Information for clinicians and researchers about the CPFT Research Database

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OVERVIEW

What is the CPFT research database?

CPFT uses software that takes electronic clinical records and automatically feeds them into a research database. The "inputs" include structured data (such as referrals, coded diagnoses, and admissions) and free-text data (such as letters and progress notes). As the data are sent to the research database, they are rendered anonymous, using a "pseudonymisation" de-identification method.

All records in the research database are identified only by a **research ID number.** There are no names, exact dates of birth, CPFT hospital numbers ('M', RiO, SystmOne, etc.), NHS numbers, and so on. Only CPFT can de-anonymise the information.

The database contains details of sex, age (month and year of birth), diagnoses, medication, and so on, including searchable free text.

How can researchers use the research database?

Researchers can use the database for epidemiological, population-based studies. They simply search it, analyse the data, and publish. For example, a putative association between two diseases might be examined in this way.

Researchers can also use the database for patient-contact research. They can search the database for anonymous patients that might be suitable for their study, and then provide a list of research ID numbers to CPFT. They can either request the patients' details and permission to write to them and view their CPFT clinical record, or address their first request to the patients' clinicians. Either way, they only receive patient-identifiable information for patients who consent.

How can clinicians and clinical managers use the research database?

Clinicians and clinical managers may use the database in the ways that researchers can. In particular, anonymous information may be useful for audit and service development (such as finding out the total number of patients with a particular condition, or significantly more complex audits).

Clinicians may also see *their* patients' information in the research database (since, to clinicians, this is identifiable and potentially useful clinical information). One reason for considering this is that the software may extract useful information from vast quantities of free-text data (e.g. letters) that would otherwise be tedious to search. Therefore, clinicians may request the research ID number of an individual patient of theirs, or of all patients for whom they are a clinician, or of all such patients who match a particular set of criteria.

As a specific example, consider the 2011 withdrawal of citalopram 60mg as a licensed dose. If the clinical record system did not include drug and dose information, it might be useful to attempt a query of the Research Database to find all patients where citalopram 60mg has been found in free text, and then to send this to the Research Database Manager requesting re-identification for any patients that are yours. Specific patient consent is not required for this, since this is part of their clinical care.

Clinicians using this process, especially those that work closely with researchers, are reminded that they may not disclose the identity of any patient in the research database to a researcher who is not also a member of the clinical team looking after the patient, without the patient's explicit consent.

What choices do patients need to make?

Patients do not need to choose about their anonymous data being used for research, since this does not require consent. CPFT goes beyond the strict legal requirements by supporting patients' ability to opt out entirely from the use of even their anonymous data for research, but by default all CPFT patients' data are rendered anonymous and made available for approved research.

Patients do not need to choose about being approached by their clinical team about research, since all clinicians may approach their patients about research participation.

The **key choice** is whether to allow all approved researchers to have access to their clinical records and permission to write to them directly ("GREEN"), to pass every request via their clinician ("YELLOW"), or not to allow any researchers access to them ("RED"). Please see the patient information leaflet (*"Taking part in research"*) for details. A summary is:

We ask that all patients be asked their preference early in their contact with the Trust, and given the leaflet and decision form. Until they have been asked, we assume "YELLOW" (meaning that all approaches about research come via the patient's own clinical team, something that is always acceptable practice).

Patients may change their preference at any time. They are reminded of their choice after they've made it, and are reminded of their ability to change their mind whenever researchers contact them, and in an annual newsletter sent to those with GREEN or YELLOW preferences. The Research Database Manager's team maintain the records of this preference.

Patients may also opt out from the use of even their anonymous data for research. Other, more detailed, preferences may be expressed directly to any relevant researchers.

As of 2017, the **traffic-light preference** and the ability to **opt out completely from the anonymous database** are part of the RiO mental health records system (see the "Research Consent" tab from the main screen).

FOR CLINICIANS

I've received an electronic request from the Research Database Computer. What should I do?

Thank you for your help! Detailed instructions are in the e-mail sent to you, and in the web form it links to. In most cases, the amount of work involved for you should be minimal: it might be just a moment's thought and a single click. (If you prefer to do more: a moment's thought, a couple of clicks, printing some pre-personalized materials, a signature, and sending the batch of materials to the patient with a Freepost envelope to return them; or a face-to-face discussion with the patient.)

The request will be about one of three types of study:

- Studies where the researcher would like to write to the patient directly, and the patient prefers that all such requests are passed via the clinical team (i.e. you) – that is, the patient has previously chosen the YELLOW mode. Please consider whether there is a strong clinical reason to veto the request. If not, please pass on the request to the patient as decribed.
- Studies where the researcher would like to write to the patient directly, and the patient has not been asked their preference in this situation (all such requests are passed via the clinical team, i.e. you). Please consider whether there is a strong clinical reason to veto the request. If not, please pass on the request to the patient as decribed. If you wish and consider it appropriate, you may delegate this process to the Research Database Manager, who will then 'p.p.' a letter to the patient from you – delegation is a one-click step. There is also a leaflet and form asking the patient's RED/YELLOW/GREEN preference.
- Studies where the researcher would particularly like your involvement. These involve the most work and discretion on your part, because the researchers would like you to provide clinical information about the patient and to make first contact with the patient about the study. If the patient is definitely ineligible for the study, or there is a strong clinical reason to veto the request, tick accordingly on the web form. If the patient might be eligible, please follow the instructions, which usually involving filling in a form supplied by the researchers. The methods used prevent any information going to the researchers without the patient's consent.

Please note the following:

- You, as the patient's clinician, do not need separate consent to identify and/or contact patients about research [1].
- In the first step, the patient is asked to consent to their details being passed to the researchers, so the researchers can send them information, and to the researchers having access to their clinical records. **They are not being asked at this stage for consent to take part in a study.** If the patient is interested in taking part, the researchers would subsequently have to obtain informed consent to participate in the study.
- The anonymous search method used by the researchers means that the patient might, but does not necessarily, fulfil the eligibility criteria. The researchers would have to establish this directly.
- If the patient falls into a special category **(children under 16, adults lacking capacity)**, please see "SPECIAL CATEGORIES OF PATIENT" below.
- Please use clinical "vetos" sparingly. If you consider that the patient may be eligible for a study, then normally the decision whether to provide further details to the research team

and to be approached by them about participation should be the patient's. However, all approaches via the clinical team, are subject to a "veto": as the clinician, you may decline to pass the request on to the patient. If you choose this option, no information about the patient will be given to the research team. Please only choose this option in exceptional circumstances, as it reduces the patient's ability to choose. Exceptional circumstances might include those in which, in your judgement, an offer to the patient to participate in research might cause extreme distress, or that the patient currently lacks the capacity to make a decision about participation. Your views on the study itself should not prompt you to select this option; all studies supported by CPFT have ethical approval and we seek to promote patient choice about research participation. Please give a reason for your choice, so that we may audit use of this option. The reason will NOT be passed on to the research team.

- A small point: It is possible that the patient may wish for further information about the study before they decide whether or not to allow the researchers to contact them. If this is the case, and the patient does *not* consent to the researchers knowing their identity at this stage, we would be very grateful if you would pass the question on to the researchers without revealing the patient's identity, and pass the answers back to the patient. We expect that this would be a very rare request, as the study details enclosed should provide enough information to allow most patients to decide whether or not they are willing to be approached by the research team. (That does not mean that the information enclosed is enough to decide whether or not to *participate*; patients who agree to contact with the research team and who meet their eligibility criteria will have the opportunity to ask any questions they wish directly of the research team before deciding whether or not to participate in the study itself, and that consent process is separate from and subsequent to this one.)
- Please telephone the Research Database Manager directly (the telephone number will be in the e-mail to you, or you can e-mail **research.database@cpft.nhs.uk**) if you have queries about this process. Don't disclose any patient details except the research ID.

What incentives are there for clinical teams to support research in this way?

Other than the obvious incentive that research benefits patients, you may be interested in the following.

- Additional funds may be made available from the Research & Development budget to clinical teams who are active in research recruitment in general.
- However, no payments to clinical teams are made on a case-by-case basis using this system: we don't wish to discourage clinicians financially from using their "veto" when clinically required.
- Instead, a small donation is made by CPFT to local mental health charities every time a clinician responds electronically to a research request made via the system (regardless of whether the response is positive or negative from the researcher's point of view). For current details, see http://www.cpft.nhs.uk/research.htm > CPFT Research Database.

SPECIAL CATEGORIES OF PATIENT

What about patients who lack capacity?

Capacity is decision-specific: one may have capacity to make some decisions but not others. Capacity can fluctuate: one can lose and gain capacity. Consequently, searches of the Research Database may yield some people who currently lack the capacity to make decisions about research participation and related matters.

Therefore, clinicians:

- should **consider capacity** when passing on requests from researchers (certainly, the capacity to decide about passing information on to a research team, but also the capacity to decide about research participation, since the researchers are fairly likely to make that request of the patient later);
- should **veto or decline to pass on requests about individual research studies to patients who do not have capacity** to decide about them, **unless the study specifically concerns such patients** (see below);
- should, if informed by researchers about a potential lack of capacity in a patient they've met, (a) consider any clinical implications and act accordingly, and (b) if the patient's approach mode is GREEN, consider overriding this and changing it to YELLOW, discussing this with the patient in the process. Clinicians may obtain a patient's current approach mode from the Research Database Manager or from the electronic clinical record, and the Research Database Manager can change a patient's approach mode under these circumstances on request.
- **If the study specifically involves patients who lack capacity,** this will be indicated on the form you receive. The form will also indicate whether the study is a clinical trial or not (as this determines who is allowed to make decisions on the patient's behalf, and how).
    - If you receive such a research request, please don't "veto" just because the patient lacks capacity.
    - If you choose to pass on the request, please do it face-to-face, not by letter.
    - Please discuss the request with the patient and their legal representative (for clinical trials) or the patient and their carer/consultee (for other studies).
    - The decision forms have a specific space for those that lack capacity.
- If you've been invited to pass a RED/YELLOW/GREEN decision on a patient who lacks capacity, please discuss it with them and their carer/consultee. (The carer/consultee is the appropriate person, as this is not a decision about a clinical trial.) The decision forms have a specific space for those that lack capacity.

The meaning of signed approval by the "legal representative" or "carer/consultee" is specific:

- For clinical trials, governed by the Clinical Trials Regulations, in England [5, 7], often known as "CTIMPs" (clinical trials of an investigational medicinal product): the clinical trial must relate directly to a life-threatening or debilitating clinical condition from which a potential participant suffers. Specific advance consent is valid, and advance refusal must be respected. Otherwise, the patient's **legal representative** (who is a person independent of the trial, who by virtue of their relationship with the potential study participant [e.g. a relative] is suitable to act as their legal representative for the purposes of that trial, and who is available and willing to so act for those purposes; or if there is no such person: a person

independent of the trial, who is the doctor primarily responsible for the medical treatment provided to that adult, or a person nominated by the relevant healthcare provider) **should be asked about the presumed will of the participant and asked to give informed consent.**

- For other studies, in England [5, 6], the research must relate to the condition impairing capacity, or its treatment. Nothing should be done contrary to an advance directive or any other statement by the potential participant. The patient's **carer or consultee** (who may be an unpaid person with an interest in the welfare of the potential participant, or failing that, a person who is independent of the project) **is asked about their opinion on the views and feelings of the participant and asked to give advice as to whether the participant would decline to take part if he or she had capacity.**
- Someone who holds a Lasting Power of Attorney may be valid as a carer/consultee, but only if they are not being paid for it (so, for example, a solicitor holding an LPA cannot act as the carer/consultee for the purposes of research) [5, 6].

Researchers:

- must be competent in capacity assessment;
- must assess capacity for every patient they seek to recruit for a study;
- must, if there is doubt regarding a participant's capacity, seek advice from their senior investigator (who should either conduct a capacity assessment personally or consult with the patient's clinical team);
- should tell the patient's clinician if a patient lacks capacity to decide about research participation, and this was not previously known (as this may have clinical implications and implications for further research recruitment).

The subset of researchers who wish to conduct research involving patients who lack capacity must adhere to stringent regulations, outlined in the "More detail..." section below.

What about children? I've received a request concerning research and the patient is under 16.

If the request is to pass on information about a study to the patient, and to solicit the patient's permission for researchers to write to him/her about study participation:

- If you choose to pass on the request, please do it face-to-face, not by letter.
- For children you judge competent to decide about receiving written communication from researchers, please explain as usual and obtain their consent (and ideally also their parent's assent – the decision form has a section to record this). If this is not given, no information will be passed to the researchers.
- For children you judge NOT competent to decide about receiving written communication from researchers, please explain as usual and obtain a parent's consent AND the child's assent or at least lack of objection (in the latter case, please annotate the decision form accordingly). If this is not given, no information will be passed to the researchers.

The decision forms have a space for under-16s, summarizing this.

There's more information below, in the "More detail..." section.

What about patients who have been discharged from CPFT?

Such patients may be very important for research. As of Nov 2016, CPFT has approval from the

NHS Health Research Authority to contact patients via their clinician for up to 3 years following discharge (or otherwise as restricted by an individual study's ethics approval), without prior explicit consent.

What if a patient's clinical condition changes materially, relevant to their consent about research?

Suppose you are a clinician and your patient has a substantial change in clinical condition, such that their previous consent to be contacted about research should be revisited. An example might be the development of an enduring capacity-impairing condition such as dementia. In this situation, please consider checking their current consent status (you may obtain their research ID and consent mode from the Research Database Manager), and whether it should be changed (e.g. from GREEN to YELLOW). See also *"What about patients who lack capacity?"*, above.

FOR RESEARCHERS

I'm a researcher. How do I use the research database for epidemiological research?

The CPFT R&D team will provide you with assistance.

- First, you must be approved to use the Research Database.
    - You will require an honorary or substantive contract with CPFT, or a letter of access. If your contract with CPFT is an honorary one, or you are using a letter of access, your substantive contract must be with a CPFT research partner organization (usually within Cambridge University Health Partners). This is so that you are under a contractual (as well as professional) obligation of confidentiality, as it is likely that you will (with the patient's consent) have access to some confidential and patient-identifiable information.
    - You must have had appropriate information governance training from CPFT.
- Second, your study must be approved.
    - It must have any necessary ethical approval (via an NHS Research Ethics Committee [REC]), and NHS approval (via the NHS Health Research Authority [HRA]), as well as any other (e.g. university) approval necessary. Suitable boilerplate text is given in the next section. However, note that epidemiological studies may not need additional approval, and will typically be covered by generic ethical approval for the CPFT research database and associated methods.
    - It must be approved by the Research Database Oversight Committee, including outline details of searches that you plan. (The reasons include the fact that certain very specific searches may have consequences for anonymity.)
- Third, you need access to a computer on the CPFT network. If you do not have secure remote access, you may use computers in the Library (Block 14, Ida Darwin Hospital, Fulbourn, Cambridge CB21 5EE).
- Fourth, conceive and run your query on the database. If you need help with this, talk to the Research Database Manager. (An audit log will be kept of your queries, to ensure they don't deviate from your study's purpose and approval.)

I'm a researcher. How do I go about recruiting patients for my study?

The CPFT R&D team will provide you with assistance.

- The starting point is exactly as for epidemiological studies (see above). Note these differences:
    - The ethics approval should include details of appropriate notifications to clinicians, such as notifying a patient's GP (± CPFT clinician) in advance if the patient is going to participate in a clinical trial (including all CTIMPs).
    - Your ethics approval should include the fact that you plan to recruit via the CPFT Research Database. Suggested boilerplate text is given below. ***If you have an existing study and you want to recruit by this method,*** check with your sponsor and REC as to whether you need to modify your ethics approval first.

[For CPFT epidemiological research, if ethical approval required at all: note the generic approval for the CPFT Research Database.]	Data will be obtained from the Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) Research Database, which contains anonymous information derived from CPFT clinical records.
[For CPFT patient contact research, with direct approach preferred.]	One method of recruitment will be via the Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) Research Database, which contains linked anonymous information derived from CPFT clinical records. The database will be queried to find patients that are likely to meet the study's eligibility criteria, yielding a list of research identification numbers. This list will be submitted to the CPFT Research Database Manager, who will enter them into an automated system that can identify the patients. For patients that consent (either having previously consented, or having given specific consent after being approached by their primary clinical team), and only those patients, the Research Database Manager will provide the patient's details to the research team, and authorize them to view the patient's CPFT clinical records and to contact the patient to discuss participation in the study. Study participation itself, or provision of any additional information, would require the patient's further consent.
[For CPFT patient contact research, with approach via clinicians preferred.]	One method of recruitment will be via the Cambridgeshire & Peterborough NHS Foundation Trust (CPFT) Research Database, which contains linked anonymous information derived from CPFT clinical records. The database will be queried to find patients that are likely to meet the study's eligibility criteria, yielding a list of research identification numbers. This list will be submitted to the CPFT Research Database Manager, who will enter them into an automated system that can identify the patients. A template form requesting further information about the patient will be attached. Each request regarding study participation will be passed to the patient's clinical team. For patients who are approached by their clinicians and who give specific consent, and only for those patients, the Research Database Manager will provide the patient's details to the research team, and authorize them to view the patient's CPFT clinical records and to contact the patient to discuss participation in the study. Study participation itself, or provision of any additional information, would require the patient's further consent.
[For all CPFT studies]	CPFT's Research Database system and related methods for patient recruitment have separate ethical approval (Research Ethics Committee references 12/EE/0407, 17/EE/0442).
[For **multi-site** studies, involving recruitment of	One method of recruitment will be via NHS Trust research databases, each approved and operated by the relevant NHS Trust. The database will be queried to find patients that are likely to

participants from other sites in addition to CPFT.]	meet the study's eligibility criteria. For patients that have specifically consented to the following (either in advance or having been approached by their primary clinical team), the Trust will provide the patient's details to the research team and authorize the research team to view the patient's records and to contact the patient to discuss participation in the study. Researchers will not be given identifiable information without the patient's specific consent. Study participation itself would require the patient's further consent.

- Conceive and run your query on the database. (For example, you might look for males aged 18–40 with a primary diagnosis of depression.) This will produce a list of research ID numbers. **Don't forget appropriate age boundaries!**
- The Research Database includes relevant consent fields, so you can restrict your search to patients with a YELLOW, GREEN, or UNKNOWN consent mode, and view any free-text special requests by the patient (e.g. "no scanning studies"), even at this (anonymous) stage. It's better to filter out patients in the RED mode at this stage; if you don't, the software will filter them out later. Likewise, any special requests will also be passed to you later as part of the approval process. Other consent-mode fields (e.g. consent to contact after discharge; maximum number of research approaches per year) may also be relevant, but the software will also apply automatic filters based on some of them.
- Next, decide whether you prefer to write to patients directly, or write to their clinicians. If you need significant clinical involvement, or clinical information beyond that which you yourself could obtain (with permission) from the clinical records, choose the latter. If you choose the latter, create a PDF form that you would like the clinician and/or patient to complete and return to you.
- You will need to supply a short leaflet about your study. This does not have to be the full Patient Information Leaflet (PIL) – particularly if the PIL is very long. You will give the patient the full PIL anyway prior to consenting, if they let you contact them. The initial leaflet should be brief, clear, and compatible with your ethics approvals.
- Finally, send the list of research ID numbers to the Research Database Manager, specifying your preferred way of contacting the patients. You will need the form titled ***"Request From Researcher For Patient Contact Details".***

You must explicitly confirm if you wish to contact:

- patients under the age of 16;
- patients who lack capacity;
- discharged patients.

If you prefer to write to patients directly, you will get details back for every patient that consents to you writing to them and seeing their CPFT records. If you prefer to write to clinicians, you will also get your own form (completed) back for every patient whose clinician agreed to ask them and who consented.

When you write to the patient, please include the following standard text:

> Thank you for your permission to write to you. You were identified as someone who might be suitable for our study via Cambridgeshire & Peterborough Foundation Trust (CPFT). You kindly consented to your details being passed to us, and for us to have access to your CPFT records. We'd like to remind you that you're always free to say yes or no about taking part in research, and any choices you make about research won't affect your NHS

treatment in other ways. If you ever want to change your mind about researchers contacting you directly, please write to the CPFT Research Database Manager, who will help you to do this. The address is: FREEPOST CPFT RESEARCH DATABASE MANAGER.

I'm a researcher. May I request patients for the same study more than once?

Yes. If you make a repeat request for the same study, the exact same procedure is followed (leading to auto-acceptance, auto-refusal, or consultation with the patient's clinical team). This is true even if you include research ID numbers that you requested last time.

Such a request from researchers may sometimes be appropriate when a study is long-running and the clinical situation for an individual patient, or their preference, may have changed.

However, please **cross-check the research IDs in advance** against prior authorizations for your study (the Research Database Manager can assist with this if necessary) to avoid re-requesting details of patients who've already consented to you contacting them, and **cross-check the patient's details on receipt of permission,** to avoid approaching the same patient twice as if afresh.

Likewise, you must not re-request permissions rapidly, because this would overburden patients and/or clinicians for any requests that turn out to involve the YELLOW mode (approach via the clinical team).

What should researchers know about confidentiality, publication limits, and data sharing?

All researchers are under a strict obligation to keep patient-identifiable information confidential and secure at all times. In particular:

- Patient-identifiable information may not be disclosed outside the research team without prior specific consent from the patient.
- For patient-contact research, your data handling procedures will also be subject to REC approval.
- For epidemiological research using CPFT's generic research ethics approval: you may publish your findings freely EXCEPT that you may not publish, or share outside your research team, any information that might inadvertently identify a patient or be recognizable by an individual patient (for example, extremely rare combinations of diseases, or free-text information, that might lead to inadvertent identification). Give sufficient detail in your project application regarding data extraction and publication that the Oversight Committee may be assured of this.

You must store data securely and for as long as is required under UK standards (see e.g. the Department of Health's "Research Governance Framework for Health and Social Care" and its Annex, and Medical Research Council guidance, for further information). You must conform with information governance policies at CPFT and at your institution (if that's not CPFT).

Enquiries from drug companies and other commercial or external organizations

Drug companies or other external organizations may seek to sponsor studies within CPFT. What special considerations apply?

- You should seek approval for such studies through the usual process (i.e. applying to the CPFT Research Database Oversight Committee and the appropriate Research Ethics Committee), making clear the exact involvement of any external (including commercial) organizations.

- If a company is seeking summary information in advance of considering a study (e.g. “how many patients with treatment-resistance schizophrenia do you see in CPFT?”), you may submit a Research Database project application in the “feasibility” category, specifically stating your aim to provide this information to an external organization, with a view to subsequent patient-contact research. If approved, you may then use the Database to extract and provide this information. If small numbers of patients are involved, you should report “fewer than 10” rather than a specific number below 10.

Avoiding deadlock: CPFT and Research Ethics Committee approval for patient-contact studies

If HRA/REC approval is conditional upon CPFT approving use of the Research Database, then CPFT will examine applications and (if appropriate) approve them in advance of HRA/REC approval, with the condition that full HRA/REC approval is obtained before work starts.

What if I inadvertently see patient-identifiable information?

Please notify the Research Database Manager immediately if you see identifiable information about a patient or their family in the Research Database. If this occurs, it is likely because a nickname, alias, mis-spelling of a name, or family member’s name has not been entered correctly into the clinical record. Following correction, the identifiable information will disappear at the next update of the research database. Please destroy any patient-identifiable information you might have obtained.

MORE DETAIL ON THE METHODS USED

What major legal and ethical principles govern the research database?

The specific methods used by CPFT were developed from those in use at South London and the Maudsley NHS Trust in 2012 (themselves approved by the NIGB, ECC 2-08/2010). They were then modified to allow methods by which clinicians (but not researchers) could contact selected patients without prior consent. CPFT's methods have been approved by the relevant REC (references 12/EE/0407, 17/EE/0442), and were discussed with the NIGB. Specific points of principle are set out below.

Regarding data protection:

- Clinical staff providing care may examine *their* patients' clinical data. Obviously, they may use these for clinical purposes. But they may also identify and contact patients to ask them about participation in research (source: [1]).
- Research staff may *not* access identifiable patient data without consent [1].
- Clinicians may, however, ask *their* patients for explicit permission for research staff to access their data.
    - Note that merely holding an NHS honorary contract does not mean that you are an individual patient's clinician. Clinical staff who are not providing care to an individual patient do not have a right to access their data.
- The only exceptions to the rule of research staff not accessing patient-identifiable data without consent (excepting dire emergency situations in the public interest) involve Section 251 of the NHS Act 2006. The NIGB ECC may authorize research studies involving patient-identifiable data without consent when this is in the public interest and there are no feasible alternatives.
    - The CPFT Research Database system does not need approval under Section 251 as researchers cannot see patient-identifiable data without consent.
    - The Research Database Manager is not part of the clinical team, so the Research Database Manager may also not see any patient-identifiable data unless the patients have consented (patients are asked to allow the Database Manager access to minimal information as part of recording their consent mode and/or returning paperwork via the Database Manager). As a consequence, to avoid needing Section 251 approval (which is discouraged and administratively complex), initial requests to clinicians regarding patients who've not specifically consented are made electronically. For consistency and simplicity, requests to clinicians for patients who have consented are also made electronically.
- The Data Protection Act 2018 [8] requires those responsible for clinical records (e.g. clinicians and NHS Trusts) to inform patients if their records may be used for research, and mandates that patients may dissent to this. It imposes additional restrictions, too. However, the Act does not apply to data that have been effectively anonymised [2]. The Information Commissioner's Office make it clear that the same data may be anonymous to one user, and identifiable to another. Their specific example is when data held by a first party has obvious identifiers (name, address, etc.) removed and an arbitrary code assigned, before being passed to a second party. Then the second party does not hold personal data [3], because they cannot identify an individual, except by passing the code back to the first party. This is exactly analogous to the CPFT Research Database: from CPFT's point of

view, it is patient-identifiable, but from a researcher's point of view, it is anonymous.

Other, locally agreed principles include:

- First contact from researchers to patients is by letter, not by telephone (to avoid cold calling).
- Contact from clinicians to patients can be by any method of the clinician's choosing, but typically by letter (to minimize workload). However, face-to-face contact is required for children and patients who lack capacity to consent.
- As capacity to consent to research studies can fluctuate, the Research Database method may involve contact with patients who currently lack capacity, and/or their clinicians. Consequently, such patients are included by the search methods, and then (in general) actively excluded by a variety of subsequent means (including judgements by their clinicians and/or members of the research team). Other principles apply to studies specifically concerning those without capacity; see below.

Why is consent sought for researchers to access the full clinical record?

Clearly, access to CPFT medical records might not be necessary for all research studies. However, consent must be sought, for the following reasons.

- *The n=1 problem.* Suppose that a researcher was to use the research database to generate a query that yielded a single patient (suspending disbelief for a moment and imagining that this got past the approvals process). The researcher could see a great deal of information about that patient in the research database, but it is anonymous. However, as soon as the researcher obtains that patient's details through the identification process, the researcher would be aware of a great deal of clinical information about that identified patient.
- *The n>1 problem.* This problem is not restricted to very small result sets. Suppose that a query returns details for 100 anonymous patients, but that 99 are in the age range 40–60 and 1 is aged 20. As soon as the researcher meets the 20-year-old, the researcher potentially knows detailed clinical details about that patient. This is a contrived example, but comparable situations are realistic, and are at the edge of a grey area of situations in which clinical knowledge about identified patients may be gained by the researchers inadvertently.
- *The sensitive query problem.* Additionally, we don't want patients to be surprised by researchers' knowledge of their clinical details by virtue of the specificity of their query. Imagine that a researcher wishes to recruit victims of sexual abuse for a study. A bland descriptor such as "researchers will know that you met their criteria" does not necessarily convey the fact that in this situation, the researchers would know that you were sexually abused, even if they could not otherwise identify which record was yours in the database.

A general solution, therefore, is to ask for patient's consent for researchers to see the whole CPFT clinical record (from which, additionally, the Research Database is derived). If such consent has been given, there should be no surprises.

Researchers are therefore given CPFT hospital numbers for patients that have consented, and, if they have been approved to access the CPFT clinical records system, may examine the CPFT record for such patients. Of course, researchers may not necessarily need to examine the clinical records in detail, and researchers will have no access to patient-identifiable detail unless the patient has consented.

Researchers will not be given research ID numbers. There are a couple of reasons:

- Firstly, although a research could probably establish the NHS-to-research-number mapping

for an individual patient once they have permission to view their NHS records, this would labour-intensive, and we don't wish to permit or make it easier for researchers to maintain information to identify patients in the Research Database for any future work.

- Secondly, providing information about many NHS-to-research-number mappings would aid in attacks on any algorithm used to create them, which we do not wish to encourage.

What information can the research database manager see?

The Research Database Manager and their team need to be able to check that researchers and research studies are approved, and to adminster the system for the entire Trust. They are therefore part of CPFT R&D, not part of a clinical team.

The system needs to be able to "de-anonymise" data and pass requests on to patients and/or their clinicians. However, the Research Database Manager and team, not usually being part of clinical teams, may not see patient-identifiable data without patient consent. This is a particular problem when the system is being asked to contact patients with an UNKNOWN approach mode — the Research Database Manager isn't allowed to see their name and address.

Therefore, the electronic system automatically contacts clinical teams as necessary. For patients who have consented to direct approaches from researchers, the system provides patient contact details for the Research Database Manager to send to the research teams.

The Research Database Manager maintain administrative information such as each patient's choices about being contacted for research; patients are always specifically asked for their consent before the Research Database Manager can do this.

However, the Research Database Manager and their team cannot see clinical details (either in CPFT's electronic records via conventional patient identifying information, or in the research database via the research ID number); such access is simply unnecessary.

What are the general principles concerning research on those who lack capacity to consent?

Some research — such as studies of dementia — necessaily involves patients who cannot consent, and is to their benefit. The general principles governing such research in England [5] are:

- It is important that adults who lack mental capacity are given the opportunity to participate in research that might lead to innovations to improve their health and quality of life and that of others with similar conditions. To exclude them from any research would be discriminatory and would diminish their ability to participate as fully as possible in society. It would also prevent researchers making progress in the understanding of many disorders that can affect the brain, and in the care and treatment of those who have such disorders. However, such research requires special safeguards to ensure that this vulnerable group are protected when they do participate in medical research. Patients who lack capacity should be given the same opportunities to participate in ethically designed research projects as those who do not lack capacity but must not be put at unwarranted risk.
- The interests of the individual must always outweigh those of science and society. It must not be possible to conduct equally effective research with adults who have the capacity to consent. The potential benefits of the project should outweigh the risks: the level of acceptable risk depends partly on the possible benefit to the individual. (If no direct benefit is anticipated, the risks must be negligible.)
- Their participation needs to be agreed by someone who is independent of the study and who can assess the potential participant's interests in accordance with current legislation

and guidance. This person may be a relative, a carer or an independent representative. Views of those close to the participant should always be sought, unless this is not possible due to particular circumstances.

- If possible, the proposed study should also be discussed or communicated with the person themselves in a way appropriate to their understanding. A participant who lacks capacity should only be included in a study when there are no indications that he or she objects to this.
- The full regulations are complex and all research must satisfy the regulations for Research Ethics Committee approval. In brief:
- For clinical trials, governed by the Clinical Trials Regulations [7], in England:
    - The clinical trial must relate directly to a life-threatening or debilitating clinical condition from which a potential participant suffers.
    - Specific advance consent is valid, and advance refusal must be respected.
    - Otherwise, the patient's ***legal representative*** (who is a person independent of the trial, who by virtue of their relationship with the potential study participant [e.g. a relative] is suitable to act as their legal representative for the purposes of that trial, and who is available and willing to so act for those purposes; or if there is no such person: a person independent of the trial, who is the doctor primarily responsible for the medical treatment provided to that adult, or a person nominated by the relevant healthcare provider) should be asked about *the presumed will of the participant* and asked to give *informed consent*.
- For other studies, in England [5, 6]:
    - The research must relate to the condition impairing capacity, or its treatment.
    - Nothing should be done contrary to an advance directive or any other statement by the potential participant.
    - The patient's ***carer or consultee*** (who may be an unpaid person with an interest in the welfare of the potential participant, or failing that, a person who is independent of the project) is asked about *their opinion on the views and feelings of the participant* and asked to give *advice as to whether the participant would decline to take part if he or she had capacity*.
    - Someone who holds a Lasting Power of Attorney may be valid as a carer/consultee, but only if they are not being paid for it (so, for example, a solicitor holding an LPA cannot act as the carer/consultee for the purposes of research) [5, 6].

What are the principles for establishing whether capacity is present?

As a reminder, the Mental Capacity Act [6] states:

- A person must be assumed to have capacity unless it is established that he lacks capacity.
- [A] person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.
- [A] person is unable to make a decision for himself if he is unable—
    (a) to understand the information relevant to the decision,
    (b) to retain that information,

(c) to use or weigh that information as part of the process of making the decision, or

(d) to communicate his decision (whether by talking, using sign language or any other means).

Are the methods safe from "consent error" with patients lacking capacity?

What could go wrong? The two factors to consider are the likelihood of "invalid consent" being given (apparent consent without capacity to make the relevant decision), and the likelihood of harm to the patient if that were to occur.

- *Likelihood of "invalid face-to-face consent".* Face-to-face consenting and capacity assessment is, of course, not infallible. Nevertheless, it is relied upon both in clinical practice to take consent for procedures where the risks to the patient can be real and substantial. The Research Database methods carry no additional risks of "invalid face-to-face consent" than standard practice.
- *"Invalid consent" via letter.* The possibility of "invalid consent" being given without face-to-face capacity assessment is limited to the following situation: (1) the clinician is unaware of the loss of capacity; and (2) the clinician passes on a request about a specific study, or a RED/YELLOW/GREEN request, by letter; and (3) the patient does not have capacity to understand what he/she is being asked; and (4) yet the patient responds affirmatively ("yes" to a study or "GREEN"), signs, and returns the form. In this situation, one or more research teams, who are bound by strict confidentiality guidelines, may be given (a) access to the patient's medical records and (b) permission to write to the patient, based on the patient's signature indicating consent, when in fact they lacked capacity to provide such consent. We believe that such situations will be uncommon (in particular, the combination of 3 and 4 is unlikely), but more importantly, carries an extremely low risk of any significant harm to the patient.
- *Even if "invalid consent" were to occur, the consequent risks to the patient are negligible.* This is the most important point. The only things the Research Database system requests consent for are (a) permission for approved researchers, operating under strict confidentiality requirements, to view a patient's CPFT records; and (b) permission for researchers to write to patients. So, if a situation ever arose where "invalid" consent were to be obtained, the risk of harm is extremely low. Consent to research itself would always be obtained through a separate process, face to face, in which researchers assess capacity and follow appropriate legal and ethical requirements.

What are the general principles governing children's participation in research?

A minor is defined as someone under 16 for studies governed by the Clinical Trials Regulations. For all other studies, though the age of majority is 18, young people between the age of 16 and 18 are presumed to be competent to give consent [4]. Therefore, the definition of "children" used here is of someone under the age of 16.

Research involving children is important, and it would be discriminatory to exclude them from research recruitment procedures, but a key first step in any consent procedure for children is to establish their competence to consent [4]. Therefore, *"Would you like to be contacted about research?"* consent forms will only be given to children under 16 in a face-to-face manner by their clinical team, if the clinicians judge that they have the capacity to consent (and if they consent to the "GREEN" mode, parental assent should ideally be obtained, but this is not necessary). Otherwise, they will remain in the "YELLOW" mode, meaning that all approaches about research must go through their clinical team. (For individual research studies involving children, the methods

used for obtaining informed consent are a matter for approval by each study's Research Ethics Committee.)

The following are general principles regarding seeking consent for research involving children [4]:

- If the child is judged to be competent to consent, then:
    - If the child does not consent, treat that as valid refusal of consent.
    - If the child consents, then ultimately that can be treated as valid consent. However, ask the child for permission to involve the parents.
        - If the child does not wish the parents to be involved, attempt to persuade, but ultimately accept the child's consent if he/she does not want parental involvement.
        - If the child is happy to involve the parents, then attempt to obtain parental assent. If this is given, proceed. If not, then the competent child's consent is sufficient, but it may be unwise to proceed without parental assent.
- If the child is judged not competent to consent, then ask the parents for consent.
    - If the parents refuse, there is no consent, and research cannot proceed (excepting a court order regarding emergency treatments only available within a research programme).
    - If the parents consent:
        - If the child also assents, one may proceed.
        - If the child does not assent but does not actively object, one may proceed.
        - If the child actively objects, research should not proceed (excepting certain circumstances involving research-based treatments where no alternative is available).

Are the methods safe from "consent error" with children?

Yes. Whereas capacity can fluctuate, date of birth doesn't — while clinicians and researchers may not at first be aware that they are asking someone without capacity, they should always be aware that they are asking someone who is under 16.

The criteria expressed in the standard "under 16s" box are for the patient's signature (consent/assent) and either a parent's signature (assent/consent) or a clinician's signature confirming Gillick competence. The "patient + parent" combination covers the two situations of "Gillick competent + patient consent + parental assent" and "not Gillick competent + patient assent + parental consent"; the "patient + clinician" signature combination covers "Gillick competent + patient consent with refusal to involve parents". The phrasing is intended to place the patient at the centre of decision-making.

In the special circumstance where (a) the child is not Gillick competent, cannot sign, but does not object, and (b) the parents consent, then an annotation can be made on the form — a special "parent + clinician" case. Failure to do this simply means that that child will not receive information about research.

What should I do if I have concerns?

If the Research Database Manager cannot help you, please contact the CPFT Research Database Oversight Committee. This committee includes senior members of CPFT and the University of

Cambridge, among others.

CPFT CLINICAL DATA LINKAGE SERVICE (CDLS)

We have set up a Clinical Data Linkage Service (CDLS), starting in 2020. This lets us join or link information ("data") from the CPFT Research Database with other data. This is done within a secure "safe haven". In the NHS, Safe Havens are set up to link confidential patient information in a way that guarantees patients' legal and ethical rights. The CDLS has been approved by an independent NHS Research Ethics Committee.

Linking data means joining two or more different databases, so that information about a person in database 1 can be connected to information about the same person in database 2. This requires some shared information. For example, someone's GP record and their hospital record will share an NHS number. Linkage helps to improve the quality of information, and means that researchers can look at patients' healthcare in more detail. For example, linking mental health data to physical health data lets researchers look at how physical health and mental health are related. Although data is sometimes linked using "identifiers" such as the NHS number, these identifiers are then all removed. The information is fully anonymised (de-identified) before any researchers see it. Sometimes, data can be linked without using any directly identifying information.

The CDLS has linked data from the CPFT Research Database with a number of different UK databases, under appropriate approvals and information governance. The linkages are described at www.cpft.nhs.uk/research.

The main differences between CDLS studies and studies using only CPFT data (from the main part of the CPFT Research Database) are as follows:

- The CDLS applies the NHS National Data Opt-Out as well as the local CPFT Research Database opt-out.
- Patients are never re-identified or contacted based on linked information. To do so might violate the Caldicott "no surprises" principle.
- Identity information (e.g. names, NHS numbers) is sometimes used temporarily for linkage and sometimes is sent to external bodies (e.g. NHS Digital). Identifiable medical information is not transferred. The use of identity information is discouraged, and requires approval under Section 251 of the NHS Act. CPFT seeks to use pseudonymisation-at-source techniques wherever supported by the external organization.
- Some external organizations require analysis of de-identified linked data in specific very-high-security environments (e.g. the Office for National Statistics [ONS] Secure Research Service [SRS]), rather than CPFT's own secure computing facilities.
- Specific subsets of data are prepared for specific studies.
- CPFT must comply with additional requirements of any external organization whose data is being linked in, as well as CPFT's own Research Database requirements.

ABBREVIATIONS USED

CAG	Confidentiality Advisory Group of the HRA
CDLS	CPFT Clinical Data Linkage Service
CPFT	Cambridgeshire & Peterborough NHS Foundation Trust
CQC	Care Quality Commission
CTIMP	clinical trial of investigational medicinal product
ECC	Ethics and Confidentiality Committee of the NIGB
FAQ	frequently asked questions
HRA	NHS Health Research Authority (as of 31 March 2016, HRA approval is the centralized process for research involving the NHS in England)
ICO	Information Commissioner's Office
MRC	UK Medical Research Council
NIGB	National Information Governance Board for Health and Social Care (now defunct; replaced by the NIGC, then the CAG)
NIGC	National Information Governance Committee (of the CQC)
R&D	research and development
REC	Research Ethics Committee

SOURCES

[1] NIGB ECC FAQ at http://www.nigb.nhs.uk/advice/indentfaqs

NIGB advice regarding CPFT's methods provided in e-mails between Martin Frowd (NIGB) and Rudolf Cardinal (CPFT), June 2012.

[2] NIGB summary of legal framework at http://www.nigb.nhs.uk/advice/legalsumm.pdf

[3] ICO advice at http://www.ico.gov.uk/news/current_topics/what_is_personal_data.aspx

[4] "MRC Ethics Guide: Medical research involving children", at http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002430

[5] "MRC Ethics Guide: Medical research involving adults who cannot consent", 2007, at http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002409

[6] Mental Capacity Act 2005 at http://www.legislation.gov.uk/ukpga/2005/9/contents

[7] The Medicines for Human Use (Clinical Trials) Regulations 2004 at http://www.legislation.gov.uk/uksi/2004/1031/contents

[8] Data Protection Act 2018 at http://www.legislation.gov.uk/ukpga/2018/12