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PHASE 2 APPLICATION GUIDELINES

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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 of the CAPSS application process and the requirements which must be met for a study to be accepted. Please note that though your application has moved from 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.
- The process from submission of the Phase 2 application 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 once every 2 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 e-card depends on the number and the nature of other studies being surveyed.

Criteria for eligibility

Applications considered **eligible** are those where:

- The condition is a relatively rare childhood condition **or** a rare event **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 CAPSS 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 establish 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 an audit.
- Require retrospective reporting.
- Are interventional studies.

Review process

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

- Phase 2 may be accepted in its entirety.
- Phase 2 accepted but several minor points still need to be addressed.
- 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.
- Phase 2 methodology approved but questionnaire needs amending.
- 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.
- 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.

Appendix A: Example reporting instructions & case definitions

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[1]
- 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.) 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.

Appendix B: Ethics, consent and confidentiality

The Child and Adolescent Psychiatry Surveillance System (CAPSS) and Patient Confidentiality

Summary

1. CAPSS and the research teams involved in studies are unreservedly committed to preserving medical confidentiality in all aspects of their work.
2. CAPSS requires study applicants to demonstrate their compliance with each of the six principles outlined in the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) as specified below.
3. CAPSS requires study applicants to comply with the principles outlined in the Caldicott Report (1997).
4. CAPSS requires study applicants to detail the security measures in place to protect patient confidentiality.
5. CAPPS requires all study applicants to apply the Confidentiality Advisory Group (CAG) for approval in England and Wales under section 251 of the NHS Act 2006.
6. CAPSS requires that all studies in other jurisdictions obtain additional approval where required. (In Scotland, studies require approval by the Scottish Public Benefits and Privacy Panel for Health and Social Care HSC-PBPP).

1. Confidentiality in Law

In the UK confidentiality of personal information is covered by frameworks including the Common Law, Human Rights Act 1998, NHS Act 2006, Data Protection Act 2018, and GDPR. The application of law in England and Wales has much in common with but is not always the same as in the other UK jurisdictions. Following from the Scotland Act 1998, devolved matters of data sharing within NHS Scotland are now dealt with through HSC-PBPP. Further advice will be required in relation to information gathered in Northern Ireland and the Republic of Ireland. Advice may be obtained from the CAPSS Executive, contact CAPSS@rcpsych.ac.uk.

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.

The Caldicott Report (1997) was a review commissioned by the Chief Medical Officer of England 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

Human Rights Act[1]

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.

Section 251 of the NHS Act 2006, allows the common law duty of confidentiality to be set aside in specific circumstances and provides a power to ensure that patient identifiable information needed to support essential NHS activity in England 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.

[1] Available at http://www.opsi.gov.uk/acts/acts1998/19980042.htm

General Data Protection Regulation (GDPR)

The General Data Protection Regulation (EU 2016/679) was converted into UK law (with some amendments) under the European Union (Withdrawal) Act 2018. The independent Information Commissioner provides a valuable UK Guide to Data Protection[2].

CAPSS data is collected under the legal basis of Article 6(1)(e) of the GDPR where the processing of personal data is necessary for the performance of a task carried out in the public interest.

CAPSS acts as the data controller along the following GDPR guidelines:

CAPSS acts as the data controller and each study's principal investigator acts as the data processor. As the data controller, CAPSS does not see the personal data and acts as the intermediary for the study to access the personal data needed to complete the study aims and purposes. This is on the basis that once a study has been through CAPSS' application processes in addition to NHS research approval, it is of scientific purpose and aims to increase society's knowledge, treatment and prevention of psychiatric disorders in children and adolescents.

GDPR Recital 53 states that special categories of personal data may be processed for health-related purposes if these purposes benefit society as a whole. As CAPSS processes data in scientific interest to benefit children and adolescents with rare psychiatric conditions and is processed in accordance with United Kingdom data protection governance under the category of public interest in the area of public health, we are able to process data under the Regulation for health-related purposes.

GDPR Recital 156 states that the data controller must have assessed the feasibility to fulfil the scientific objectives whilst safeguarding the data subject pursuant by anonymising the data. Having assessed the feasibility of this, all data collected is necessary in order to fulfil a study's aims of mapping rare conditions. Analysing an individual's background, symptomatology, diagnosis and investigations, alongside their personal data such as date of birth and ethnic group is essential to the scientific purpose of gathering this data with the aim of eventually improving quality of life for individuals. The name of the data subject pursuant is not asked, as this is not necessary information. All studies receive ethical approval and will be bound by NHS and/or University data processing regulations.

Under GDPR Recital 159, all personal data collected for CAPSS is conducted in the area of public health in the public interest. Research and NHS ethical approval ensure that there will be no dissemination, disclosure or publication or any data or journal article which means that a data subject is identifiable.

[2] Available at https://ico.org.uk/for-organisations/guide-to-data-protection

Under GDPR Article 6 where personal data are processed for scientific or historical research purposes or statistical purposes pursuant to Article 89(1), the data subject, on grounds relating to his or her particular situation, has the right to object to processing of personal data concerning him or her. Children and their parents are given an information sheet by their psychiatrist when they are identified by the psychiatrist as someone who can take part in the study. This information sheet explains what CAPSS is, explains the disorder under study, what data is collected, what happens with the information and how to opt out from the study. The information sheet also explains a data subject's rights under GDPR, who to complain to and who to contact on the CAPSS team.

GDPR Article 89 covers safeguards and derogations relating to processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes. Data collected is subject to appropriate safeguards. Data will only be looked at by authorised members of the research team and other authorised members of staff to ensure that the study is being carried out correctly. All information will be stored in secure cupboards in a locked office and on a password protected database and will not be shared with anyone else. The data storage will comply with the UK Data Protection Act 2018 and any amended laws in relation to data protection in the UK and Europe. The data will be kept for 20 years. Personal data is processed for scientific purposes and subject to conditions and safeguards as far as is possible without impairing the achievement of the studies.

Data Protection Act 2018[3]

The Act updates data protection laws in the UK, supplementing the GDPR. It provides a comprehensive package to protect personal data. If a living person (data subject) can be identified from any information in your possession this information is considered personal data. A living individual can be identified, directly or indirectly, in particular by reference to:

- an identifier such as a name, an identification number, location data or an online identifier; or
- one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the individual.

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 2018. This places obligations on those who record or use personal data and gives certain rights to persons about whom information is held. The six principles of the Data Protection Act are summarised as follows:

- processing must be lawful, fair and transparent
- for processing to be lawful at least one of the Schedule 9 conditions must be met and in addition, for sensitive processing at least one of the Schedule 10 conditions
- purposes of processing must be specified, explicit and legitimate

[3] Available at http://www.legislation.gov.uk/ukpga/2018/12/contents

- personal data must be adequate, relevant and not excessive
- personal data must be accurate and kept up to date
- personal data must be kept for no longer than is necessary; and
- personal data must be processed in a secure manner.

The accountability principle requires you to take responsibility for what you do with personal data and how you comply with the other principles. You must have appropriate measures and records in place to be able to demonstrate your compliance.

There are still requirements relating to overseas transfers. These are outlined in Chapter V of GDPR instead of being one of the principles.

Current Administrative Frameworks:

Following the passage of the Health & Social Care Act 2008 the NIGB was set up as a statutory body for England and Wales. From January 2009 the NIGB oversaw the administration of applications under section 251 of the NHS Act 2006. This task was formerly carried out by the Patient Information Advisory Group (PIAG) which had been abolished on 31 December 2008. In April 2013 powers in relation to section 251 in England and Wales transferred from NIGB to the Confidentiality Advisory group (CAG). If Section 251 approval is granted by CAG the study is placed on the Section 251 register and approval is reviewed annually[4].

National data opt-outs apply to a disclosure when an organisation such as a research body confirms they have obtained an approval from CAG for the disclosure of Confidential Patient Information held by another organisation responsible for the data (the data provider) such as an NHS Trust.

The national data opt-out was introduced for the health and social care system in England on 25 May 2018 and applied by NHS Digital. Since then Public Health England have become compliant with national data opt-out policy and all health and adult social care providers across England are required to comply with national data opt-out policy by March 2020. Patients can set their national data opt-out preference via both digital and non-digital services. Their preference will remain in place unless and until such a time that the patient decides to change their opt-out preference. A patient's preference to opt-out will continue to be applied after the person's death.

The responsibility for complying with national data opt-out policy rests with the data provider (as Data Controller) or processor acting on behalf of the data provider. In practice this means that national data opt-outs are applied by the health and adult social care provider of the data, i.e. disclosing the CPI, (e.g. a hospital trust), not by the recipient of CPI, (e.g. a research body). To be

[4] Available at http://www.hra.nhs.uk/resources/confidentiality-advisory-group/

clear national data opt-outs are applied to CPI before it is received by a researcher. Researchers are not required to apply national data opt-outs to the data they receive.

From May 2015 on behalf of NHS Scotland, the Public Benefit and Privacy Panel has undertaken the task of approving the use of confidential patient information in relation to principles within a the Scottish legal framework[5].

2. CAPSS Methodology and Confidentiality

2.1 CAPSS Reporting Mechanism

Explicit patient consent is not sought. 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.[6] 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 a REC and funding confirmed before it can be included on the CAPSS surveillance 'YELLOW e-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

- Anonymised notifications are provided to the CAPSS office by members of the Royal College of Psychiatry (RCPsych) using CAPSS methodology i.e. the 'YELLOW e-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

[5] Available at https://www.informationgovernance.scot.nhs.uk/pbpphsc/who-are-the-public-benefit- and-privacy-panel-and-what-do-they-do/

[6] Membership of the Committee includes consultant psychiatrists and psychiatrists, epidemiologists, as well as a representative of the British Paediatric Surveillance Unit and the English Department of Health (TBC)

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 (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.
- 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[7].
- Surveillance data should be analysed as a whole and not subdivided in ways that may uncover the identity of subjects even though standard person identifiable data has been removed. Where data is subdivided by region or jurisdiction there may be an inadvertent breach of confidentiality. For example, the incidence of a rare condition in Scotland or Wales might be so low and the options for specialist advice so limited that any detail of the case might be recognised in a way that could identify both the patient and the clinical team involved.

2.3 Ethical Approval

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

2.4 Section 251 Approval

- CAPSS will work with CAG to ensure that the studies conducted under its remit fulfil the obligations set down in Section 251 of the Health & Social Care Act.
- All CAPSS studies will have to complete an application to CAG to obtain support for Section 251 approval. For England and Wales. Submissions can be made directly using the on-line IRAS form.
- Applications that are supported by CAG and approved by the Health Research Authority are placed on the Section 251 Register.
- Approved applications are reviewed/renewed annually by CAG.

[7] Available at www.mrc.ac.uk/pdf-pimr.pdf

2.5 Additional Requirements for studies across UK and Ireland

- All CAPSS studies that collect data from Scotland require approval from the Scottish Public Benefits and Privacy Panel for Health and Social Care[8].

- Studies that collect data from Northern Ireland and Republic of Ireland require appropriate approval, where not covered by REC/CAG. This is currently automatic but the processes for confirming approval may change and applications should be discussed with BPSU scientific coordinator.

[8] Available at http://www.informationgovernance.scot.nhs.uk/pbphsc/

Appendix C: Guidance for CAPSS investigators on patient confidentiality

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, see Appendix B), those contained in the GDPR, 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
    - 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 D: Example of a letter to the reporting psychiatrist

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

[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 Psychiatry 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 XXXXXXX 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 E: 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 F: 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 £15,000 + VAT in advance (or a reduced rate of £12,500 to studies which are run jointly between CAPSS and the BPSU). 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

a) 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. Information about studies that remain unpublished after completion will remain on the CAPSS website and researchers will be offered the opportunity to supply a paragraph to explain why their findings are not available.

b) 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.

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, CAG & PBPP approval

The CAPSS methodology now has CAG approval to collect minimal identifier information without patient or guardian consent. However individual studies are also required to have CAG approval for the collection of their data without consent. Data collection in Scotland will also require approval from the Public Benefit and Privacy Panel (PBPP).

If you have not yet done so please supply documentation that confirms REC and CAG (and PBPP, if required) 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

CAPSS Programme 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 **……**