Guidelines for Writing and Reviewing an “Informed Consent Manuscript”
From the Editors of Clinical Research in Practice: The Journal of Team Hippocrates

1. □ Title
   a. Emphasize the clinical utility of the research papers used.
   b. Informed consent is a conversation—not a piece of paper. You are portraying that conversation in this type of manuscript.

2. □ Clinical Context
   a. The clinical context should be based on an actual patient care situation.
   b. The description of the patient should include enough detail to formulate the clinical question.
   c. □ The patient’s individual preferences and concerns should be described.
   d. □ Submissions must include the social context of the patient. Health decisions and health care occur within a social context. This journal is seeking to understand how evidence is deployed in social settings related to the individual patient circumstances.
   e. The patient’s “voice” must be included in the clinical context. You should use a narrative style, including dialogue between the patient and the doctor. Remember this section is a blend of the doctor’s perspective AND the perspective of the patient at the time a decision must be made.

3. □ Clinical Question
   a. □ State the question clearly in one sentence as if the patient or the patient’s family asked the question.
   b. □ Is the question specific enough? If not, then develop the clinical scenario further so that the question is answerable.
   c. □ Is this a question that is relevant to the patient, and able to be answered with a body of literature?
   d. □ Is the topic important to the general readership audience? This is not an opportunity to publish interesting cases on rare disease. The goal is describing the application of clinical research to patient care. However, if there is enough clinical research on a rare topic, it may be within the scope of the journal.

4. □ Description of Related Literature
a. This is the most time-consuming step, but the one that provides the greatest educational opportunities.

b. □ At the end of this section, the reader should be convinced that the author found EVERY primary research article that might answer the question. They should also be convinced that the author selected the best articles available to answer the question.

c. Look on Up-to-Date® or equivalent resource to get a feel for the problem at hand. What is the historic standard of treatment? What are the current areas of controversy? Having a basic understanding of the clinical question is necessary to write or understand an informed consent manuscript.

d. □ the author must search a publication database. Pubmed is a preferred database, and the one we typically use. However, Google Scholar, EMBASE and CINAHL may also be used if available.

e. □ the author must describe a systematic search strategy.

   i. □ This must include search terms.

   ii. □ a review of the articles cited in other trials, systematic/clinical reviews and meta-analyses is an appropriate additional step in finding primary research.

   iii. The search can be refined until it results in a reasonable number of articles. We find about 200 papers is doable. One can quickly read the titles to decide which articles might be primary research. A reading of the abstract should confirm.

   iv. When searching Pubmed, the following search modifiers are helpful:

      1. term[title] – the search returns articles that have “term” in the title.
      2. term[tiab] – the search returns articles that have “term” in the title or abstract
      3. term[MeSH] – the search returns articles that contain “term” the Medical Sub-Headings, which are tags that describe the most relevant concepts of the article.
      4. term* - the search returns articles containing words that are partial matches with term. For instance, term* may return “termite”, “terminal” or “termination” as potential results.
      5. AND/OR – AND will help to specify the clinical context. OR will help to broaden the search for synonymous terms (lactams OR penicillins).
      6. Parentheses can be used to clarify the intent of your Pubmed search.
      7. More information can be found here:

         http://guides.lib.wayne.edu/c.php?g=174848&p=3252652
v. If you find a systematic review or meta-analysis, it may assist with the literature search. It is not a replacement for a literature search, however. The literature must still be searched for recent studies published since the review, as well as any studies that the review may have missed for various reasons.

vi. Saying “I looked at UpToDate®/DynaMed® and read their citations” is unacceptable as the only search strategy. It can/should be used as an adjunct.

f. □ After describing the search strategy, the author must describe why the methods of the chosen articles are superior or more relevant than other articles for answering this question.

i. A brief PICO description of the most relevant articles is a good approach for therapeutic trials.
   2. Intervention – description of the intervention/experimental therapy.
   3. Control – description of the control/comparator group.
   4. Outcome – description of the outcome.
   5. An example: “The Genderson study was a prospective cohort study of hospitalized patients with severe pneumonia [patient]. Patients who were given antibiotic therapy [intervention] had improved length-of-stay [outcome] when compared with patients who were given placebo [control].”

ii. The author should cite primary research they have reviewed from the literature search. For areas less extensively studied, they would ideally cite EVERY paper found. For areas more extensively studied, this may be too cumbersome. However, they should still reference high impact studies that were found.

iii. □ The author needs to justify their choice of articles, especially if the issue is controversial. The author should do this by comparing validity of research papers found in the search. The validity of research papers is based on the research methodology and the risk of bias that comes from the methodology. It does not come from the results. They should appraise the article that is most likely to guide clinical care.

5. □ Critical Appraisal—document NOT included in the manuscript, but uploaded separately

   a. This section is not included in the manuscript proper, but should be uploaded in the “supplemental materials” section during the submission process.

   b. The purpose of this section is to allow for peer review. You may briefly summarize the papers reviewed, but include enough detail to justify your statements during the informed consent discussion.
c. Review the high impact papers that inform the discussion between the patient and the physician. This may include systematic reviews or meta-analyses as long as they are consistent. Avoid these types of papers if there is controversy and review the primary literature instead.

d. You must be selective in what details to include. Various considerations below may be important, but not of equal value.

e. This section is a SUMMARY ONLY. To guide how much information to include, as yourself, “Did I demonstrate why I spoke to the patient about this information?” Giving informed consent is work. This section is like doing mathematical problems—show your work.

f. **You may provide the information in outline, chart, or in narrative form.**


g. □ The critical appraisal should not be primarily guided by the discussion of the authors of the original research. Our authors must utilize their critical thinking skills.
   
   i. Our aim is to encourage authors to ask questions and engage the methods and data directly.
   
   ii. Without engaging your own critical thinking skills, it is easy to miss important biases, confounders and other important issues.
   
   iii. Do not rely on the Discussion section of papers reviewed.

h. □ The **level of evidence** for the body of literature must be reported, and the tool used to identify the level of evidence referenced appropriately. Preferred taxonomy is:

   i. SORT ([http://dx.doi.org/10.3122/jabfm.17.1.59](http://dx.doi.org/10.3122/jabfm.17.1.59))
   
   ii. Make a brief statement as to why you chose that level of evidence based on the type of papers reviewed.

i. □ The **study designs** should be identified and commented on. If not a double-blinded placebo controlled RCT, why not? Does the study design favor one group or outcome?

j. □ Some **comment on effect sizes** is mandatory. This may or may not be a numerical value, but if possible, NNT/NNH or likelihood ratio should be calculated and presented.

k. □ The **study protocols should be described** in enough detail to justify the level of certainty (uncertainty) in the phrasing of the discussion with the patient.

l. Critical appraisal questions related to an article on therapy:

   i. □ **Selection Bias:** How were patients enrolled or selected for the study? By doing it this way, are we getting a representative sample?
   
   ii. □ Was the assignment of patients to treatments really randomized? Was the randomization successful? Usually addressed in Table 1.
iii. □ Participation Bias: How were patients recruited? Patients who volunteer for studies are more likely to pay close attention to their health and have less disease burden.

iv. □ What is the intervention group exposed to that the control group is not?

v. □ Were all clinically relevant outcomes reported? What were they?

vi. □ Were the study patients similar to your own?

vii. □ Were both clinical significance and statistical adequacy considered?

viii. □ Is the therapeutic maneuver feasible in your practice?

ix. □ Attrition Bias: How many patients dropped-out of the study?

x. □ Were patients analyzed in the groups to which they were randomized? If so, this is an intention-to-treat analysis, which is stronger. If not, it is likely a per-protocol analysis.

xi. □ Performance Bias / Detection Bias: Were all patients, health workers, and study personnel blinded? Was this blinding sufficient? Was there anything in the study protocol that may have allowed any party to guess what group they were allocated to?

xii. □ Aside from the experimental intervention, were the groups treated equally?

xiii. □ Indication Bias: For cohort studies, why was the therapy given? Are patients who are started on that therapy typically because they are sicker or their disease is more poorly controlled?

m. Critical appraisal questions related to a diagnostic article:

i. □ Were patients recruited in a consecutive manner?

ii. □ Was there an independent comparison against a “gold standard”?

iii. □ Was this comparison blind? Were the investigators responsible for assessing the diagnostic test aware of the result of the gold standard beforehand?

iv. □ Was the setting for the study as well as the filter through which study patients passed, adequately described? (Inclusion/Exclusion Criteria)

v. □ Did the patient sample include an appropriate spectrum of patient to whom the diagnostic will be applied in clinical practice?

vi. □ Have the reproducibility of the test result and its interpretation been determined?
n. Identify other potential sources of confounding or bias.
   i. Funding Bias: Was the study sponsored in any way? What role did the sponsor have in the design, monitoring and analysis of the study? Did they provide money/medication only? Did they perform safety monitoring, perform statistical analysis or edit or write the manuscript?
   ii. Publication Bias: Was the trial registered prospectively? (ClinicalTrials.gov, or equivalent) If so, are there significant deviation from the study protocol? Are the reported outcomes different than those registered? Are there missing data that was collected, but not reported?
   iii. Any other sources not already mentioned.

6. Informed Consent
   a. Use narrative form as if you were speaking to the patient.
   b. Try to keep the reading level to sixth grade level. (Flesch-Kincade Reading level calculator included in Microsoft Word® )
   c. To the extent possible, the patient’s individual preferences and concerns should be described again.
   d. This section must address the social determinants of how care and treatment suggestions fit with the individual’s life. If transportation, financing, insurance, family structure, disabilities, housing, nutrition, activities of daily living, etc. cause barriers to care, demonstrate how they can be overcome or how the treatment decisions are modified as a result.
   e. What is the conclusion drawn from the study?
   f. Internal Validity: Does the conclusion of the research article make sense, based on the results of the study?
   g. External Validity: How was this conclusion applied to the particular patient in question?
      i. Are there any patient specific factors that make this body of research more or less applicable? This can turn a good manuscript into a great manuscript.
   h. What are the potential benefits and harms of applying the research?
   i. Did the patient meet the study’s inclusion criteria? If not, is it still reasonable to apply the conclusions?

7. References / Bibliography
   a. We highly recommend the use of a citation manager, such as EndNote®. EndNote® is freely available to the Wayne State University community here.
b. □ AMA format (http://www.amamanualofstyle.com/)

c. □ All claims of fact require reference, unless they can be considered common knowledge. When in doubt, cite.
   i. Requests for citation will be considered very seriously. Inadequate citation is a bad habit and leads to propagation of falsehood.

   ii. The references are to support statements made to the patient and should be included in the “Informed Consent” section of the manuscript.

8. Quality of manuscript (this is a not a required section)

   a. Manuscripts should be of high technical quality on first submission. They should not be sloppily written or have extensive typographic or grammatical errors.

   b. Reviewers and editors are expected to identify errors or confusing passages and suggest corrections or improvements. Your job is to assist the authors in improving the quality of their manuscripts. Your greatest success is a published manuscript.

   c. Feel free to comment on writing style, but remember that style is subjective, and oftentimes up to preference. You must try to keep the manuscript clear, but also allow the author to speak in their own voice. It is often a difficult balance.

   d. □ The word limit for informed consent manuscripts is **1500 words**. The count does NOT include references, but does including everything else, such as section headings.