Standard Format

We suggest you also review the “IRB Review Form” to be sure you have answered the issues we typically review. Forms should be submitted electronically with IRB in the subject line. The IRB usually meets the first Friday of the month; deadline is the 15th of the month for the next meeting.

Title of Study
Principal Investigator (and name and title of advisor, if a student). Qualifications of PI to conduct the study (attach a CV/biosketch). If the PI is a student and the advisor is non-TUCOM faculty, we will need the CV/biosketch of the advisor.

Abstract: A paragraph. Optional; intended to provide a very brief outline of the entire proposal.

Introduction (aka Background and Significance):

This section should cover these questions: (not necessarily in order)
1. What do you plan to do? (What is your research question)? State your hypothesis. This is often the most difficult part; refining a research question. The most common problem is making the question too big. If you’re having trouble, let us know or talk with a research-oriented colleague.
2. Why is this study important? (How will it add to what we know now and who cares anyway)?
3. What has already been done (and how will yours add to it or further the inquiry)? There should be evidence of an adequate search of the literature, usually of materials within the last 5 years. Be sure to cite your references!

Study Design

1. How do you plan to do it? What kind of study is it? How will it answer your research question? Be specific. Who/what will be included/excluded and why? (What are recruitment/exclusion criteria? Be sure to include women, minorities, other groups if appropriate, and how they will be recruited). Randomization and/or controls? What data/specimens will you collect? Is this the best, safest way to collect it? Where will it be performed? How long will it last? Who will perform the collections/analyze the data?
Are any drugs or tests involved? Will any remuneration be provided? Address confidentiality.

2. **What are the potential risks and benefits?** Be sure to be as specific as possible; include loss of time or other inconveniences to participants. Don’t overstate benefits; if they are hypothetical benefits this must be clearly stated. How will you obtain consent? Provide for translation, reading for illiterate participants; whatever else may be necessary.

3. **What will you do with the data?** Where and how will it be stored and for how long? Who will have access to it? How will it be analyzed? Will there be follow-up?

4. **Appendices.** Questionnaires, consent forms, patient handouts.
   Note: Contact information for the PI and for the IRB MUST be included in patient consent documentation.