



BRITISH NEUROLOGICAL SURVEILLANCE UNIT

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GUIDELINES ON APPLICATIONS FOR INCLUSION OF STUDIES

1. INTRODUCTION

- 1.1 Applications for inclusion of a study in the BNSU reporting scheme are currently overseen by Prof Rustam Al-Shahi Salman and are independently reviewed by the Clinical Academic and Research Committee (CRAC) of the ABN. This document gives detailed guidance on completion of the application form, requirements and considerations which are liable to influence CRAC.
- 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.
- 1.3 Applications should be submitted on the BNSU application form.
- 1.4 **A fee of £250 for the duration of the BNSU study is requested by the ABN as a contribution towards BNSU administration costs.**

2. 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 for 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, so applicants may want to consider applying to the British Paediatric Neurology Surveillance Unit (www.bpnsu.co.uk) instead/aswell.
- 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 each 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 that 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 is 15, but other factors are also taken into consideration when determining the composition of the portfolio.

3. IDEAL STUDY DESIGN

- 3.1 The neurologist is asked to convey information about a study to the patient or complete a more detailed case report form (which does not identify the patient).
- 3.2 A patient is left to 'opt in' to a study by contacting the investigators, having been provided with information about the study by their neurologist.

4. REGULATION

Research ethics

- 4.1 Ethical considerations are vitally important and CRAC will take this into account when it reviews applications.
- 4.2 Issues that will be looked at are:
 - a. preservation of patient confidentiality,
 - b. use of data obtained,
 - c. consequences for the patient of being reported to the BNSU.
- 4.3 Research ethics committee (REC) approval, or confirmation that it is not required, must have been received prior to any study starting. In particular, REC approval must have been obtained for the method used to identify participants (including using BNSU), whether the ideal method described in section 3, or an alternative described in section 4.7. No conditions will be accepted onto the system without evidence of REC approval.

Confidentiality and information governance

- 4.4 The patient does not need to give consent for a neurologist to report their diagnosis to BNSU, since reports are anonymous.

- 4.5 Neurologists should not be asked to release identifiable patient data (such as hospital notes) to the investigator without the written informed consent of the patient, unless approval to do so has been obtained from the Health Research Authority (HRA) informed by its Confidentiality Advisory Group (www.hra.nhs.uk/hra-confidentiality-advisory-group). Instead, Caldicott Guardian approval for disclosure of patient identifiable data in the public interest without informed consent is required in Scotland.

Research governance

- 4.6 Section 3 above describes a *modus operandi* that does not require a neurologist to obtain patient consent or research governance approval for the BNSU study from their local R&D department.
- 4.7 If study investigators need neurologists to get involved with patient recruitment, then according to current guidelines they will need to obtain research governance approval at sites enrolling patients as follows:
- a. **Research sites.** These are NHS organisations where participant recruitment and study-related procedures take place, and each requires local R&D approval.
 - b. **Participant Identification Centres (PICs).** A PIC is where an organisation: identifies participants, largely (but not exclusively) through patient records, for possible participation in studies; provides information about / or informs patients directly about a study, eg a clinician speaks directly to a patient; advertises the opportunities to participate in a specific study, eg via posters in waiting rooms; and where the research is taking place elsewhere. See this leaflet for more details of the permissions required: www.crncc.nihr.ac.uk/Resources/NIHR%20CRN%20CC/CSP/PICS%20leaflet%20Final.pdf
 - i. When the activity at the PIC is limited to leaving study-specific leaflets or displaying a study specific poster in public areas, only study-wide review is required. In these cases, PICs do not need to be named in the R&D Form (Part C Overview of Research Sites). Local NHS organisations only need to register the study as potentially involving its patients, but no other local review or assessment should be necessary. Sponsors should not request display of such materials at the PIC until confirmation of the acceptability of the documents has been given following the study-wide review. See NIHR CSP Operating Manual section 8.1.7.
 - c. Where generic leaflets or posters about research (eg on behalf of a network or department) are to be displayed, these should be assessed through the organisation's normal public communication routes, and NHS organisations are expected to consider displaying such materials as part of their normal public engagement in research. Requests to display generic leaflets or posters should not be reviewed as research sites or PICs. Organisations or units developing such generic materials are

encouraged to consider seeking REC review through voluntary arrangement with the REC (see NRES Standard Operating Procedures (SOPs) 4.55). See NIHR CSP Operating Manual section 8.1.3.

- d. If a clinical trial offers access to treatment not otherwise available, there is no requirement for additional review by the local R&D department. See NIHR CSP Operating Manual section 8.1.3.

5. REQUIREMENTS

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

- a. Evidence of REC approval (if required).
- b. The patient information leaflet and informed consent form (if it authorises activities to be performed by the patient's neurologist).
- c. Agreement to submit the findings of the study to an ABN meeting.
- d. Confirmation that the assistance of the BNSU will 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 use the BNSU.
- e. Confirmation that the investigator will produce:
 - i. an annual account of study progression during the course of the study
 - ii. a brief report of 400 words to the BNSU on completion of the study

6. 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.