowledgeable colleague has checked through your application, and that it is appropriately approved within your organisation. A poor application is likely to take far longer to work its way through the approval process than a well-considered one.
- 6) Produce three copies and send into the PIAG Secretariat. Ensure that you allow plenty of time for photocopying, packaging and getting the full application couriered or otherwise delivered to the PIAG Secretariat in Leeds. Electronic copies of application materials are helpful, but the PIAG Secretariat cannot undertake to be able to print out any electronic files in the appropriate format, so do not hope to submit an electronic copy on the deadline date itself – only a paper copy will be accepted.

The PIAG Principles

These ‘principles’ are points that have been identified by the Patient Information Advisory Group as they have discussed applications in the past. They are ‘principles’ rather than rules, so there may be exceptions and other considerations that may affect particular applications. The overall aim is to balance the need for confidentiality and individual consent with the need to run an efficient and quality health service for the public good.

Ask or Anonymise

- All organisations using Section 60 support should make information materials available to patients describing the information they use and why they need it
- That where an organisation has a direct relationship with a patient then it should be aiming to obtain consent
- Organisations that have regular contact with patients should be able to quickly implement procedures for obtaining consent
- “Third Party” organisations or applications other than for direct care should be seeking anonymised/pseudonymised data

Section 60 provides on temporary abeyance of Common Law

- Organisations need to recognise that Section 60 support is only an interim measure
- Must be clear general good or of benefit to patients, e.g. not just for PhD thesis or to generate a paper
- Provisions are only temporary, requiring an ‘exit strategy’ with defined end dates for one of the following solutions:
 - patient consent,
 - anonymisation, or
 - explicit legal support

Support Choice

- It is never necessary to have 100% population coverage in research studies – it should be possible to support opt-out without significantly affecting the outcome of the research
- Organisations should not hold secondary data on patients who specifically refuse consent
- Have involved patients and/or patient organisations in the development of the project and the associated policies

Must meet legal and other requirements

- Must meet Data Protection and security requirements, e.g. formal policies and procedures which are enacted
- Must have Caldicott approval

PIAG prefers to receive ‘group’ applications for related activities rather than multiple identical applications

Criteria for approving applications for S60 support	YES	NO
Is the activity a medical purpose as defined in Section 60 of the Health and Social Care Act 2001?		
Is there a clear and acceptable description of how the activity may improve patient care or be in the public interest?		
If the activity to be supported is research, has appropriate Ethics Committee approval been gained?		
Will the research require use of patient identifiable data? If not, then there should be no potential for breach of confidentiality and S60 approval would be unnecessary.		
Is there an acceptable justification why data cannot be anonymised or pseudonymised? ⁷		
Is there an acceptable justification why consent cannot or should not be obtained by either your organisation or the holder of the information you require? ^{8,9}		
Is it clear why the purpose cannot be satisfied in another reasonably practicable way which does not require patient-identifiable data?		
Is there clear evidence that the organisation seeking support is following best practice in terms of confidentiality (e.g. Caldicott Guardian in place, adherence to national guidelines)? ¹⁰		
Is there clear evidence that the organisation seeking support is following IM&T security best practice? (e.g. access controls, security policy, staff contracts etc)		
Where more than one organisation is seeking support, has the lead/sponsor organisation taken sufficient steps to ensure that the other organisations are maintaining the same IT security standards?		
Is there clear evidence that the organisation seeking support is complying with the Data Protection Act 1998? (Satisfies fair processing ¹¹ , subject access provisions, notification/registration, etc.) ¹²		
Is there a clear commitment to making improvements wherever practicable?		
Is there clear evidence that the organisation has made improvements in obtaining		

⁷ ‘Third-party’ organisations (viz. those without a direct relationship with the patients) should be seeking to receive anonymised or pseudonymised data

⁸ PIAG is unlikely to approve applications from organisations with a direct relationship with the patients involved, as such organisations should be aiming to seek consent through normal interactions with the patients. Organisations that have regular contact with patients should be able to quickly implement procedures for obtaining consent

⁹ Medical research does not require 100% coverage of the surveyed population in order to derive valid results – arguments that any patients ‘opting out’ of the study would bias or invalidate the research are unlikely to be accepted without clear evidence

¹⁰ If patients refuse consent or register objections to the storing, use, or sharing of their information, then such wishes should be respected, even if S60 approval is given. Clearly, data properly required for healthcare delivery would be unaffected, but should not be shared further

¹¹ All S60 applicants should make information materials available to patients covering the information they use and why they need it (this is a ‘fair processing’ requirement of the Data Protection Act 1998)

¹² PIAG will expect applications to conform to Data Protection Act 1998 requirements such as holding minimum data necessary with purpose, and use of privacy-enhancing techniques and technologies to minimise risk of identification or release of confidential information.

consent from patients since previous application(s) were submitted?		
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Detailed Guidance

1. *Introduction*

Section 60 approval does not allow the setting aside of obligations under the Data Protection Act 1998 or any other legislation (e.g. Human Rights Act 1998), only obligations under the Common Law of Confidentiality, which is not codified and is established through case law. This can make it difficult to know in advance whether a use of medical records could be a potential breach of confidentiality, and hence whether Section 60 exemption is appropriate to set aside an individual's rights of redress under common law.

Clearly, the simplest approach is to consider that any sharing of patient identifiable information other than for the provision of direct care to the patient could lead to a potential breach of confidentiality.

The concept of confidentiality

Patients may provide information to doctors to help in the identification and treatment of their condition. This information is shared with the clinician under a common law duty of confidentiality to help resolve the patient's difficulties and improve their health – the precise purposes and any pre-conditions will depend on the nature of the consultation and the circumstances of the patient.

If this information is shared further then it must either be in the clear interests of the patient, or with the clear understanding by the patient, ideally expressed as consent.

Changing circumstances

While paper records had the advantage of being limited to one place, usually the surgery or clinic where the patient was seen, so that confidentiality was often protected by the nature of paper records, rather than strict observance of duties of confidentiality. Paper records might be accessed by researchers without patients being aware of this use – a breach of trust perhaps, rather than a breach of confidentiality leading to damages to the patient's interests.

With the advent of electronic systems, which greatly improve the efficiency of healthcare delivery in terms of range, speed, and potentially lower costs, there is an increased risk to individual patients if their medical information is used improperly. Information is more readily available and can be collated to a far greater degree, so permitting greater opportunities for abuse or accidental disclosures, not only for individual patients, but for potentially large numbers of people. For this reason, there needs to be a far greater emphasis on the security of the data and ensuring the confidentiality of patients through better anonymisation processes.

- 1.1 Section 60 of the Health and Social Care Act 2001 enables the Secretary of State to support and regulate the use of confidential patient information in the interest of patients or the wider public good. Parliament agreed to the creation of this power to ensure that patient identifiable information currently needed to support essential NHS activity can be used, without the consent that should normally be obtained, *where there is no reasonably practicable alternative*.
- 1.2 Regulations made under Section 60 can provide a basis in law for patient identifiable information to be disclosed to specified bodies, (e.g. cancer registries), for specific purposes. This type of ‘**specific support**’ is required if the intended purposes for obtaining the information are controversial or complex and need detailed description within the regulations. The approval of Parliament, advised by the independent statutory Patient Information Advisory Group (PIAG), is required before such regulations may be brought into force. This may take some months to prepare and will depend on Parliamentary timetables as to when it will actually be debated by Parliament – and may not be passed, despite approval by PIAG.
- 1.3 Parliament has also agreed to the establishment of ‘**class support**’ that will provide a lawful basis for using and disclosing patient identifiable information to support relatively uncontroversial processing, for limited and defined purposes, without the need for dedicated Parliamentary consideration. The approval of the Secretary of State, advised where appropriate by PIAG, is required in these circumstances.
- 1.4 Section 60 requires an annual review of the regulations. The Secretary of State, supported by PIAG, will keep under review the need for support and aim to revoke it as soon as it is practicable. Support under Section 60 is intended as a transitory measure. That said, there might be a small number of uses for which informed consent or anonymisation will never be practicable. Through transparent and robust annual review, Section 60 will be used to determine whether or not this is the case. In these instances, specific and permanent legislation (outside Section 60) may be the only long-term solution.
- 1.5 Section 60 support is not unconditional. A number of requirements impact upon those who receive support, with the twin goals of ensuring that there are adequate safeguards for patients and that options for improving consent practice and/or introducing anonymisation techniques are actively pursued:
 - The need to effect an appropriate long-term solution
 - The need to report progress towards a long-term solution and meeting any conditions required by PIAG, e.g. better information provision to patients.

2. Who should consider applying?

- 2.1 If an activity requires the disclosure of identifiable patient information from an NHS body to another organisation or individual without the consent of the patients concerned, then an application for support under Section 60 may be required. Annex A outlines exceptional circumstances where identifiable patient information may be disclosed without either consent or Section 60 support.

- 2.2 Applications should generally be submitted by those wishing to use patient identifiable information, not by those asked to disclose it – if support is provided it will extend to all bodies from which disclosure is required, and these should be identified in the application.
- 2.3 Applications are generally required whether there is a perceived need for specific support or where it is thought class support will suffice. The exception being that **class support** for certain **internal** – i.e. where there is no disclosure to a third party - uses of information may be provided by the Secretary of State without the need for each organisation to submit an application (see section 3.6 below).

3. What can be supported by Section 60?

- 3.1 **Basic purpose:** The proposed use of patient identifiable information to be supported must be an acceptable purpose as defined by the Health and Social Care Act 2001. Acceptable purposes are:
- Preventative medicine
 - Medical diagnosis
 - Medical research
 - Provision of care and treatment
 - Management of health and social care services, and
 - Informing individuals about their physical or mental health or condition, the diagnosis of their condition or their care or treatment.
- 3.2 The primary purpose cannot be to *determine* the care and treatment of specific patients, though decisions about care and treatment may be informed by uses of information that have a different primary purpose.
- 3.3 If there are practicable ways of gaining patient consent or using anonymised information, then the application will be refused. Section 60 exemption is only appropriate where there is no immediately practicable way of gaining patient consent or switching to using anonymised data.
- 3.4 A case must be successfully made that the purpose for using patient identifiable information is in the best interest of patients or, alternatively, serves a wider public good.
- 3.5 **Specific support**, if approved by Parliament, can relate to any form of information processing – obtaining, holding, recording, using or disclosing. At the time of writing (October 2003), there were only 2 ‘specific support’ approvals¹³ for:
- Communicable disease and other risks to public health
 - Medical purposes related to the diagnosis or treatment of neoplasia (viz. activities carried out by cancer registries)

¹³ The Health Service (Control of Patient Information) Regulations 2002, in force from 1st June 2002, <http://www.hmsa.gov.uk/si/si2002/20021438.htm>

3.6 **Class support**, if approved by the Secretary of State, may permit the processing of patient identifiable information without consent for one or more of the following five purposes:

- I. To obtain anonymised data from individual identifiable patient records to support medical purposes, i.e. the process of extracting and anonymising the information
- II. To look at patient identifiable information in order to
 - select patients who are to be invited to participate in medical research
 - contact patients to obtain their consent for their information to be used
 - contact patients to obtain their consent for use of tissue and other biological samples
- III. To obtain and use information about past or present geographical location from patient records – e.g. full postcode is needed for precise analysis, but, in some circumstances, it could be used to identify individual patients, so is regarded as patient identifiable information.
- IV. To link patient identifiable information obtained from more than one source in order to validate the completeness or quality of the information or to avoid the impairment of the quality of the data by unintentionally including the same information more than once.
- V. To process patient identifiable information for the purpose of auditing, monitoring and analysing patient care and treatment.

Additionally, a sixth purpose is supported essentially as a ‘technical’ measure to ensure that the data controller that is releasing the information to support one or more of the above five purposes may do so lawfully.

- VI. To process patient identifiable information to provide access to an authorised user for one or more of the purposes outlined above (I – V).

3.7 Those authorised to process patient identifiable information with Section 60 support must also comply with the requirements set out in the Health & Social Care Act 2001, in Section 60 regulations, or otherwise imposed by the Secretary of State as conditions of approval. In addition to the limitation to medical purposes that are in the interest of patients or the wider public and the test of whether a reasonably practicable alternative exists, requirements include:

- Ensuring that all staff with access to the information have contractual obligations of confidentiality, enforceable via disciplinary procedures;
- Limiting access to the information whilst it is in a form that might identify individual patients to the minimum necessary to satisfy the purposes for which the information was made available;
- Be contractually bound or otherwise undertake not to disclose identifiable patient information except:
 - to the data controller that made the information available;
 - to other data controllers similarly supported in law for limited uses of data;

- to others on a need to know basis where there is a significant public health interest justification for doing so;
- where there is a specific statutory requirement to do so.
- Only hold patient information in a form that might identify individual patients for the minimum time period necessary;
- Only process patient identifiers that are needed to satisfy the purpose(s);
- Document and make available to any who request, details of how the conditions set out in Section 60 are being met;
- Facilitate and support reasonable audit of data processing by designated agents of the Secretary of State.

4. Section 60 Register

- 4.1 The PIAG secretariat will maintain a register of all activities that have received approval for support under Section 60. The register will be publicly available through the internet.
- 4.2 All approved applications will be allocated a registration number by the PIAG secretariat. The PIAG secretariat will update the register to include the successful application, and will provide written confirmation of their registration number to the applicant.
- 4.3 The information contained on the register will include
- The registration number
 - the title of the activity,
 - the type of activity,
 - categories of class support approved,
 - a list of all the data items held in relation to each patient,
 - the name of the principal applicant,
 - a brief description of how the data are to be used,
 - other people involved in the project,
 - the date of approval
- and, in the case of medical research,
- a record of LREC approval.
- 4.4 Those receiving support will be open to scrutiny by the Department of Health, CHI, the Information Commissioner and other independent bodies.

5. Annual Review

- 5.1 The regulations will be reviewed annually by PIAG to ensure approved projects are progressing as planned, that the use of patient identifiable information is consistent with what was agreed and that security is maintained. In year monitoring of a sample of approved projects will also take place. Activities may lose Section 60 support if they fail to meet the standards anticipated by PIAG.
- 5.2 All applications will be reviewed/renewed annually, the date of the review being determined by the date on which approval was given. Applicants will be required to provide evidence of how they are moving towards informed consent or anonymisation/pseudonymisation. Where it is claimed that this is not practicable, evidence will be sought of the steps taken to test this assertion and to develop alternative ways of working or establish alternative legal frameworks.

6. Enforcement Procedure

- 6.1 Where activities have been approved by Parliament or the Secretary of State for Health under the powers created by Section 60, there are no legal barriers to patient information being passed to organisations for the specific purposes described in the Section 60 Register (see above). In most cases Regulations will permit, but will not require as a matter of law, that patient information should be disclosed. This means that any objections raised by patients should be respected. However, NHS bodies may be directed to disclose information where patients have not objected and the requirements to inform patients have been met.
- 6.2 In rare circumstances, when permitted by the existence of a reserve power within Regulations and when so advised by the Patient Information Advisory Group, the Secretary of State may introduce a legal requirement to disclose in specified circumstances. There are no plans to do this, but the capability exists if it is the only way to effectively address a currently unforeseen development.
- 6.3 All organisations that obtain patient identifiable information with support under these arrangements will be required to comply with regulations made under Section 60 of the Health and Social Care Act 2001 and any additional conditions attached to the approval of their applications.
- 6.4 Any organisation that fails to comply with the conditions placed upon their receipt of patient identifiable information may be subject to a civil penalty up to £5,000. If Section 60 is used to introduce a legal requirement to disclose, this penalty might also apply to those who fail to comply. In the circumstances where such a requirement might be introduced, i.e. where PIAG has advised it is necessary in the public interest, it seems likely that disciplinary or professional regulatory procedures would be a more appropriate response.

7. How to apply

- 7.1 First, the applicant should obtain a sponsor (usually the applicant's employing organisation). Sponsors should provide a written recommendation, a copy of which must be retained by the applicant.
- 7.2 Applicants undertaking medical research must first obtain research ethics committee (REC) approval. Medical researchers are strongly advised to read these notes for guidance carefully before approaching the REC, and should ensure that all the required information is included in their application to the REC. Copies of the research protocol and L/MREC approval must be included with the application for Section 60 support. Failure to do so could lead to delay.
- 7.3 There is a standard application form for support under Section 60 and it can be completed either on-line or on a printed paper copy (See Annex B).
- 7.4 The power provided by Section 60 of the Health and Social Care Act 2001 will not be used without due consideration of both the appropriateness of providing support and the safeguards needed to protect the interests of patients. This inevitably necessitates a process of scrutiny that is both time consuming and bureaucratic. The PIAG secretariat will endeavour to process applications and provide advice as swiftly as possible.
- 7.5 The PIAG secretariat will scrutinise each application. If the PIAG secretariat has concerns with an application, they will contact the applicant for clarification and will return applications that are clearly inappropriate. Where responsibility for approving an application for class support has been delegated to officials, a decision should be conveyed to the applicant within one month of submitting an application.
- 7.6 For an application to be considered at a given PIAG meeting, applications need to be received by the PIAG secretariat one month in advance of the meeting. The PIAG meets quarterly (usually early in March, June, September, and December) and all meeting dates are given on the web site. The applicant may be invited to present and support their application at a PIAG meeting. Where responsibility for approving an application for class support has been delegated to PIAG a decision should be conveyed to the applicant within two weeks after the date of the PIAG meeting.
- 7.7 Where an application for specific support has to be considered by Parliament and requires both public consultation and the drafting of Regulations, a decision and the provision of support in law may take between 3 to 6 months from the date of the PIAG meeting.
- 7.8 The broad criteria used to determine whether or not approval should be granted are listed below. The criteria are likely to evolve and may become more tightly focussed on securing improvements to the way that patient information is used.

Lawful Disclosure of Patient Identifiable Information

Everyone working for or on behalf of the NHS is under a legal duty to keep identifiable patient information confidential. This means, in most circumstances, not disclosing it to others without the consent of the patient concerned. The exceptions to this are when required to do so by the law or by the Courts or when the public good that might result from disclosure outweighs the duty of confidentiality. This latter justification needs to be considered on a case by case basis, rendering the public good (or public interest) an unsatisfactory basis for routine disclosures.

Statutory obligations to disclose

There are a variety of Acts which include provision to disclose identifiable patient information in certain circumstances. Generally, these preclude routine disclosures. The precise provisions are not detailed here, but relevant statutes are:

Legal Restrictions on Disclosure

Sexually Transmitted Diseases (STD)¹⁴

Existing regulations require that every NHS trust and Primary Care Trust shall take all necessary steps to secure that any information capable of identifying an individual obtained by any of their members or employees with respect to persons examined or treated for any sexually transmitted disease (including HIV and AIDS) shall not be disclosed except:

- a. where there is explicit consent to do so
- b. for the purpose of communicating that information to a medical practitioner, or to a person employed under the direction of a medical practitioner in connection with the treatment of persons suffering from such disease or the prevention of the spread thereof, and
- c. for the purpose of such treatment or prevention

Whilst the existing regulations do not extend to all NHS and partner organisations, it is clear that many patients would regard information about STDs as particularly sensitive and private. It should never be assumed that patients are content for this information to be shared unless it has a direct and significant bearing on their healthcare and where the regulations apply it must not be disclosed other than as described in the previous paragraph.

¹⁴ AIDS (Control) Act 1987; NHS (Venereal Diseases) Regulations 1974; NHS Act 1977, NHS Trusts and Primary Care Trusts (Sexually Transmitted Diseases) Directions 2000. [Legislative amendments may be necessary to reflect organisational change.]

Human Fertilisation & Embryology¹⁵

Disclosure restrictions can also apply to fertilisation and embryo treatments where individuals can be identified. Generally, explicit consent is required, except in connection with the:

- a. provision of treatment services, or any other description of medical, surgical or obstetric services, for the individual giving the consent,
- b. carrying out of an audit of clinical practice, or
- c. auditing of accounts.

Adoption and Children Act 2002

This ensures that the release of sensitive information about adopted people and their birth relatives is protected and that its disclosure is subject to safeguards

Legally required to disclose

Some statutes place a strict requirement on clinicians or other staff to disclose information. Care should be taken however to only disclose the information required to comply with and fulfil the purpose of the law. If staff have reason to believe that complying with a statutory obligation to disclose information would cause serious harm to the patient or another person, they should seek legal advice. The main requirements to disclose are detailed on the Department of Health web-site.

The courts, including coroner's courts, and some tribunals and persons appointed to hold inquiries have legal powers to require that information that may be relevant to matters within their jurisdiction be disclosed. This does not require the consent of the patient whose records are to be disclosed but he/she should be informed, preferably prior to disclosure. Disclosures must be strictly in accordance with the terms of a court order and to the bodies specified in the order. Where staff are concerned that a court order requires disclosure of sensitive information that is not germane to the case in question, they may raise ethical concerns with the judge or presiding officer. If however the order is not amended it must be complied with.

Legally permitted to disclose

Legislation may also create a statutory gateway that allows information to be disclosed by a NHS body where previously it might have been unlawful to do so, e.g. section 115 of the Crime & Disorder Act 1998. This sort of permissive gateway generally stops short of creating a requirement to disclose, therefore the common law obligations of confidentiality must still be satisfied, as must the requirements of the Data Protection Act 1998. Details of current statutory gateways can also be found on the Department of Health website.

¹⁵ Human Fertilisation and Embryology Act 1990: ss 31 & 33; Human Fertilisation and Embryology (Disclosure of Information) Act 1992:

Use of Anonymised Information

Anonymised patient information can also be used without consent. This was established in the *Source Informatics* case¹⁶. It should not, however, be considered a ‘free good’ to be used without constraint, as it may yet fall under the Data Protection Act 1998 (DPA98).

There is, however, no legal definition of ‘anonymised data’. The DPA98 establishes a definition of ‘**personal data**’ as ‘*data which relate to a living individual who can be identified (a) from those data, or (b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual*’. The DPA98 was intended to ensure that personal data was appropriately protected, so uses a very broad definition, including information which might potentially identify some individual, even if no obvious mechanism exists.

Pseudonymised data (where the data is effectively anonymised, except for a coded identifier, and where the recipient of the data does not have access to the coding mechanism and so cannot identify the patient) is ‘personal data’ within the meaning of the DPA98, but could be considered to be anonymised information in the hands of the recipient

Requirements of Data Protection Act 1998

In addition to the requirements of confidentiality, Data Protection legislation¹⁷ also imposes requirements on those who use identifiable patient information. Key amongst these is a requirement for patients to be told, at least in general terms, how information about them may be used and who may see it.

Section 60 does not change the Data Protection requirements, but does set aside the legal duty of confidentiality. It replaces this duty with a range of safeguards intended to ensure that the use of a patient’s information has no detrimental effect on that patient. It is therefore lawful to disclose identifiable patient information where Section 60 support has been approved so long as the recipient of the information satisfies the requirements set out in:

- Section 60 of the Health & Social Care Act 2001;
- regulations made under Section 60; and
- conditions for approval introduced by the Secretary of State.

¹⁶ Regina v Department of Health, Ex parte Source Informatics Ltd. (2000) 1 All ER 786.

¹⁷ See www.dataprotection.gov.uk

Annex B

GUIDANCE ON COMPLETING THE APPLICATION FORM

Each application will be reviewed based on the PIAG principles detailed on page 4, as well as the principles established by the Caldicott Committee¹⁸.

1. Register Details

This information will appear on the Section 60 Register on the Department of Health web-site. In this section you must provide:

- a. A title for the Application, normally the title of the study or the activity e.g. Smallville Pancreatic Cancer Registry
- b. Describe succinctly the purpose of the work for which you are seeking access to patient identifiable information. Sufficient detail must be provided to enable the reader to understand the purpose of the activity.
- c. The name of the organisation/individual that is applying for access to patient identifiable information.
- d. The name of the appropriate contact at the applicant organisation for queries in respect of the application.
- e. Address for formal correspondence.
- f. Name and telephone contact details of the Information Custodian. This person will be responsible for ensuring that data is held securely and processed in accordance with the provisions of the Data Protection Act 1998, and may be distinct from the application contact above.
- g. The name of the NHS organisation which is acting as sponsor for the application. In most circumstances this organisation will have commissioned the work covered by the application. The application must include a separate written recommendation from the Caldicott Guardian of the sponsoring organisation confirming that they have approved the work described in the application.
- h. A brief description of the cohort or population which comprises the data subjects, e.g. Pancreatic cancer patients in Greater Smallville between 1967 and 1997 treated at Smallville Hospital
- i. A description of the information being recorded/used – this should be down to field-level for potential identifier attributes (e.g. name, address, data of birth, Hospital Number)
- j. Tick the levels of S60 support required (either Specific or Class support but not both)

¹⁸ see <http://www.doh.gov.uk/ipu/confiden/report/calcrep.pdf> for the Caldicott Report and <http://www.doh.gov.uk/ipu/confiden/index6.htm> for related information.

2. Justification of Purpose

In this section you must:

- k. Describe more fully the purpose of the work for which you are seeking access to patient identifiable information. Sufficient detail must be provided to enable the reader to understand the proposal and to ascertain whether or not the purpose(s) can be covered by Section 60. The description should also be comprehensive, with all purposes detailed.
- l. Describe how this work will benefit patients or the wider public. The sponsor's letter may support this.
- m. List the data items you wish to collect in respect of each patient (eg Name, Postcode, NHS Number, Date of Birth, etc) and briefly explain why each of these items is required. The reasons why anonymised or coded data cannot satisfy the purpose(s) should be explained here.
- n. The type of support required should be detailed. If the requirement for patient identifiable information can be covered by class support, the type of class support that is required should be outlined.

N.B. For research activity, the applicant must provide copies of the research protocol and L/MREC approval letter.

3. Consent Issues

In this section you must:

- o. Explain why it is not practicable for either your organisation or the current holder(s) of the information you require to obtain consent from patients to use their information. Robust arguments are sought here. For example if 100% coverage of patients is required, explain why and what the consequences of lesser coverage might be. What is the evidence to support any assertions? Where you argue that it is impracticable to obtain informed consent from patients, you must also explain why you cannot use alternatives to identifiable data.
- p. State how you have involved patient and user organisations or their representatives in the development of your project and provide copies of patient information leaflets used to inform the public with details of how these are given out. Please note that failure to consult patient/user organisations in the development of your work is likely to lead to rejection of your application for Section 60 support unless you can provide strong justification.

4. Caldicott

In this section you must:

- q. Provide justification for the use of patient identifiable data, including details of:
 - Evidence of independent support for the proposal;
 - The consequences of the activity not going ahead;
 - why it is necessary to use patient identifiable data rather than anonymised or coded information, including details of:

- what would be required for anonymised or coded data to be used to support this or similar purposes in the future;
 - the steps being taken to develop this as an option.
- r. Describe how your organisation satisfies the requirements of the Data Protection Act 1998 and other legislation, including details of how you meet the 8 Data Protection principles which state that personal data must be:
- fairly and lawfully processed;
 - processed for specific purposes;
 - adequate, relevant and not excessive;
 - accurate;
 - not kept longer than necessary;
 - processed in accordance with the data subject's rights;
 - secure;
 - not transferred to countries without adequate protection.

Details of confidentiality policies, confidentiality clauses in staff contracts and measures to ensure that all staff are aware of and work to appropriate confidentiality standards should also be supplied.

5. Measures to prevent disclosure of patient identifiable information

The Patient Information Advisory Group will not approve any application where there is insufficient evidence that patient identifiable information will be used only for the purposes described in the application, that access to the information is restricted, and that it is stored securely. In this section you must:

- s. Explain what steps have been taken to limit the use of, and access to, patient identifiable information, including details of how the use of patient identifiable information will be restricted to the purposes set out in your application.
- t. Demonstrate that your organisation has adequate IM&T security and confidentiality standards. NHS organisations must confirm that they comply with the NHS security standards that include the BS7799.
- u. Confirm that your organisation is committed to achieving the standards set out in BS7799, the Code of Practice for Information Security Management (2000).
- v. Provide details of Data Protection Registration/Notification. Applicants must supply a copy of their Data Protection Registration in order to confirm that they are registered for the purposes of analysis and classes of data described in the application.
- w. A description of the physical security arrangements in place where patient identifiable information is to be processed (and stored if different).

x. System Information:

Provide details of the types of systems and applications to be used. Applicants must supply a copy of the System Security Policy describing the arrangements for security management of the system, its software and its users' access rights and privileges, and arrangements for secure archiving and storage of in-use media and for the secure destruction of data that is no longer required.

Provide details of network connections and remote access. Where data is accessible from either a LAN or WAN network applicants must supply a copy of the Network Security Policy.

Provide details of access and/or firewall controls in place within systems.

y. System-Level Security:

Provide details and a reference copy of any system level security policies.

Provide details of any current security risk review and whether the recommendations from such a review have been implemented.

Describe audit and monitoring arrangements to spot system misuse/abuse.

z. Data Retention & Destruction:

Provide justification for retention of patient identifiable information for more than 12 months from date of collection.

Describe how patient identifiable information will be destroyed once work is complete.

6. Information Custodian

The Information Custodian should sign and date the application.

Whilst compliance with legal requirements, including any obligations or restrictions imposed by Section 60, is the responsibility of everyone working within an organisation, a named individual is required to serve as the point of contact for the Patient Information Advisory Group. In most circumstances we would expect this person to be the head of the unit where the work will be carried out.

It will be the responsibility of the Information Custodian to provide the Advisory Group, on request, with evidence that the organisation works within the conditions for processing patient identifiable information provided under the Data Protection Act 1998 and Section 60 of the Health and Social Care Act 2001.

SECTION 2: JUSTIFICATION OF PURPOSE	
<p>(k) Detailed Description of purpose: *</p> <p><i>(Description of purpose of the proposed research/study/activity for which support is sought?</i></p> <p><i>NB For research activity you must provide copies of the research protocol and of L/MREC approval letter.)</i></p>	
<p>(l) How will the proposed use of patient information help to improve patient care or serve the wider public interest?</p>	
<p>(m) Please list each of the data items you will hold in relation to each patient, and describe briefly why each data item is required.</p>	
<p>(n) Are you seeking specific support or class support? If class support, detail which of the purposes that may be covered do you need support for?</p>	

SECTION 3: CONSENT ISSUES	
<p>(o) i. Why is it not practicable for either your organisation, or the current holder of the information you require, to seek or obtain patient consent for the proposed use of patient identifiable information? ii. Why is it also impracticable to use anonymised or pseudonymised information?</p>	
<p>(p) How have you involved patient and user organisations/representatives in the development of the activity for which you seek Section 60 support? What safeguards have you introduced in response to their input?</p>	
SECTION 4: CALDICOTT	
<p>(q) What is the justification for using patient identifiable information?</p>	

Guidance Notes: Section 60 of Health & Social Care Act 2001

<p>(r) Does the proposed use of patient identifiable information satisfy the requirements of the Data Protection Act and other legislation?</p> <p>Do you have a confidentiality policy?</p> <p>Are confidentiality clauses included within staff contracts?</p> <p>Are all staff aware of their responsibilities?</p> <p>Provide details of how you comply with each of the eight principles outlined in the Data Protection Act 1998:</p>	<ol style="list-style-type: none"> 1. Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless at least one of the conditions in Schedule 2 is met; and in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met 2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes. 3. Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed. 4. Personal data shall be accurate and, where necessary, kept up to date 5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes. 6. Personal data shall be processed in accordance with the rights of data subjects under this Act. 7. Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data 8. Personal data shall not be transferred to a country or territory outside the European Economic Area, unless that country or territory ensures an adequate level of protection of the rights and freedoms of data subjects in relation to the processing of personal data.
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SECTION 5: MEASURES TO PREVENT DISCLOSURE OF PATIENT IDENTIFIABLE INFORMATION

<p>(s) What security and audit measures have been implemented to secure access to, and limit use of, patient identifiable information within your organisation?</p>	
<p>(t) Provide details of the data security policy to be used by all organisations party to this application. Please provide copies of the data security policies for each organisation, together with details of officers responsible for their implementation.</p>	

Guidance Notes: Section 60 of Health & Social Care Act 2001

<p>(u) Provide written confirmation that the organisation's data security policy is fully implemented (and complies with the management and control guidelines contained in the BS7799 "code of practice for information security management", also known internationally as ISO/IEC 17799).</p>	
<p>(v) Provide confirm that your organisation has Data Protection Registration for purposes of analysis and classes of data requested. Please provide a copy of your Data Protection Registration.</p>	
<p>(w) Describe the physical security arrangements for the location where patient identifiable data is to be:</p> <ul style="list-style-type: none"> i) Processed; and ii) Stored (if these are different) 	
<p>(x) System Information:</p> <p>Identify the type of system and application to be used for information processing including product version numbers where known (e.g. desktop PC, Laptop PC, MS Access, etc)</p> <p>Confirm if the computer system will be entirely standalone or connected to a LAN or WAN network, or be otherwise accessible remotely by another means such as dial-up modem. If so please confirm which networks these are and what they are used for, and provide a copy of the Network Security Policy.</p> <p>Provide details of access and/or firewall controls implemented on:</p> <ul style="list-style-type: none"> i) This system; and ii) Any LAN or WAN to which it is connected <p>Please also identify who is responsible for the management of these arrangements.</p>	

Guidance Notes: Section 60 of Health & Social Care Act 2001

<p>(y) System-level Security:</p> <p>Is there a system level security policy for this system? If yes, please supply a reference copy and confirm its status.</p> <p>Has the system ever been the subject of a security risk review? If so, please provide details and confirm whether all the necessary recommendations have been implemented.</p> <p>Please provide details of the arrangements you have implemented to routinely monitor and audit the security of this system for potential misuse or abuse.</p>	

<p>(z) Data Retention & Destruction:</p> <p>How long will the information be retained? If longer than 12 months please provide justification.</p> <p>Describe the method of data destruction you will employ when you have completed your work using patient identifiable data.</p>	

SECTION 6 INFORMATION CUSTODIAN

This form should be signed and dated by the Information Custodian.

SIGNED:	DATE:
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Return completed application to:

**PIAG Secretariat
Second Floor, Princes Exchange
Princes Square
Leeds LS1 4HY**

Application Checklist

- Have you read the whole of the Guidance Notes to fully understand what is required for your submission?
- Have you had a colleague check through your application form so that it is complete and conforms with actual practice?

Have you included the following with your Application Form:

- Written recommendation from the Caldicott Guardian of the sponsoring NHS organisation
- Copy of your organisation's Confidentiality Policy, including staff information leaflets and example(s) of confidentiality clauses in relevant staff contracts
- Copy of your organisation's Security Policy, covering physical and system security
- Copy of your organisation's Data Protection Notification including registered uses
- Copy of your organisation's Research Protocol (if research application)
- Copy of your project's LREC/MREC approval letter (if research application)
- Examples of Patient Information Leaflets provided to the public