



The BPSU Study Application Handbook

A guide to gaining ethics committee, NHS Trust R&D and National Information Governance Board approval for your BPSU Study.

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Overview

This document provides a step-by-step guide to getting approval for your study from the BPSU, Executive Committee (BPSU EC), the multi-centre research ethics committee (REC), the Ethics and Confidentiality Committee (ECC) of the National Information Governance Board (NIGB) and your local NHS Trust Research and Development (R&D) Department.

This guide includes a list of key contacts, abbreviations and a flowchart of the application process. Additional helpful documents which may be found on the BPSU website www.bpsu.inopsu.com are also referenced in this document.

Key contacts

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The Scientific Co-ordinator and Research Facilitator are the first point of contact for general enquiries, including operational and process matters, meeting dates and press releases. Initial enquiries about undertaking a BPSU study should be directed to the BPSU Office.

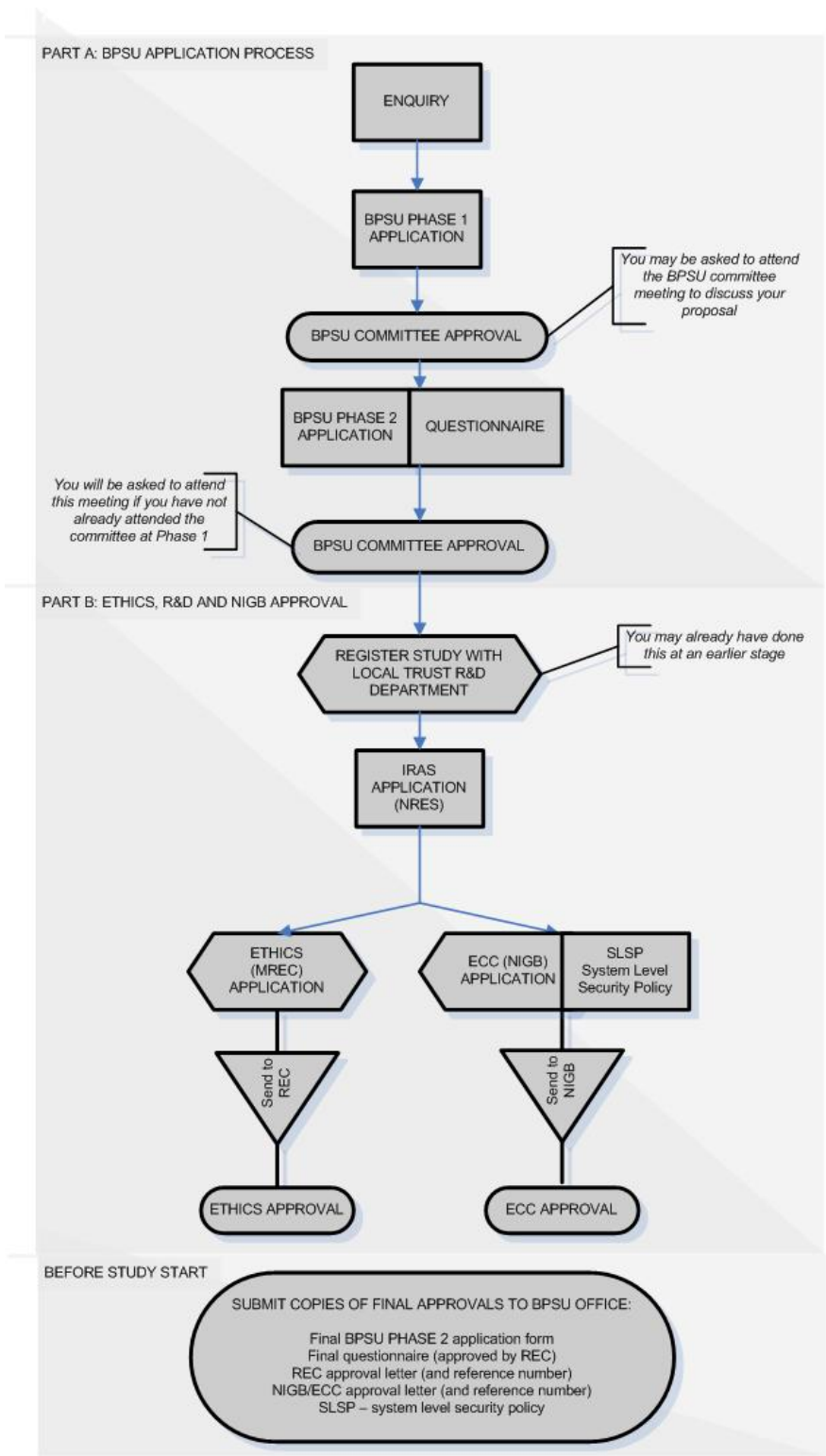
For advice on development of an application, such as details of surveillance methodology, ethics or questionnaires, contact should be made with the relevant medical adviser (for communicable or non-communicable diseases). Contact details for medical advisers can be provided by the Scientific Co-ordinator or Research Facilitator. Medical advisers correspond with applicants and convey the views of the committee regarding research proposals.

The Chair of the BPSU Executive Committee (EC) may be contacted directly, however this would not usually be necessary during the course of a normal application procedure.

Abbreviations

BPSU EC	British Paediatric Surveillance Unit Executive Committee
(M)REC	(Multi-centre) Research Ethics Committee
NRES	National Research Ethics Service
NPSA	National Patient Safety Agency
MRC	Medical Research Council
NIGB	National Information Governance Board
ECC	Ethics and Confidentiality Committee (of the NIGB)
PIAG	Patient Information Advisory Board (now disbanded)
Section 60	Health and Social Care Act 2001 provision for unconsented data use
Section 251	NHS Act 2006 provision for unconsented data use (superseding Section 60)
R&D	Research and Development (Department within NHS Trusts)
NHS	National Health Service
IRAS	Integrated Research Application System
PAC	Privacy Advisory Committee (Scotland only: advises ISD Scotland on data release) <i>PAC being established in Northern Ireland</i>

Flowchart of the Application Process



Contents ([click on section title to jump to relevant section](#))

Part B - After your study has been accepted by the BPSU	6
Section 4: Ethics, research governance and confidentiality	7
Section 5: Research Ethics Application.....	8
Section 6: The Integrated Research Applications System (IRAS)	11
Section 7: NIGB Ethics and Confidentiality Committee Application	15
Section 8: NIGB System Level Security Policy (SLSP)	17
Section 9: NHS Trust Governance (R&D Applications)	28
Appendix 5: Ethical Approval in Ireland.....	30

Part B - After your study has been accepted by the BPSU

Section 4: Ethics, research governance and confidentiality

Important note

Any applications to a research ethics committee (REC) or the National Information Governance Board (NIGB) should be delayed until after a study has been given final approval by the BPSU EC.

This is because the REC will only approve the version of the questionnaire and study protocol that is submitted to them; further changes should not be made to these during the study without seeking further REC approval to do so through a substantive amendment. Thus if the REC approves the questionnaire before the BPSU EC has approved the questionnaire and the BPSU EC then asks for changes, another submission to the ethics committee would be required.

Outline of BPSU Requirements for Applicants

The BPSU requires study applicants to

- obtain multi-centre **ethics approval**
- apply to the **Ethics and Confidentiality Committee of the National Information Governance Board** for approval under Section 251 of the NHS Act 2006 (to collect personal data about NHS patients without their consent)
- demonstrate compliance with the eight principles of the **Data Protection Act 1998**
- demonstrate compliance with the principles of the **Caldicott Report (1997)**
- detail measures to protect patient confidentiality and data security.

Section 5: Research Ethics Application

The Integrated Research Applications System (IRAS) was devised by a partnership of organisations involved in research ethics and governance to create a single portal through which ethics, R&D and NIGB applications for research studies could be undertaken. The idea of IRAS is that information is completed once only on the main ethics form and this is automatically duplicated on the other forms. The main form is sent to the ethics committee (REC). The other forms will have some additional questions to complete (these are not duplicates of the ethics questions so are not automatically completed) and then should be sent to the respective organisations that will review them (e.g. the NIGB).

The IRAS website is <https://www.myresearchproject.org.uk/signin.aspx>

Ethics Application Form (England, Wales, Scotland and Northern Ireland)

A BPSU study must be approved by a REC (that can approve multi-centre studies involving more than one site in **England, Wales, Scotland and Northern Ireland**) before it can commence.

The ethics form, accessed through IRAS, has several parts and is summarised in guidance notes on the IRAS site.

The BPSU Office is always happy to advise and review these forms before submission to the REC. We can also advise on which RECs favourably review BPSU applications.

There are some important answers to questions that you will be asked when completing the application form:

Why does the BPSU not seek individual patient consent for data collection?

You will need to explain to the REC and NIGB that the BPSU reporting methodology does not require patient consent and justify this by stating that to do so would reduce and bias case ascertainment, i.e. certain groups or types of individual might be more likely to refuse consent. In a study of a rare disorder in which the number of cases is small, refusal to contribute data by one or two individuals will result in under-ascertainment of cases and incorrect calculation of incidence. If all the refusals occurred in a single region or were from children who had less severe disorder, then this would 'bias' the results. To avoid bias, a BPSU surveillance study is undertaken without seeking individual consent and uses limited identifiable data to protect confidentiality.

Why does the BPSU not collect anonymised data only?

Data collection cannot be anonymous as you would not know if two clinicians, or two sources, had reported the same child. Minimal identifiers are required to match duplicate cases reported to the study. If a laboratory and clinician do not use the same reference number system, then more than one identifier might be needed for matching, e.g. date of birth and sex. A hospital reference number is usually required for the study investigator to refer to if they have a query for the notifying paediatrician. Some identifiers are also important pieces of clinical data in children, for example the exact date of birth is required to calculate age at diagnosis in days or weeks. In studies

involving adults, it might be acceptable to know the age to the nearest year, but in studies of neonates or children, this is unlikely to be sufficiently accurate.

How does the BPSU reporting system work?

Anonymised notifications are provided to the BPSU office by members of the Royal College of Paediatrics and Child Health (RCPCH) using the BPSU 'Orange Card' which is sent out to all college members every month. This card has a list of disorders currently being studied and the clinicians ticks a box if they have seen a case or ticks 'nothing to report' if not. This is called 'active surveillance' as the card is sent out on a regular basis and a response is expected. The BPSU receives the card and informs the study investigator that a case has been reported and passes on the contact details of the notifying clinician. The BPSU records only the number of cases 'ticked' and does not receive details of any case. The investigator sends the 'anonymised' study questionnaire directly to the clinician reporting a case.

NB: No patient identifiable information is received from the reporting paediatrician by the BPSU.

What does the questionnaire contain?

The 'anonymised' questionnaire asks for clinical details of the case and for minimal identifiers. Questionnaires are structured so that the front page, which contains information only essential for case verification and de-duplication, can be separated from the remaining pages that contain clinical research data.

How many research sites are involved?

The 'research sites' are sites where the research team is based and data will be analysed. For most BPSU studies, this is only **one** site. NHS Trusts in which there are paediatricians reporting cases are not research sites. You will be asked to complete an R&D application for every research site, which will include seeking approval from the R&D Office, Caldicott Guardian and Data Protection Officer, so it is important to be clear about which of the sites involved in your study are designated research sites.

How will patient identifiable data be maintained securely?

Patient identifiable data must be held in a secure location (e.g. a locked cabinet in a locked room) and within secure electronic databases, e.g. using password, encryption, firewalls and/or other security measures. The NIGB will require details of institutional arrangements for secure electronic data handling, including data that are archived once the study has been completed.

How long will patient identifiable data be stored?

Secure archiving of patient identifiable data should occur once the study is completed and destruction of data should take place after a specified time period (currently the MRC recommends data archiving for 20 years to allow re-appraisal of research data and to safeguard against fraud: <http://www.dt-toolkit.ac.uk/resourceindex/data.cfm>)

Who is the research Sponsor?

The IRAS form will ask you about your Sponsor as all research studies require a sponsor. This is usually the NHS Trust in which the study is taking place but may be the funding body or research institution, it is not the BPSU. As it is sometimes a lengthy process to get the sponsor to approve and sign the form, it is worth alerting them early on to the study.

How am I allocated a REC?

On submission of the IRAS form, you will be contacted with a REC and meeting date. You can request specific RECs and this may be helpful if you wish to choose RECs that have previously reviewed BPSU or paediatric studies. Please contact the BPSU Office or look online at recent BPSU study protocols to find which RECs these are. Those with a particular understanding of BPSU methodology include Central London REC 1, Central London REC 2, North West 7, GM Central and the Scottish MREC

Ethics Application Form (Republic of Ireland)

In the Republic of Ireland, BPSU studies are considered as audit and applications for ethics approval are not required, however to be regarded as such, they must meet the following criteria:

1. All studies must receive ethical approval from the institution where the principal investigator is based. In addition, studies included in the BPSU must be passed by the UK National Governance Information Board-Ethics and Confidentiality Committee.
2. No personally identifiable information is collected on cases reported to IPSU or BPSU. Only minimal identifier information, to exclude duplication, is collected.
3. No additional investigations or therapeutic interventions are requested on cases reported to IPSU or BPSU.
4. Study data must be easily obtainable from normal clinical notes. No additional data is required from cases, or their carers.

BPSU studies have usually met these criteria in the past, but if you are in any doubt then please discuss your concerns with the Scientific Co-ordinator or Medical Adviser. The UK REC may enquire about ethical approval to undertake the study in Ireland and a copy of the waiver letter is therefore provided in Appendix 5.

Section 6: The Integrated Research Applications System (IRAS)

This section will guide you as to what is required by different questions and parts of the IRAS process but you will need to adapt responses so they are appropriate to your study.

The IRAS Filter

The first IRAS form to be completed is the 'form filter'. When you answer questions, new forms are generated that are applicable to your study, such as the NIGB application form. It is important to answer the filter questions correctly or else you may generate forms that you do not require, such as R&D Site Specific Information (SSI) Forms for multiple NHS Trusts, or you may incorrectly define your study as audit or outside the NHS, so not requiring REC approval.

This is how you should answer each question:

Question 1: Your study is research – YES

<p>1. Is your project research?</p> <p><input checked="" type="radio"/> Yes <input type="radio"/> No</p>

Question 2: Your study is either 'limited to the use of data' or 'other study' – ticking one or the other of these boxes would be correct and two different forms of Question 2a are generated as shown in the examples below.

Question 2a: Tick **NO** where tissue samples are involved and **YES** for the question to confirm that you will be using identifiable data. Identifiable data are patient data that are not fully anonymised as they contain items such as full date of birth, sex, ethnicity and partial/full postcode. You will be asked in Question 11 of the filter about use of identifiable data without consent.

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial or clinical investigation
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples, other human biological samples and/or data (*specific project only*)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

- Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? Yes No

b) Will you be taking new human tissue samples (or other human biological samples)? Yes No

c) Will you be using existing human tissue samples (or other human biological samples)? Yes No

OR

2. Select one category from the list below:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial or clinical investigation
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
- Study involving qualitative methods only
- Study limited to working with human tissue samples, other human biological samples and/or data (*specific project only*)
- Research tissue bank
- Research database

If your work does not fit any of these categories, select the option below:

- Other study

2a. Please answer the following question(s):

a) Will you be taking new samples primarily for research purposes (i.e. not surplus or existing stored samples)? Yes No

b) Will you be using surplus tissue or existing stored samples identifiable to the researcher? Yes No

c) Will you be using only surplus tissue or existing stored samples not identifiable to the researcher? Yes No

d) Will you be processing identifiable data at any stage of the research (including in the identification of participants)? Yes No

BPSU Study Handbook: Part B – After your study has been accepted by the BPSU

Question 3 and 3a: Tick the appropriate country for the site at which the **investigating team** is based. **Do not** tick all countries as the reporting clinicians are not considered to be researchers, only the lead investigator and team.

3. In which countries of the UK will the research sites be located?(Tick all that apply)

- England
- Scotland
- Wales
- Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- England
- Scotland

Question 4: BPSU studies should tick NHS R&D Offices, REC and NIGB only. This will generate a form for each of these. As there are no ‘researchers’ in individual NHS Trusts, then the R&D form will be for the lead investigator’s NHS Trust only.

Question 4a: Most BPSU studies should tick **NO** (unless using additional relevant data).

Question 5: BPSU studies should tick **YES** as data is being collected through NHS Trusts. If you do not tick yes, then your study will be deemed as non-NHS and not requiring ethics approval.

Question 6: BPSU studies should tick YES.

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
- Social Care Research Ethics Committee
- Research Ethics Committee
- National Information Governance Board for Health and Social Care (NIGB)
- Ministry of Justice (MoJ)

4a. Will you be seeking data from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS)?

- Yes
- No

5. Will any research sites in this study be NHS organisations?

- Yes
- No

6. Do you plan to include any participants who are children?

- Yes
- No

BPSU Study Handbook: Part B – After your study has been accepted by the BPSU

Questions 7 & 8: BPSU studies should (usually) tick NO.

Question 9: This will depend on the project. A supervisor usually takes responsibility for research governance if it is an educational project.

Question 10: This is usually **NO**.

Question 11: For BPSU studies, the answer is **YES** and this means that an NIGB form is generated and NIGB approval must be sought.

7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity? *The guidance notes explain how an adult is defined for this purpose.*

Yes No

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?

Yes No

9. Is the study, or any part of the study, being undertaken as an educational project?

Yes No

10. Is this project financially supported by the United States Department for Health and Human Services?

Yes No

11. Will identifiable patient data be accessed outside the clinical care team without prior consent at any stage of the project (including identification of potential participants)?

Yes No

15-2. Have you tested the acceptability of using patient identifiable data in this project without consent?

Yes No

Section 7: NIGB Ethics and Confidentiality Committee Application

ECC (NIGB) Application Form

BPSU studies require approval from the ECC of the NIGB to collect unconsented identifiable data.

HPA studies: Studies undertaken under the auspices of the HPA may be covered by HPA organisational Section 251 support (approval). Information about this can be found on the HPA website and you can enquire of the HPA representative whether a separate NIGB application is required for your study or whether existing HPA support under Section 251 applies to your study.

The ECC application process includes:

1. Completion of an NIGB application form on IRAS (this must be printed and sent to the NIGB)
2. Completion of a System Level Security Policy (SLSP) – the template is found on the NIGB website: <http://www.nigb.nhs.uk/ecc/applications/SLSP.doc>.

Approved applications are placed on the Section 251 Register, i.e. they are 'supported' under Section 251. Approved applications are reviewed/renewed annually and the implication is that an attempt should be made towards reducing the identifiable data collected or anonymising the data. As BPSU studies are short, most do not have to renew their Section 251 support. If studies are longer, it is usually sufficient to re-state the reasons why anonymisation is not practicable during the coming year.

NIGB Form generated through IRAS

Sections 1 and 2 are completed automatically by data entered into the main ethics form. These concern the study administration and methodology. In completing the main ethics form, you should ensure that the information is suited to the NIGB form also by reading and checking these questions on the NIGB form. The NIGB form is printed off and sent separately to the ECC of the NIGB who do not see the ethics application.

An important question in Section 2 is whether the acceptability of using patient identifiable data has been tested. Tick '**YES**' as the use of patient identifiable data without consent in a study undertaken through the BPSU has been addressed. The BPSU has evaluated the need for a broad reporting base to achieve complete case ascertainment¹ and reviewed evidence demonstrating a risk of bias when consent is sought for population-based studies.²

¹ Knowles R, Smith A, Lynn R et al. What is the contribution of notification by specialists to the ascertainment of rare childhood conditions through the British Paediatric Surveillance Unit? *Arch Dis Child* 2006;91(Suppl 1):A86-88

² McKinney PA, Jones S, Parslow R, et al. A feasibility study of signed consent for the collection of patient identifiable information for a national paediatric clinical audit database. *BMJ* 2005;330:877-9.

Possible answers to Questions 19 and 20 in Section 2 are:

19. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

We are seeking information as a secondary user. There will not be any direct contact with the patient and all information will be derived from the patient's notes by the study respondent.

20. What is the potential for benefit to research participants?

Surveillance study only - there will be no direct immediate benefits to the patients whose data will be used in the study who will be managed according to standard national guidelines.

At Question 21 (Section 2), you should tick 'independent external review':

Science
21. How has the scientific quality of the research been assessed? Tick as appropriate:
<input checked="" type="checkbox"/> Independent external review

To justify this, state that the application has been submitted to the review process operated by the BPSU, which is a two-stage peer review process including submission of the study protocol and questionnaires and discussion of these by the Executive Committee (comprised of clinicians and lay members).

Fast-track application process

The NIGB produce a guide to their fast-track application and approvals process. Essentially, the paperwork to be submitted is the same but the secretariat will review it outside of normal committee meetings to enable approval to be expedited. The fast-track system is open to specific types of study and the ECC have agreed that they will review BPSU studies through the fast-track process. If there are concerns about a study, then it may be referred to the main committee for review but this has not yet occurred for a BPSU application.

When submitting paperwork to the ECC for approval, BPSU investigators should attach a covering letter stating clearly that this is a BPSU study and that they wish it to be considered through the fast-track process. For further information about fast-tracking, please see the guide produced by the NIGB: <http://www.nigb.nhs.uk/ecc/applications/fasttrack.pdf>

Section 8: NIGB System Level Security Policy (SLSP)

Applications for approval under section 251 have to provide evidence that they have appropriate security arrangements. All applicants need to develop and submit a System Level Security Policy (SLSP). The SLSP describes in detail the confidentiality and security arrangements for the study. It includes those of the organisation (hospital Trust or university) within which the investigating team are based but is more specific than an organisational level policy. It also covers the data-handling, security and confidentiality measures throughout the whole duration of the study from data collection to analysis/onward disclosure. The link to the SLSP document on the NIGB website is:

Even if a study is not required by the ECC to submit an SLSP for approval, ***the BPSU requires all studies to have an SLSP and to submit a copy to the BPSU Office before study commencement.*** An important element of the SLSP is the description of data-flows within the study, particularly if more than one source is being used and matching on multiple identifiers is required.

The following sections describe different elements of the SLSP and provides a guide as to how the questions within it can be addressed using examples from previous SLSPs. If you require further examples or advice, please ask the BPSU Scientific Co-ordinator or Medical Adviser.

System Details

The first section of the SLSP asks for basic information about the study. The study is referred to as the 'system'; essentially it is being considered as a 'system' for secure and confidential data-handling.

- 1. The System shall be known as <<INSERT TITLE OF STUDY>>**
- 2. The System's responsible owner shall be <<INSERT NAME OF PRINCIPAL INVESTIGATOR>>**
- 3. The System's Caldicott Guardian or Data Controller shall be <<FOR THE MAIN RESEARCH SITE/BASE FOR THE STUDY: NAME OF CALDICOTT GUARDIAN (FOR NHS TRUSTS) OR DATA PROTECTION OFFICER (FOR UNIVERSITIES/OTHER RESEARCH INSTITUTION)>>**

System Security

The next section of the SLSP checks what organisational and local system level policies are in place to ensure data security. The document leads you through electronic and physical security measures. These include how data are submitted, stored and processed, matched to duplicates, analysed and archived after the study. It is important to consider if encryption or passwording will be required for e-mail correspondence or database extracts.

Team members who have access to the data should be named and their employment contracts should contain appropriate confidentiality clauses. All staff should be trained in confidential data-handling. The electronic standard BS7799 / ISO 27002 is the standard for the NHS firewall and university institutions should state whether they are already compliant or working towards compliance.

Examples of suitable information to provide are given in italics below each of the questions. Whilst it is not necessary to have all the arrangements detailed here in place, it is essential to be clear about what measures have been taken to ensure security of data. The ECC will take into account the adequacy of the whole system with regard to the specific study and advise if additional measures are required.

4. Security of the system shall be governed by the corporate security policy of ...

(Note - reference the lead organisation including identity of the relevant document).

Example: 'Security of the system shall be governed by the corporate security policy of XYZ NHS Trust/ University available from ... '

5. The System's responsible security manager shall be

(Note - lead individual responsible for accrediting the system's security implementation)

Example: 'The system's responsible security manager is XXX (Manager of XYZ Information Systems Unit).'

6. The security manager duties shall include.....

(Note - list expected responsibilities – remember also relevant issues of security sign-off / accreditation and staff security awareness and training)

Example: 'S/he is the individual responsible for:

- *Accrediting the system's security implementation*
- *Maintenance of the IT network including firewall and virus protection*
- *Security sign-off/accreditation*
- *Staff security and training'*

7. The System shall incorporate the following security countermeasures....

• **Physical security measures (E.g. secure room, cabinet, etc)**

Example: 'Paper records consisting of the front and clinical data sheets of the questionnaire will be stored separately in two locked cabinets and linked only by unique BPSU and study case codes.'

• **Logical measures for access control and privilege management**

Example: 'The locked cabinets are in a room that is accessible to and locked/requires a keycode to enter at the following times...'

• **Network security measures (E.g. firewalls, network segregation, etc)**

Example: 'The network is protected by the institutional firewall, which limits external access to computers on the network. The Information Systems Unit is in regular contact with computer security teams who oversee IT security throughout the organisation. Specific security measures which have been implemented include:

1. *Firewall*
2. *Virus protection*
3. *Password protection*
4. *Locked rooms/cabinets*
5. *IT disposal policy'*

• **Other (including authentication or certification arrangements, security testing, and audit)**

(Note - list according to their nature i.e. technical, operational, procedural and include reference to standards used where these are known.

Example: 'The computer and network are bound by XYZ NHS Trust/University policies which cover data protection, connection to the network, appointment of custodians of computer systems and network administrators as well as computer security incident reporting procedure. Additionally, local policies exist covering computer accounts, disposal of equipment holding sensitive information and security of data. XYZ is compliant with/ working towards compliance with BS7799/ISO 17799.'

System Management

The following section requires consideration of who develops the system and takes responsibility for its day-to-day running, as well as arrangements for monitoring, checking and dealing with breaches in the system. If members of the study team are based on different sites, how can data transfer be minimised and if required, how will data be encrypted and protected for transfer between sites? An example of a typical problem, is that a clinician may send disclosive information in an e-mail. Ensuring that the information in this e-mail is then deleted to prevent wider disclosure or 'leakage', and providing advice to the clinician about future e-mail contacts is important. Another possible situation is where a study employee's contract comes to an end, in which case passwords and protection on the system should be reviewed and appropriate changes made. Not all problems with the system can be foreseen, but appointing a named system manager responsible for addressing any issues that do occur is essential.

8. The System shall be developed / provided by

(Note - if the system is developed or provided under commercial contract, then the relevant contract schedules that bind the contractor to the lead organisation's corporate security policy and to this system level security policy should be referenced)

<<PROVIDE NAMES OF STUDY TEAM MEMBERS OR ORGANISATION DEVELOPING PART OR ALL OF THE SYSTEM>>

9. The System shall be implemented by, maintained by

(Note - under what arrangements? Include responsibility for relevant aspects of security configurations. Also, identify the conditions applicable for the repair / replacement / disposal of equipment or media that may contain patient identifiable data)

<<PROVIDE NAMES OF STUDY TEAM MEMBERS OR ORGANISATION IMPLEMENTING AND MAINTAINING THE SYSTEM>>

10. The System shall be shared or used by the following organisations.....

(Note - record all participating bodies (NHS or otherwise) and their purposes)

<<PROVIDE NAMES OF STUDY TEAM MEMBERS AND/OR ORGANISATIONS INVOLVED IN USING THE SYSTEM>>

System Design

The SLSP asked for an illustrated flowchart of data flows and links in, out and around the system. As a starting point, it is useful to describe the BPSU system of surveillance, followed by specific details pertaining to dataflow within the study.

11. The System shall comprise

If the system is paper based, please describe the elements of the system, and paste a flowchart at end of the SLSP.

For electronic based systems please: -

i Describe the system and paste a simple diagram at the end of the SLSP, showing the local network that will house the system. This diagram should show the device(s) (E.g. file server) where the data will reside, links to any wider network clouds (E.g. site LAN, Internet and / or any other external networks), and any relevant firewalls / gateway control devices.

ii Describe the means by which unauthorised access to the system and its data will be prevented.

Example: 'The study complies with BPSU policy on data handling and data storage. Individual steps in the data-handling process are:

- BPSU office receives an 'orange card' indicating that a case of X has been seen by a clinician
- BPSU office informs the study applicants – <<NAME>> - that a case has been notified to them by a clinician
- The study applicants send a questionnaire to relevant clinician for completion

- *On receipt of a completed questionnaire the study applicants detach the front sheet of questionnaire (containing patient identifiable information) from the clinical data sheets of the questionnaire (containing research data)*
- *The front sheet and the clinical data sheets have a code assigned to the case it represents (BPSU case code)*
- *Front sheet and clinical data sheets are stored separately in secure locked cabinets and accessed only by the nominated study applicants*
- *Clinical data sheets contain research data only – they are linked to the corresponding front sheet (which contains patient identifiable information essential for the identification of duplicates and case verification) by means of the unique BPSU case code*
- *Patient identifiable information essential for the identification of duplicates and case verification will be removed from the front sheet once the process of case verification and de-duplication has been completed.*
- *Research data held on the clinical information sheets, including that required for de-duplication, are entered on computer.'*

Operational Processes

The following questions are asked about security relating to operational processes. Most questions provide a clear guide as to what arrangements should be implemented and described here. Some examples have been given but it is likely that you will need to repeat some answers in responding to different questions as there are many which appear to overlap.

12. The patient identifiable / sensitive data will be collected

E.g. by on-line means, paperwork through the post, data on CD, etc. Security arrangements need to be indicated. E.g. encryption standards for on-line / CD, follow-up arrangements (to identify lost post) for posted paperwork.

Anonymised notifications are provided to the BPSU office by members of the RCPCH using BPSU methodology i.e. the orange card. The BPSU informs the lead investigator, or their nominated staff, of the notifying member's details so the investigators can request further details. Members notifying cases subsequently submit patient data to the investigator and patient data are not held by the BPSU.

13. The data will be stored

i In what format (paper or electronic), where will it be stored and under what security controls?

Example:

- '1. Desktop computer holding electronic research data (clinical data sheets of questionnaire)*
- 2. Paper records consisting of the front and clinical data sheets of the questionnaire.'*

ii Any anonymisation process for patient identifiable / sensitive data will need to be described.

Example: 'Clinical data sheets contain research data only – they are linked to the corresponding front sheet (which contains patient identifiable information essential for the identification of duplicates and case verification) by means of the unique BPSU case code. Patient identifiable information essential for the identification of duplicates and case verification will be removed from the front sheet once the process of case verification and de-duplication has been completed. Front and clinical data sheets are stored separately in locked cabinets and are accessed only by nominated members of the study team.'

iii How (and under what security controls) will patient identifiable / sensitive data be loaded onto any file server / storage device

Example: 'Research data held on the clinical information sheets, including that required for de-duplication, will be entered on computer. Only anonymised clinical research data will be held on computer systems and cases will be identified by the unique study code and BPSU case code. Only nominated members of the study team will enter data and have access to the electronic database. The database will be password-protected and accessed through a computer and file-server that are also password-protected and accessible to named members of the study team only.'

iv Encryption standards to be employed for stored data. (Note - any device not in a secure area that will cache or store patient identifiable / sensitive data needs to do so on an encrypted drive, or within an encrypted container. Backup copies of patient identifiable / sensitive data also need to be encrypted).

v Note - for added risk protection applicants are encouraged to encrypt patient identifiable / sensitive data stored on devices located in secure areas. Although not a NHS requirement, it may be prudent that such a step is taken should it be perceived a possibility of equipment loss or other attack.

14. The data will be processed

For paper based systems please describe the data handling process (referencing any flowchart at the end of the SLSP)

For electronic based systems please: -

i List the user devices (desktop, laptop, PDA, etc) that will access and process the data.

ii State whether any of these devices will cache or store any of the data. If so, indicate the encryption standards to be employed. (Note - any device not in a secure area that will cache or store patient identifiable / sensitive data needs to do so on an encrypted drive, or within an encrypted container).

iii State whether remote access (over the Internet or otherwise) will be employed to access the data.

iv Describe measures in place to prevent the interception of transmitted data (E.g. standalone network, encrypted path, etc).

v Include any policy to prevent (or at the very least severely restrict) the copying of patient identifiable / sensitive data to removable media.

vi If applicable, include any policy to prevent the printing of patient identifiable / sensitive

data.

Authorised users

All those members of the study team with access to any study data should be named as authorised users of the system. If these users are based on different sites or within different collaborating organisations, issues such as data transfer, access and responsibility should be clearly laid down.

15. The System's authorised users shall be

(Note - Where the system is shared across multiple legal entities it is essential to identify how this security policy will apply to all parties and how its effect will be measurable)

Archiving and destruction of data

It is important to consider how long data will be stored, at which point any data can be destroyed and what arrangements can be made for secure destruction or archiving. Archiving of data should be available within the organisation in which the study team is based. There are guidelines from the MRC regarding the storage of research data after study completion to allow review of study documents if there is any question about research conduct or fraud [Reference: Medical Research Council. *Personal Information in Medical Research*. Available at

<http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002452>

16. When the system or its data has completed its purpose / has become redundant or is no longer needed, the following methods will be adopted to dispose of equipment, back-up media or other stored data

(Note - that operating system provided utilities such as 'erase' may not destroy unwanted data – it is therefore desirable to employ a commercial strength data shredder or equivalent to prevent unauthorised disclosure of sensitive data)

In accordance with Medical Research Council (MRC) guidance, paper records i.e. front and clinical data sheets will be held for a total of 20 years to allow adequate time for review or reappraisal and to allow any concerns about the conduct or consequences of the study to be resolved. Paper records will then be permanently destroyed by shredding. The exception to retention of paper records is patient identifiable information collected for the purposes of case verification and de-duplication. This will be destroyed once this process has been completed (usually within 12 months).

When the study is complete the following methods will be adopted to dispose of all stored data

- 1. Patient identifiable information, essential only for the process of de-duplication and case verification will be permanently destroyed once this process has been completed.*
- 2. Data entered on computer will be permanently wiped from the hard drive*

An arrangement must be made for regular audit and risk assessment, usually on an annual basis.

17. The System shall benefit from the following internal / external audit arrangements (Please list all arrangements)

18. The System shall be risk assessed every months

18.1 - By applying the risk assessment method.

'The system shall be risk assessed on an annual basis by <<NAME>> using an audit checklist (attached). Any deficiencies, including security or confidentiality matters, identified will be discussed with <<NAME AND ROLE>> and solutions implemented.'

18.2 - A risk management / security improvement plan shall be established to address all unacceptable risks.

Note -

- i Remember to take account of cross-boundary risk / dependency issues where the system is part of a larger service or multiple organisation arrangement
- ii Applicants are recommended to risk assess their system & process(es) at least every 12 months, using a recognised risk assessment method. A summary of this review should be forwarded to NIGB - ECC / DMsG.
- iii It is incumbent on the applicant to notify NIGB - ECC / DMsG of any proposed material change to the agreed SLSP, so that any additional security review can be carried out.

System Protection

You should consider what back-up arrangements are in place and how regularly the system will be backed up. Ensuring against data loss also includes contacting clinicians who do not return questionnaires to check if these have been lost in the post. Off-site back-up might be a useful method of minimising disruption due to electronic data loss. A simple procedure should be drawn up and specific study team members named to deal with a security or confidentiality breach.

19. The System shall benefit from the following resilience / contingency / disaster recovery arrangements.....

(Note - identify any separate plans and status)

Example: 'Electronic research data are backed up daily on the network and a copy of research data that have been entered is held securely off site on an encrypted drive. In the event of an electronic system failure the database system can be retrieved from the offsite facility and re-loaded in an appropriately secure system.'

20. In the event of serious disruption or total system failure, business continuity shall be provided by the following means

21. In the event of a security or confidentiality breach occurring the following procedure shall be followed

BPSU Study Handbook: Part B – After your study has been accepted by the BPSU

The lead investigator is the named owner of the SLSP and therefore has the responsibility for ensuring that it is adhered to by all members of the study team.

- 22. This SLSP shall be the responsibility of <<<NAME OF LEAD INVESTIGATOR>>>**
22.1 - Shall be reviewed on an annual/..... basis for its completeness and for relevant update.
(Note – it would be helpful to explain the relationship to the organisation’s corporate or other security policies)
- 23. The SLSP shall be available / distributed to**
- Through which secure means

Data Protection Registration

Consult your organisational Data Protection Officer to find out about the Data Protection Registration arrangements for the organisation in which the system is based.

- 24. Please confirm that your organisation has Data Protection Registration to cover the purposes of analysis and for the classes of data requested.** (Note - Please provide a copy of your Data Protection Registration.)

System Overview and diagram of data flows

It may also be useful to add a brief outline of the research objectives of the study, for example:

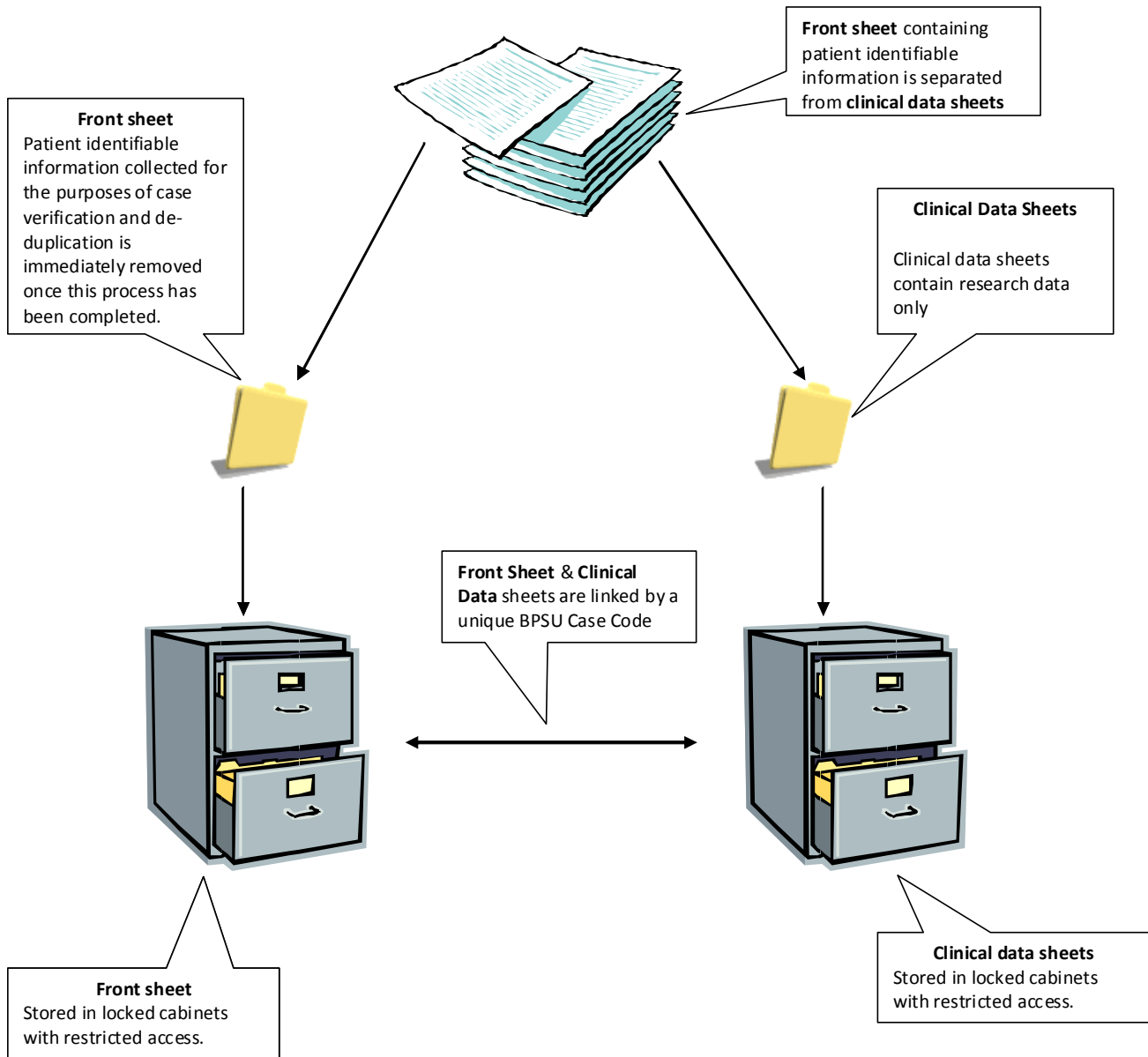
System Authorised Purpose

Specific aims of the project are to:

- 1. Determine the incidence of X in children under the age of 16 years in the UK.*
- 2. To report its distribution by age, sex and ethnic group.*
- 3. To report the clinical features at presentation.*
- 4. To report early clinical management and morbidity and mortality up to one year post diagnosis.*

Diagram of data flows within the system

An example of a diagram illustrating study data flows is provided below, however these will be specific to each study so will need to be redrawn for each system.



Good data management practices

1. Identifiable patient data

- Collect *only* the minimum amount of identifiable data required to undertake the project
- Ensure you can justify all the identifying information you are seeking

2. Data storage

- Store patient identifiable data (electronic and paper) such as postcode, hospital number and date of birth, in a way that is unlinked to the clinical data
- Long-term storage should be in a secure data archive

3. Data handling

- Make sure the access to the data (electronic and paper) is restricted to only those with direct involvement in the project
- Be aware of your hospital/research institution policy on data-handling

4. Data security

- Make sure that data are secured in a lockable cabinet and room
- Electronic storage – are the data on a networked computer, if yes who can access this
- Make sure the data files password protected. These should be changed regularly
- If data are not inputted into the system for more than 10 minutes the screen should revert to screen saver mode
- Make sure electronic data is backed up regularly – at least weekly, preferably daily

5. Risk assessment

- Consider possible leaks to the data flow system you have put in place
- Put into place arrangements to deal with confidential data when investigators are on holiday
- Confidential correspondence/data should be shredded at the earliest opportunity

6. Data exchange

- Data exchanged by email or disc should be anonymised. Where this is not the case, robust encryption methods should be used.

7. Use of other IT equipment

- The security principles outlined in 1-6 above apply equally to the use of laptops, USB devices and home computers

Section 9: NHS Trust Governance (R&D Applications)

Applying to NHS Trust R&D Departments

The only R&D Department that requires information about the study is that within the NHS Trust where the study investigator is based. An application **does not** need to be made to all NHS Trusts from which paediatricians notify cases as these notifying clinicians are not researchers (they are 'data collectors').

Site Specific Information (SSI) Forms do not need to be generated and sent to individual NHS Trusts. It is also not necessary for you to inform the NHS Trust when a clinician from that trust returns a form to you.

If your study is based in an NHS Trust, your local Trust will require information about your study and will have an R&D governance process for approving or registering your study. You should contact your local NHS Trust R&D department for information and they will probably give you local forms to complete. They may also wish to have a copy of your ethics and NIGB forms.

If your study is based in a university or non-NHS institution, then there will be different arrangements for registering your study. You will need to enquire locally about these. In many cases, the information that you need to gather for your ethics and NIGB applications will also help you to complete any local forms.

The BPSU Office is able to advise on ethics and governance applications.

Appendix 5: Ethical Approval in Ireland



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

National Office Health
Protection
Health Service
Executive
31/33 Catherine Street
Limerick

Tel: (061) 483347
Fax: (061) 464205

12TH. February 2010

Re: Need for ethical approval for participation in IPSU and BPSU studies.

To whom it may concern,

Paediatricians in Ireland provide data to surveillance studies organised by both the Irish Paediatric Surveillance Unit (IPSU) and the British Paediatric Surveillance Unit (BPSU). These studies require paediatricians to report on a monthly basis on any new case of a number of conditions listed on the IPSU and BPSU surveillance cards. Studies accepted for inclusion in both surveillance systems must meet a number of strict criteria, namely:

1. All studies must receive ethical approval from the institution where the principal investigator is based. In addition, studies included in the BPSU must be passed by the UK National Governance Information Board-Ethics and Confidentiality Committee.
2. No personally identifiable information is collected on cases reported to IPSU or BPSU. Only minimal identifier information, to exclude duplication, is collected.
3. No additional investigations or therapeutic interventions are requested on cases reported to IPSU or BPSU.
4. Study data must be easily obtainable from normal clinical notes. No additional data is required from cases, or their carers.

Based on the above, it is clear that IPSU and BPSU studies are a form of audit or surveillance, and do not represent interventional research. Therefore, provision of data to IPSU or BPSU studies does not require ethical approval from the institution where the paediatrician providing the data is based. Likewise, national level ethical approval is not required for IPSU studies, or participation in BPSU studies by paediatricians based in the Republic of Ireland, provided the criteria listed above have been.

Yours sincerely,

DR. KEVIN KELLEHER
ASSIST. NATIONAL DIRECTOR FOR POPULATION HEALTH – HEALTH PROTECTION
MEDICAL REGISTRATION NUMBER 19719