GUIDELINES FOR SUBMITTING A PHASE ONE APPLICATION FOR INCLUSION OF A STUDY

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INTRODUCTION

Applications for inclusion of a study on reporting cards are considered by the CAPSS Executive Committee, which meets every three months. As the success of the CAPSS methodology relies entirely on willingness of consultant psychiatrists to complete and return the monthly card, the CAPSS Executive needs to be certain that CAPSS studies are worthwhile, well designed, adequately resourced and practical without putting too great a burden on reporting doctors. The application process has been developed to reflect these responsibilities. However, CAPSS is also committed to assisting potential investigators (especially those less experienced in research methodology) by improving potentially good studies with advice from the medical advisers.

There is a two-stage application procedure; Phase 1 (P1) is an outline application to establish if the study meets the CAPSS criteria. Applications should be submitted on the P1 application form. If the study is considered to meet the essential criteria a more detailed Phase 2 (P2) application will be invited. For P2 applications there is a longer application form, which should be completed and accompanied by any letters and questionnaires, which are to be used in the study. Decisions on the outcome of either P1 or P2 applications are usually made at the meeting at which they are considered although the Committee may also seek further clarification from the researchers. An applicant may be invited to attend a CAPSS Executive Committee meeting to present their proposal and discuss any queries that have arisen.

Unfortunately, some applications will be unsuccessful however good the research idea may be. Applications are most often turned down because the Committee feel the study is not suited to the CAPSS methodology. If this is the case the Committee may be able to advise on an alternative study methodology.

When planning your application, it may be helpful to take into account the following:

- Make sure your study meets the CAPSS eligibility criteria (see below). Please discuss your application with the Medical Adviser/Scientific Coordinator beforehand if these are unclear.
- Study aims must be appropriate for surveillance methodology such as studies to investigate variations in management, establishing incidence/prevalence figures, or looking at geographical variation.
- As the Committee only meets every three months it can take several months to complete the application process. In exceptional circumstances such as for a study on a topic considered to be a public health emergency this process can be accelerated.
- Applications should reach the CAPSS office four weeks prior to the Executive meeting; dates of forthcoming meetings are available from the CAPSS office.
- The study surveillance period is usually 13 months though this can be extended if it is felt that additional ascertainment is required to allow for meaningful analysis.
- There is a £15,000 administrative charge for undertaking a study through CAPSS and applicants should have appropriate funding in place at the time of application. The £15,000 charge covers having your study added to the monthly CAPSS yellow card and being informed of positive reports by the CAPSS office each month, along with all the work involved in keeping the CAMHS consultant database up to date. The CAPSS office undertakes no data processing for external researchers.

CRITERIA FOR ELIGIBILITY

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 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

OUTCOME FOLLOWING CONSIDERATION BY THE EXECUTIVE COMMITTEE

Following consideration of the P1 application you will be contacted by either the medical adviser appointed to review the application or the scientific coordinator.

The following outcomes are possible:

1) P1 may be accepted and a P2 sought without specific modification
2) You are asked to give a presentation to the committee before a decision is made

3) Further details may be sought before a decision is made on the P1 acceptability as a potential CAPSS study
4) P1 accepted but several points still need to be addressed when preparing the P2 application
5) The application is rejected

NB: Acceptance of the P1 does not imply that the P2 will necessarily be approved, only that it is a study that the CAPSS could possibly undertake.

COMPLETING THE PHASE 1 APPLICATION FORM

Please read these details carefully before completing your Phase 1 application. Failure to do so could lead to a delay or even rejection of the application.

Submitting a Phase 1 (P1) application: prospective applicants are advised to submit their application at least six months before the proposed starting date, although a proposal can be considered more speedily if there is a genuine public health medical urgency.

The P1 application procedure allows potential investigators to submit an outline proposal for initial consideration and discussion.

1) Title of study

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

2) Investigators

Please list and indicate clearly the principal contact for correspondence on this application, giving full personal address, e-mail address and telephone number.

3) Describe the study

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.

4) 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) With no direct contact with patients

b) Without seeking investigations that would normally not have been undertaken by the psychiatrist

c) Without a comparison group

5) Case definition

Give a clear case definition for the condition of interest, preferably one that is internationally accepted. A number of studies now include a surveillance case definition with a narrower case definition subject to analysis.

6) Expected numbers

Please supply an estimate of the number of cases expected each year, i.e. yearly incidence rate. More than 30 reports a month would normally be considered too high a number for the CAPSS. Indicate source of denominator data for calculating incidence. Are there other groups besides psychiatrists who are likely to see cases? If so it is essential that there are plans are in place to seek cases through them as this improves ascertainment and reduces bias.

7) Alternative sources of data

8) Proposed level and nature of public involvement

9) Proposed territorial coverage

10) Funding, Personnel and Resource Arrangements

If known, outline the funding arrangement for the project, naming the bodies to which a grant application has been submitted. State whether funding is from a commercial source; whether you are personally in receipt of funds to undertake the research.

11) References

A list of any applicable reference should be included. Attach the most relevant references if these are not available online.