GUIDANCE FOR PUBLICATIONS CONSEQUENT TO ACCESS TO DATA FROM THE CRPS UK REGISTRY.

Collaboration and ownership of data

1. The CRPS UK Clinical Research Network was established in 2006 and is a research collaboration between a number of clinicians and academics working in UK NHS Trusts and academic institutions with an interest in Complex Regional Pain Syndrome. The CRPS UK Registry was established by this group in 2008 to facilitate research studies including clinical trials. The Registry is accessed through secure Web-based software (EDGE) that is currently hosted by the University of Southampton and funded by *ad hoc* grants. Dr. Nicholas Shenker is the Registry's Chief Investigator and is supported by members of the Network. Cambridge University Hospitals NHS Foundation Trust sponsor the Registry. A Registry Steering Committee will be formally convened as part of this Guidance document to be Chaired by the Registry Chief Investigator.

2. Once data is donated to the CRPS UK Registry by members of the CRPS UK Network who have MREC/NRES/IRAS and local organisational ethics and Research and Development approvals (PIs of those applications to be now known as the Working Group). No further consent procedures are required for use of the These approvals have been facilitated by the Chief Investigator and Network administrator and a single Registry access point is allocated to each participating Centre (i.e. an NHS Trust).

3. The CRPS UK Registry data can be used for any study approved by the CRPS Registry Steering Committee without the explicit consent of the individual centres. All members of the Working Group that provide data should be informed of any analysis being carried out on the Registry data.

4. The Working Group agrees that any future developments of the CRPS UK Registry will be in line with the spirit of collaboration that has resulted in the development of this Registry. The Working Group also agrees that collaboration of CRPS UK Registry data with other projects on CRPS incidence and treatment is to be encouraged.

5. Registry data that has been collected can be accessed by any study approved by the Steering Committee. Any approach to an individual centre in the CRPS UK Network to participate in a study should only be made following approval of the Steering Committee. A coherent research strategy maximising the resources available can then be achieved. Furthermore, the Registry can be seen to comply with good research governance.

6. To ensure transparency of process and exclude any potential conflicts of interest the identity of all members of the CRPS UK Clinical Research Network, membership of all groups/committees within that Network, names of external advisors and sources of financial support will be clearly stated on the CRPS UK Network web-site (http TBC).

Authorship

7. All publications based on pooled data must mention the CRPS UK Registry Working Group among the authors (or as the author), a suitable authorship formula being: >Authors A, B, C, ... and the CRPS UK Registry Working Group, with all members listed in a footnote or appendix to the article.

8. The first author must provide a justification to the Steering Committee for the names of all authors appearing separately in the authorship list. Normally, this will simply involve verification that journal recommendations have been complied with. The list of individual authors should be kept short.

9. In general, the researchers who performed the analyses and wrote the paper will be first authors in the publication.

10. Analyses and publications can be proposed and carried out by any member of the Working Group or by other researchers not belonging to the Working Group, and will be supervised by the Steering Committee.

Role of Steering Committee

11. The functions of the Steering Committee are

 (i) To approve studies access to the CRPS-UK Registry and individual Network centres. These studies should not be limited to members of the CRPS-UK Network. Approval for studies should be made by a majority vote by the Steering Committee, following a relevant time period and discussion. Votes need not be made at official meetings.

 (ii) To plan and supervise analyses and publications. To achieve this, a central list of ongoing studies will be maintained and discussed at each meeting as an ongoing agenda item. A nominated lead for each study from the Steering Committee will be allocated to report back to the Committee as required.

 (iii) To ensure adherence to good research governance. To achieve this, a central list of studies will be kept along with which centres have agreed to participate.

 (iv) To provide a coherent, efficient coordination of the research effort in the UK for studying patients with CRPS. To achieve this, a list of publications and research-active groups should be kept. Any request for study (outside of audit and service evaluation) to an individual centre should be passed to the Steering Committee for discussion.

It is envisaged that these lists should be made available to interested parties, not necessarily restricted to members of the CRPS-UK Network and put onto the Website.

12. The Steering Committee is composed of members of the Working Group who are willing to devote time to the project and co-opted members such as those with specialist expertise in epidemiology, health economics and statistical analysis. Co-opted members are not required to be members of the CRPS UK Network. Minutes from each meeting are to be circulated to members of the Steering Committee and the Working Group (thereby achieving point 3).

13. Steering group meetings will normally be held three times per year (these maybe face to face or via telephone or video conferencing) and Chaired by the Registry Chief Investigator. Agenda and minutes will be published on the CRPS UK Network website.

14. Where consensus cannot be achieved within the Steering committee on data access or publication issues contained within this Guidance document then advice will be sought from the External Advisor (see Steering Committee Terms of Reference Appendix 3).