

Table 2. Questions for Study Evaluation -- Part 1

A. UNBLINDED REVIEW	
<u>Source of the Information</u>	<p>Was the paper published in a peer reviewed journal or, if not, was the study reviewed by some other group?</p> <p>Is the purpose of the trial indicated in the publication?</p> <p>If unpublished information from the investigator is required, are there problems of recall or missing information?</p> <p>Are the investigators well qualified to undertake the study?</p> <p>Are all institutional affiliations identified?</p> <p>When was the information collected?</p>
<u>Funding</u>	<p>How was the study funded?</p> <p>If outside funding was used, what was the role of the funding agency?</p> <p>Were the investigators independent of the sponsoring agency?</p> <p>Did the investigators have any financial interest in the outcome?</p>
B. BLINDED REVIEW	
<u>Study Design</u>	<p>Is the design described?</p> <p>Is the design appropriate to the study questions?</p> <p>Are there clear inclusion and exclusion criteria?</p> <p>Are the procedures for randomization (if appropriate) and blinding described?</p> <p>Are experimental methods, such as dosages and treatment schedules clearly defined?</p>
<u>Study Outcomes</u>	<p>Are the outcomes clearly defined, including methods of measurement?</p> <p>Do the outcome measures answer the study questions?</p> <p>If the study is unpublished, is the investigator willing to assure that this is final, clean data?</p>
<u>Study Subjects</u>	<p>Did the subjects meet the inclusion/exclusion criteria?</p> <p>Are methods of diagnosis defined and reliable?</p> <p>Are demographics for all subject groups included?</p>
<u>Controls</u>	<p>If there are parallel controls, are they comparable to the subjects?</p> <p>If it is a crossover study, is there sufficient wash-out time?</p> <p>If historical controls are used is the data of good quality from known sources? Can it be determined that they are comparable to the subjects?</p> <p>If population parameters, e.g. norms, are used, how were they derived and were they from subjects comparable to the study population?</p>

Table 2. Questions for Study Evaluation -- Part 2	
<u>Study implementation</u>	<p>Were inclusion and exclusion criteria strictly adhered to?</p> <p>Was the randomization schedule followed and the blinding maintained?</p> <p>Are non-compliant subjects and subjects dropping-out accounted for?</p> <p>In a multi-group study, were the groups comparable at baseline for prognostic factors?</p> <p>How was inter-rater reliability achieved and evaluated (this is particularly important for multi-center studies)?</p> <p>Have test methods, population demographics and/or reporting methods changed since the study was implemented?</p>
<u>Treatment Protocol</u>	<p>Were the treatment regimens followed?</p> <p>Were there concomitant medications taken?</p> <p>Was there a high rate of drop-outs or non-compliant subjects?</p>
<u>Methods</u>	<p>Were the laboratory methods known to be accurate and are they still considered valid?</p> <p>Were all assays done in the same laboratory using the same methods? If not, what steps were taken to assure inter-assay reliability?</p> <p>Have social and psychological scales been validated?</p>
<u>Statistics</u>	<p>Are the analytic methods clearly described and appropriate for the data and study design?</p> <p>Are summary statistics needed for the meta-analysis in the paper or available from the investigator?</p>