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GUIDELINES FOR PLANNING AND CONDUCTING A RETROSPECTIVE STUDY UNDER THE AUSPICES OF EUPSA

All studies conducted within EUPSA should be:

- proposed by a EUPSA member
- performed by at least one EUPSA member
- submitted to the EUPSA Network Office for advice and approval prior to being circulated
- on a topic relevant to pediatric surgery and/or pediatric urology

Study proposal

- all proposals should be accompanied be a succinct but clear protocol that clearly outlines (as a minimum) the rationale for the study, the aim of the study, methods to be used, the inclusion and exclusion criteria for cases, outcomes to be recorded, and planned statistical analyses.
- data provided MUST include data from ALL CONSECUTIVE cases from a participating centre, treated in the study period
- collected data should be as 'SMART' as possible: Specific, measurable, achievable, results-focused, time-bound. The protocol should clearly define all outcomes to be recorded.
- for outcome parameters, if possible, generally accepted Core Outcome Sets (COS) should be used (see here for an example: https://pubmed.ncbi.nlm.nih.gov/33630468/)
- the number of data points collected for each study should be limited to the items necessary to answer the research question
- the protocol should include a clear plan on the proposed analyses to be performed
- the protocol should include a clear statement on the processes in place for obtaining the necessary ethical approval at each centre
- the protocol should include a clear statement on the policy for authorship of any publication; group authorship allowing recognition of all those contributing is encouraged

Conducting the study

- the study may only start once the network office has given approval
- the coordinating centre is responsible for ensuring that each centre has the necessary ethical approval in place prior to a commencing the study and recording the ethical approval statements from each participating centre
- data collection, analysis and storage need to meet the criteria set in the latest EU regulation on the protection of personal data. https://www.eu-patient.eu/globalassets/policy/data-protection/data-protection-guide-for-patients-organisations.pdf
- data sets remain the property of participating centre and cannot be used for other studies, unless there is written consent from the centre
- studies are coordinated by the study lead under auspices of the EUPSA Network Office

Reporting the study

- the study lead should provide a written report to the EUPSA Network Office which, once approved will be made available on the EUPSA website

- the results of the study should be submitted in abstract form to the EUPSA Annual Congress
- all study reports should be approved by the EUPSA network office prior to submission to a journal for publication
- the EUPSA Network Office should be acknowledged in the manuscript using the following text "The authors acknowledge the support of the EUPSA Network Office for providing advice on the study design and for distributing information about the study to EUPSA members".
- the manuscript should be prepared following the STROCSS 2021 guidelines (Mathew et al; STROCSS Group. STROCSS 2021: Strengthening the reporting of cohort, cross-sectional and case-control studies in surgery. Int J Surg. 2021 Dec;96:106165. doi: 10.1016/j.ijsu.2021.106165)

Study leads will be required to sign their agreement to these regulations above prior to approval being given by the EUPSA Network Office

Nigel Hall
EUPSA Network Office Chairperson
February 2023