**THE TITLE OF YOUR BME SENIOR DESIGN PROJECT**

John Doe, Jane Doe, Dane Joe, Biomedical Engineering

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BME Mentor: Dr. So Andso, Biomedical Engineering, The University of Iowa

**Problem Statement**

This is the problem you have identified that you plan to solve. It should be a single sentence, and contain specific information about what currently happens, and to whom. For example:

*Hip implants to treat degenerative hip disease in the elderly can become infected and require removal.*

Catheters are limited in precision and degrees of motion because of their reliance on mechanical movements which leads to extended procedure times.

**Need statement**

Translate your problem statement into a needs statement. Remember, a needs statement contains three components: Problem, Population, Outcome. This is an iterative process – by the time you turn in your need statement, you should have gone through several revisions.

A way to improve the usability and actuation of steerable catheters controlled by surgeons to increase surgical accuracy and decrease procedural time.

**Questions from the Advisory Board**

What questions did the advisory board or others ask you? (There should be several questions.)

* What sort of methods are used for catheter sterilization?
* How much do we know about ISO standards for catheter development?
* Have we looked through all relevant patents?
* How much do we know about the approval process through the FDA?
* We have been focusing on cardiac diseases, but have we considered a pulmonary catheter?
* What conditions would our product be used to treat?
* Quantitatively, how will we know when the product is successful?

**Next steps based on feedback from the Advisory Board**

What steps will you take to address the questions listed above? Be as specific as you can.

Next we plan to investigate other surgeries that could use this device outside of for cardiac disease. Once we have a working proof of concept, we will consider disease-specific catheter designs. Understanding the possible diseases and needs of specific surgeries now will help us specialize later.

We are continuing to search for patents for similar designs. None of the published designs we have found are electric and handheld, but we need to do a more thorough search.

To address the standards the catheter needs to adhere to, Medical Murray is going to send us the specific relevant ISO standards and lists of equipment they use to test the product against the standards. They also are sending us the FDA guides for developing a product. We will review these guides to address what standards we need to follow. We also plan to talk with our mentors and other members at Medical Murray about their methods of sterilization for similar products.

To show that there is an improvement, we could 3D print a model vascular system with a target to be hit. Then, surgeons would try to hit the target with existing catheters and then repeat with the electronic catheter. By doing this, we can measure the time it takes for each procedure and compare the times to see if the electronically controlled catheter reduces procedure time.

**Poster session impact**

How did the poster session impact your project?

The poster session was quite useful in exposing a significant lack of prior consideration given to manufacturability, standards/compliance, and existing patents. For many of these central concerns, we were unable to field a proper response because they had been overlooked entirely. While many concrete details regarding manufacturability and compliance cannot be addressed until a more concrete design has taken shape, this session clearly identified the fact that without first knowing the actual lay of the land, it is impossible to design around the real-world hurdles we will inevitably face.

Overlooking manufacturability or sterilizability of a chosen material, for example, may in turn necessitate significant redesign efforts further down the line which may threaten project success. As design goes through successive iteration, design decisions may become increasingly complex and interdependent and thus it will become increasingly more costly to redesign. By understanding general manufacturability limitations upfront and being acutely aware of the regulatory burdens we will face, significant redesign efforts may be avoided with much more attention directed towards improving final design.

**Questions/Concerns**

What questions or concerns does your team have moving forward? Be as specific as you can.

How materials to concept and prototype our project will be funded? Will it come from us? Do we have a budget? Will our mentors cover some cost?

How large will the total cost be? We already know that the final cost will be higher than our initial expectations.

How large of a scope this project should capture? Just the mechanism? Or entire catheter for specific procedure?

Will we be able to fit all necessary components in a reasonable handle size?