



**GUIDELINES FOR SUBMITTING A  
PHASE TWO APPLICATION FOR INCLUSION OF A STUDY**

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## INTRODUCTION

Applications for the inclusion of a study to CAPSS are considered by the CAPSS Executive Committee. This document gives detailed guidance on how to complete PHASE 2 (P2) of the CAPSS application process and the requirements which must be met for a study to be accepted. The CAPSS Executive will give fair and impartial consideration to the applications. 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 this stage. If appropriate, advice from independent referees may be sought. Principal investigators may be invited to a meeting of the Executive Committee to discuss this proposal more fully.

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

- The criteria for study application to CAPSS (Appendix 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. The CAPSS office must receive finalised applications which are ready for submission one month prior to the Executive meeting, to allow time to circulate documents for review.
- The CAPSS Executive meets every three months. Dates are available from the CAPSS office.
- 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 CAPSS card depends on the number and the nature of other studies being surveyed.

## ELIGIBILITY

- If the condition of interest is a relatively rare childhood condition 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. CAPSS may also consider inclusion of a short-term study of comparatively more common conditions.
- For the success of the scheme it is important that the workload of the mailing list is kept to a minimum. Accordingly, the Executive Committee must be certain that studies conducted through CAPSS are a) worthwhile b) well designed c) adequately resourced and d) practical. The Executive Committee takes into consideration the scientific interest and public health importance of the proposed study, its methodology and the suitability of the condition for ascertainment through the CAPSS scheme. CAPSS is however also committed to assisting potential investigators (especially those less experienced in research methodology) in improving potentially good studies.
- Normally the study surveillance period would be for 13 months though this can be extended if it is felt that additional ascertainment is required to allow for meaningful analysis.

## INELIGIBILITY

Applications considered ineligible are those that involve:

- a) retrospective surveillance
- b) case control methodology
- c) audit or enrolment into clinical trials
- d) direct patient contact
- e) lack MREC/NIGB-ECC approval

For further criteria on eligibility please see Appendix 1.

## REVIEW PROCESS

The CAPSS Executive Committee meets every three months to consider applications. The following outcomes are possible

- 1) P2 may be accepted in its entirety - rarely the case.
- 2) P2 accepted but several minor points still need to be addressed.
- 3) Further details may be sought before a decision is made on the potential acceptability as a CAPSS study. Applicant may be invited to present their case in person.
- 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 CAPSS scheme. The CAPSS Executive Committee will give reasons for its decision and offer suggestions on how the study could be undertaken outside of the CAPSS scheme.
- 6) Following acceptance and the receipt of MREC and NIGB Ethics and Confidentiality Committee [ECC] approval, arrangements will be made to place the study on the card. This will usually follow a period of advertising to raise awareness of the project.

If you have any further queries relating to the CAPSS application procedure please do not hesitate to contact our office.

## COMPLETING THE PHASE 2 APPLICATION

### 1) Title of study

Give the accepted name of the condition followed by the recognised abbreviation, if any.

### 2) Title of study to appear on yellow card (if different from above)

No more than 30 letters.

### 3) Investigators

Give the names, appointments and institutions of the investigators. Indicate clearly (a) the principal contact for correspondence on this application (b) the contact for reporting of cases if different; for both give full postal address, telephone, fax number and e-mail address.

### 4) Lay summary for public

Give a brief statement in layman's terms outlining a) the need for the study b) main aims of this study.

### 5) Describe the study in lay terms

This should explain a) need to study the condition, b) review of the background to the proposal, c) draw attention to the state of current knowledge, including incidence, prevalence and indicating public health and scientific importance.

### 6) Proposed starting date

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.

### 7) Proposed duration of study

CAPSS 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 phase two application how long they wish for the initial surveillance to be undertaken and also any subsequent follow-up. Justification for the proposed study duration should be included in the supporting statement. Continuation thereafter is subject to receipt of a yearly progress report. 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 CAPSS Annual Report. Please note that the CAPSS Executive Committee has the option to limit initial surveillance duration to 13 months.

8) **Proposed territorial coverage**

Studies normally cover the whole of the UK, the Republic of Ireland and the Channel Islands. Justification of the proposed territorial coverage, if less than this, should be included in the supporting statement. You are strongly advised to seek an Irish link for your project.

9) **Case definition and reporting instructions**

Give a clear case definition for the condition of interest, preferably one that is internationally accepted. State the desired age limits (usually up to the 16th birthday except for neonatal conditions). Any specialist terms or abbreviations, which will not be familiar to paediatricians, should be explained in full.

Surveillance and analytic case definition. A number of studies now include a surveillance case definition (simple and practical and capturing all cases) and a narrower case definition subject to analysis (Appendix 2).

Reporting Instructions

You may give different reporting instructions for (a) the first mailing in which the condition is included, and (b) subsequent months. A sample set of reporting instructions can be found at the end of these guidelines (Appendix 2).

10) **Expected numbers**

Not more than 300 cases. If more expected please argue your reason for inclusion.

11) **Research questions/surveillance objectives**

Give a clear statement of the specific research questions that will be answered by this study e.g. 1) estimate incidence, 2) review clinical features, 3) presentation and outcome.

These questions must be addressable through the surveillance system:

- a) without any direct contact with patients
- b) without seeking investigations that would normally not have been undertaken by the psychiatrist
- c) without a comparison group

What will answering these questions achieve?

12) **Study methods**

- The BEC needs to be convinced that the methods used in the study are essential to answer the study's research questions, that the methods are practically possible and that they will not overburden the mailing list.
- Please identify the denominator you intend to use to calculate incidence.

- This section should also include arrangements for protecting confidentiality and justification of collection of patient identities and implications for the patient/parent. Copies of questionnaires and covering letters to respondents must be attached even if they are only in draft form. The CAPSS Executive will request final versions of these before final acceptance.

13) **Alternate sources of data**

Are there other groups besides psychiatrists who are likely to see cases not seen by psychiatrists? If so it is essential that there are plans to seek cases through them, as this improves ascertainment and reduces bias.

14) **Proposed level and nature of public involvement**

Applicants are encouraged to involve the public in their studies wherever possible. In addition 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 CAPSS website. Contact the office for further information.

15) **Questionnaire design**

Please note that CAPSS has instructions for the design of questionnaires. It is strongly advised that you liaise with the designated Reviewer before submitting your questionnaire as failure to do so may lead to delay in processing your application or its rejection. You are advised to pilot your questionnaire before submitting to CAPSS for consideration.

16) **Ethics approval**

Prospective investigators are referred to the attached CAPSS document on ethics and confidentiality (Appendix 3). Submission should be made only after the application has been approved by CAPSS. Please use the on-line IRAS system.

17) **Funding arrangements**

Outline the funding arrangements for the project, naming the body(ies) to which grant application(s) have been submitted and giving the date by which arrangements are expected to be agreed. Inflationary costs for the contribution rates should be included if applying for more than one year's surveillance. State whether funding is from a commercial source; whether you are personally in receipt of funds to under take the research. Where the study is funded by a third party (commercial or non-commercial source), CAPSS prohibits access to raw data.

18) **Organisational arrangements**

Give an outline of other arrangements (e.g. location, resources) 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. We strongly advise that a research administrator or officer is employed either part time or full time if the expected number of case

*Date.*

reports is greater than 100 a year. You should be aware of the of the study's arrangements for data handling (Appendix 4).

## DESIGN OF QUESTIONNAIRES

Investigators are welcome to discuss questionnaire design with the CAPSS Executive and copies of questionnaires used by existing studies are available on request.

A letter of introduction should be sent with the questionnaire and a thank you letter should be sent on return of the questionnaire (Appendix 5 and 6). This is vital in keeping the continued support of the clinicians.

- Questionnaires should be brief and as 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.
- CAPSS at The Royal College of Psychiatrists should be included in the heading of questionnaires and covering letters.
- Information sought should be easily accessible to the reporting clinician. Anonymised discharge notes can not usually be sought.
- 'Tick box' format should be used wherever possible. Remember to include a DK or not tested box where appropriate.
- The top page of the questionnaire should contain the hospital and minimal identifiable data; this can then be separated from the clinical details sought thereafter.
- The questionnaire should take no longer than 15 minutes to complete.
- Specialist terms or abbreviations that may not be familiar to psychiatrists should be explained in full.
- Names and addresses should not be included, though a unique identifier (e.g. NHS number) is usually essential. However minimal patient personal information to allow identification of duplicate reports and collection of follow-up data (e.g. initials, date of birth, sex, or NHS number) is currently accepted by CAPSS, but you will need to justify this to REC and ECC.
- Standard accepted classifications should be used where possible, for example to record ethnic group or social class. Office of National Statistic or equivalent offices for Scotland, Northern Ireland, and the Irish Republic.
- If there is good reason for investigating geographic variation using postcode the first three letters can be requested.
- Respondents should be asked to return the questionnaire even if they are unable to complete all items. Anonymised request for notice is acceptable in certain circumstances.
- A reply paid envelope for return of the data collection sheet is essential.
- You should pilot the questionnaire.

### Requesting microbiological specimens

- If you are requesting specimens please make sure the details of the requirements are easily understood.
- Make sure the arrangements for transport are as un-onerous on the reporting clinician as possible.

## APPENDIX 1

### Criteria for Consideration

Applications considered **eligible** are those where:

- the condition should be a relatively rare childhood condition **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. The BPSU may also consider inclusion of short-term studies of comparatively more common conditions.
- the condition studied should have an expected incidence in the UK of no more than 300 cases per year (for more common conditions regional studies work better).
- all or the majority of cases should be expected to be seen by a psychiatrist.
- cases can be easily identified and defined.
- study data is easily accessible from the normal clinical notes.
- ethics approval from an MREC and ECC is to be sought.
- consideration of an alternative source of case ascertainment, e.g. microbiology laboratory reports, specialty groups should be given. This is especially important if one of the study aims is to establishing incidence.

Applications considered not **eligible** are those which:

- do not intend to seek MREC approval
- require direct patient/parent consent
- intend to use the case cohort to establish a disease register
- require long term follow up (< 2 years)
- require the need to seek controls
- involve any additional clinical intervention for reported cases (other than additional diagnostic tests on samples collected during routine clinical management)
- are really audit
- require retrospective reporting
- are interventional studies

## APPENDIX 2

### Example reporting instructions & case definitions

#### 1) Early onset eating disorder

##### Case definition

Please report 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 exercising<sup>1</sup>
- recurrent episodes of binge eating or abuse of laxatives

<sup>1</sup> "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.) This definition has been included in the questionnaire.

##### 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.

#### 2) Conversion Disorder

Any child younger than 16 years newly diagnosed with Conversion Disorder during the previous month in Britain and Ireland. Conversion disorder is DEFINED as:

The presence of one or more symptoms and or signs affecting motor function (e.g. weakness, abnormal gait or movements, difficulty with swallowing, or loss of speech), and or sensory function (e.g. loss or diminished sensation of touch, sight, or hearing), and or non-epileptic seizures (also known as pseudo seizures). AND

The symptoms and or signs:

1. Cannot be adequately explained by a medical condition after full investigation (according to the judgement of the treating clinician), and
2. Have no evidence that they have been intentionally produced, and
3. Cause significant distress and or interference in daily activities such as with self care, school attendance, play, or family activities for up to 7 days or longer, and
4. Are accompanied by psychological factors that are judged to be associated with or have contributed to the presentation

#### EXCLUSION CRITERIA

1. Cases where the clinical picture is predominantly or exclusively pain or fatigue, and/or
2. Cases where the dominant picture is another psychiatric disorder such as depression or psychosis diagnosed by a child and adolescent psychiatrist, and/or
3. Tic disorder

#### **Reporting Instructions**

Please report any child, aged up to (but not including) 16 years of age, with suspected or confirmed Conversion Disorder seen by a Child and Adolescent Psychiatrist for the first time in the last month. If a Child and Adolescent Psychiatrist is uncertain or awaiting confirmation, the child should still be reported.

Date.

## APPENDIX 3



# Ethics, Consent & Confidentiality

## **The Child and Adolescent Psychiatric Surveillance System (CAPSS) and Patient Confidentiality**

### Summary

- CAPSS and the research teams involved in studies are unreservedly committed to preserving medical confidentiality in all aspects of their work.
- CAPSS requires study applicants to demonstrate their compliance with each of the eight principles outlined in the Data Protection Act 1998.
- CAPSS requires study to comply with the principles outlined in the Caldicott Report (1997).
- CAPSS requires study applicants to detail the security measures in place to protect patient confidentiality.
- CAPSS requires study applicants to apply to National Information Governance Board Approval Section 251 approval.

### **1. Confidentiality in Law**

In the UK there are a number of pieces of legislation that address confidentiality of personal information including Common Law, Data Protection Act 1998 and Human Rights Act 1998.

#### **Common Law**

In Common Law anyone who receives information must respect its confidentiality i.e. not disclose it without consent or other strong justification. Common Law enshrines the principle that to disclose confidential information about a living person without consent is, generally speaking, to wrong an individual. In law any information doctors have about their patients must be regarded as confidential. Common Law does however recognise that it can be in the public interest for doctors to disclose confidential personal information and that the nature and scale of the disclosure has to be balanced against the benefits to society. While Common Law establishes some core principles it does not specify when confidential information may or may not be disclosed to others in research or most other activities.

#### **Data Protection Act 1998**<sup>1</sup>

If a living person (data subject) can be identified from any information in your possession this information is considered personal data. Personal data stored in computers and/or paper files (ward notes, X-rays, lab reports etc) is safeguarded by the Data Protection Act 1998. This places obligations on those who record or use personal data and gives certain rights to persons about whom information is held. The eight principles of the Data Protection Act are summarised as follows.

1. Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless at least one of the conditions in Schedule 2 is met; and in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met.

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<sup>1</sup> Available at <http://www.opsi.gov.uk/acts/acts1998/19980029.htm>

2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes.
3. Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed.
4. Personal data shall be accurate and, where necessary, kept up to date
5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or those purposes.
6. Personal data shall be processed in accordance with the rights of data subjects under this Act.
7. Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.
8. Personal data shall not be transferred to a country or territory outside the European Economic Area, unless that country or territory ensures an adequate level of protection of the rights and freedoms of data subjects in relation to the processing of personal data.

### **Human Rights Act <sup>2</sup>**

The Human Rights Act 1998 allows UK citizens to assert their rights under the European convention on human rights in UK courts and tribunals and states that "*so far as possible to do so, legislation must be read and given effect in a way which is compatible with convention rights*". The European Convention on human rights, so called "the Convention", was ratified by the UK in 1951 and enshrines a right to respect for individual private lives and prescribes the circumstances in which it is legitimate for a public authority to interfere with the enjoyment of this right.

### **Caldicott Report**

The Caldicott Report (1997) was a review commissioned by the Chief Medical Officer to make recommendations to improve the way the National Health Service handles and protects patient information.

The Caldicott Committee was set up to review the confidentiality and flows of data throughout the NHS for purposes other than direct care, medical research or where there is a statutory requirement for information. Its recommendations are now being put into practice throughout the NHS and in the Health Protection Agency.

The Caldicott report identified six principles, similar in many respects to the principles outlined in the *Data Protection Act*.

1. Justify the purpose(s) for using patient data
2. Don't use patient-identifiable information unless it is absolutely necessary
3. Use the minimum necessary patient-identifiable information
4. Access to patient-identifiable information should be on a strict need to know basis
5. Everyone should be aware of their responsibilities to maintain confidentiality
6. Understand and comply with the law, in particular the Data Protection Act

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<sup>2</sup> Available at <http://www.opsi.gov.uk/acts/acts1998/19980042.htm>

## 1.5 Section 251 of the Health & Social Care Act 2008 and National Information Governance Board (NIGB)

Following the 2008 act the NIGB has been set up as a statutory body. From January 2009 the NIGB functions includes administration of applications under section 251 of the NHS Act 2006 which allows the common law duty of confidentiality to be set aside in specific circumstances. This function was formerly carried out by the Patient Information Advisory Group (PIAG) which was abolished on 31 December 2008.

- Section 251 of the NHS Bill 2008 provides a power to ensure that patient identifiable information needed to support essential NHS activity can be obtained without the consent of patients. The power can only be used to support medical purposes that are in the interests of patients or the wider public, where consent is not a practicable alternative and where anonymised information will not suffice. It is intended largely as a transitional measure whilst consent or anonymisation procedures are developed, and this is reinforced by the need to review each use of the power annually.
- The Ethics and Confidentiality Committee formerly the Patient Information Advisory Group (PIAG) was established to provide advice to the Secretary of State for Health involving the use of patient information. The terms of reference for the Ethics and Confidentiality Committee (ECC) are still in development; however, in essence, the ECC has been established to consider ethical issues related to the processing of patient data and to consider applications under Section 251 of the NHS Act 2006. Its membership is drawn from patient groups, healthcare professionals and regulatory bodies.
- CAPSS will work with ECC to ensure that the studies conducted under its remit fulfil the obligations set down in Section 251 of the Health & Social Care Act.

## 2. CAPSS Methodology and Confidentiality

### 2.1 CAPSS Reporting Mechanism

Explicit patient consent is not sought. The CAPSS mechanism is shown Figure 1. Applicants wishing to undertake a surveillance study put forward a detailed protocol. Successful applicants are selected following a detailed, two-phase scientific review by the CAPSS Executive Committee, which has a broad multidisciplinary representation.<sup>3</sup> Priority is given to conditions or issues of public health importance, conditions of low incidence and where near-complete reporting is required.

All studies have to be approved by an REC and funding confirmed before it can be included on the CAPSS surveillance 'YELLOW' card.

Particular attention is taken to ensure that the patient information to be gathered by the investigator is the minimum necessary to allow for optimal case ascertainment matching and removal of duplicate case reports, contacting notifying clinicians and achieving the research objectives.

### 2.2. Maintaining confidentiality in CAPSS investigations

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<sup>3</sup> Membership of the Committee includes consultant psychiatrists, and psychiatrists, epidemiologists, as well as a representative of the British Paediatric Surveillance Unit, the English Department of Health,(TBC)

- Anonymised notifications are provided to the CAPSS office by members of the Royal College of Psychiatry (RCPsych) using CAPSS methodology i.e. the 'YELLOW Card'. CAPSS informs the lead investigator or their nominated staff of the notifying member's details so the investigators can request further details.

No patient identifiable information passes to CAPSS itself from the reporting psychiatrist.

- Study investigators request the RCPsych member who has notified a case to complete a short 2-3 page questionnaire
- The CAPSS Executive reviews in detail the questionnaire of each study. The CAPSS Executive keeps to an absolute minimum the number of patient identifiable information fields. Some patient identifiable information is necessary to allow for case verification (including correspondence with the clinician who notifies the case) or matching and removing duplicate notifications, whilst other patient identifiers are an essential part of the clinical research data, for example dates of birth, sex and first part of postcodes.
- 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.
- Patients identifiable data must be held in a secure location (eg. 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.
- 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: [www.mrc.ac.uk/pdf-pimr.pdf](http://www.mrc.ac.uk/pdf-pimr.pdf) ).

### 2.3. Ethical Approval

A CAPSS study must be approved by a Research Ethics Committee (Type 3) (REC) before it can commence.

### 2.4 CAPSS ECC Application Form

- All CAPSS studies will have to complete an ECC (formerly PIAG) application to obtain Section 251 support. The CAPSS have yet to establish a formal agreement with ECC therefore you will need to complete the IRAS section on ECC.

Specific advice and guidance notes regarding the ECC application procedure are available from the CAPSS office.

- Approved applications are placed on the Section 251 Register.

Approved applications are reviewed/renewed annually.

## APPENDIX 4

# Guidance for CAPSS investigators on patient confidentiality

## Introduction

The aim of CAPSS is to facilitate the work of surveillance projects that are involved in the collection, storage, analysis, and reporting of information on patients. In some studies particularly those involved in communicable diseases, surveillance groups may offer diagnostic test on individual patient specimens. To undertake these projects effectively it is often necessary to collect and process some patient identifying data.

Under the agreement with CAPSS, which investigators sign before starting a project, there is a duty to observe general rules regarding confidentiality of information concerning patients. CAPSS strongly advises that all investigators handle patient data in accordance with the principles of the Caldicott Committee Report on the Review of Patient-Identifiable Information (attached), those contained in the Data Protection Act 1998 and in the attached CAPSS statement.

Below are a series of questions investigators should ask themselves when planning to handle data. If further advice or further information were required, the CAPSS operations manager would be pleased to help. CAPSS will routinely ask all investigators to complete a questionnaire providing information about issues relating to data confidentiality in their project.

### Actions required for good data management practice

1. 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
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
3. 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
4. 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 can access this
  - Make sure the data files are 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
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

*Date.*

- 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 current 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

## APPENDIX 5

**On headed paper from the investigator to include 'in conjunction with the Child and Adolescent Psychiatric Surveillance System of the Royal College of Psychiatrists'.**

EXAMPLE OF A LETTER TO THE REPORTING PSYCHIATRIST

[Name]

[Address]

[Address]

[Address]

[Date]

Dear [Name],

**Re: Study**

Thank you for notifying a case(s) for this study, which is being undertaken by the Child and Adolescent Psychiatric Surveillance System of the Royal College of Psychiatrists.

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 National Governance Information Board – Ethics and Confidentiality Committee.

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 CAPSS 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

## APPENDIX 6

### EXAMPLE OF A THANK YOU LETTER FOLLOWING COMPLETION OF THE QUESTIONNAIRE

Dear [Name],

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

The simple questionnaire will help us to define further the basic epidemiology of this intriguing series of childhood conditions. **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.

## APPENDIX 7

### EXAMPLE CAPSS LETTER OF UNDERSTANDING

Dear \_\_\_\_\_

#### **CAPSS LETTER OF UNDERSTANDING**

Prior to commencing the 13-month surveillance of \_\_\_\_\_, there are some particular points that need to be agreed between the investigator and CAPSS.

#### **I Contributions**

The contributions payable for the 13-month surveillance period are £10,000 + VAT in advance. An invoice will be sent to you for this amount prior to surveillance commencement (enclosed).

b) The contribution rate is reviewed annually. If a study is extended beyond a first year, the contribution for the extra period will be at the rate applicable in the first month of the extension.

c) CAPSS reserves the right to vary the contribution requested in individual cases should special circumstances apply, and to make additional charges for any extra printing or other expenses beyond those usually involved.

#### **II Conduct of the Study**

Documentation: Investigators will provide the CAPSS office with any revised documents relating to the study, preferably via email or on CD ROM, if they have not already done so.

Information exchange: You should be available to answer queries from clinicians. You are required, when requested, to produce short summaries about study progress for the CAPSS quarterly bulletin. This gives us an opportunity to publicise the study and to review progress. You are also asked to produce a summary for the CAPSS Annual Report. The initial report will be produced from the summary protocol circulated at the commencement of the project.

Dealing with the Press and media: All CAPSS studies are required to produce an initial press statement. This is not for circulation but to be available if requested. The release will be placed on the CAPSS website. A final statement should be produced once the data has been accepted for publication. Advice regarding the preparation of this document is available from the RCPsych Head of Media: Investigators MUST inform CAPSS if they are aware of any press interest in their study. They must also follow the contract requirements of their funders.

Case notification: Once a new case is notified for your study you will be emailed a notification form with details of the reporting doctor, their reference number and a CAPSS reference number. For future cross-referencing, it is advisable that your numbering system at least includes the CAPSS case reference number.

Questionnaires: It is important that you contact the clinician as swiftly as possible after receiving the notification. It is important that on receiving confirmation of the status of a report you inform the CAPSS office through returning the relevant notification form or spreadsheet.

Source ascertainment: It is important that any cases that may come direct to you and NOT through CAPSS are eventually notified to CAPSS to allow its performance to be assessed.

Case confirmation: Once you have details of the case reports the follow-up spreadsheet must be completed and returned to the office, preferably via email. CAPSS will supply every three months, or on request a spreadsheet of case reports and follow-ups for cross checking.

Confidentiality and data handling: Please be aware that you need to comply with the CAPSS documentation on this. Please refer to the enclosed advice on good data management practice.

The data sheet with the identifier data should be separated from the clinical data at the earliest opportunity after receipt. This identifier data must be held separately from the clinical data in its paper and electronic form. The unique CAPSS number can then be used to link the data until the case has been confirmed and de-duplication has taken place. Following this data analysis can be undertaken. Potential identifiers such as sex and age can for this purpose be considered part of the clinical data.

### III Reporting Study Findings

The study has been approved by CAPSS because important clinical or public health issues are being addressed, so publication of the findings is expected. Material for publication should be prepared within a year of final data collection, and the Scientific Coordinator must be sent a draft copy of the study report before it goes for publication. Investigators must also follow the contract requirements of their funders.

Content and title of papers and presentations are entirely at the discretion of the researcher. Though the CAPSS Executive Committee can advise on the wording of any CAPSS methodology section used in the paper CAPSS does not require its acknowledgement in the title of a paper or collectively in the list of authors. However, when a member of the committee contributes to a project to such an extent that the study or resulting paper could not be completed without the contribution, consideration should be given to the inclusion of that individual as an author on any publication, in accordance with existing recommendations regarding authorship of scientific papers

c) Acknowledging funding sources: All sources of funding should be declared as an acknowledgment at the end of the text. At the end of the Methods section, under a subheading "Role of the funding source", authors must describe the role of the study sponsor(s), if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication. If there is no Methods section, the role of the funding source should be stated as an acknowledgment. If the funding source had no such involvement, the authors should so state.

Date.

d) CAPSS and the clinicians should be acknowledged in any relevant papers or presentations. Suggested wording could be. "We acknowledge CAPSS, supported by XXXXXX, for facilitating the data collection and the reporting clinicians, particularly those who completed the questionnaires. Any views expressed (in publications) are those of the investigator and not necessarily those of CAPSS or XX".

IV REC and ECC approval

The CAPSS methodology now has NIGB-ECC approval to collect minimal identifier information without patient or guardian consent. However individual studies are also required to have NIGB-ECC approval for the collection of their data without consent.

If you have not yet done so please supply documentation that confirms REC and ECC approval for this study

Finally, please let me know of any problems that arise during the survey and of any other advice or assistance you may require.

Yours sincerely

**Dr Alan Quirk**  
**CAPSS Operations Manager**

I/we have read and agreed to the conditions outlined in the CAPSS letter of understanding in respect of the XXX survey.

**Signed** .....

**Name** .....

**Date** .....