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Research Capability Programme
Patient Consent Approach
(PD15)

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Related Documents:

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1	NPfIT-RCP-PID-0001	Research Capability Programme – Enabling Phase, Programme Initiation Document.	1.0
2	N/A	Report of the Research Simulations, UKCRC Advisory Group for Connecting for Health http://www.ukcrc.org/publications/reports.aspx	N/A

Contents

1.	Purpose	4
1.1.	Introduction	4
1.2.	The Information Governance and Threat Assessment Work Stream.....	4
1.3.	This Document	5
2.	Consent Issues in Research Studies	6
2.1.	Using Patient Data to Identify and Invite Potential Candidates	6
2.2.	Using Patient Data Directly to Conduct Research	9
3.	Next Steps	13

1. Purpose

1.1. Introduction

This document is part of a series of 21 products (PD00 to PD20) that make up the Enabling Phase of the Research Capability Programme (RCP). The Programme comprises six work streams:

- Technical Architecture
- Functional Scope and Business Case
- Data Quality, Standards and Linkage
- Information Governance and Threat Assessment
- Infrastructure
- Communications and Stakeholder Engagement.

These work streams are highly inter-related and the products of the individual work streams should not be read in isolation. For example, many of the products will highlight Information Governance issues which may not be directly addressed by the specific product itself, but which will be addressed by the relevant product within the Information Governance and Threat Assessment work stream.

Further information on the overall RCP providing the background and context for this document is included in RCP programme document PD00.

This document, PD15, forms part of the Information Governance (IG) and Threat Assessment work stream.

1.2. The Information Governance and Threat Assessment Work Stream

The Information Governance (IG) and Threat Assessment work stream of this Enabling Phase of the Research Capability Programme (RCP) has the following aims:

- To define a series of approaches for IG that will help to establish the Programme on a sound legal footing that balances the needs of the research community with the rights of individual patients to privacy and data confidentiality;
- To define an appropriate position on patient consent;
- To carry out an assessment of the potential threats to patient confidentiality of data linkage;
- To identify practical “next steps” including setting the scope for discussions with the National Information Governance Board (NIGB), as well as other legal and governmental bodies; and
- To ensure that all other work streams work within an appropriate governance framework.

This work stream will have the following phases:

- Consolidating the current views and experiences of different stakeholders on IG issues;
- Defining key IG and Linkage issues that require specific legal or ethical clarification, and which require technical implementation;
- Assessing the IG implications and feasibility of options presented by other work streams; and
- Providing input into the Business Case that concludes the Enabling Phase of the Programme.

This work stream will require close working and consultation with a wide range of research organisations, patient and public representative bodies, and legal and policy experts.

1.3. This Document

This document expands the requirements and concerns expressed in the 'Report of the Research Simulations' by the UKCRC Advisory Group to Connecting for Health. It aims to represent the Programme's understanding of the current legal requirements for obtaining Consent for recruitment to research studies and Consent for conducting research studies. Where possible, these are translated into technical requirements. This document has been produced in consultation with members of the ERG and the Programme Chair.

This document does not intend to argue the case for allowing access to data, or to revisit the wider issues surrounding the Information Governance of data for research, as these have been described elsewhere. PD15r aims to highlight the specific issues that relate to Consent in research, in particular as they relate to this Programme.

The outputs of the work described in the document will feed into other products of the Information Governance and Threat Assessment work stream, in particular PD16: *'Information Governance Framework'*.

Document Overview

- Section 1 (this Section) introduces the document and describes the context of its production.
- Section 2 describes the issues around Consent in research studies, drawing out the legal and technical issues.
- Section 3 describes, at a high level, the next steps required to clarify the issues.

2. Consent Issues in Research Studies

This Section provides a generic description of the issues surrounding Consent that arise when setting up and running research projects that require access to patient data¹. The aim is to draw out the legal, procedural and technical issues that need to be tackled in order to ensure that research studies are conducted within an appropriate governance framework. This must meet patient and public expectations by using a lawful and robust Consent model.

A balance must be struck between protecting patients' rights to privacy and allowing important research to proceed (or continue), in appropriate circumstances. A detailed discussion of the issues is outside the scope of this document. Further information may be found in '*Personal Data for Public Good: Using Health Information for Medical Research*²', the CRDB Report on Secondary Uses of Patient Information³ and the related PIAG Response⁴.

Research studies may require patient data either:

- To identify patients for potential inclusion in a research study, and for study planning and conduct, possibly followed by direct contact with the patient; or
- To use directly as the "raw material" for research e.g. in observational studies, usually without any direct contact with the patient.

Table 1 overleaf illustrates the Consent model that is used for different types of research project.

2.1. Using Patient Data to Identify and Invite Potential Candidates

The first stage of many (interventional) research projects is for the researcher to identify patients who satisfy the particular entry criteria for that project, and to identify and exclude patients whom it might be inappropriate to contact. For some studies, this type of scoping exercise has been performed by researchers, either directly or indirectly accessing the patients' notes following specific approval from PIAG under Section.60 of the Health and Social Care Act 2001 (HSCA 2001), on a case-by-case basis.

More recently the concept of "Consent for Consent" has arisen, where the patient's own GP (or another health professional) makes the initial approach. The patient is asked whether they would mind having their notes examined by a researcher at a later date and then potentially being invited to participate in a study. Although this process seems to satisfy all reasonable information governance principles, many researchers have argued that it may lead to biases in research participation⁵. The process for identifying potential candidates for research is currently being redefined with the creation of the National Information Governance Board, in line with the Health Service (Control of Patient Information) Regulations 2002.

It should be possible to perform early scoping work to assess the potential numbers of patients appropriate for a given study without requiring access to patient identifiers. Anonymised or aggregate reports of the numbers of patients that meet the inclusion criteria for a study could be provided. As such, reports would not contain identifiable patient information. There would be no requirement for either Consent or for approval under Section 60 HSCA. Such a process may reduce the number of applications for access to identifiable information, as some studies may not proceed beyond this early scoping phase.

¹ The term "patient data" is used in this document generically to include anonymised, pseudonymised, aggregate, and identifiable data, and is not limited to "health" data e.g. it may include population data such as demographic information.

² The Academy of Medical Sciences, January 2006.

³ See http://www.connectingforhealth.nhs.uk/crdb/work_streams/secusesreport.pdf

⁴ See <http://www.advisorybodies.doh.gov.uk/piag/piagresponse-CRDB-SUS.pdf>

⁵ Further data on the potential biases that may be introduced using health professionals to recruit patients on research is required.

Table 1. Classification of Research Studies with Consent Models

Type of Research				ACTIVITY 1	GOVERNANCE					ACTIVITY 2	GOVERNANCE				
					Type of data	Patient Consent	Ethics	Scientific	PIAG		Type of data	Patient Consent	Ethics	Scientific	PIAG
A	<i>Interventional</i>	A1	Clinical Trial	Central Recruitment	Initially anon. or aggregated for estimation of numbers etc. For recruitment via a central system- PET can be used to send personal letters.	Implicit by Opt-out with statement of facts about PET	Each study	Each study	Yes, for principal of PET used for recruitment	Doctor or HP dealing directly with patient	Personal with HP, then pseudonymised via key codes to researcher	Obtained and documented- intervention + data- as required for study. Single study approval only	Each study	Each study	NO
		A2	Genetic linkage												
		A3	Prospective patient collection of data												
B	<i>Observational</i>	B1	Retrospective	Hypothesis Generation	Anonymised	Implicit by Opt-out**	Over-arching single approvals by type	Each study	Required for linkage using identifiers via TTP						
		B2	Prospective		Pseudonymised, where way back required	Implicit by Opt-out									
		B3	Plus additional health professional collection		Hypothesis Testing	Identifiable- No suitable anon. system can be found- geographic research	Covered by "rarely" used clause in OPT-out + PIAG			Each study or by study types	Required				

**** NB There is no legal requirement to obtain Consent to use anonymised data. However, further clarification is required about the circumstances in which patients should be informed about potential uses for their anonymised data and given the opportunity to opt out.**

Where studies do proceed, there may be the opportunity to invite patients “blindly” i.e. in such a way that no human hand has been involved in the production of the invitation letters. For example, a researcher could query a central database to find people that meet particular inclusion criteria and then request that an automated system generates letters sent to these patients inviting them to participate in a study.

Policy and Legal Issues

The following issues will need legal and ethical clarification. In particular, it is necessary to determine whether a “class approval” might be possible or whether all applications must continue on a case-by-case basis¹. We need:

- Clarification of the legal position on producing “blind” invitations for research participation.
- Clarification of the rules surrounding the use of data within “Sealed Envelopes²” and/or within “Sealed and Locked Envelopes” as part of initial, anonymous scoping studies.
- Clarification of the rules surrounding the use of data within “Sealed Envelopes” and/or within “Sealed and Locked Envelopes” to automatically generate letters³.
- Clarification of the processes⁴ required for the use of identified data for scoping studies and for inviting participants. In particular, whether patients are required to give their Consent to be contacted by researchers, whether this consent should be opt-in or opt-out and whether this should be a general consent for particular classes of study or datasets, or on a case-by-case basis.
- Clarification of the processes required where it is impracticable or impossible to obtain Consent (where it might be deemed to be required) e.g. where research subjects lack the appropriate capacity.

Information Systems Issues relating to Invitations to Research Participants

The information systems solutions required to support invitations to research participants will be delivered by the Technical Architecture and Functional work streams of the RCP. The specific solutions will depend largely on the answers to the policy and legal questions above.

However, it is likely that the following will be required:

- An interface that allows researchers to formulate research queries on the data held within the research system. This may include:
 - Queries across all of the data within the system, or specific subsets; and
 - Queries that include all of the data held or queries that exclude “Sealed Envelope” and/or “Sealed and Locked” data.
- Outputs in the following formats:
 - Aggregate and/or anonymised information about patients who meet inclusion criteria;
 - Output to an automated mailing system to allow participants to be invited to participate in research without human intervention; and

¹ Class approvals have become acceptable for Ethics approvals of standard observational studies (by example GPRD has two MREC approvals that give cover to about 120 studies per year, but each has scientific approval). Additionally, the recent development of the PIAG “fast track” application process seems to indicate a move towards class approval.

² Although “Sealed Envelope” data areas highlighted in this document, similar clarifications will also be required for other similar data e.g. data from genitourinary medicine clinics and data about terminations of pregnancy that have other statutory protections.

³ For example, patients must be made aware that if they lock data away that could be used in an anonymised manner they are not helping the system of ensuring medicines are safe and effective. That may impact on them but will impact on society as a whole. Using GPRD as an example, there are no locked data and there have been no issues over its 20 year history. Rates of opt-out from anonymised use are almost negligible.

⁴ For example, using a “Trusted Third Party” system with clear separation between different parts of the research process.

- Identifiable data (with the minimum amount of data necessary to contact patients who are to be invited to participate).
- A system to record whether individual patients have agreed that they are happy to be invited by a researcher to participate in a study. This will need to consist of a number of Consent (and withheld Consent) “flags” depending on the results of clarification of the legal and policy position above. There may be:
 - No flags at all, if it is decided that patient consent is not required for invitation;
 - A single consent flag, the presence of which indicates that the patient may be contacted about any information in their records (either including or excluding “Sealed Envelope” data by default);
 - Several consent flags, with separate consent flags for “Sealed Envelope” and/or “Sealed and Locked Envelope” data;
 - Several consent flags, with separate consent flags for different types of study; and
 - An “opt-out” flag that records a patient’s express wish never to be approached about research.
- Each Consent flag will need associated auditing facilities and metadata to record, for example:
 - When Consent was recorded.
 - By whom and how that Consent was obtained.

2.2. Using Patient Data Directly to Conduct Research

Where patient data are used directly for research, the following rules relating to Consent appear to apply:

- If the data are “effectively anonymised” (e.g. where the subject cannot be identified because the researcher has no access to any key codes for anonymised data) then there is no requirement to seek Consent for the use of patient data. This rule appears also to apply to data in “Sealed Envelopes”.
- For “sensitive personal data”¹ in an identifiable form (i.e. where that data in itself or in combination with other data in the possession of a data controller could identify an individual) then some form of Consent may well be required before researchers are allowed to access it.

It is universally agreed that a researcher may legally use sensitive personal data if the data subject has given explicit Consent for that use. However, access to this type of data is seldom requested by researchers.

The Data Protection Act 1998 sets out the rules for the processing of personal data. It states that “Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless—

(a) at least one of the conditions in Schedule 2 is met, **and**

(b) in the case of sensitive personal data [which includes medical records], at least one of the conditions in Schedule 3 is also met.”

The Schedule 2 conditions are:

1. The data subject has given his Consent to the processing.
2. The processing is necessary:
 - (a) for the performance of a contract to which the data subject is a party; or

¹ As defined in DPA 1998 – this would include medical records that can be related to an individual. Clarification of how this definition applies to anonymised and pseudonymised data is being requested as part of this work.

- (b) for the taking of steps at the request of the data subject with a view to entering into a contract; or
- (c) for the exercise of any functions of the Crown, a Minister of the Crown or a Government Department.

3 The processing is necessary for compliance with any legal obligation to which the data controller is subject, other than an obligation imposed by contract.

4 The processing is necessary in order to protect the vital interests of the data subject.

5 The processing is necessary:

- (a) for the administration of justice;
- (b) for the exercise of any functions conferred on any person by or under any enactment;
- (c) for the exercise of any functions of the Crown, a Minister of the Crown, or a Government Department; or
- (d) for the exercise of any other functions of a public nature exercised in the public interest by any person.

6 (1) The processing is necessary for the purposes of legitimate interests pursued by the data controller or by the third party or parties to whom the data are disclosed, except where the processing is unwarranted in any particular case by reason of prejudice to the rights and freedoms or legitimate interests of the data subject.

(2) The Secretary of State may by order, specify particular circumstances in which this condition is, or is not, to be taken to be satisfied.

Schedule 3 includes the following, of relevance to medical research:

1. The data subject has given his explicit Consent to the processing of the personal data.

(1) Processing is necessary for medical purposes and is undertaken by:

- (a) a health professional; or
- (b) a person who in the circumstances owes a duty of confidentiality, which is equivalent to that which would arise if that person were a health professional.

(2) In this paragraph “medical purposes” includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of safe care and treatment, and the management of healthcare services.

It is important to note that “medical research” is expressly included as a medical purpose within these rules, and thus the use of sensitive personal data for medical research is permissible as long as one of the Schedule 2 conditions is satisfied. This legal position seems to be at odds with the position taken by PIAG and the NHS Code of Practice (Confidentiality), which define research as a “secondary use”, which should therefore have a separate consent approach from other “medical purposes” or “healthcare purposes”. This is a critical area of disagreement that requires urgent adjudication.

According to the DPA there are therefore several circumstances where, prima facie, it may be lawful to use sensitive personal data for research without the explicit Consent of the individual. Example might include pursuing functions of a Minister of the Crown, matters in the Public Interest, or where there is a statutory basis (e.g. via Section 60 HSCA). There may be scope to extend these provisions so that legitimate research studies might be able to proceed using sensitive personal data without patient Consent. However, this would probably require new legislation, which might be unpopular in the current climate. At the very least, such legislation would have to define legitimate research closely and would have to establish appropriate checks and balances on access to sensitive personal data.

The most contentious debate has been around the omission of the requirement for Consent to be explicit in Schedule 2. Again, according to the letter of the law, the use of sensitive personal data for medical research would be legal as long as the data subject has given “Consent”. The implication of omitting the word “explicit” in Schedule 2 is that implied Consent may be acceptable. However, the circumstances under which Consent can be assumed are unclear. It should additionally be noted that there is the requirement that Consent need be in writing.¹

“For consent to be legally valid, it must be:

- Informed – patients must be informed at the very least in a broad way.
- Understood – patients must have the capacity to understand what is being asked.
- Voluntary – patients must not be under undue pressure to consent.
- Specific – consent needs to be sufficiently defined”².

Legal clarity is required on the meaning of all of these terms as they relate to, for example, the use of mass mailings or poster campaigns to inform patients about the routine use of their data for research. Such modes of contact may sufficiently inform patients and may be specific enough in law, but it would probably be improper to assume that patients had understood their meaning or that Consent is entirely voluntary, without positive confirmation that this is the case.

Additionally, clarity is required around which rules apply to pseudonymised data in particular, and more generally about where the line between anonymised data and data that may potentially identify a patient lies.

Assuming it is legal for patients to Consent to data use for research generally (e.g. UK Biobank) and that patients may alternatively refuse Consent for all research, there needs to be clarification of when these general Consent decisions might be overridden.

Legal Issues

The following will need legal clarification about likely interpretation by the courts of current law and whether new legislation is required to clarify or establish the principles around the use of patient data for research:

- What can be included as within the “public interest” and other conditions in Schedule 2 of the DPA 1998, in particular whether any medical research activities could satisfy any of these conditions?
- That medical research is included with other medical purposes (such as the treatment of patients) and so should not be treated differently in terms of Consent.
- The definition of “medical research” (for example to include both interventional and observational studies), including the definition of provisions to ensure that research is legitimate e.g. as evidenced by Research Ethics Committee approval and clarification of whether the provisions relating to “research purposes” in Section 33 DPA apply.
- Confirmation that medical researchers may be included under the DPA as “people who in the circumstances owe a duty of confidentiality which is equivalent to that which would arise if that person were a health professional” either prima facie or if extra conditions are met.
- Confirmation that explicit Consent is not always required for medical research.
- Clarification about the scope of Consent where it is given e.g. whether it can be “general and in perpetuity” or whether new Consent must be gained for follow-on research studies.
- Clarification of the rules around the “Consent” condition in Schedule 2 of the DPA e.g. whether this could be satisfied by the general posting of information stating that NHS personal data may be used in research (i.e. for gaining implied Consent) without further explicit Consent being required.

¹ See Data Protection (2004) Peter Cary, Oxford University Press

² From PIAG’s Response to the CRDP Secondary Uses Report

- Clarification of whether provisions for “class guidelines” for Consent can be created either directly in legislation or as guidance for bodies such as PIAG or the NIGB.
- Clarification of the rules for the use of data within “Sealed” and “Sealed and Locked” envelopes for research, whether or not Consent has been given by the patient for the use of their whole record and / or the data within the envelope.
- Clarification of the meaning of withdrawal of Consent, in particular where another DPA condition (such as public interest) may allow a researcher access to the same data.
- Clarification of the definitions of “effectively anonymised” data and the consequent rules for the use of pseudonymised data (and anonymised and aggregate data), where there is a finite risk that researchers may be able to infer the identities of patients.¹
- Clarification of the processes required where it is impracticable or impossible to obtain Consent (where it is deemed to be required) e.g. where research subjects lack the appropriate capacity.

Information Systems Issues Relating to the Use of Patient Data for Research

The information systems solutions required to support the provisions about patient Consent will be delivered by the Technical Architecture and Functional work streams of the RCP. The specific solutions will be determined by the answers to the legal questions outlined above. However, assuming that there will be some requirement to record individual patient choices, some or all of the following will be required:

- A system to record whether individual patients have given Consent that they will participate in a study. This will need to consist of a number of Consent “flags” depending on the results of the clarification of the legal and policy position above. These flags may be set to “yes” or “no” by default. There may be:
 - Several Consent flags, with separate Consent flags for the use of “Sealed Envelope” and/or “Sealed and Locked” Envelope data, to indicate “opt-out” of all uses of data, to indicate withdrawal of consent, etc. (all with date and time stamps)
 - Several consent flags, with separate consent flags for different types of study and/or different data sets (e.g. Primary Care vs. Hospital Data)
 - A single consent flag, the presence of which indicates that the patient has consented to the use of their data for all research (either including or excluding “sealed envelope” data by default)
 - No flags at all, if it is decided that patient consent is not required for any study
- Each consent flag will need associated auditing facilities and metadata, to record, for example:
- When consent was recorded
 - By whom and how consent was obtained
- A system that allows access to data (either the whole record or data only outside sealed envelopes) based on:
 - Particular values of consent flags
 - All data regardless of consent flags (for example in cases where consent is deemed irrelevant and access without consent is therefore lawful).

¹ It has been suggested that in deciding the appropriate type of data to use, a “risk management” approach should be adopted that balances the risk of potential harms caused by identification against the potential benefits of research, taking into account the trustworthiness and ethical codes of data recipients.

3. Next Steps

Given the legal ambiguities and uncertainties around the requirements to establish and record consent at the different stages of the research process, the work in this area is necessarily ongoing. Finding answers to all of the legal issues is outside the scope of the current enabling phase of the Programme. The following steps will be required, within the wider IG work plan for the Programme. PD16 (Information Governance Framework) will contain further updates on this work.

ERG Input

The External Reference Group is asked to confirm that the approach set out in this product is acceptable - in particular that the specific legal questions above represent the major concerns of the research community. It is expected that members of the ERG will wish to work with the IG Work stream Lead and the Programme Board to formulate detailed briefs for legal opinions on behalf of the Programme.

Discussions with Representatives from PIAG / NIGB, the Information Commissioner's Office and the DH

Representatives of the Programme are currently in discussion with PIAG and with Marc Taylor (Head of R&D Systems and Governance at the DH). Discussions with the chair of the NIGB and with the Information Commissioner¹ are planned. Discussions will be held with the NHS CFH Digital Policy and Information Governance teams as required. It is anticipated that these discussions will indicate where a formal legal opinion is required. Discussions may lead to the development of general policy / position statements for the NHS (e.g. the development of a "researchers' charter" / "research record guarantee" and/or amendments to the NHS Constitution).

Consultation with Other Parties to Ensure the Approach is in Line with International Best Practice

There is considerable experience in the UK and abroad in the use of patient data to support research, using different consent models. The Programme will consult with others working in this field to understand how they have dealt with specific issues. Potential consultees include UK Biobank (consented research), the UK Cancer Registries (who have an opt-out model of consent) and other research organisations (e.g. the UK Medical Research Council).

Preparation of Instructions to Counsel, Submissions to PIAG, etc.

Drafts of instructions to counsel and to PIAG/the NIGB with any supporting documentation, will be produced as required as part of the wider IG work.²

A review of the DPA (the "Walport Review") is currently being undertaken by the Ministry of Justice (see <http://www.justice.gov.uk/reviews/datasharing-intro.htm>). The views of the ERG and the Programme will be communicated to this review.

Assumptions and Interaction with the other work streams

In order to ensure that IG concerns do not delay other work streams it is assumed that the outstanding issues will be overcome in a way that will allow research to proceed. The government has recognised the importance of research and has committed to providing support to enable research to proceed.

¹ Particularly in light of recent directions to the ICO from the EU Article 29 Working Party on definitions of "personal data".

² NB GPRD hold a document related to GPRD data uses and the DPA but commissioned by DH in 1998- IN THE MATTER OF MEDICAL CONFIDENTIALITY UNDER COMMON LAW AND THE DPA 1998. With the appropriate approvals this could be made available.

It is additionally assumed that the technical options presented within this document should be relatively straightforward to implement. The larger challenge will be to establish appropriate procedures to ensure that data is released to researchers under an appropriate, and audited, consent model. The aim of the programme is to develop a technical architecture and robust processes that can provide data to researchers in a way that meets their needs, but which at the same time reassures patients and the public that their privacy and confidentiality is adequately protected.

The Programme will consider the opinions of the wider stakeholders via the separate consultation work stream that will gather the views of patients, clinicians and other interested parties.

The final products of the enabling phase of the RCP are PD10 (Business Case) and PD21 (Full Programme Initiation Document) which will document all the relevant information relating to the subsequent phases (beyond the enabling phase) of the Programme. These documents will produce indicative plans and costings, in particular to indicate the timings and cost of obtaining expert legal opinions.