Responsible Conduct of Research: Objective Reporting

References:

Moher D, Schultz KF, Altman D. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomized trials. *JAMA* 2001; 285:1997-1991.

This statement has been accepted in and published by a number of top-tier medical journals. It includes a 22-item checklist of items that should be included in a report of a clinical trial and a diagram of patient flow that can serve as a useful template. Many items apply not just to clinical trials, but to any clinical research.

The CONSORT statement has been used as a starting point for publication guidelines for other kinds of studies, too.

Stone SP, Cooper BS, Kibbler CC, Cookson BD, Roberts JA, Medley GF, Duckworth G, Lai R, Ebrahim S, Brown EM, Wiffen PJ, Davey PG. The ORION statement: guidelines for transparent reporting of outbreak reports and intervention studies of nosocomial infection. *Lancet Infect Dis.* 2007 Apr;7(4):282-8.

This paper extends the guidelines to infectious disease study reports.

McShane LM, Altman DG, Sauerbrei W, Taube SE, Gion M, Clark GM; Statistics Subcommittee of the NCI-EORTC Working Group on Cancer Diagnostics. Reporting recommendations for tumor marker prognostic studies (REMARK). *J Natl Cancer Inst*. 2005 Aug 17;97(16):1180-4.

This version addresses the reporting guidelines for tumor biomarker studies.

Campbell MK, Elbourne DR, Altman DG; CONSORT group. CONSORT statement: extension to cluster randomised trials. *BMJ*. 2004 Mar 20;328(7441):702-8.

The CONSORT guidelines have also been extended to cluster randomized designs.

Squires K, Pozniak AL, Pierone G, *et al*. Tenofovir disoproxil fumarate in nucleoside-resistant HIV-1 infection: a randomized trial. *Ann Intern Med* 2003; 139:313-20.

This paper, in a journal that subscribes to the CONSORT principles, illustrates how to use the guidelines in reporting a clinical trial. Note the nice flow chart based on CONSORT.

Devereaux PJ, Manns BJ, Ghali WA, *et al.* The reporting of methodologic factors in randomized clinical trials and the association with a journal policy to promote adherence to the Consolidated Standards of Reporting Trials (CONSORT) checklist. *Controlled Clinical Trials* 2002; 23:380-388.

This paper studied 105 RCT's in 29 medical journals and found that of the 11 methodological factors, the average was 6 reported in CONSORT-standard journals and 5 in non-CONSORT. There is still room for improvement in reporting.

Tufte, ER. *The Visual Display of Quantitative Information.* Graphics Press, Cheshire, CT: 1983. (Also *Visual Explanations* and *Envisioning Information*)

These three books provide a beautifully illustrated and thoughtful tutorial into how good graphics can inform readers, and bad graphics can mislead them. For a particularly dramatic example, read Tufte's section on the Challenger explosion: the data were trying to warn people but were hidden in abysmal displays.

Lang TA, Secic M. *How to report statistics in medicine: annotated guidelines for authors, editors, and reviewers.* American College of Physicians, 1997.
This book is available in paperback and gives a good overview for the practicing physician of what to include and how to say or show it.

Some web sites that may be helpful:
http://onlineethics.org/reseth/mod/data.html

This web site is very nice, has a lot of references and links.

If you do biomedical research, it is useful to read the following brief sections of the International Committee of Medical Journal Editors' "Uniform Requirements for Manuscripts Submitted to Biomedical Journals." This statement was published in 1997 in the New England Journal of Medicine 335: 309-315, and was updated May 2000.

* Corrections, Retractions, and" Expressions of Concern" about Research Findings
* Medical Journals and the Popular Media,
* Human subjects protection,
* Publication of industry-sponsored research.

The UNC web site you can link to from this web site has an excellent “text” on statistical ethics and responsible analysis.

NIH recently instituted a policy that requires that all proposals for contracts and grants for research involving human subjects submitted after October 1, 2000 certify that all key personnel have received education on the protection of human research subjects. This requirement applies to all applications for grants or proposals for contracts submitted to NIH after October 1st and to all new and all non-competing grants for which an award is issued after October 1st. NIH has posted a web series of "frequently-asked questions" regarding these new requirements. The frequently asked questions can be accessed at: http://grants.nih.gov/grants/policy/hs_educ_faq.htm.
Here is one NIH certificate web site:
http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp

A terrific web site for statistical practice in medicine is Jerry Dallal’s “Little Handbook of Statistical Practice”:
http://www.tufts.edu/~gdallal/LHSP.HTM
Jerry also has links to all the articles in the BMJ series on statistical practice in medicine, a superb series, very well written.