

PHASE 1 APPLICATION GUIDELINES

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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 is an outline application to establish if the study meets the CAPSS criteria. Applications should be submitted using the Phase 1 application form. If the study is considered to meet the essential criteria a more detailed Phase 2 application will be invited. For Phase 2 applications there is a longer application form, which should be completed and accompanied by any letters and questionnaires (CAPSS letter of understanding, CAPSS data handling questionnaire, NIGB ECC application form and NIGB ECC system level security policy) to be used in the study. Decisions on the outcome of either Phase 1 or Phase 2 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. The Executive Committee will issue written feedback on each application received as to how the proposal can proceed to a Phase 2 application.

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

- The CAPSS eligibility criteria (see below). Please discuss your application with a Medical Adviser 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 examining geographical variation (with due diligence to avoid identifying patients, clinicians or services).
- 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. If you think your study merits this fast track process please contact the CAPSS coordinator with an explanation of why this is so.
- Applications should be sent to the CAPSS inbox four weeks prior to the Executive meeting; dates of forthcoming meetings are available from the CAPSS team.
- 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. The first month is treated as a pilot month and discarded from the figures.
- 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 e-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.
 - A reduced charge of £12,500 applies to studies which are run jointly between CAPSS and the BPSU.

Criteria for eligibility

Applications considered **eligible** are those where:

- The condition 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. 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 follow up of greater than 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).
- Could be addressed by an audit.
- Require retrospective reporting – the system operates on prospective surveillance.
- Are interventional studies.

Outcome following consideration by the Executive Committee

Following consideration of the Phase 1 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) Phase 1 may be accepted and a Phase 2 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) Phase 1 accepted but several points still need to be addressed when preparing the Phase 2 application;
- 5) The application is rejected'

NB: Acceptance of a Phase 1 application does not imply that the Phase 2 application will necessarily be approved, only that it is a study that the CAPSS could possibly undertake.