

EXPLANATION OF NEW GUIDELINES FOR AUTHORS

Editor's Note: Please see Randoms, page 3A, for Introduction.

AUTHORSHIP

When a name appears on a manuscript, it is presumed the individual has played a meaningful role in the investigation. Specific activities that merit authorship include conceptualization of the study, performance of the work; analysis of the results; and/or preparation of the manuscript. All authors should understand the full scope of the work and agree with the information presented. Honorific authorships are undesirable for several reasons, not the least of which is the potential injury to a person's reputation, should the work ever come into question. The work of individuals who have made contributions to the project but who do not merit authorship should be noted in the acknowledgments.

CONFLICTS OF INTEREST

The potential of financial gain brings the work under close scrutiny. This scrutiny, however, *will not preclude publication if the work is scientifically valid*. A potential financial conflict of interest exists when an author or an immediate family member is: on the board of directors of a company whose product is the focus of the manuscript, a shareholder of >5% or >\$5,000 of stock, or will personally receive direct remuneration for the work. Authors will be asked to indicate any potential financial conflict of interest in the cover letter accompanying the manuscript. This information will not be forwarded to the reviewers, but will be considered when the reviewers' comments are returned and the manuscript is discussed with the editorial board. If the article is accepted, a synopsis of the potential conflict would be included in a footnote appearing at the end of the article.

An insidious conflict of interest grows from the desire of investigators to present a "positive result" from their investigation. While it is scientifically desirable to have a hypothesis before starting a project, it is not acceptable to "massage" the data until a correlation is found that makes it come true. Good science has both a hypothesis and well-defined plans for analysis of the data before the work is done. That is not to imply that additional analyses are not useful once the study is completed. However, the rearrangement of data, selective elimination of some subjects and other forms of data manipulation can only be done with the full understanding of their distortion of the observations. The approaches to experimental design and analysis are one of the important areas scrutinized by our reviewers.

ETHICS

Ethics, conforming to professional standards of conduct, should serve as guiding principles for our activities. Although the fine points are debateable, most investigators are well versed in the strictures of ethical patient care and animal experimentation. What is new is the requirement to document the process of protocol review and oversight.

To ensure that investigators have carried out the work in ac-

cordance with accepted standards of conduct, a statement indicating approval by the appropriate committees within the institution will be required in the Methods section of the manuscript.

Society should not stand in the way of an investigation because it is risky. Parachute jumping, mountain climbing, driving race cars, and crossing the street are accepted activities associated with some level of risk. Committees should, however, make clear the level of risk and benefit to the subject, to allow the most informed consent to be obtained.

As the term "informed consent" implies, the risk and benefits of a procedure are presented and the patient is asked to consent to its performance. Although committees oversee the process, the investigator is trusted to present the alternatives fairly and clearly for the patient to consider. Gaining consent for research that has not had an adequate review is a serious breach of this trust. Under this circumstance, the information offered to the patient may fall far short of the disclosure desired to ensure that the subject understands to what they are agreeing. An investigator obtaining "informed consent" in such a manner may place the research group in jeopardy at some later time, when their behavior is questioned by their peers.

What happens when the investigator wants to be the guinea pig? The investigator is more knowledgeable about the procedure than any subject could be. The history of science and medicine is replete with many larger than life figures who "went first." However, in today's environment where caution, liability, and detailed documentation have replaced the adventuresome spirit of yesteryear, it is important to play by the rules. A committee should review the protocol to ascertain that the "experiment" is likely to provide the desired information with the least risk to the subject.

ORIGINALITY

The role of the scientific literature is to present new ideas. This is particularly difficult in this era of the "least publishable unit," when results are parsed into atomic pieces for publication. It is better to combine it all in one article that is worth reading than in many that will go *forever* unread. The requirement for originality makes it difficult to repeat the work of another investigator without adding something new. This is in keeping with the spirit of this requirement.

REFERENCES

As a final note, it is important to be fair in referencing the work of others. None of us got to where we are without the benefit of our predecessors. Giving credit to their work implies that we understand that we are adding to a structure whose foundation was laid by others. The reviewers and editors of the *Journal* evaluate the quality of references as one indication of the care and completeness of the authors' understanding of the subject of their report.