

## ***Ethical Approval of Studies, Informed Consent and Identifying Details***

For all manuscripts reporting data from studies involving human participants or animals, formal review and approval, by an appropriate institutional review board or ethics committee is required and should be described in the Methods section. For those investigators who do not have formal ethics review committees, the principles outlined in the Declaration of Helsinki should be followed.

Manuscripts describing research involving human subjects should indicate that a written informed consent was obtained from the parents or guardians of the children who served as subjects of the investigation and, when appropriate, from the subjects themselves.

Information that could potentially reveal the identity of a patient or study participant should not be included unless this information is essential for scientific purposes and the patient (or the patients' parent or legal guardian) provides a written informed consent. A signed statement of informed consent to publish (in print and online) patient descriptions, photographs, video, and pedigrees should be obtained from all persons (parents or legal guardians for minors) who can be identified (including the patients themselves) in such written descriptions, photographs or pedigrees, and should be submitted with the manuscript and indicated in the Acknowledgment section of the manuscript. Such persons should be shown the manuscript before its submission.

For research involving animals, the journal requires the authors to affirm that a study submitted for consideration was conducted in accordance with relevant institutional and national guidelines for the care and use of laboratory and other animals.

## ***Clinical Trials***

PAEDIATRIA CROATICA requires authors to disclose whether or not a work reports the results of a clinical trial in accordance to ICMJE ([http://www.icmje.org/update\\_may05.html](http://www.icmje.org/update_may05.html)) and Declaration of Helsinki (<http://www.wma.net/e/policy/b3.htm>) requirements.

ICMJE defines clinical trial as "any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. A trial must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration. If authors report the results of a clinical trial, they must affirm that the study has been registered at a qualified national or international registry.

Investigators should use registries that meet the following minimum requirements: is available to the public at no charge; is open to all prospective registrants; is managed by a non profit organization; has a validation mechanism of the registration data; is electronically searchable; contains the following information: unique identifying number; official scientific title of the study, intervention(s)/condition(s) and comparison(s) studied; study type, study hypothesis; primary and secondary outcome measures; eligibility criteria; target number of participants; key trial dates (registration, anticipated or actual start of study, anticipated or actual last follow-up, planned or actual closure to data entry, and completion of data); funding sources; research ethics review, and contact information on the principal investigators.