DATA PROTECTION AND CONFIDENTIALITY

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When carrying out your survey, you will need to ensure that you comply with the Data Protection Act 1998, and ensure that all responses are kept confidential**.** If you have not already done so, please ensure that you add research to your Data Protection Act registration, as one of the purposes for processing personal data supplied by data subjects.

You will also need to comply with the NHS Code of Practice on Confidentiality (2003), which incorporates the Caldicott Principles. You should take particular care to ensure that your use of patient data complies with these principles. In particular, you should be aware of the flows of patient data, and the issues which these present.

It is your legal responsibility to ensure that you meet any guarantees of anonymity or confidentiality made in covering letters and on the questionnaire.

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It will also be necessary to establish appropriate contractual arrangements with any contractors. Your trust's Caldicott Guardian and legal advisors should advise you on these matters.

Guidelines on the use and security of the data collected have been agreed by the Care Quality Commission (CQC) and the Survey Coordination Centre for the NHS Patient Survey Programme (NPSP). These guidelines will help to ensure that data are handled in a manner most in keeping with the spirit of the Data Protection Act 1998 and the Social Research Association and Market Research Society's *Guidelines for social research* (2005). They have implications for approved contractors and for NHS trusts conducting surveys in-house.

Information about the Data Protection Act 1998 can be found at the Information Commissioner's Office (ICO), and the Market Research Society provides further guidance on data protection.

Statements of compliance with data protection

Each NHS trust has a Caldicott Guardian responsible for overseeing the proper use of patient data. Under Section 251 approval, both the Caldicott Guardian and the person drawing the sample must complete their respective Sample Declaration Forms. The Sample Declaration Form constitutes a legal document whereby the trust authorises the sample to be transferred outside the trust. Sample Declaration Forms are different for each survey and can be found in their respective folders.

If you are conducting the survey in house…

Please send your Sample Declaration Form to the Survey Coordination Centre.

If you are using an approved contractor to run the survey on your behalf…

Please send your Sample Declaration Form to your contractor.

Approval under section 251 of the NHS Act 2006

Approval for surveys in the NPSP are sought under **Section 251 of the NHS Act 2006**. This approval allows the common law duty of confidentiality to be put aside in order to enable the processing of patient identifiable information without consent. The survey methods are reviewed by the Health Research Authority (HRA), and the Confidentiality Advisory Group (CAG) of the Health Research Authority grants a recommendation of support. Although the support is for the transfer of names and addresses to contractors, which does not apply to in-house trusts, it is still expected that in-house trusts follow the instructions in full.

Any deviation from the procedures described may lead to breaches in patient confidentiality, or could have implications for the comparability of data and its use by CQC and others, and would lead to action being taken against an NHS trust.

The recommendation of support does not cover the transfer of patient identifiable information where a patient has indicated **dissent** - by this we mean instances where a patient has indicated that they do not want their information to be shared for purposes such as patient surveys, or specifically stated that they do not want their details shared outside of the trust. It is strongly advised that trusts follow the same procedures as outlined in the recommendation for support from the CAG.

- Patients who have indicated they do not want their records used for secondary purposes (e.g. they have asked to be excluded from all surveys or they do not want their address details shared for any reason other than clinical care) must be excluded from your sample.
- This should be done using your local records.

Following the requirements of the Section 251 approval for the NPSP, trusts are required to process any opt outs from parents/carers as follows:

1. Any objection is to be recorded immediately and checks made to determine whether a mailing is underway. If a mailing is underway the caller will need to be advised that it might not be possible to prevent this mailing but assured that they will receive no future mailings.
2. People wishing to receive no further questionnaires can be identified with a flag/code/number on the mailing file.
3. When speaking to callers wishing to opt-out of future survey mailings, it is not appropriate to try and dissuade them from their intent. Even a well-intentioned discussion around the benefits of the survey could be perceived as applying pressure to participate. The benefits of the survey should only be mentioned by call-takers in response to queries from callers. If someone feels strongly enough about the survey that they initiate contact to object, this needs to be respected and acted upon immediately to avoid upset and misunderstanding.
4. Callers are advised they are being removed from the mailing list for this survey only and that if they wish to register their dissent against wider research participation at their trust, they need to speak to their trust (via PALS or the trust's Information Governance Team).

5. Additionally, you are required to discuss this issue with your Caldicott Guardian to ensure that any patients who have indicated that they do not wish to have their details shared for purposes such as this survey, yet may have sufficient address details visible in PAS, are not included in the sample that is submitted to the Survey Coordination Centre.

The Q&A section on the NHS surveys website contains further details about this.

Keeping patient mailing data and sample data separate

For patient confidentiality reasons, patient responses must never be matched to the patients that made them. The best way to ensure this is to store patient name and address details separately from sample information or survey response data.

If you are conducting the survey in house…

Once the sample has been returned from DBS and your sample is ready to submit, you need to remove patient names, addresses and postcodes from the sample file to a 'mailing file':

1. First, give each patient a unique number (a Patient Record Number, or PRN). You will use this number to link both files, the mailing file and the sample file. This number must be available and correctly matched on both the mailing file and the sample information file.
2. Second, split your file in two: one file will be the mailing file, and will have the PRN and all the patient's details (name, address); the other file will be completely anonymous and will only have the sample information (gender, year or birth, and so on)
3. You will use the mailing file to mail the survey via the postal service. This file must not leave your trust.
4. You will submit the sample file to the Survey Coordination Centre via a secure FTP.

If you are using an approved contractor to run the survey on your behalf…

You should send one single file containing both the mailing data and the sample data to your contractor via their secure way of data transfer. Your contractor will give you instructions on how to do submit the data via their secure FTP.

- You must **never send patient identifiable data via email.**
- This will constitute a breach of the Section 251 approval for the survey and will result in action by the CQC. Your Trust would also have to consider reporting the breach against your Information Governance Toolkit as a 'Serious Incident Requiring Investigation (SIRI).

After running the required checks, your contractor will separate the mailing data from the sample data.

Mailing questionnaires to patients

The envelope(s) used to mail out your survey materials to patients must not show any indication of the NHS trust name. This is because some patients may not have told family or friends that they have gone to hospital and, under Data Protection regulations, it is important that this information remains confidential to the patient.

Assurances of patient anonymity

It is important to ensure that any claims you make about patient anonymity are accurate; you are obliged by law to honour any statements that you make.

In most cases it is not accurate to tell patients that their responses will be anonymous: often, the person who receives the completed questionnaires may be able to match these responses to patient names and addresses. Instead, you should inform patients that their data are treated confidentially.

Patient confidentiality

It is essential that any patient survey is conducted in such a way that patient confidentiality is respected and given a high priority. The covering letters that accompany the mailed questionnaires inform patients that their name and address will never be linked to their responses. Furthermore, patients' responses must not be presented to anyone in a way that allows individuals to be identified. For example, if a patient is known to have stayed on a particular ward and his or her year of birth, sex and ethnic category are known from their survey responses, it might be possible to use this information to identify them. It would be unlawful to provide staff who may have had contact with respondents any information that would allow these respondents to be identified.

The following recommendations are made:

1. The raw data set should not be provided to any member of staff at the trust who does not need to view it, i.e. those who are not directly working on the project.

2 If data are to be presented to other trust staff only the aggregated totals for each question should be provided. If analysis by subgroup is carried out the results for any group consisting of **fewer than 30 respondents should be suppressed (replaced by a dash)**. The data should be presented as in the example Table 1 below. In this case, responses for the 'Mixed' and 'Asian' ethnic categories are suppressed (though the subgroup totals are shown):

Table 1

Ethnic category	Were you ever bothered by noise at night from hospital staff?		
	Yes	No	Total responses
	%	%	n
White	81	19	261
Mixed / Multiple	-	-	8
Asian	-	-	18
Black / African / Caribbean	79	21	52
Other	85	15	36

3 Do not present response information (including comments) in a form that allows an individual patient to be identified by the group receiving the information. For example, if you are presenting the results for a small number of patients, make sure that it will not be possible for the reader/audience to identify individual patients from their responses.

4 Free text comments do not need to be anonymised. A statement has been added to the questionnaire stating that any information provided in the free text box will be shared. **This does not apply if you are publishing the comments**. Any comments that are published must have any identifiable information removed such as a patients' or staff members' names, ethnicity, condition or health details.

5 The electronic file containing the patients' names and addresses should be stored securely (i.e. password protected).

Storing completed questionnaires

Completed questionnaires must be stored in a separate location to lists of patients' names and the questionnaires kept until 6 months after the end of fieldwork.

All mailing lists of patients' names and addresses should be stored on a separate computer to that containing survey data. Mailing lists of patients' names and addresses should be destroyed when the mailing process is complete.

Encryption of personal data

Any patient identifiable information sent between trusts and contractors must be in an encrypted format with password protection, following the requirements in the box below:

When you send data you must use…

- An encrypted session based on the Transport Layer Security (TLS) or Secure Sockets Layer (SSL) protocol (for example as with HTTPS or SFTP)
- A key size of 256 bits or greater

This will protect against any accidental or intentional interception during the transfer of patients' details.

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