The following are provided as triggers to assist you in addressing issues broadly regarding ethics in your oral and written communications within the BME course. Many overlap with other criteria necessary for successful technical writing. These items are not meant to be an all inclusive list. Given the breadth of BME project titles, this would be quite difficult. Rather, they are intended to provoke thought that will produce a higher quality communication. Obviously, the written reports allow for more discussion of these topics. But even in oral communications, precise language can often cover these topics effectively, with further detail provided by the written report.

Simply stating that your client addressed an ethical concern is at best incomplete and at worst negligent. Your communication should discuss details that demonstrate where your project lies in the process of meeting ethical concerns, as is often demonstrated through professional and regulatory standards. Some projects will be in the process of meeting compliance, others will have fully met them by the end of the semester.

Ethical concerns are often addressed through professional and regulatory standards. These are met as a minimum safeguard. Examples of such criteria are below. Strong papers will address how these standards have been met. If you feel that your project brings in new concerns that go beyond current standards, address these new concerns after demonstrating how current standards were or could be met.

<u>Human subject and patient safety:</u> Before discussing broad ethical concerns, demonstrate what in your project was done to meet professional standards for human safety. Examples of such standards include FDA 510k approval for devices, UL standards, ISO 9000, or Institutional Review Board approval for human subjects work. What are the established criteria in the area of your project?

If you performed a study with human subjects, how were subjects recruited for your experiments? Who was included/ excluded? Were any outliers removed and why were they removed? This information also helps reviewers to gauge the significance of your results.

Summarize future work that your project would need to complete to meet professional standards for safe operation with humans.

Training regarding IRBs and Human Subject protection can be found at: <u>http://www.grad.wisc.edu/research/wkshop/index.html#HST</u>. Your client may also be able to direct you to resources and individuals knowledgeable on pertinent human subjects concerns relating to your project.

<u>Animal care</u>: If your project concerns animal models or builds devices used in animal experiments, demonstrate what in your project was done to meet professional standards for animal care Such standards include those utilized by the Institutional Animal Care and Use Committees (IACUC). Work with your client to understand possible concerns the IACUC might have with your work. What are the standard criteria for animal care pertaining to your project? Holly McEntee (<u>mcentee@rarc.wisc.edu</u>) can be a useful first

resource. http://www.rarc.wisc.edu/

<u>Honest Data:</u> Imagine yourself as a knowledgeable and skeptical reviewer of your communication. What details would you need to be convinced of the significance of your data? Technical communications use standards of statistics to demonstrate the reliability of data. What measure did you take to demonstrate the accuracy and/or precision of your measurements? For example, beyond simply providing a single measurement or a mean measurement, providing some measure of the variance of the measurement is often necessary. To allow the reader to judge the significance of your data, it is often necessary to understand the setup of the experiment. Provide details that indicate the strengths and weaknesses of your measurements. If time limited the measurements you could take, how would you take better ones in the future?

<u>*Citations:*</u> What efforts did you make to attribute previous work that is pertinent to your project? As the pertinent work becomes more recent, moving from web pages to journal articles demonstrates a better effort in attributing the advance. More established theory can be attributed to text books.

While novelty and creativity in design is generally valued in this class, novelty and creativity in ethical concerns is usually problematic. Citing the relation of your work to previously approved devices, experiments, protocols, etc. generally provides your work with a firm foundation regarding ethical concerns. If applicable, discuss where your project breaks new ground and would need further effort to meet ethical concerns.