

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**

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1. **Introduction**

- 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.
- 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 may be the 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.

2. **Who should consider applying?**

- 2.1 If an activity requires the disclosure of identifiable patient information from one body to another 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.

- 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. Where this sort of blanket support is provided details will be available on the section 60 website.

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 There cannot be a reasonably practicable alternative way, at the current time, of satisfying the purpose without support from Section 60. In particular, it cannot be practicable to rely upon patient consent or to work only with 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.
- 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 could be used to identify individual patients so is regarded as patient identifiable.

- 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 web-based and publicly available.

- 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 or to develop alternative ways of working.

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 however, i.e. where PIAG has advised it is necessary in the public interest, it seems likely that disciplinary or professional regulatory procedures will 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 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 data 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.

Criteria for approving applications for Section 60 Support

CRITERIA	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?		
Is there an acceptable justification why data cannot be anonymised or pseudonymised?		
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?		
Is it clear why the purpose could not be satisfied in another reasonably practicable way?		
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)		
Is there clear evidence that the organisation seeking support is following best practice in terms of IM&T security? (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, subject access provisions, notification/registration etc)		
Is there a clear commitment to making improvements wherever practicable?		
Is there clear evidence that the organisation has made improvements in obtaining consent from patients since previous application(s) were submitted?		

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.

Anonymised (or effectively pseudonymised) patient information can also be used without consent.

In addition to the requirements of confidentiality, Data Protection legislation 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.

**SECTION 60: SUPPORT FOR USE OF PATIENT IDENTIFIABLE INFORMATION
Application Form**

To be completed by the applicant:

SECTION 1: APPLICANT'S DETAILS	
(a) Name of Applicant(s):	
(b) Name of Sponsor Organisation: <i>(Sponsor's written recommendation to be attached including approval from local Caldicott guardian(s))</i>	
(c) Address for correspondence:	
(d) Name and telephone number of Information Custodian in case of queries: <i>(see Section 6 below)</i>	
SECTION 2: BASIC PURPOSE	
(e) What is the purpose of the proposed research/study/activity for which support is sought? (NB For research activity you must provide copies of the research protocol and of L/MREC approval letter.)	
(f) How will the proposed use of patient information help to improve patient care or serve the wider public interest?	
(g) 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>(h) 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>(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?</p>	
<p>(j) 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>(k) What is the justification for using patient identifiable information?</p>	

<p>(l) 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 the eight principles outlined in the Data Protection Act 1998.</p>	
SECTION 5: MEASURES TO PREVENT DISCLOSURE OF PATIENT IDENTIFIABLE INFORMATION	
<p>(m) What security and audit measures have been implemented to secure access to, and limit use of, patient identifiable information within your organisation?</p>	
<p>(n) 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>	
<p>(o) 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>(p) 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>(q) 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>(r) Identify the type of system and application to be used for information processing including product version numbers where known (eg desktop PC, Laptop PC, MS Access, etc)</p>	
<p>(s) 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>(t) 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>	
<p>(u) Is there a system level security policy for this system? If yes, please supply a reference copy and confirm its status.</p>	

<p>(v) 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>(w) 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>(x) How long will the information be retained? If longer than 12 months please provide justification.</p>	
<p>(y) 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:

Return completed application to:

**PIAG Secretariat
Room 1N35A, Quarry House
Quarry Hill
Leeds LS2 7UE**

SECTION 60 OF THE HEALTH & SOCIAL CARE ACT 2001

GUIDANCE ON APPLICATIONS

Each application will be subject to the following considerations, which build upon the principles established by the Caldicott Committee.

1. Applicant's Details

In this section you must provide:

- (i) The name of the organisation/individual that is applying for access to patient identifiable information.
- (ii) 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.
- (iii) Address for formal correspondence.
- (iv) 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.

2. Basic Purpose

In this section you must:

- (v) Describe 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.
- (vi) Describe how this work will benefit patients or the wider public. The sponsor's letter may support this.
- (vii) 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.
- (viii) 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.
- (ix) 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:

- (x) 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?
- (xi) State how you have involved patient and user organisations or their representatives in the development of your proposal.

4. Caldicott

In this section you must:

- (xii) Provide justification for the use of patient identifiable data, including details of:
 - The organisation sponsoring the proposal;
 - 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.
- (xiii) 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 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:

- (xiv) 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.
- (xv) 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.

- (xvi) Confirm that your organisation is committed to achieving the standards set out in BS7799, the Code of Practice for Information Security Management (2000).
- (xvii) 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.
- (xviii) A description of the physical security arrangements in place where patient identifiable information is to be processed (and stored if different).
- (xix) 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.
- (xx) 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.
- (xxi) Provide details of access and/or firewall controls in place within systems.
- (xxii) Provide details and a reference copy of any system level security policies.
- (xxiii) Provide details of any current security risk review and whether the recommendations from such a review have been implemented.
- (xxiv) Describe audit and monitoring arrangements to spot system misuse/abuse.
- (xxv) Provide justification for retention of patient identifiable information for more than 12 months from date of collection.
- (xxvi) Describe how patient identifiable information will be destroyed once work is complete.

6. Information Custodian

- (xxvii) 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 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.