GUIDELINES ON APPLICATIONS FOR INCLUSION OF STUDIES

1 INTRODUCTION

1.1 The ABN’s Rare Disease Ascertainment & Recruitment platform is designed to capture cases of rare neurological conditions or rare neurological complications that would not be feasible to do through single centre or standard multi-centre collaborative arrangements. Capture of cases, and related clinical information, may be for epidemiological or other descriptive research, public health, biomarker development or therapeutic trial opportunities.

1.2 Applications for inclusion of a study in RaDAR will be considered by the Research Committee (RC).

1.3 RC will give fair and impartial consideration to all applications received. The lead applicant must be a member of the ABN.

1.4 Applications should be submitted on the RaDAR application form enclosed with these guidelines.

1.5 For studies that are in receipt of any institutional or external funding, a first year fee of £300 is requested as a contribution towards administration costs, followed by a further £200 to cover both years 2 & 3 if continued (total £500 for three years). Please contact the ABN office to discuss any case for exemption.

2 IMPORTANT CONSIDERATIONS

2.1 A study is eligible for inclusion if the condition of interest is a 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 meaningful study.

2.2 The maximum number of conditions under surveillance by RaDAR at any one time is 8. A waiting list will operate for all additional studies deemed acceptable.

2.3 All financial support for the proposed study, commercial or charitable, must be declared.

2.4 As well as ethical considerations (below), it is important not to overburden respondents. RC will therefore take into account the demands individual studies will make on their time and goodwill of referring clinicians.

2.5 There is no defined age limit for case inclusion. Ascertainment of paediatric cases will be very limited through ABN membership channels and inclusion must be specifically justified.

2.6 RC recognises that more than one year may be required for a very rare condition. Inclusion of a study will be initially be for one year, with renewal for a
maximum of two more years, provided at least one case has been identified in the first year of surveillance.

2.7 Extension of inclusion of a study beyond 3 years will require a written case for support to be reviewed by RC and weighed alongside any studies-in-waiting. A further administrative fee is likely.

3 ETHICAL CONSIDERATIONS

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

3.2 Issues that will be considered include:

- preservation of confidentiality
- use and retention of data
- consequences (including time burden) for the patient or neurologist respondent

3.3 REC approval must have been received prior to application.

4 STUDY DESIGN

4.1 There are two pathways for RaDAR study Investigators to receive responses:

- Patient-driven. **This is the most effective and simplest route, practically and ethically, with the lowest burden for the neurologist and is the ABN’s preferred model.** The study Investigator provides an email contact or webpage via their RaDAR listing, which may include a poster that clinicians may place in clinic. The responding ABN member relays this directly to the patient, who makes their own decision on whether to engage, and any wider involvement based on a REC-approved patient information sheet provided to them by the Investigator.

or

- Neurologist-driven. A questionnaire is sent to the responding ABN member by the Investigator for completion. Where clinical information is required, permission for sharing this must have been fully addressed by the Investigator, particularly around any personally identifiable data or study-related direct patient contact proposed by the study team. The respondent should be told if a personal acknowledgement or co-authorship is proposed for them in any publications arising from the data they provide, or if not. **The ABN does not assume any responsibility for chasing up responders for information nor for issues around personal acknowledgements and authorship in publications.**

5 FORMAL REQUIREMENTS

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

5.1 The Investigator should indicate the pathway for data collection (patient or neurologist-driven).
5.2 The proposed study must have REC approval appropriate for the pathway proposed and any clinical data to be collected from the ABN member or from the patient directly. Written details of the approving committee must be included.

5.3 The investigator must agree to provide an annual account of referral numbers during the course of the study, and a brief report (<500 words) upon completion. Investigators should be willing to submit the findings of completed studies to a subsequent ABN meeting.

5.4 Any material assistance of the ABN RaDAR should be acknowledged generically in publications and the Investigator agrees to send a copy to the ABN office.