NHS Health Research Authority

FAQs about the law	
What is 'section 251'?	This is a short-hand term, and refers to <u>section 251 of the National</u> <u>Health Service Act 2006</u> and its current Regulations, the <u>Health</u> <u>Service (Control of Patient Information) Regulations 2002</u> .
What does 'section 251' support allow?	The NHS Act 2006 and the Regulations enable the common law duty of confidentiality to be temporarily lifted so that <u>confidential</u> <u>patient information</u> can be transferred to an applicant without the discloser being in breach of the common law duty of confidentiality. In practice, this means that the person responsible for the information (the data controller) can, if they wish, disclose the information to the applicant without being in breach of the common law duty of confidentiality. They must still comply with all other relevant legal obligations e.g. the Data Protection Act 1998. Approval also provides reassurance that that the person(s) receiving the information has undergone an independent review of their purposes and governance arrangements.
What is 'confidential patient information'?	This is set out in the <u>NHS Act 2006</u> . In short, this covers patient information generated in circumstances leading to an obligation of confidence (e.g. a patient attending Accident and Emergency). The requested information must also be identifiable. What is identifiable is often a case-by-case assessment; however, common identifiers include NHS Number, name, address and date of birth, or where, for example, the activity requires information on rare illnesses that could potentially identify a patient. 'Confidential patient information' also covers information related to deceased persons.
What is outside the scope of 'section 251 support'?	 Activities must fall within a <u>medical purpose</u> to be considered, so, for example, requests to access patient



	 information to inform road traffic management planning could not be approved as the primary purpose would not support health service improvements. Non-research activities taking place under Regulation 3 'Communicable Disease surveillance and other risks to public health' are excluded from CAG consideration as these are managed by Public Health England. Processing of genuinely anonymised data would not fall within the scope of the Regulations as access to anonymised information would not involve a breach of confidentiality.
What legal safeguards are in place?	The NHS Act 2006 and Regulations have a number of inbuilt safeguards that the CAG considers as part of its assessment of applications. Examples include:
	 The activity must be a medical purpose as defined in <u>s251</u> (<u>12</u>) of the NHS Act 2006. Medical purposes include medical research (that has received ethical approval by a research ethics committee) and the management of health and social care services The activity must be in the public interest or in the interests
	 of improving patient care The activity must be compliant with the provisions of the Data Protection Act 1998 All applications must undergo an annual review to evidence whether support is still necessary.
	In addition, it has been agreed that as part of any approval conditions of support, a mechanism to register and respect patient objection must be in place, except in the most exceptional of cases such as a pandemic situation.
Is 'section 251' a new power?	This legal power has been in operation since 2002 and was widely debated in Parliament at the time. The CAG advisory function was previously carried out by the National Information Governance Board's Ethics and Confidentiality Committee (ECC, 2009-2013) and prior to that, the Patient Information Advisory Group (PIAG, 2001-2008).



All advice and applications considered by these predecessor
bodies are readily available in their detailed minutes here: http://www.hra.nhs.uk/about-the-hra/our-committees/section-
251/cag-advice-and-approval-decisions/

