



The BPSU Study Application Handbook

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

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BPSU Study Handbook: Part A – Applying to the BPSU

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

BPSU Office

Mr Richard Lynn, Scientific Coordinator

Tel: (020) 7092 6173 Email: bpsu@rcpch.ac.uk

Ms Helen Friend, Research Facilitator

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BPSU Medical Advisers

Dr Rachel Knowles, Medical Adviser (non-communicable disease)

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BPSU Chair

Professor Alan Emond, Chair of the BPSU Executive Committee

Email: alan.emond@Bristol.ac.uk

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.

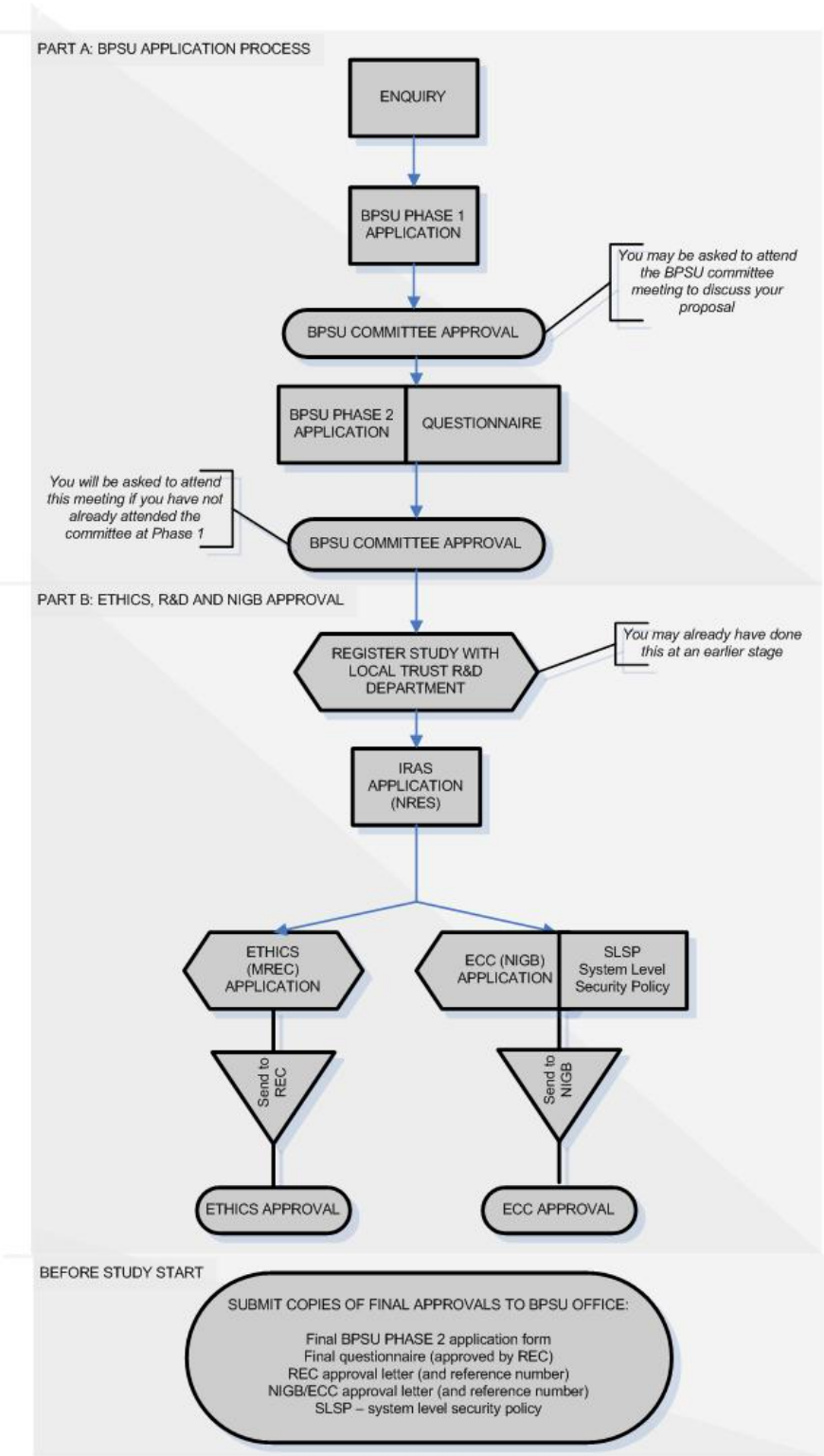
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Abbreviations

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>

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Flowchart of the Application Process



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Part A - Applying to the BPSU

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Section 1: Introduction - Making an enquiry to the BPSU

Introduction

Applications for inclusion of a study on reporting cards are considered by the BPSU Executive Committee (BPSU EC), which meets every two months. As the success of the BPSU methodology relies entirely on willingness of consultant paediatricians to complete and return the monthly Orange Card and study questionnaires, it is essential that BPSU studies are scientifically robust, adequately resourced and contribute to clinical and public health practice without putting too great a burden on reporting doctors. The application process has been developed to reflect these responsibilities. However the BPSU is also committed to assisting potential investigators (especially those less experienced in research methodology) with advice from the medical advisers.

There is a two-stage application procedure. Phase 1 (P1) is an outline application to establish if the study meets the BPSU criteria. Applications should be submitted on the P1 application form. If the study is approved by the BPSU EC, a more detailed Phase 2 (P2) application will be invited. Sometimes, applicants are invited to attend a BPSU EC meeting to discuss a revised P1 application if a decision cannot be made on the basis of the P1 documentation.

For P2 applications there is a longer application form, which should be completed and accompanied by any letters and questionnaires that are to be used in the study. An applicant is invited to attend the BPSU EC meeting to discuss their proposal and any queries that have arisen.

Unfortunately some applications will be unsuccessful, however good the research idea may be. Applications are most often turned down because the BPSU EC considers that the study is not suited to BPSU surveillance methodology.

Important considerations before applying

- Make sure your study meets the BPSU eligibility criteria (see next section). Please discuss your application with a Medical Adviser or the Scientific Coordinator beforehand if these are unclear.
- Study aims must be appropriate for national surveillance methodology, for example studies to establish incidence of a rare disorder or investigate variations in management
- It takes several months to complete the application process as revisions to the methodology and questionnaires are often required. Please make an enquiry directly to the Scientific Coordinator if you consider your study should be considered more urgently.
- Applications should reach the BPSU office four weeks prior to the BPSU EC meeting to allow Medical Advisers to comment on the application and revisions to be made prior to committee papers being sent out. You may choose not to ask Medical Advisers to review the application but this may result in the need for resubmission of a revised Phase 1 application. Deadlines for forthcoming meetings are available from the BPSU Office or on the BPSU website.

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- The study surveillance period is usually 13 months though this can be extended if it is felt that additional case ascertainment is required to allow for meaningful analysis.
- There is an administrative charge for undertaking a study through the BPSU and applicants should have appropriate funding in place by the time the study commences. The charge is currently £300 per month. The initial 13 month payment of £3,900 is required advance plus the cost of the protocol card production (approximately £500). Further details of these costs can be obtained from the BPSU Office.

Enquiring about undertaking a BPSU study

An enquiry about undertaking a study through the BPSU can be made by telephone, e-mail or in person to the BPSU office (Mr Richard Lynn, Scientific Coordinator, or Ms Helen Friend, Research Facilitator).

Any interest in a particular topic is recorded by the BPSU alongside the enquirer's name and contact details. The earliest enquiry about a specific topic is given precedence. If after 12 months, an enquiry has not been followed up by a Phase 1 application, then the BPSU Office would contact you to discuss removing your name from the enquiry list and to give you an opportunity to make a formal application before any action is taken.

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Section 2: The BPSU Phase 1 Application

Eligibility Criteria

Studies considered eligible to be undertaken through the BPSU are those where:

- The condition is a relatively rare childhood disorder or a rare complication of a more common disease of such low incidence or prevalence as to require ascertainment of cases on a national scale in order to generate sufficient numbers for study. In practice, the condition studied should have an expected incidence in the UK of *no more than 300 cases per year*
- The majority of cases are seen by a general paediatrician
- Cases can be easily identified and defined using a clear case definition
- Study data is easily accessible from the normal clinical notes
- Ethics approval is sought
- Approval to collect unconsented identifiable data is sought from the Ethics and Confidentiality Committee (ECC) of the National Information Governance Board (NIGB).

Examples of studies which would not be eligible for study through the BPSU are those which:

- are interventional studies
- require controls
- intend to use the case cohort to establish a disease register
- require direct patient/parent consent
- can be undertaken through a regional study
- can be undertaken through a study involving specialist clinicians only
- do not intend to seek ethical approval
- require long term follow up (greater than 2 years)
- require retrospective reporting
- involve any additional clinical intervention for reported cases (other than the results of diagnostic tests on samples collected during routine clinical management).

Outcomes from a Phase 1 application

Following consideration of the P1 application you will be contacted by letter to inform you of the outcome. The following outcomes are possible.

- 1) The P1 may be accepted and a P2 sought with/without specific clarifications
- 2) Further details and a revised P1 application may be sought before a decision is made
- 3) You may be asked to attend and discuss your application with the BPSU EC before a final decision is made
- 4) The application may be rejected.

NB: Acceptance of the P1 does not imply that the P2 will be approved.

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Completing the Phase 1 Application Form

Please read these details carefully before completing your P1 application. Failure to do so could lead to delay or even rejection of the application.

Prospective applicants are advised to submit their application at least twelve months before the proposed starting date.

Please check that you are using the current version of the P1 application form – the number and date of the current version is clearly stated on the BPSU website: <http://www.bpsu.inopsu.com/apply/phase1.html>.

Guidance on individual questions in the Phase 1 Application

1) Title of the study

Please provide the full title of the study. If you consider the condition to be sensitive, you may wish to omit the condition name from the study title. If and when the study is finally accepted onto the orange card, please be aware that the title which appears on the orange card has a maximum length of 65 characters. You may also wish to provide an abbreviation or acronym in the title is long.

2) Name of the investigators

Please list all investigators involved in the study, their job title, affiliation, and contribution to this study. Please also indicate clearly the principal contact for correspondence on this application, giving a full contact address, e-mail address and telephone number. Please indicate also the individual who is the designated Principal Investigator – this person will be responsible for research governance. At least one of the study investigators should be a paediatrician receiving the Orange Card.

3) Describe the study

This should explain a) the condition to be studied, b) a review of the background to the study proposal, including current knowledge about incidence and prevalence, c) the public health and scientific importance of the study, d) the study methodology, and e) the expected benefits of the study. This explanation should be easily understood by a lay person as the BPSU EC includes lay and medical reviewers.

4) Lay summary

This should be a short, clear summary of the condition and study in terms that can be understood by a lay person. This will be the publicly available summary that is put on the BPSU website if the study is accepted. The lay summary should be no more than 250 words.

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5) *Research questions/surveillance objectives*

Give a clear statement of the specific research questions that will be investigated by this study. These usually fall into the categories of 1) estimating incidence/prevalence, 2) describing the clinical features at presentation, 3) describing management and short-term outcomes.

It must be possible to address these questions

- a) Without direct contact with patients
- b) Without seeking investigations that would normally not have been undertaken by the paediatrician
- c) Without a comparison (control) group.

There does not need to be a long list of objectives. Consider how you will ask suitable questions in the questionnaires to gather information to answer your research objectives. Consider if you will have a sufficiently large sample size to address your objectives, for example regional variations in incidence could not usually be addressed by a BPSU study as the sample size would be too small. Please note also that the BPSU surveillance methodology is not suitable for identifying causal relationships, as the frequency of 'risk' factors identified amongst notified cases cannot be compared with the frequency of these factors in unaffected 'control' children.

6) *Case definition*

Give a clear case definition for the condition of interest. The **surveillance case definition** is a case definition which may be wider than the analytic case definition in order to ensure cases are not missed. For example, the surveillance case definition will often include suspected cases where confirmation is awaited. The **analytic case definition** describes very carefully those children who will be included in the study, i.e. will become your 'confirmed cases' for further analysis. Examples of case definitions used in previous studies are provided in Appendix 2.

In most studies, the age range for cases will include ages from birth up to but not including 16 years. Please consider if children in the upper age range will be seen by paediatricians for this condition.

7) *Expected numbers*

Please supply an estimate of the number of cases expected each year, i.e. yearly incidence rate, indicate the sources that you have used to estimate this. More than 300 cases per year (or 30 per month) would normally be considered too high for the BPSU due to the monthly volume of notifications and the fact that regional studies may be sufficient. Please note that there are often duplicate reports so that the number of cases reported might be considerably higher than the number of true cases included in the analysis.

Indicate the source of denominator data for calculating incidence. This is often a routine data source, such as the Office for National Statistics mid-year population estimates or birth statistics (www.statistics.gov.uk/). In Northern Ireland (www.nisra.gov.uk/), the republic of Ireland (www.cso.ie/) and Scotland (www.isdscotland.org/), other bodies collate these statistics.

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8) Alternative sources of reporting

Are there other clinicians besides paediatricians who are likely to see cases? If so, it is essential to consider whether to involve these clinical specialists in case reporting as this improves ascertainment and reduces bias. Please list any additional sources of case reporting that you are currently considering. Further details of these will be required in a P2 application.

9) Proposed level and nature of public involvement

You will be expected to engage with public or patient organisations relevant to your study as early as possible. Please give this consideration and state which organisations you would be likely to approach and how you would plan to engage with them. You may also ask for advice from the BPSU Office or EC.

10) Proposed territorial coverage?

The Orange Card is sent to paediatricians in England, Wales, Scotland, Northern Ireland and Ireland. If you wish to exclude any of these countries, then you must state this and provide justification for this. This will only be permitted in exceptional circumstances, for example when the Irish Paediatric Surveillance Unit is already conducting a similar study.

11) Funding, personnel and resource arrangements

Please confirm that you are arranging funds to undertake the study, even if these are not yet confirmed. Please name any bodies to which a grant application has been submitted or for whom one is being prepared. If funding is already in place, please state whether this is from a commercial source or whether you are personally in receipt of funds to undertake the research. If funding is from a commercial source, you may be expected to demonstrate, for example through a contract with the funders, that this will not influence the reporting of results.

12) References

A short list of any references relevant to the application should be included. If possible, attach copies of any papers which are not likely to be electronically available to the medical advisers.

Covering letter

Please attach a signed covering letter from the main contact/principal investigator for the study.

Supporting letters

Please attach any letters of support that you consider relevant for the committee to consider, for example award letters from funding bodies or letters confirming support by collaborating partners.

Signature

An electronic version of the application can be submitted directly to the BPSU Office at bpsu@rcpch.ac.uk at least 2 weeks before the BPSU EC meeting. A signed paper copy must also be sent to the BPSU office.

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Section 3: The BPSU Phase 2 Application

The Phase 2 application

This section gives detailed guidance on how to complete Phase 2 (P2) of the BPSU application process. The BPSU EC will give fair and impartial consideration to the applications. If appropriate, advice from independent referees may be sought. Please note that though your application has moved from a Phase 1, this in no way implies that the study is likely to be accepted at P2. Principal investigators are usually invited to attend a meeting of the BPSU EC to discuss their P2 proposal more fully.

When planning your application submission investigators are asked to take into account the following:

- The criteria for study application to the BPSU (Section 1).
- The process from submission of the P2 to acceptance may take several months. This process can be accelerated for conditions of public health importance which require immediate evaluation.
- Medical adviser must receive applications four weeks before the BPSU EC meeting date if you would like their comments on the application.
- The BPSU office must receive finalised applications which are ready for submission two weeks prior to the BPSU EC meeting, to allow time to circulate documents for review.
- The BPSU EC meets ever two months. Dates are available from the BPSU Office or on the website.
- Please read and follow the guidance for completing the application form as failure to do so can delay or even lead to rejection of the application.
- Timing of inclusion of new studies onto the BPSU card depends on the number and the nature of other studies being surveyed.

Outcomes from a Phase 2 Application

The BPSU EC meets five times per year to consider applications. The following outcomes are possible:

- 1) P2 may be accepted without revisions or clarifications
- 2) P2 accepted but with several minor points needing to be addressed or clarified
- 3) Further review, or specialist advice, may be sought before a final decision is made
- 4) P2 methodology approved but questionnaire needs amending
- 5) The study is rejected

Rejection of an application indicates simply that it is not a suitable application for the BPSU scheme. The BPSU Committee will give reasons for its decision and offer suggestions on how the study could be undertaken outside of the BPSU scheme.

Following acceptance of the study proposal and questionnaire at P2, ethics and NIGB approval will be required. Please refer to the flowchart of page 4 and to Sections 4-9 for details of these processes. If you have any further queries relating to the BPSU application procedure please do not hesitate to contact the Medical Advisers.

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Guidance on specific questions in the Phase 2 Application

1) Title of the study

Please provide the full title of the study. If you consider the condition to be sensitive, you may wish to omit the condition name from the study title. If and when the study is finally accepted onto the orange card, please be aware that the title which appears on the orange card has a maximum length of 65 characters. You may also wish to provide an abbreviation or acronym in the title is long.

2) Title to appear on Orange Card

The character limit is 65 for the Orange Card study title.

3) Name of the investigators

Please list all investigators involved in the study, their job title, affiliation, and contribution to this study. Please also indicate clearly the principal contact for correspondence on this application, giving a full contact address, e-mail address and telephone number. Please indicate also the individual who is the designated Principal Investigator – this person will be responsible for research governance. At least one of the study investigators should be a paediatrician receiving the Orange Card.

You should have a named contact in Ireland who can support and promote the study, and advise on the suitability of your study methods and questionnaire for Irish paediatricians. The BPSU or Irish Paediatric Surveillance Unit can help you find a suitable contact that has a specialist interest in the condition that you are studying.

4) Describe the study

This should explain a) the condition to be studied, b) a review of the background to the study proposal, including current knowledge about incidence and prevalence, c) the public health and scientific importance of the study, d) the study methodology, and e) the expected benefits of the study. This explanation should be easily understood by a lay person as the BPSU EC includes lay and medical reviewers.

5) Lay summary

This should be a short, clear summary of the condition and study in terms that can be understood by a lay person. This will be the publicly available summary that is put on the BPSU website if the study is accepted. The lay summary should be no more than 250 words.

6) Research questions/surveillance objectives

Give a clear statement of the specific research questions that will be investigated by this study. These usually fall into the categories of 1) estimating incidence/prevalence, 2) describing the clinical features at presentation, 3) describing management and short-term outcomes.

It must be possible to address these questions

- a) Without direct contact with patients

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- b) Without seeking investigations that would normally not have been undertaken by the paediatrician
- c) Without a comparison (control) group.

There does not need to be a long list of objectives. Consider how you will ask suitable questions in the questionnaires to gather information to answer your research objectives. Consider if you will have a sufficiently large sample size to address your objectives, for example regional variations in incidence could not usually be addressed by a BPSU study as the sample size would be too small. Please note also that the BPSU surveillance methodology is not suitable for identifying causal relationships, as the frequency of 'risk' factors identified amongst notified cases cannot be compared with the frequency of these factors in unaffected 'control' children.

7) Case definition

Give a clear case definition for the condition of interest. The **surveillance case definition** is a case definition which may be wider than the analytic case definition in order to ensure cases are not missed. For example, the surveillance case definition will often include suspected cases where confirmation is awaited. The **analytic case definition** describes very carefully those children who will be included in the study, i.e. will become your 'confirmed cases' for further analysis.

In most studies, the age range for cases will include ages from birth up to but not including 16 years. Please consider if children in the upper age range will be seen by paediatricians for this condition.

Finally, you should have a set of **reporting instructions** telling clinicians which children should be reported to you. The reporting instructions will reflect your surveillance case definition but are likely to be a shortened or simplified version of these. Examples of case definitions used in previous studies are provided in Appendix 2.

8) Methods

Please provide clear details of the study methodology that you intend to employ to answer your research objectives. If you plan to request clinical specimens or vary your methods from conventional BPSU studies, then please provide details.

9) Expected numbers

Please supply an estimate of the number of cases expected each year, i.e. yearly incidence rate, indicate the sources that you have used to estimate this. More than 300 cases per year (or 30 per month) would normally be considered too high for the BPSU due to the monthly volume of notifications and the fact that regional studies may be sufficient. Please note that there are often duplicate reports so that the number of cases reported might be considerably higher than the number of true cases included in the analysis.

Indicate the source of denominator data for calculating incidence. This is often a routine data source, such as the Office for National Statistics mid-year population estimates or birth statistics

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(www.statistics.gov.uk/). In Northern Ireland (www.nisra.gov.uk/), the republic of Ireland (www.cso.ie/) and Scotland (www.isdscotland.org/), other bodies collate these statistics.

10) Alternative sources of reporting

Are there other clinicians besides paediatricians who are likely to see cases? If so, it is essential to consider whether to involve these clinical specialists in case reporting as this improves ascertainment and reduces bias. Please list any additional sources of case reporting that you intend to use (and provide letters of support as appropriate). Describe also the purpose of each additional source, how you will collect data and match between sources, and your proposed plan for analysis.

11) Proposed level and nature of public involvement

You will be expected to engage with public or patient organisations relevant to your study. Please describe how you have involved, or intend to involve, the public in your study and whether this is consultation, collaboration or user-led (see below). Please then supply further details of this activity, including the organisations that you have approached and how they have been and will be involved in your study. Please attach any letters of support. For further information on public involvement in research visit http://www.invo.org.uk/Key_Publications.asp

Definitions for the terms you are being asked to assess are included here:

Consultation

Researchers consult members of the public about the research e.g. through individual contacts, one-off meetings

Collaboration

This includes active, on-going partnership between researchers and the members of the public e.g. involvement of members of the public on the project steering group, or as a research partners on a project.

User led / user controlled

Members of the public lead the research and are in control of the research. This is often, through a community or voluntary organisation led by the service users.

It is recommended that researchers produce a public information leaflet including information about the condition and the study which can be distributed to relevant groups / organisations and posted on the BPSU website. Please state if you will do this and provide an example of any information leaflet or poster that you have produced for the study.

12) Questionnaires and letters to notifying paediatricians

Copies of questionnaires and covering letters to respondents must be attached even if they are only in draft form. The BPSU EC will request final versions of your questionnaires and letters before final acceptance. It is essential to pilot your questionnaire with general paediatricians before submitting it to the BPSU for consideration. Please describe any pilots and changes made to questionnaires subsequent to this. It is advisable that you also consult any lay/public involvement representatives involved in the study about the questionnaire.

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Please note that the BPSU provides instructions for the design of questionnaires (see below and Appendix 3) within this guide. The BPSU has also devised a template questionnaire with additional guidance, which you are strongly advised to use. It is strongly advised that you liaise with the designated Medical Adviser before submitting your questionnaire as failure to do so may lead to delay in processing your application or its rejection.

13) Identifiers

Provide details of the identifiable data that you will be collecting and justify why each identifier is required, e.g. for de-duplication or clinical data analysis.

14) Proposed Duration of Study

Remember that the report card is sent to respondents at the end of each month, for cases seen in that month. The application and ethics approval process can take six to twelve months.

The BPSU recognises that two or more years of surveillance of a very rare condition may be required to provide adequate cases for the study. Applicants must therefore specify in their P2 application how long they wish to undertake surveillance and subsequent follow-up. Justification for the proposed study duration should be included in the supporting statement. Continuation of surveillance beyond one year is subject to receipt of a yearly progress report.

The follow-up period for further data collection should be no more than 2 years. Each investigator must also contribute a short report on their study each year to form part of the BPSU Annual Report. Please note that the BPSU EC has the option to limit initial surveillance duration to 13 months.

15) Funding arrangements

Outline the funding arrangements for the project. BPSU costs are £3,900 + £500 for protocol card printing for a 13 month study. Inflationary costs for the contribution rates should be included if applying for more than one year's surveillance. Funding arrangements should not only cover BPSU costs but also administrative costs including research assistance/secretarial salaries.

Please name the body(ies) to which grant application(s) have been submitted or from whom funds will be available. Give the date by which arrangements are expected to be agreed. State whether funding is from a commercial source or whether you are personally in receipt of funds to undertake the research. If funding is from a commercial source, you may be expected to demonstrate, for example through a contract with the funders, that this will not influence the reporting of results, and you may wish to discuss this with the Medical Adviser. Where the study is funded by a third party (commercial or non-commercial source), it is unlikely to be acceptable for them to have access to identifiable data.

16) Organisational Arrangements

Provide details for managing the project, such as administrative, scientific and computing support. Particular attention will be paid to whether the resources are sufficient to run a successful project, processing reports in a timely manner, information technology support etc.

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We strongly advise that a research administrator or officer is employed either part time or full time if the expected number of case reports is greater than 100 per year. You should be aware of the requirements for security and confidentiality in handling patient identifiable data described in Part B.

17) References

A list of any references should be included. If possible, attach copies of any papers which are not likely to be electronically available to the medical advisers.

Additional documents

Covering letter

Please attach a signed covering letter from the main contact/principal investigator for the study.

Supporting letters

Please attach any letters of support that you consider relevant for the committee to consider, for example award letters from funding bodies or letters confirming support by collaborating partners.

Questionnaires and covering letters

Please attach all questionnaires and letters that will be used within the study. Please provide a version number and date for each.

Public information leaflet/poster

Please attach any public information material, if appropriate.

Supporting letters

Please attach any letters or statements of support, if appropriate.

Letter from funding body

Please attach confirmation of funding, if appropriate.

Signature

An electronic version of the application can be submitted directly to the BPSU Office at bpsu@rcpch.ac.uk at least 2 weeks before the BPSU EC meeting. A signed paper copy must also be sent to the BPSU office.

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Questionnaire Design

A questionnaire template can be downloaded from the [BPSU website](#)

Listed below are some key issues to keep in mind when designing your questionnaire. A questionnaire template can be found on the BPSU website and general advice on questionnaire design is also provided in Appendix 3.

Investigators are welcome to discuss questionnaire design with the medical advisers and/or BPSU EC and copies of questionnaires used by existing studies are available on the BPSU website or on request from the BPSU Office.

A letter of introduction should be sent with the questionnaire and a thank you letter should be sent on return of the questionnaire (Appendix 4). This is vital in keeping the continued support of the clinicians.

Key points

- Questionnaires should be as brief and simple as possible, so as not to impose an excessive burden on the paediatrician. Two A4 pages are usually adequate for the questionnaire. Reasons for requiring a longer questionnaire must be outlined in the application. However, a well-laid out four-page questionnaire is preferable to one of two pages that is cramped and difficult to complete. As a guide, the questionnaire should take no longer than 15 minutes to complete.
- ‘The British Paediatric Surveillance unit of the Royal College of Paediatrics and Child Health’ should be included in the heading of questionnaires and covering letters
- Information sought should be easily accessible to the reporting clinician from medical case notes. Anonymised copies of discharge letters cannot be sought.
- A ‘tick box’ format should be used wherever possible, remember to include a ‘don’t know’ or ‘not tested’ box where appropriate.
- The cover page of the questionnaire should contain the hospital and minimal identifiable data; this can then be separated from the clinical details and stored separately to protect confidentiality. Names and addresses should not be sought although a unique identifier (e.g. NHS or CHI number) is usually essential. Minimal patient personal information to allow identification of duplicate reports and collection of follow-up data (e.g. initials, date of birth, sex, partial postcode or NHS number) is accepted by the BPSU, but you will also need to justify this to REC and ECC.
- You may wish to use a study title that does not state the condition if this is particularly sensitive, e.g. HIV.
- Specialist terms or abbreviations that may not be familiar to paediatricians should be explained in full.
- Standard accepted classifications should be used where possible. Ethnic group should be requested using the 2001 Census Classifications.

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- Respondents should be asked to return the questionnaire even if they are unable to complete all items.
- A reply paid envelope for return of the data collection sheet is essential.

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

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

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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.

li 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*

System Audit

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

System Level Security Policy Ownership

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:

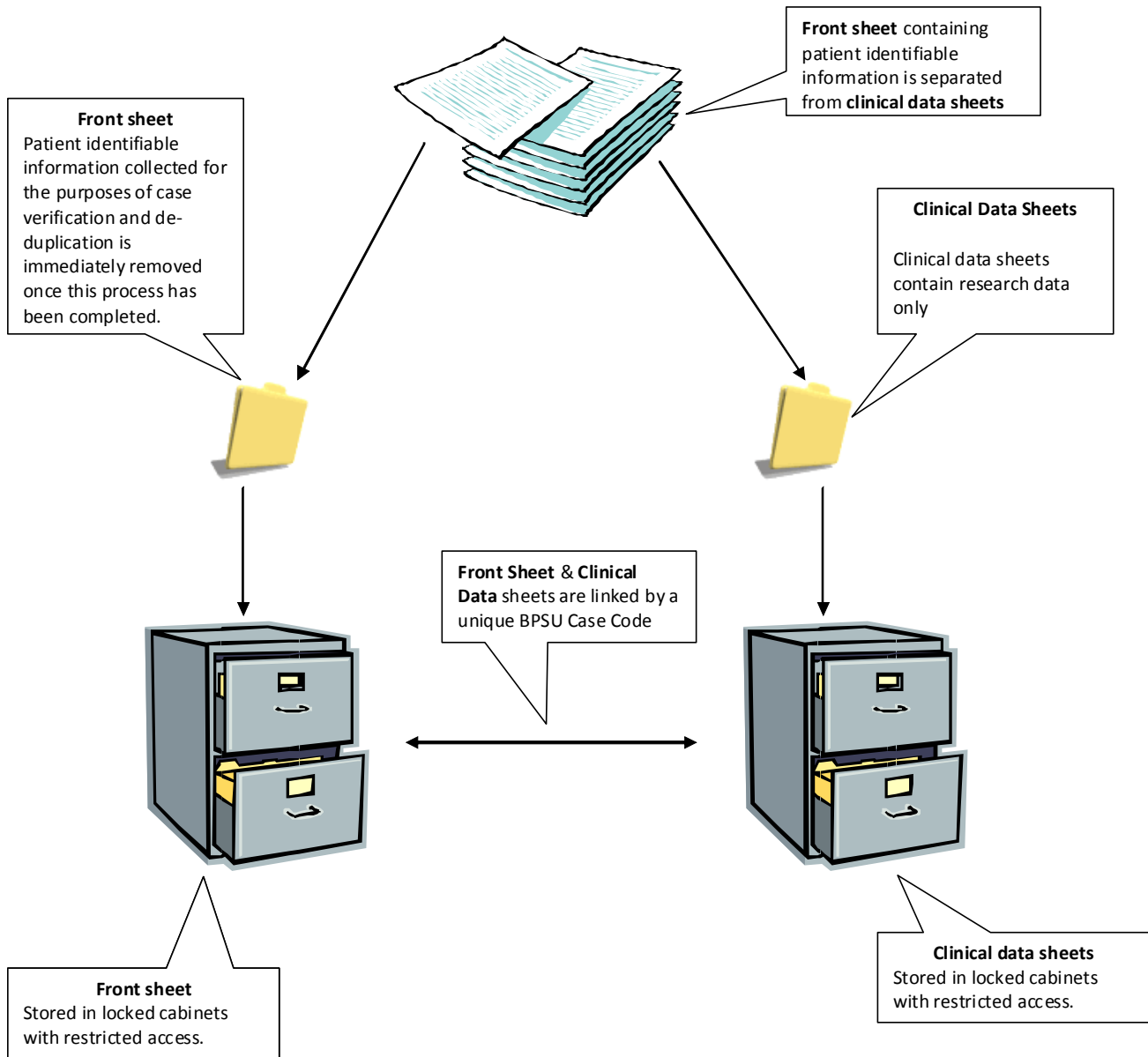
System Authorised Purpose

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.

Part C - Appendices

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Appendix 1: Abbreviations and Useful Web Addresses

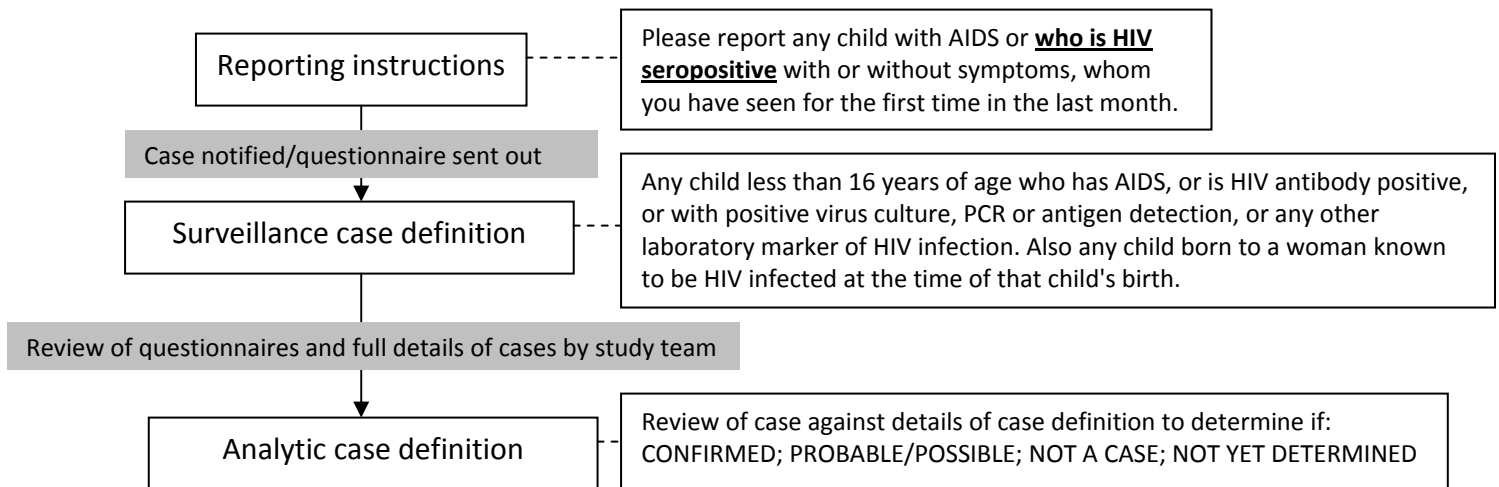
Abbreviation		Weblinks
ECC	Ethics and Confidentiality Committee (of the NIGB)	www.nigb.nhs.uk/ecc
GROS	General Register Office for Scotland	www.gro-scotland.gov.uk/statistics/
HES	Hospital Episode Statistics	www.hesonline.nhs.uk/
IC	NHS Information Centre	www.ic.nhs.uk/services/medical-research-information-service
IRAS	Integrated Research Applications System	www.myresearchproject.org.uk/
ISD	Information and Statistics Division (Scotland's ONS)	www.isdscotland.org/
MRIS	Medical Research Information Service (NHS Information Centre)	www.ic.nhs.uk/services/medical-research-information-service
NIGB	National Information Governance Board	www.nigb.nhs.uk
ONS	Office for National Statistics	www.statistics.gov.uk/default.asp
PAC	Privacy Advisory Committee (Scotland and Northern Ireland only)	www.isdscotland.org/isd/3048.html
PIAG	Patient Information Advisory Group (role taken over by ECC)	www.advisorybodies.doh.gov.uk/PIAG/Index.htm
SLSP	System Level Security Policy	www.nigb.nhs.uk/ecc/applications/SLSP.doc/view?searchterm=slsp
UKCRC	UK Clinical Research Collaboration	www.ukcrc.org/regulationgovernance.aspx
Other useful weblinks		
	Research Database forms (and other example forms from IRAS)	www.myresearchproject.org.uk/Help/PdfFiles.aspx
	NHS Information Governance Toolkit (from Connecting for Health)	www.igt.connectingforhealth.nhs.uk/
	MRC Data and Tissue Toolkit	www.dt-toolkit.ac.uk/home.cfm
	MRC Personal Information for Medical Research Guidance	www.mrc.ac.uk/pdf-pimr.pdf

Appendix 2: Case Definition – Development and Examples

Developing a case definition

If you are developing a case definition, consider which symptoms, signs and tests you use to make the diagnosis. Symptoms and signs, such as fatigue or fever, which are common to many conditions are unlikely to be useful elements of a case definition on their own, however they may be clearly diagnostic of a disorder when found in association with other specific symptoms or signs.

The **surveillance case definition** defines clinically the cases that investigators are aiming to identify. It should state the age range, clinical symptoms and signs and results of investigations which would indicate a child is definitely or is likely to be a case. The surveillance case definition may be broader (less specific) than the **analytic case definition** applied using information from the questionnaires. For example, the surveillance case definition may include suspected but unconfirmed cases, whilst the analytic case definition for incidence estimates should include confirmed cases only. The **reporting instructions** are based on the surveillance case definition and state simply which cases should be notified to the study by clinicians.



Examples of the reporting instructions and case definitions used in some current and previous BPSU studies are provided on the next page.

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EXAMPLE REPORTING INSTRUCTIONS & CASE DEFINITIONS

1. HIV infection & AIDS

Case definition: Any child less than 16 years of age who has AIDS, or is HIV antibody positive, or with positive virus culture, PCR or antigen detection, or any other laboratory marker of HIV infection. Also any child born to a woman known to be HIV infected at the time of that child's birth, regardless of the child's infection status.

Reporting instructions: Please report any child with AIDS or **who is HIV seropositive** with or without symptoms, whom you have seen for the first time.

2. Progressive intellectual and neurological deterioration (PIND)

Case definition: Any child under 16 years of age at onset of symptoms who fulfils **all** of the following three criteria:

1. Progressive deterioration for more than three months with
2. Loss of already attained intellectual/developmental abilities and
3. Development of abnormal neurological signs.

excluding : Static intellectual loss e.g. after encephalitis, head injury or near drowning.

including :

- Children who meet the case definition even if specific neurological diagnoses have been made.
- Metabolic disorders leading to neurological deterioration.
- Seizure disorders if associated with **progressive** deterioration.
- Children that have been diagnosed as having neurodegenerative conditions but who have not yet developed symptoms

Reporting restricted to: Cases seen in the last month but including those whose conditions began earlier (i.e. including 'old cases' of children in follow-up if seen in that month).

Reporting instructions: Please report any child seen in the last month who meets the case definition, including those who have already been given a specific diagnosis.

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3. Neonatal Herpes Simplex Virus (HSV) Infection

Surveillance Case Definition

1. Any infant under one month
 - (a) with a diagnosis of HSV infection, based on virus detection by culture, PCR or IF, or serology – IgM and/or seroconversion, **or**
 - (b) treated with antiviral drugs for suspected HSV infection
2. Any stillborn infant in whom HSV infection is suspected

Analytic Case Definition

Confirmed case of neonatal HSV:

1. Virus detection by culture, PCR or IF, or serology – IgM and/or seroconversion, confirming HSV infection on a specimen taken within four weeks of birth, or
2. Typical clinical manifestations with maternal infection confirmed by either seroconversion during pregnancy or virus isolation around the time of delivery

Suspected case of neonatal HSV:

Typical clinical manifestations and treated with antiviral drugs for suspected HSV infection.

Reporting Instructions: Any live born or stillborn infant born since the beginning of 2004 in the UK or Ireland

with confirmed or suspected neonatal HSV infection, seen by you for the first time in the last month.

4. Medium Chain Acyl CoA Dehydrogenase Deficiency (MCADD)

The diagnosis of MCADD can be made following clinical presentation, investigation of a sudden unexpected death, diagnosis in an affected family member or through newborn screening. A child will be considered to have a diagnosis of MCADD if one or more of the following criteria are met:

- Elevated octanoyl carnitine in blood test using tandem mass spectrometry (or in other body fluids if a post-mortem diagnosis)
- Characteristic urine profile of organic acids with hexanoyl, suberyl and phenylpropionyl glycine
- Molecular genetic studies confirming presence of a mutation characteristic of MCADD
- Enzyme studies based on skin fibroblasts showing reduced activity of medium chain fat oxidation

Reporting Instructions Please report any newly diagnosed cases seen for the first time in the past month, which meet the surveillance case definition, including those where the child may have died. If the paediatrician is not certain or awaiting confirmation, the case should be reported anyway.

5. Early onset eating disorders in children less than 13 years

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Case definition: Any child aged under 13 years, newly diagnosed with early onset eating disorder which is defined as:

TWO OR MORE OF THE FOLLOWING

- weight loss or failure to gain weight during a period of expected growth, not due to any identifiable organic cause
- determined food avoidance
- fear of weight gain
- preoccupation with body weight or energy intake
- self induced vomiting
- excessive exercising¹
- recurrent episodes of binge eating or abuse of laxatives

¹*Exercise may be considered to be excessive when it significantly interferes with important activities, when it occurs at inappropriate times or in inappropriate settings, or when the individual continues to exercise despite injury or other medical complications." (American Psychiatric Association. DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision. Washington, D.C.: American Psychiatric Association; 2004; pp. 590-591.)*

Reporting Instructions: Please report any **new** cases meeting the surveillance definition seen by you for the first time **even if** you believe the case may have been reported from elsewhere.

6. Methicillin-resistant Staphylococcus aureus (MRSA)

Case definition: Isolation of Methicillin-resistant Staphylococcus aureus (MRSA) from blood cultures of children less than 16 years of age.

Reporting Instructions: Please report any cases seen within the last month that meet the case definition. Please note that BPSU surveillance does not replace other forms of routine Staphylococcus aureus reporting to the Health Protection Agency (HPA).

7. Malaria In Children

Case Definition: Any child less than 16 years of age who is diagnosed with malaria through either microscopic examination of thick and thin blood smears or malaria antigen detection in the blood using commercially available assays.

Reporting Instructions: Please report any cases seen in the past month that meet the surveillance case definition. Please note that BPSU surveillance does not replace other ongoing reporting systems for malaria (e.g. enhanced surveillance through the Malaria Reference Laboratory mandatory notifications to the HPA).

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Appendix 3: Guidance on Developing A Questionnaire

(We are grateful to Helen Bedford for her help with this guidance).

This is an introduction to some of the considerations involved in questionnaire design including practical suggestions.

Self completion questionnaires – by clinicians

The advantages of these are that they are:

- Less costly than interviews, requires less time and energy to administer
- Can include a national, geographically spread sample using a mailed questionnaire

The disadvantages are:

- Possible response bias, i.e. non-responders differ in some way from responders giving an unrepresentative picture.
- Questionnaire design is crucial; it must be absolutely clear as there is no opportunity to explain questions.
- Responses are final - no opportunity to probe.
- Responses are limited to what is available in clinical notes.
- No control over who actually completes questionnaire, this may be the intended consultant or a junior staff member.

Questionnaire design

You will require a well designed questionnaire. In practice designing a questionnaire is a skilled job and there are many pitfalls. Key points are:

- Avoid ambiguity, bias and confusion.
- Don't underestimate the time it will take to construct the finished product. The more intelligible it seems, the greater the expertise that has gone into it. Always seek views of intended audience during drafting, i.e. discuss with colleagues
- Using questionnaires or parts of questionnaires that have been previously tried and tested is acceptable and also provides you with the additional advantage of being able to compare your findings with that of others.
- Pilot questions or the whole questionnaire with a local sample of clinicians, preferably against real sets of case notes.

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Letters of introduction

You need to introduce the study by letter. Letters should include:

- Aims of study and what you hope to get out of it e.g. 'we hope that the findings will help to improve services for children with disabilities in Brighton'.
- Assurance that information will be treated as confidential – it is best to state CONFIDENTIAL on the front sheet.
- Who you are, and your credentials
- Recognition of the effort required by the respondent
- Thanks
- Instructions re returning questionnaire
- Who to contact for more details
- Use plain English

The Questionnaire

- Length – 2-3 sides of A4 is considered to be maximum
- Layout is important, it must look attractive and not too formidable, subjects must feel able to answer it.
- Using sections and boxes to separate different parts of the questionnaire can make it clearer and more inviting.
- Put instructions for completing at the top e.g. 'Tick the box next to the answer that applies to you'.
- If you are asking for more detail make sure there is enough space for people to write in.
- Skips are useful but must be clearly indicated e.g. ' GO TO QUESTION 3b'
- Language used is very important, should be appropriate to the sample e.g. language used for general public would differ from that used for health professionals.
- Don't be tempted to ask too many questions, stick to the minimum only, keep your research questions in mind all the time.
- It's occasionally useful to invite people to tell you anything else they want to at the end of the questionnaire but consider how this will be analysed
- Sensitive questions should be placed towards the end, then if the respondent does not wish to answer these, they may still have answered the others.

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Types of question

'Closed' or pre-coded questions, e.g. *'Was the child born preterm (before 37 weeks gestation)?'*

- Yes
- No
- Don't know

Advantages

- This is useful if the range of answers to a question is limited and well established but always remember to include a 'don't know' option where relevant.
- Means people have to write very little, maybe useful for busy people.
- Makes analysis more straightforward.
- Make group comparisons easier
- Useful for testing specific hypotheses.

Disadvantages

- May be problem if all options are not included.
- Spontaneous response lost
- May be bias in answer categories, e.g. if respondents prefer to opt for 'socially acceptable', 'don't know' or 'middle' option.
- Can be too crude

Open-ended questions

Allows respondent to answer in their own words, and highlight the particular issues that are important to them. e.g. *'How would you describe your relationship with your doctor?'*

Advantages

- Useful if you can't determine in advance what the main categories will be, useful in pilot surveys, means rich data is collected but dealing with the information in analysis is more difficult because if you have 50 responders you may get 50 completely different answers.
- Can place a burden as more time/thought required by respondents.
- More difficult to analyse against specific objectives.

In practice most questionnaires use a combination of closed and open-ended questions e.g.

'Does the child have any problems with his/her eyesight?'

- Yes
- No
- Don't know

If YES, please describe

It is often useful to begin with a closed 'yes/no' questions, then follow-up with an open-ended question that asks for detail.

Summary of question types

Open-ended: These allow a respondent freedom to write detail and express opinions, e.g. please describe..., tell me about...

Closed: These require a selection from a fixed set of answers, e.g. yes/no/don't know or male/female. A rating scale may be used to offer a wider range of answers.

Leading: These suggest a 'correct' answer to the respondent and are poor questions, e.g. *Do you think seatbelts should be compulsory in cars?*

Double-barrelled: These have two different questions rolled into one so it is not clear which is being answered, e.g. *Do you agree or disagree with ...*, or *Was the child unwell or in a state of collapse at the time of diagnosis?*

Hypothetical: These cannot be confirmed so are about opinion only, e.g. *Would the patient have been better without treatment?*

Measurement scales

These can be very useful for questions about health which tend to be on a continuum. Whether you choose a question or a scale depends on the nature of the variable you are measuring, e.g. whether it is categorical or continuous.

Examples of measurement scales:

Likert scale: used to indicate various degrees of strength of agreement or disagreement; commonly used to measure attitude, e.g.

'I would like my child to have his/her vaccinations in one injection rather than two'
strongly agree/ agree/ undecided/ disagree/ strongly disagree.

There are usually five or seven points on the scale, as an odd number allows respondent to express a neutral response to the statement. Responses can be allocated a score.

Guttman scale: This is also used to measure attitude and consists of a set of items with which people are asked to agree or disagree. The number of items usually small and a number of statements relate to a single concept. One score is allocated to each of the statements with which the person agrees, and they are allowed to agree with one or more statement.

e.g. *Statements relating to social isolation:*

- 1. I feel lonely*
- 2. I'm finding it hard to make contact with people*
- 3. I feel there is nobody I am close to*
- 4. I feel I am a burden to people*

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Semantic differential scales: These are based on the importance of language reflecting a person's feelings. Respondents asked to make judgments about certain concepts and bipolar adjectives are stated at either end of a 7 point scale. These are only useful when responses to questions or statements can be categorised into conflicting adjectives.

e.g. *The session on questionnaire design was:-*

- | | | | | | | | | | |
|----|----------------------|---|---|---|---|---|---|---|--------------------|
| 1. | <i>Unhelpful</i> | 1 | 2 | 3 | 4 | 5 | 6 | 7 | <i>Helpful</i> |
| 2. | <i>Bad</i> | 1 | 2 | 3 | 4 | 5 | 6 | 7 | <i>Good</i> |
| 3. | <i>Uninformative</i> | 1 | 2 | 3 | 4 | 5 | 6 | 7 | <i>Informative</i> |

Visual analogue scales: These are frequently used in the clinical setting, e.g. measurement of pain

No pain at all *worst pain imaginable*

_____X_____

Traditionally the line is 100mm in length and subjects are asked to mark a point on the scale which represents the amount of sensation they are experiencing. The mark on the line can be measured and a score allocated between 0 and 100mm.

Rating scales: These are used to evaluate performance or for the prediction of risk, and are necessary when objective measures of some skills are not available or are too complicated for general use. The points on the scale are derived from expert ratings and the methods of rating may be complex or simple. Examples are the Glasgow coma scale and Edinburgh postnatal depression score. Assessors must be well practiced in the use of the scale to ensure high degree of inter-rater reliability.

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Question construction

- Use plain English and the most simple language you can
- Avoid double barrelled questions, e.g. 'Do you agree or disagree with the following statement: Examinations are a poor method of assessing ability and should be banned'.
- Avoid ambiguity – e.g. as in this question taken from a survey questionnaire sent to all female staff irrespective of whether they were pregnant or not: 'Is your work made more difficult because you are expecting a baby?'
- Avoid leading questions, e.g. 'You don't think.....do you?'
- Be specific, e.g. if you want opinions on how an outpatients department organised their appointments system, it is no good asking 'Are you satisfied with the outpatients department at X hospital?'
- Avoid vague words like regularly, frequently, occasionally, which might be interpreted differently. Define things like 'collapse' or 'crisis', which may mean different things to different people.
- The wording of the question is crucial, for example when the General Household Survey was collecting information on chronic illness they asked 'Do you suffer from any disability?' and the response was far lower than they expected. Next time they asked 'Do you have any disability?' and got a more accurate response.

Obtaining a good response rate with a mailed questionnaire

- Follow up non responders twice with reminders - can expect about 1/2 final response rate with first letter, another 1/3 with second and a few more with third.
- Need to be able to identify those who have not responded, so note consultant names/patient codes at the top of the questionnaire.
- Send reminders when replies stop coming back, usually after about 2-3 weeks with second class post. E-mail and telephone reminders are also acceptable.
- Always include another copy of the questionnaire in case it has been mislaid.
- FREEPOST or reply paid envelopes are essential.
- Printing questionnaire on coloured paper means it stands out from other correspondence.
- White envelopes differentiate from business mail.

Assessing the quality and adequacy of a questionnaire

Reliability of a questionnaire is a main criterion – this is the extent to which a questionnaire produces similar results under the same conditions on all occasions.

Validity - many different types of validity exist but it broadly refers to the extent to which a questionnaire measures what it is supposed to measure. Establishing validity can be difficult but piloting is a very important exercise in achieving validity and reliability.

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Pilot Studies

It is sensible to pilot your questionnaire, so difficulties can be ironed out before the main study starts. It is best to ask several clinicians to test the questionnaire against a set of real notes and provide feedback on questions which are difficult to understand or data which is hard to find in the notes.

Analysis

Always think about your method of analysis when you are designing the questionnaire, as this may affect the design. For example, specific questions may relate to specific fields in an electronic database. Coding of responses, that is transforming them into numerical data to enable analysis, may be carried out during the planning stage of questionnaire design in which case you will need a coding frame either printed on the actual questionnaire or separately, or after the data is collected. The majority of closed questions can be pre-coded.

Examples of BPSU questionnaires

Current questionnaires are available on the BPSU website.

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Appendix 4: Examples of Letters to Accompany Questionnaires

On headed paper from the investigator and including a logo from the British Paediatric Surveillance Unit of the Royal College of Paediatrics and Child Health

EXAMPLE OF A LETTER TO THE REPORTING PAEDIATRICIAN

[Name]
[Address]
[Date]



Dear [Name],

Re: Study

Thank you for notifying a case(s) for this study, which is being undertaken by the Royal College of Paediatrics and Child Health Surveillance Unit.

We are writing to gather further information about this case on the enclosed questionnaire. We should be very grateful if you could complete it and return it in the enclosed reply paid envelope. **Please return the questionnaire, even if there are some sections you are unable to complete.**

We will not be contacting your patient or his/her family at any time. Some patient identifiable data are needed to avoid duplication and to allow an estimation of the completeness of reporting. These will be removed once the case has been confirmed to be a unique case and all information you provide will be treated in strict confidence.

The study is funded by the XXXX and has been approved by the XXXXXXXX Region MREC and by the Patient information Advisory Group.

Please do not hesitate to contact XXXXXX if you have any queries about the questionnaire, or any aspect of the study. If you need any clinical advice regarding the eligibility of a particular case for inclusion in the study please contact Dr XXXXX (contact details below).

We are very grateful to you for reporting to the BPSU and for taking the time to provide further information about your patient. It is our intention to send a short follow-up questionnaire in 12 months time to confirm outcome status.

Finally we will also ensure that you are sent a copy of the final report of the study.

With many thanks for your help,

Yours sincerely

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EXAMPLE OF A THANK YOU LETTER FOLLOWING COMPLETION OF THE QUESTIONNAIRE

On headed paper from the investigator and including a logo from the British Paediatric Surveillance Unit of the Royal College of Paediatrics and Child Health



[Name]
[Address]

[Date]

Dear [Name],

Re: Study

Thank you for completing the questionnaire which we have just received and processed.

This questionnaire will help us to gain further information about XXXXXX in infants and children. **There is no intention to contact either the patient or their relatives and this data will not be converted into a registry.**

We will be contacting you in one year's time to see how the patient has fared.

We would like to thank you for your past and continuing assistance and please do not hesitate to contact us at the above address if there are any queries you would like to discuss further.

With many thanks for your help,

Yours sincerely

Phone:

Email:

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EXAMPLE OF FOLLOW-UP LETTER TEMPLATES

On headed paper from the investigator and including a logo from the British Paediatric Surveillance Unit of the Royal College of Paediatrics and Child Health

[Name]
[Address]



[Date]

Dear [Name],

Re: Study

We would like to thank you for your notification of a case of XXXXXX to the British Paediatric Surveillance Unit (BPSU) and for completing the initial questionnaire we sent you. We are now contacting you to establish clinical outcomes at one year. We would be grateful if you would complete the enclosed questionnaire and return it in the prepaid envelope provided. Please try to complete the questionnaire, even if the child has died or has not been seen for some time.

If the child is no longer being cared for by you, we would be very grateful if you would let us have details of the child's new paediatrician or someone we could write to obtain this information.

Thank you for taking the time to be a part of this study. We will provide a report of the study to all notifying clinicians once it concludes. In the mean time, if you have any further questions regarding the study or the questionnaire, please do not hesitate to contact us by phone or e-mail.

Yours Sincerely,

Dr
Principal Investigator

BPSU Study Handbook: Part C - Appendices

Header and Address

FOLLOW-UP LETTER REMINDER TEMPALTE

On headed paper from the investigator and including a logo from the British Paediatric Surveillance Unit of the Royal College of Paediatrics and Child Health

[Name]

[Address]

[Date]



Dear [Name],

Re: Study

Thank you for reporting a case of confirmed or suspected XXXXXX through the British Paediatric Surveillance Unit (BPSU) 'orange card' scheme and completing the initial questionnaire. We recently sent you a follow up questionnaire regarding this child, but have not yet received your reply. If this has been sent in the last week, please ignore this letter. If it has not, we would be most grateful if you would complete and return the questionnaire in the envelope provided. This information is important to us to understand clinical outcome and morbidity associated with this condition.

If the child is no longer being cared for by you, we would be very grateful if you would let us have details of the child's new paediatrician or someone we could write to obtain this information.

We will provide a report of the study to all notifying clinicians once it concludes. In the mean time, if you have any further questions regarding the study or the questionnaire, please do not hesitate to contact us by phone or e-mail.

Yours sincerely,

Dr
Principal Investigator

BPSU Study Handbook: Part C - Appendices

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