



BRITISH NEUROLOGICAL SURVEILLANCE UNIT

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GUIDELINES ON APPLICATIONS FOR INCLUSION OF STUDIES

INTRODUCTION

Applications are welcomed from all ABN members and also from other neurologists and related specialists who have been regular contributors to the BNSU surveillance system.

1.1 Applications for inclusion of a study in the BNSU reporting scheme will be considered by the Clinical Academic and Research Committee (CRAC), currently led by Dr Rustam Al-Shahi Salman. This document gives detailed guidance on completion of the application form, requirements and considerations which are liable to influence CRAC. It is assumed that the nature and operation of the scheme are familiar to the reader.

1.2 CRAC will give fair and impartial consideration to all applicants. However, applicants (at least one) have to be members of the ABN or have been regular contributors to the BNSU surveillance system. Applicants may be invited to a meeting of CRAC to discuss their project.

1.3 Applications should be submitted on the BNSU application form enclosed with these guidelines.

1.4 A fee of £250 for the duration of the BNSU study is requested by CRAC as a contribution towards BNSU administration costs.

IMPORTANT CONSIDERATIONS

2.1 A study is eligible for inclusion in the scheme if the condition of interest is a relatively rare neurological disorder (or a rare complication of a more common one), of such low incidence or prevalence as to require ascertainment of cases on a national scale in order to generate sufficient numbers for study. CRAC will also consider applications of short-term or geographically limited studies of comparatively more common conditions.

2.2 "Disorder" means any condition or event that comes under the care of a neurologist.

2.3 There is no age limit, but obviously ascertainment of paediatric cases will be very limited.

2.4 CRAC will take into consideration the scientific interest and general neurological importance of the proposed study, its methodology, and suitability for ascertainment via the BNSU scheme.

2.5 CRAC recognises that two or more years of surveillance may be required for a very rare condition. However inclusion will **only initially be for one year and then renewal must be sought provided at least one case has been ascertained in the first year of surveillance**. Annual reports are required prior to extension of the study being granted.

2.6 It is important not to overburden the reporting doctors. CRAC will therefore take into account the demands individual studies make on the time and goodwill of ABN members.

2.7 The maximum number of conditions under surveillance by BNSU at any one time should be fifteen.

ETHICAL CONSIDERATIONS

3.1 Ethical considerations are vitally important and CRAC will take this into account when it reviews applications.

Issues that will be looked at are:

- preservation of patient confidentiality,
- use of data obtained,
- consequences of being reported to the BNSU to the patient.

3.2 MREC approval is necessary for any study involving patients outside the local investigator's area, and must have been received prior to any study starting. No conditions will be accepted onto the system without evidence of MREC approval.

3.3 Consultants should not release identifiable patient data (such as hospital notes) to the investigator without the written and informed consent of the patient, unless NIGB or Caldicott Guardian approval has been obtained. CRAC will need to see the proposed consent form (passed by MREC). It is up to the investigator to get the patient's GP or consultant to get the consent form completed prior to the release of any patient information.

3.4 The patient does not need to give consent for the reporting consultant to return a positive response by email, because the responses are anonymous.

STUDY DESIGN

4.1 The normal design is by obtaining relevant copies of the patient's notes from the consultant, or by a short questionnaire sent to the consultant.

4.2 Further data can be obtained by direct patient contact, special blood tests, scans etc. Where this is required the ethical ramifications must have been fully addressed.

FORMAL REQUIREMENTS

Prior to acceptance, the BNSU requires the following in writing:

5.1 The proposed study must have REC approval (if required) and written details must be included.

5.2 A patient consent form must be produced by each investigator and sent to each reporting doctor before any patient details are released to the investigator.

5.3 Every investigator must agree to submit the findings of their study to one of the ABN meetings.

5.4 The assistance of the BNSU must be acknowledged in all publications and the investigator agrees on acceptance of their study to **send copies of all publications** that come out of studies that utilise the BNSU.

5.5 The investigator must agree to produce a brief report of 400 words to the BNSU on completion of their study, together with an annual account of study progression during the course of the study.

REPORTS

6.1 The BNSU does not exercise control over results or reports. However the assistance of the BNSU should be acknowledged in manuscripts submitted for publication.

6.2 Regular feedback to reporting clinicians is important so investigators will be asked to contribute a short report for inclusion in the BNSU section of the ABN annual report.