PRE-PUBLICATION WORKSHEET FOR OBSERVATIONAL STUDIES AND CLINICAL TRIALS
Scientific Publications, Texas Heart Institute, Houston, Texas

Section I—Administration

1.	Title	
2.	Principal author/investigator	
3.	Departments and Institution(s)	
4.	Co-author(s)/Co-investigator(s) in order of their level of participation	
5.	Database of interest	
6.	If for manuscript, proposed journal	
7.	Have you received IRB or IACUC approval? Completed all necessary forms?	
8.	Deadline	

Section II—Audience

Who is the target audience for your study? Carefully consider the target journal.

Section III—Hypotheses

State briefly what your study will address (broad objective, primary aim and hypothesis, secondary aims and hypotheses, or uniqueness of case).

Section IV—Background

State why you are doing this study and how it will fill a gap in the scientific literature.

Section IV—Study Design (NA for all sections not applicable to your study/report)

Definitions and examples can be found on the Scientific Publications page of the THI website at http://texasheart.org/scipub.

1. What type of study/manuscript is this: case series, cross-sectional, case control, cohort, clinical trial? Why did you choose this design? For case reports, see the checklist on the Scientific Publications Web page.

2. What are the key messages to be conveyed?

3. Number of patients or animals (with species) to be included in the study:

4. Eligibility Criteria:

   - Inclusion criteria. What characteristics, traits, procedures, etc., of patients will allow them to be enrolled in the study?

   - Exclusion criteria. What characteristics, traits, procedures, or drug therapies will exclude patients from enrollment in the study?

5. Interventions of exposures (experimental and comparison).

6. For matched studies (cohort and case control), what criteria will you use for matching?

7. Outcome variables (dependent variables). What is the characteristic or outcome that is considered an endpoint for this study? (There may be more than one outcome variable in a study.)

8. Predictor variables (independent variables). What patient characteristics, traits, procedures, monitoring modalities, or therapies are being examined that may correlate with or precede (predict) the endpoint of interest? These variables may or may not be related to each other. For example, age, height, and weight may be predictors of postoperative death. Height is related to weight, and age is related to height in younger age groups.

9. Method of randomization and blinding, if applicable.

10. Statistics.

    Which statistics will you use in this study? What is the probability of detecting a result if the result really exists (the power calculation)? How was the sample size determined? Definitions and examples of types of statistics can be found on the Scientific Publications page of the THI website at http://texasheart.org/scipub.

11. Limitations. Please list any problems you anticipate having with your data (inaccurate measurements, absence of certain necessary variables, too few patients with a particular characteristic, too few patients with outcome, etc.) and how you will control for potential error, confounding, and bias.

Section V—Significance/Potential Impact on Practice or Research

Section VI—Anticipated diagrams, tables, charts

Section VI—Key References (if applicable)

1. _____

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2. _____

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3. _____

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Section VII—Remember to review the appropriate checklist when writing your paper and before submitting it to Scientific Publications. References to checklists are listed below. Additional information is available at http://www.equator-network.org/index.aspx?o=1032.

1. Moher D, Schulz KF for the CONSORT Group. The CONSORT statement: revised recommendations for improving the quality of parallel-group randomised trials. JAMA 2001;285:1987-91 (more information and checklist available at http://www.consort-statement.org/index.aspx?o=1011 [accessed on August 25, 2008])
2. Stroup DF, Berlin JA, Morton SC, et al., for the Meta-Analysis of Observational Studies in Epidemiology (MOOSE) Group. JAMA 2000;283:2008-12 (checklist available at http://www.greenjournal.org/misc/moose.pdf [accessed on August 25, 2008])
3. Von Elm E, Altman DG, Egger Mm et al., for the STROBE Initiative. PLoS Medicine (www.plosmedicine.org) 2007;4:e296 [accessed August 25, 2008] (checklist available at http://www.greenjournal.org/misc/strobe.pdf [accessed on August 25, 2008])

4. Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF, for the QUOROM Group. The Lancet 1999;354:1896-900 (checklist available at http://www.greenjournal.org/misc/quorom.pdf [accessed on August 25, 2008])
5. Bossuyt PM, Reitsma JB, Bruns DE, for the STARD Group. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD Initiative. Clin Chem 2003;49:1-6 (more information and checklist available at Standards for the Reporting of Diagnostic Accuracy Studies (STARD Statement). http://www.stard-statement.org/ [accessed on August 25, 2008])
6. Boutron I, Moher D, Tugwell P, et al. A checklist to evaluate a report of a nonpharmacological trial (CLEAR NPT) was developed using consensus. *J Clin Epidemiol.* Dec 2005;58:1233-40. (checklist available at https://www.cebp.nl/media/m1194.pdf [accessed on August 25, 2008])
7. Des Jarlais DC, Lyles C, Crepaz N, and the TREND Group. Improving the reporting of nonrandomized evaluations of behavioral and public health interventions: the TREND Statement. Am J Public Health 2004;94:361-66.
8. Clark JP. How to peer review a qualitative manuscript. In *Peer Review in Health Sciences.* Second edition. Edited by Godlee F, Jefferson T. London: BMJ Books; 2003:219-235 (more information available at http://www.biomedcentral.com/info/ifora/rats (Qualitative Research Review Guidelines [RATS] [accessed on August 25, 2008])
9. Hopewell S, Clarke M, Moher D, et al., for the CONSORT Group. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Medicine (www.plosmedicine.org) 2008;5:e20 [accessed on August 25, 2008]

Section VII—Budget or Funding Source (if applicable)

☐ **Approvals**

By (signature): _____

Date: _____

