British Paediatric Surveillance Unit

Starting and Running a BPSU Study

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Part A – Introduction

Section 1: Introduction

This document leads you through the process of undertaking a BPSU study once you have received approval of your P2 by the BPSU scientific committee and have gained ethics approval.

Please bring to attention of the BPSU any problems that may arise during the study period, however small – we have heard most of them!

If, after undertaking your study, you have any further suggestions that will aid in the development of this document, please do pass them on.

Section 2: Checklist for study researchers

Before the study starts please make sure the following documents have been sent to the BPSU office.

		Completed and sent to BPSU Office
a.	IRAS Form	☐
b.	REC approval letter	☐
c.	CAG approval letter	☐
d.	PBPP approval letter	☐
e.	System Level Security Policy	☐
f.	Final Phase 2 application with all agreed amendments	☐
g.	Questionnaire(s)- final format	☐
h.	Public information leaflet	☐
i.	Study flyer (see page 4)	☐
j.	Protocol card (see page 4)	☐
k.	Signed memorandum of understanding (see page 5)	☐
l.	Project timeline chart (see Appendix 1)	☐
m.	Bulletin article	☐
n.	Any other publicity material.	☐

We encourage you to publicise the study as widely as possible– such as consider producing articles for specialty newsletters

Part B – Publicising your Study through the BPSU

Prior to the study commencing please ensure the following documentation is sent to the office:

- study flyer
- protocol card
- article for bulletin
- information for website

Section 3: Flyer to paediatricians

- This is a one-sided A4 sheet which is sent out the month before the study starts to all those who receive the orange cards
- The flyer needs to be produced by the study team and must be sent to the BPSU for any comments or amendments and final approval
- Final sign-off of the flyer is required at least 8 weeks prior to the study start
- An example of a study flyer can be seen in Appendix 2

Section 4: Protocol card and optional documents

- The protocol card is an A5 two sided cards which is sent out with the first Orange Card on which your study appears.
- Example of other studies protocol cards can be found on the BPSU website at www.rcpch.ac.uk/bpsu/currentstudies.
- The protocol card needs to be produced by the investigating team and then sent to the BPSU for any comments or amendments and final approval
- Final sign-off of the card is required at least 6 weeks prior to the study start (suggested it is completed at the same time as the study flyer)
- An example of a protocol card can be seen in Appendix 3

Section 5: BPSU e-bulletin

The BPSU sends out a bulletin 3 times a year. Articles are included on new studies. The investigating team is required to produce an article for the next copy of the bulletin (dates can be obtained from the BPSU office)

- Articles are expected to be between 150- words and should be written in a newsletter format (rather than like a protocol card) and can include a "quote" from the investigators
- Examples of past bulletins can be viewed at www.rcpch.ac.uk/bpsu/bulletins.
- You are also required to send a picture of the principle investigator or study team. This will be used in the bulletin and the annual report.

Section 6: BPSU website

- The details of new studies are added to the BPSU website.
- We place the principle investigators contact details, a copy of the protocol card, a brief outline of the study and the public information leaflet.
- Please provide a brief outline that can used for this purpose, and a photo of the PI or investigation team

Section 7: Advertising to other sources used for case ascertainment

It is important that you make close links with those who are to be your alternate source of reporting e.g. a non-paediatric specialty group, microbiologists etc. We advise you to:

- Send an introductory letter with specific documentation about the project before its commencement.

- Aim to get the support of any relevant association. If possible try to present the project at their scientific meeting or research seminars. It is important to encourage their involvement and interest in the project.
- Enquire if you can have the study protocol included on the association and your trust websites.

Section 8: Presenting at local hospitals

You are encouraged to present the project at hospital grand rounds and lunchtime seminars.

We are aware that hospitals are often looking for lunchtime presentations. Please let us know when you are available.

Section 9: The press

- Be aware of approaches from press – please be careful when talking to press whilst the study is in progress.
- If you require advice please contact the RCPCH press office (margaret.donnellan@rcpch.ac.uk).
- The RCPCH run annual science media training courses. Please let us know if you are interested.
- Your own institution may have specific requirements when dealing with the press and we advise you to enquire if this is the case.
- It is very important that you let us know if you have spoken to the press as we are obliged to inform the Royal College of Paediatrics and Child Health, Public Health England and UCL GOS ICH.

Part C: Starting the study

Section 10: Memorandum of Understanding: expectations of researchers

- Before the study commences you will receive a memorandum of understanding (MoU) for signature and return, please keep a copy for your records.
- The MoU outlines the requirements expected of the investigators, many of which are contained in this document.
- Areas covered include financial, ethics, study conduct, publications and appropriate wording for acknowledgements
- The MoU also outlines the BPSU's commitment to the study and what we can offer to assist in running a successful study.
- Periodically this document will be updated and we will make you aware of any amendments during your study period
- The MoU does not supersede any agreement you may have with the Department of Health or any other funder.

Section 11: Invoices

- An invoice will be sent at the start of the study. This will cover the first 13 months surveillance and charges for the printing of protocol cards.
- Please arrange for prompt payment to the Royal College of Paediatrics and Child Health
- If the study runs for longer than 13 months further invoices will be sent on the anniversary of the study's start.

Section 12: Preparing the questionnaire

- We encourage data collection via an online web-collection tool such as RedCap. This is safe secure and easy to complete.
- The data collection form could be produced as a MSWord document and emailed to the reporting clinician via an nhs.net account. Where the clinician has no NHS.net account it can be sent to the trust address password protected.
  As a last resort the form can be sent through the post but needs to be returned securely – preferably by recorded delivery.

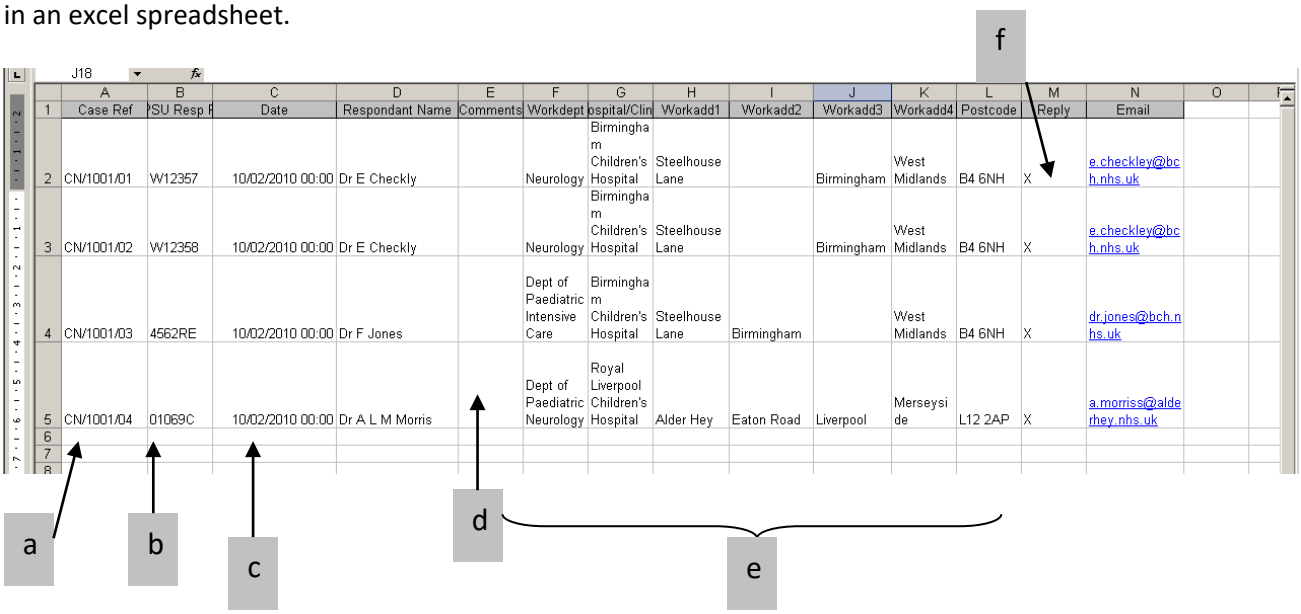
Part D: During the study

Section 12: Receiving case notifications from the BPSU Office

Notification of cases

Cases are usually reported to the BPSU office within the first 14 days of each month. These are generally cases for the preceding month, although on occasions we are notified of older cases.

The BPSU office will send you details of these cases once they have been processed by email in an excel spreadsheet.



The notification forms from the BPSU will contain the following information:

a. BPSU case report number.
b. Reporting clinicians identification number
c. Date report was received
d. Any relevant notes
e. Clinicians address and email
f. Reply column (see page 9 on how to complete this)

- As soon as possible after they receive a notification the investigators are encouraged to contact the reporting clinician by email to confirm contact details
- The covering letter and questionnaire should then be to the reporting clinician.
- **The questionnaire must include the case number as provided by the BPSU**. It can however include your own numbering system as well.

The BPSU is aware of the problems that occur when there is a delay in sending out the questionnaires: for example, the record of the identity of the notified case or the case notes may no longer be available to the reporting clinician.

Issues that may arise

Paediatricians (who receive the orange card) report case directly to you
If you are informed of a case directly by a paediatrician you should let the BPSU know the clinician's details so that a case number can be generated for the case **DO NOT** attempt to generate a BPSU case report number.

Alternatively, encourage the Clinician to identify the case when they return their next orange card.

Clinicians (who DO NOT receive the orange card) report case directly to you
If they are a **Paediatric Consultant or Associate Specialist,** please let the BPSU know and they will be added to the orange card database. The office will then generate a case number.

If they are **not** a **Paediatric Consultant or Associate Specialist** they should report cases through their consultant lead.

You receive a case report from an alternative source
If you are notified of a case from a source that is not on the BPSU list **DO NOT** attempt to generate a BPSU case report number. We advise you to add it to your own numbering system.

Paediatrician notify one-off case when they have several
Occasionally a respondent will tick a box without identifying that they have more than one case to report. When such a clinician receives a single questionnaire, they may photocopy it to use it for their other reports. Therefore, these additional questionnaires will be returned to you without a BPSU case number. If this occurs let the BPSU know and we will send you an additional BPSU case number.

Paediatrician ticked a box by mistake
On rare occasions a clinician may tick a box by mistake, when you send a questionnaire they may let you know that they did not intend to report a case. Record these cases as 'E' (see below) and let the BPSU office know.

DO NOT attempt to generate a BPSU case report number

Paediatrician does not respond to questionnaire
If you have not heard from the reporting clinician within 2-3 weeks we suggest you send out a reminder with an additional copy of the questionnaire attached. If you have not heard after a further 2 weeks phone the clinician to see if they are having particular difficulties in completing the questionnaire or if they think/know someone else has completed a questionnaire, ask for the name (these are then duplicates, check to see if you have received the "duplicate" questionnaire).

If you receive no response the BPSU suggests that you contact the clinician directly Alternatively offer to complete the form via a telephone appointment at a time of their convenience. If they are overworked and can't do it, consider completion by phone, by a secretary, junior doctor or even just getting the key details (sex, age, obesity, presenting symptoms, ethnicity) which the doctor may know off the top of their head. Then you can include these details in your analysis and know that you have incidence correct.

Phone in batches – leave messages with secretaries, etc. Try to establish whether the case has already been reported by collecting case identifiers e.g. DOB, sex and work out if it is a duplicate of a case already in your database – if you can't, send them a questionnaire and ask them to complete it and follow this up after 2 weeks with reminder e-mails, chats with their secretary. If the clinician has forgotten who they notified, there is no solution (but this should be only 4% on average).

If after all these attempts you have not heard contact the BPSU office and we will make contact; we have noted that some do respond to the BPSU.

Section 13: Returning case notifications to the BPSU office

Completing the Notification Form

On receiving the completed questionnaire, the investigators **must** complete **Reply column** of the spreadsheet (see figure on p.7) and return it to the BPSU office **via email as soon as possible** using the codes listed below. Every couple of months the office will remind you to do this

Confirmed (C) - If the notified case conforms to the surveillance case definition,

Duplicate (DP/DN) - If the notified case is a duplicate report of the same individual already reported by another paediatrician through the BPSU (e.g. a case is reported from a district general hospital and later from a tertiary centre), please tick the 'duplicate' box. Please add the BPSU case number for the previous duplicate report and whether it is a duplicate confirmed case or a duplicate error.

Already known (R) - If the notified case has already been reported to you through another route indicate the other source of the report e.g. laboratory, microbiologist etc.

Error (E) - If for any reason the notified case **DOES NOT** conform to the surveillance case definition. This would also be the situation if the case is reported outside of the surveillance period or the case was reported in error. Please indicate the reason that the notification is considered an error in the comment section of the form.

Unable to follow up (UF) - unable to follow up, for example not receiving a questionnaire from the consultant

C	Confirmed case
DP	Duplicate of a positive case. Please provide case number
DN	Duplicate of negative case. Please provide case number
R	Reported already from another source
E	Error
UF	Unable to follow up
X	Leave as this if you have no further information

At regular intervals, the BPSU office will supply you a list of all notification reports and their outcome as status for you to confirm or amend.

Summary

Case details received from BPSU

⬇

Email to confirm contact details

⬇

Questionnaire sent immediately

⬇

Followed up email after 2-3 weeks

⬇

Followed up with a phone call 2 weeks after if no response

⬇

Once case outcome has been determined fill in REPLY column on spreadsheet and email to BPSU office

Section 14: Data collection

Auditing the paper trail

The amount of information coming in once a study has commenced can be overwhelming, especially for less experienced researchers. For this reason, we advise you develop an audit trail. Such a trail should be prepared before reports start to come in and questionnaires returned. Below we have produced a suggested trail that can be set up in either a spreadsheet or database. If you intend to send out a follow-up questionnaire, you may want to add details about whether the follow – up has been sent, when a reminder has been sent and if the data been entered.

Study Number	As the reports are sent to you give them your own unique number 1-2-3 is fine
BPSU case reference	Supplied by BPSU. A monthly number unique for the condition month and report
Source of case report	Paediatrician/surgeon/psychiatrist
Month Reported	E.g. May 2010. Note this is not the month you receive the report but the month it was reported by the clinician
BPSU Response reference	Unique BPSU number identifying the reporting paediatrician
Name of Doctor	Supplied by BPSU
Hospital/clinic	Supplied by BPSU
Address 1	Supplied by BPSU
Address 2	Supplied by BPSU
Address 3	Supplied by BPSU
Address 4	Supplied by BPSU
Postcode	Supplied by BPSU
Email	Supplied by BPSU or doctor
Date case reported	Supplied by us on the notification email
Date questionnaire sent out	When investigator sent out Questionnaire - should be ASAP after receiving report
Date reminder e-letter sent	Usually after 2-3 weeks
Date 2nd reminder letter sent	Optional - usually after 2 weeks
Date telephone reminder	After a further 2 weeks
Date thank you letter sent	Sent out by investigator after receipt of Questionnaire
Date QA completed	Supplied by reporting clinician
Date QA received	Completed by investigator on receipt of Questionnaire
Clinicians telephone number	Supplied by clinicians on Questionnaire
Has the clinical data been entered	Yes/No
Patient referred?	Yes/No
Referred To	If they have referred the case on
Referred From	Hospital that referred case to this clinician
Status of case	Required by BPSU- Confirmed, error, duplicate positive, duplicate negative, not yet known, unable to follow up
Case Checked	Final status confirmed once the Questionnaire have been reviewed and signed off
Duplicate case reference	Reference number of duplicate case
Date record created	Date
Date record last updated	Date
Comments	

Section 15: Processing data

Preparing for data entry

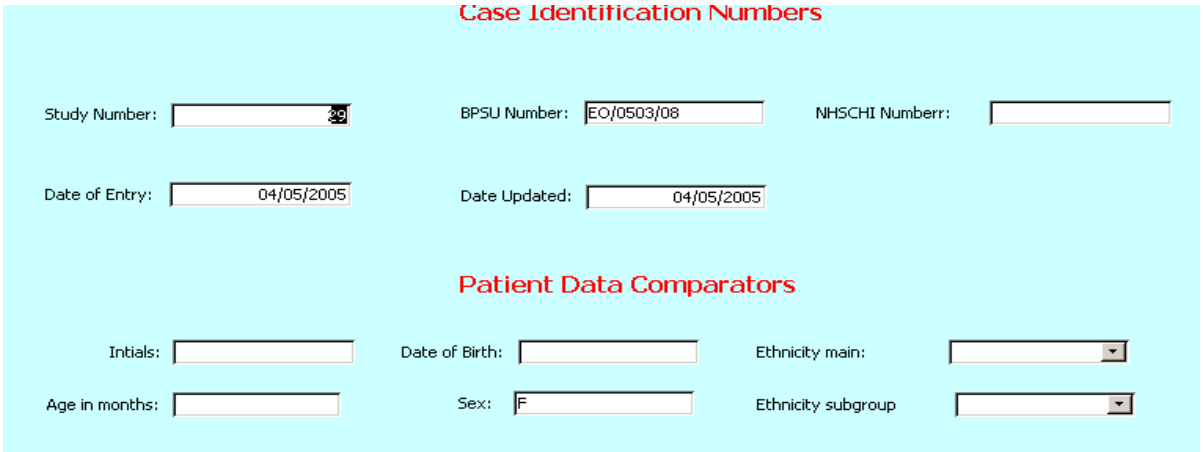
1. Produce your data entry tables/spreadsheet at the start of the study
2. Produce a protocol or set of rules for entering data. This will help when dealing with missing, duplicate or conflicting data. It will also help with dealing with data from multiple sources i.e. in the case of infectious disease data from labs as opposed to data from clinicians
3. Keep the child identifiers separate from the clinical data
4. Use the BPSU code/your code as a link key between the two files/tables/spreadsheets
5. We can advise on:
   - a data entry system
   - the importance of producing a data audit trail
   - developing on-line data collection
   - resolving data entry problems
   - how to de-duplicate data

On receipt of the questionnaire

1. Write the date on the top identifier sheet and the clinical sheet
2. Make sure the BPSU code and your code is on all the sheets
3. Go to your audit trail and enter the date the questionnaire was received and the details of the reporting clinician and enter any referral data
4. Quickly review the questionnaire - if it is possible identify from the data whether the case fits the definition or not and whether it is a duplicate case or not
5. Prepare the thank you letter, which you have as a template – if there is any specific data missing point this out in the thank you letter and return a copy of the questionnaire

Entering data from the main questionnaire

1. Enter the data as soon as you can rather than entering all the data in one go near the end of the study
2. Go to your patient identifier data table/sheet and enter the patient identifier data first – example below
3. Check to see if this patient has already been reported – the NHS/CHI number will be the best identifier for this



4. Your clinical data entry screen should include fields such as the case identifier; whether the case is confirmed or not; date when record was made/updated
5. You may wish to include a check box which can be used at the end of the data entry and cleaning-up process to confirm that the record has been signed off before analysis
6. Now go to your clinical data entry screen or worksheet and enter the clinical data

- **Q**. I have a duplicate report do I enter the data in a new record?
    - **A**. We would recommend you enter all the data from all the datasheets. But identify that this is a duplicate and of which other record
- **Q.** Both questionnaires have useful but slightly differing data – what should I do?
    - **A.** As previously stated you should develop a set of rules on how address multiple data sets on a single individual e.g. use the earliest diagnosis data; use earliest date for treatment, use the last dated outcome data
    - If the other questionnaire has useful information include in the comment fields you should have set up.
- **Q.** I have entered the data, now what?
    - **A.** If you are sure you have categorized the case appropriately as a case, duplicate etc. locate the spreadsheet sent to you by the BPSU with the appropriate BPSU reference number. Update the status column and email back to the BPSU

7. If a study project board meeting has to be arranged to discuss the status of the reports, please let the BPSU office know when these meetings are to take place
8. If you have alternate sources of reporting it may be that the data available may not be in the form that fits the questionnaire e.g. laboratory data may have minimal clinical information. See if it is possible to get the names of the reporting clinicians to try and collect this data.

- **Q.** How do I enter data from these alternate sources when there is no corresponding paediatric report?
    - A. Produce a new record and enter as much data as you can; identify in the record that this is data from your alternate source.

Enter data from questionnaires as they arrive.
DO NOT leave them all to the end of the study to process

Entering data from the follow-up questionnaire

1. Collecting follow-up data may not be easy as the reporting clinician may have retired, or moved; the child may have moved or been referred on.
2. Where the same case has been reported by differing clinicians in differing hospitals i.e. DGH and tertiary centre; you should consider sending a form to each.
3. When entering the follow-up data you may wish to add the data to the existing record, alternatively you might consider setting up a new datasheet using the case reference number as the link.
4. On receipt of the follow-up questionnaire review to see if there is any missing data.
5. Write and send a thank you letter to the clinician asking for any final data if necessary

How to de-duplicate data

1. Identify the data fields which will allow for effective de-duplication
2. You should have REC/CAG/PBPP approval to include at least three of these identifiers in your data set
3. Those specifically related to the child will be the strongest identifiers e.g. NHS/CHI number; Hospital number; initials; sex; date of birth and partial postcode
4. Additional data fields from your datasets can also be used, but these may be weaker. These would include sites of reporting clinicians; other clinical data i.e. data of diagnosis; weight and/or height; date of discharge; outcome etc
5. Order your dataset by the fields in the order given in 3. This should allow you to identify duplicates

Data Processing - An example from a recent study

Functional Requirements

1. *Star Database* : Essential

Ability to have a centralised table with all the relevant case information required for analysis using information derived from <<*number*>> independent data sources (<<*number*>> tables: BPSU data; <<*name additional source(s)*>>).

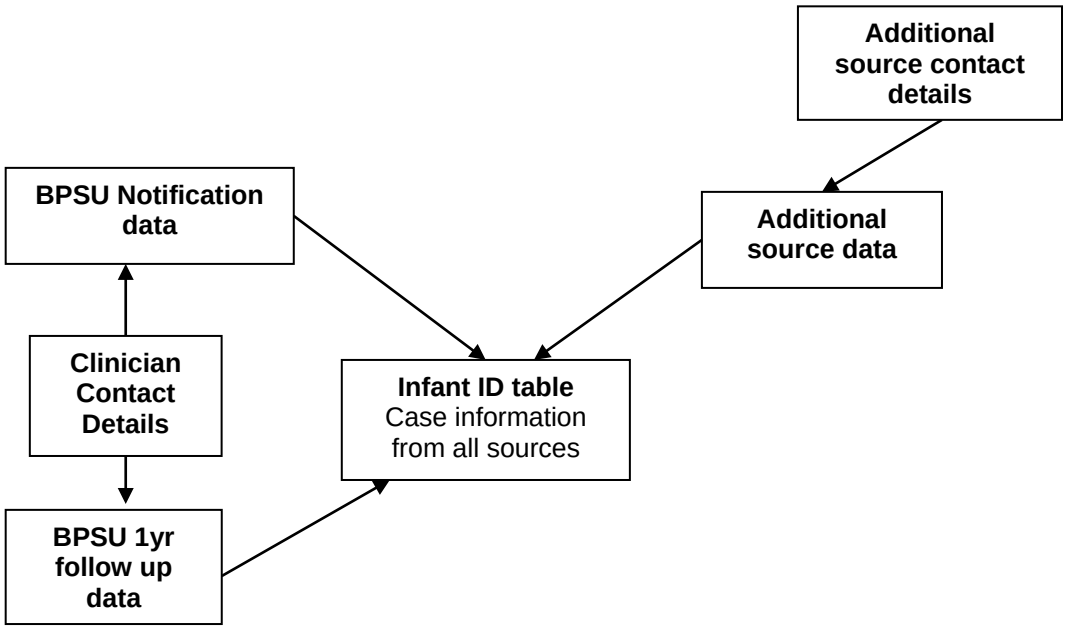


Figure 2: Star Database

2. *De-duplication of records*: Essential

Ability to run a query based on initials and date of birth to assign a unique study ID to each case ensuring no duplicate records are present in the centralised table.

Section 16: Analysing the data

Planning

1. Set an end date for chasing-up outstanding data
2. Make sure you have processed all data before commencing analysis
3. Identify the records which you wish to analyse - i.e. identify those records that you identify as confirmed cases and, if a duplicate is confirmed, identify the primary confirmed record
4. Start to clean the data from these records – by this we mean go through the data and make sure the details are in a form that can be easily extracted and analysed. Is text in the right case; is it consistent in that you are using the same terms throughout. With numerical data make sure decimal points are in the right place and that you have standardised the units you are to analyse the data in. Make sure dates are consistent e.g. the diagnosis date is not before the presentation date
5. Once de-duplication has taken place and data entry has been finalised anonymise the records in your data set
6. Look at the research objectives and using these as guidance list the analysis you wish to undertake.
7. Think about how you wish to present this data in a paper(s). Do you wish to write an epidemiology short paper and a more extensive clinical paper?
8. It is inappropriate to undertake post-hoc analysis. Analysis should address only the research objectives stated in the study protocol
9. It is very easy to get confused about what analysis you have undertaken. So, we recommend you make a spreadsheet audit of the analysis you undertake. This should name the analysis file which should include a date e.g. Cases_AgexSex – 01-03-10 and describe the analysis undertaken and when
10. Identify the particular statistical analysis you wish to do on the data
11. Start with the easier pieces of analysis such as demographic breakdown

12. For incidence calculations you will need denominator data. Population data is available from ONS (http://www.statistics.gov.uk/STATBASE/) and Central Statistics Office - Ireland (https://www.cso.ie/en/statistics/population/) or contact the BPSU office
13. Do not try to over analyse your data looking for statistical significance
14. Have a look at previous BPSU papers to see how they have presented data

Alternate sources of data

15. When analysing your data be careful when undertaking capture – recapture. Are the sources truly independent and are they sampling from the same population? BPSU can advise on this.

Anonymising Data

16. Date of birth - As soon as possible convert date of birth into age in months
17. Sex – this can be coded as 0 and 1
18. Keep identifiers separate from clinical data – use the BPSU code as a link

Section 17: Monitoring of security, data handling and confidentiality

Below are a series of questions investigators should ask themselves when planning to handle the data you have collected.

Actions required for good data management practice

1. **NHS IG Toolkit/System Level Security Policy (SLSP)**
   - Review your data handling management regularly against your SLSP
2. **Identifying patient data**
   - Collect *only* the minimum amount of identifying data to undertake the project
   - Ensure you can justify all the identifying information you are seeking
3. **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
4. **Data handling**
   - Make sure the handling and 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 storing archive paperwork
5. **Data security**
   - Make sure that data is secured in a lockable cabinet and room
   - Electronic storage – are the data on a networked computer, if yes who has access
   - Make sure the data files password protected. These should be changed regularly
   - If data is 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
6. **Risk assessment**
   - 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
7. **Data exchange**
   - Data exchanged by email or disc should be anonymised. Where this is not the case current robust encryption methods should be used.
8. **Use of other IT equipment**
   - Patients identifiable data must be held in a secure location (e.g. a locked cabinet in a locked room) and on protected computer databases, e.g. using password or other security measures. This includes data that is archived once the study has been completed.

Section 18: Ongoing report production

Annual report to the BPSU

- In February each year you will be requested to fill in a report form on your study.
- A covering letter giving guidance on what is required will be sent with the request.
- The report will then be edited in order to be inserted in the Annual Report.
- If your study has just ended and you are concerned that publication of data may hinder acceptance for publication, please do let us know.
- In the final study report we will require information relating to any problems that may have arisen during the study; identification of potential further research and whether you will be pursing this.

  Please let the office know of any other comment you may feel is valuable to help improve the BPSU effectiveness.

REC, HRA-CAG, PBPP and funders reports

Each year you will be asked to produce a short report for either/both ethics authorities. This will normally include a short synopsis of the study; progress to date and whether there have been any problems in relation to ethics aspects of the study. At the end of the study you may be asked for a more extensive report.

Depending on the requirements of your funding grant you may have to submit an end of study report to your funder. If this is the Department of Health you must follow their guidance on presenting and publishing the study.

Section 19: Requesting a study extension

In some study's the report numbers received over the surveillance period are not as great as had been estimated. This may be due to poor ascertainment or a lower incidence. If you feel your study will require an extension to the surveillance period to meet the research objectives please contact the BPSU.

You will need to submit an extension request to be reviewed by the BPSU Scientific Committee. The extension request should include:

- summary of the project;
- the research objectives;
- some initial data analysis;
- identification of any problems that may have led to a lower number than expected reports and whether such problems have been addressed
- any other problems that may have arisen

If you believe there is lower than expected incidence please state. You will also need to confirm how long you wish the extension for (it is usually one year in the first instance) and whether funding is in place. Any extension approval will be subject to approval from the REC and HRA-CAG.

Please check the dates of future Scientific Committee meetings on the BPSU website and ensure that paperwork is received by the BPSU office no later than 2 weeks prior to the meeting. Your request will only be considered by the committee if it is received within the deadlines published on the BPSU website.

If it is not received in good time your request will not be considered and you will have to wait until the next meeting.

Part E – Near study completion

Section 20 – As your study comes to an end

In the final report to the BPSU please:

- produce your timeline for publication
- identify any problems arising during the study
- identify potential future areas for researcher – e.g. guideline development; policy proposals
- Send a final case list to the BPSU so that we can update our records
- If the funders of your study are the Department of Health follow the arrangements outlined in their contract to you.
- Be prepared to attend a BPSU Scientific Committee meeting to discuss the study findings

Section 21: Notifying the BPSU about the release of data to the scientific and wider community

In order to measure impact on the scientific and wider community it is important that the BPSU is notified of release of data.

The type of publication that the BPSU needs to be made aware and receive a copy of include

- Abstracts/posters for conference
- References of such abstracts if they are included in a journal
- Journal articles. BPSU will need to see a copy of final draft of the paper **before** submission to a journal
- Press releases

Please note the BPSU is obliged under its contract with Public Health England to pass them a copy of any abstracts, publication. Also if you intend to circulate a press release a copy will need to be cleared by Public Health England, UCL-ICH and RCPCH press offices. We need these no later than 28 days before submission. This is not required for studies commencing after September 2012, though the BPSU office will be required to see the paperwork.

If your study is funded by the Department of Health please follow the requirements of the contract you have with them.

Section 22: Archiving

- 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 (https://mrc.ukri.org/publications/browse/good-research-practice-principles-and-guidelines/).

Appendices

Appendix 1: Timeline for Research

Completed Work Anticipated Work

Proposed Time Period for Research (in months) – October 2018 – September 2021 (3 yrs = 36 mths)

MONTHS		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Research	Action																								
1.1	Discuss research with Supervisors / Clinical Consultant																								
1.2	Update Literature Review																								
1.3	Refine Aims / Objectives of Study																								
1.4	Design Questionnaire																								
1.5	Discuss and Decide on Data Analysis																								
1.6	Submit Phase 2 Application to BPSU																								
1.7	Complete Ethics Forms																								
1.8	Commence Compilation of Dissertation																								
1.9	Data Collection																								
1.10	Data Input																								
1.11	Data Analysis																								

MONTHS		25	26	27	28	29	30	31	32	33	34	35	36												
Research	Action																								
(1.9)	Data Collection - continued																								
(1.10)	Data Input - continued																								
(1.11)	Data Analysis - continued																								
1.12	Write-up Findings																								
1.13	Submit Thesis																								
1.14	Disseminate Findings; ▪ Write Journal Article / Conference Submissions											→	→												

Appendix 1: Timeline for publication

Completed Work Anticipated Work

Proposed Time Period for Research (in months) – October 2018 – September 2021 (3 yrs = 36 mths)																									
MONTHS		31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
Research	Action																								
1.1	Data collection near completion																								
1.2	Data cleaning																								
1.3	Update systematic review – for references																								
1.4	Decide on message and target audience																								
1.5	Identify appropriate journal																								
1.6	Final data analysis																								
1.7	Statistical review																								
1.8	Write Background and methods – ahead of analysis and discussion																								
1.9	Draft report																								
1.10	Sign off																								
1.11	Post publicity																								
MONTHS																									
Research	Action																								
1.12	Disseminate Findings; Write Journal Article / Conference Submissions																								
1.13																									
	▪											→													

SHALL WE STILL PRODUCE THIS – AS CAN USE WEB TEXT FOR INFORMATION

Appendix 2: Flyer Template

BPSU Surveillance of XXXX

Commences in XXXX XXXX
(Short Study Name: XXXX)

Please describe briefly in lay terms the purpose of your study. Do not use complicated medical terms as this summary. This information may be lifted from you P2 application

Duration: *BPSU surveillance will be undertaken for 13 months, commencing in XXXX XXXX.*

Case definition:

Reporting Instructions: *Please report any child seen in the last month who meets the case definition in the UK or the Republic of Ireland from XXXX XXXX.*

Website: www.rcpch.ac.uk/bpsu/XXXX

Funding: XXXXX

Ethical approval: XXXXX

Further information:

If you would like any advice regarding the eligibility of a particular case for inclusion in the study please contact:

Dr XXXX XXXX,
Address: XXXXX
Tel: *XXXX* **Email:** *XXXXXX*

Appendix 3: Protocol card template

BRITISH PAEDIATRIC SURVEILLANCE UNIT
Royal College of Paediatrics and Child Health
5-11 Theobalds Road, London WC1 X 8SH
Tel: 020 7092 6173 Email: bpsu@rcpch.ac.uk Web:

STUDY TITLE

Abstract	Summarize key elements of study in approximately 150 words
Principal Investigator	List all principle investigator(s) of the study and contact details
Co-investigators	List co-investigator(s) of the study, where relevant
Website	www.rcpch.ac.uk/bpsu/XXXX
Background	Summarize key background points of study in approximately 100
Coverage	Where was the research conducted e.g. United Kingdom
Duration	Time taken to carry out study (e.g. September 2009 – September 2010 13 months) Follow – up 12 months to September 2011
Research Questions	
Case definition	Define the condition/disease of study
Reporting instructions	To report any cases seen within the last month that meet the case
Methods	List in chronological order how the study will be carried out
Ethics approval	Details of approval
Funding	List of organisations who have funded the study
References	