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**APPENDIX**
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**H. conduct CONDUCT AND COMMUNICATION OF CLINICAL TRIALS**

The **AJO** recommends that researchers and authors (and commercial companies) adopt and adhere to the Pharmaceutical Research and Manufacturers (PhRMA) "Principles for the Conduct of Clinical Trials and Communication of Clinical Trial Results" listed at the [http://www.phrma.org/sites/default/files/pdf/042009_clinical_trial_principles_final.pdf](http://www.phrma.org/sites/default/files/pdf/042009_clinical_trial_principles_final.pdf). These principles describe the relationship of PhRMA member companies with others involved in clinical research and set forth the rules companies have volunteered to follow in order to protect the safety of research participants wherever the companies conduct clinical trials. In the principles, the
PhRMA companies commit to the timely communication of all meaningful results of clinical trials, whether those results are positive or negative. The principles further state that the results should be communicated in an objective, accurate, balanced, and complete manner.

I. access  AJO ACCESS TO SCIENTIFIC DATA
Thorough peer review by the AJO may require that organizations that sponsor research provide access to data and analyses that are not provided in a submitted manuscript, and sometimes such access is needed after publication as well. The opportunity also exists to post this information on the AJO website as Supplemental Material in association with the published manuscript.

J. microb  REPORTING NEW MICROBIAL ORGANISMS IN OPHTHALMIC INFECTIONS
The AJO is interested in confirming that certain organisms participate in ocular disease. The text must provide adequate laboratory information that can substantiate the microbial identification. This requires that any unusual pathogen be confirmed by two different methods or at two independent laboratories. The journal Cornea initiated this confirmatory policy (Wilhelmus KR. New corneal infections: preventing a crisis of identity. Cornea 2003;22:95-96).

K. cancer  CANCER CLASSIFICATION SCHEME
Authors should use the American Joint Commission on Cancer classification scheme when describing patients with ophthalmic malignancies; see American Joint Committee on Cancer.ACC Cancer Staging Manual, Seventh Edition, Springer, New York.

L. ocular  OCULAR TRAUMA TERMINOLOGY

M. regis  CLINICAL TRIALS REGISTRATION
The AJO requires that human clinical trials are registered before enrollment in order for the results to be published in the AJO. See Arch Ophthalmol 2005:123:1263-1264 for complete statement. Phase III trials should be registered as well as many phase II trials. Most phase I trials do not need to be registered. The Methods section should contain a statement about where the registration information is available to the public. Satisfactory public databases include the National Institute of Health maintained site at http://www.clinicaltrials.gov (for either NIH or non-NIH sponsored studies) or the International Standard Randomized Controlled Trials at http://www.controlled-trials.com.

N. refractive surgery  STANDARDIZED GRAPHS AND TERMS FOR REFRACTIVE SURGERY RESULTS

Forms
A.flow  CONSORT STATEMENT
B.idphoto  CONSENT FORM FOR IDENTIFIABLE PHOTOGRAPHS

Glossary of study designs
Randomized Clinical Trial: A human trial involving at least one experimental treatment group and one control treatment group, concurrent enrollment, and follow-up of the experimental and control groups with assignment to experimental and control groups by a randomization process. Persons responsible for treatment and subjects are not able to influence the treatment assignment, and assignment remains unknown to the staff and subjects until eligibility has been determined.

Nonrandomized Clinical Trial: A human trial involving at least one experimental treatment group and one control group, concurrent enrollment, and follow-up of the treatment and control groups. Assignment to experimental control groups is by a process other than randomization.

Interventional Case Series: Three or more cases, which may or may not be consecutive, that describe the outcome of an intervention without a control group for comparison.
**Cohort Study**: A longitudinal observational study that includes subjects with identifying characteristics and involves measurements or observations on more than one occasion.

**Case-control Study**: An observational, and usually retrospective, study of subjects with identifying characteristics and a disease or abnormality (cases) for comparison to subjects with similar characteristics, but without the disease or abnormality (controls). Comparison proceeds from effect to cause and generally yields odds ratio (usually an approximation of relative risk).

**Cross-sectional Study**: An observational study that identifies subjects with and without the disease or abnormality being studied at the same time. Study yields prevalence data and may or may not be population based.

**Observational Case Series**: Three or more cases in which natural history of the disease or abnormality is described. Cases may be collected and studied retrospectively or prospectively over any time frame.

**Experimental Study**: Animal or laboratory research describing observations, surgical or medical interventions, testing, or devices. Experimental studies are generally prospective and utilize a protocol in which controls are included.

**Meta-analysis of Literature**: Analysis of literature using statistical methods to integrate and summarize several studies.

**AUTHOR INQUIRIES**

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