Progress Report 8

Week of 11/5/18

Alex Goodman

Work/Research Accomplished:

- Met with Dr. Doro to discuss new route of project
 - Submitted order form, parts are on their way
 - Specifically, ISFET sensor, pH meter, orginal pH probe used by Doro in ACS study
- Developed testing protocols to prove our concept of ISFET sensor in comparison to original ACS probe
 - Drift test
 - Observe if pH remains constant over time
 - Comparison test
 - Compare the readouts of two probes across different pHs
 - Temperature test
 - Vary the temperature across a constant pH and compare readings
- Discussed show-n-tell meeting with group and developed physical model
 - Materials:
 - Sponge
 - 16-gauge Needle
 - Wire
 - Plan:
 - Place the 16-gauge needle in the sponge
 - Place the wire in the needle
 - Hopefully, this will demonstrate to a layperson how we plan to insert the needle deep within a person
 - The wire will emulate a micro-pH sensor

Problems:

- What other tests can we perform on our bought pH sensor to give a very solid proof-of-concept
 - Meaning, what would a company or funding source want to *know* about the ISFET technology and why it's able to work better than current models
 - Miniaturization is a big one
 - Durability and protection of a sensor is another
 - How can we quantify these two characteristics?

Will Bacon

Work/Research Accomplished:

- Met with Dr. Doro again this week to finalize ordering parts discuss our testing plan for the upcoming weeks
 - Doro referred us to who we should contact about reimbursements
 - Doro gave his overall approval for the process going forward
- Designed various tests that we will need going forward, as seen in Alex's section above

• Finalized materials including testing and pH detecting materials

Problems:

• We will need to find a company or method to miniaturize the ISFET technology

Mark Austin

Work/Research Accomplished:

- Met with Dr. Doro to discuss purchasing and future direction
- Agree to purchase probes & analyzer to achieve proof of concept and eventually hope to attempt measurement in dog
 - Began setting up testing protocols for temperature variance, signal drift, ion-selectivity, etc.
 - Plan to test in meat before even considering testing in dogs
 - Major issue in testing on dogs is the diameter being too large (10mm) look to get this down to 3-4mm if possible
 - Could we strip the probe to acquire the raw sensor? We might find that it is significantly smaller than the diameter of the probe it is currently housed by
- Begin looking forward towards the submission of a proposal to test the ISFET technology in dogs

Problems/Concerns:

• What are the odds that if we stripped down the probe to the bare minimum that the sensor would actually be smaller than the current diameter of this probe?

Kelsey Murphy

Work/Research Accomplished

- Looked into and verified that we have the materials we need to perform our tests
 - Looked into IACUC rules for using meat in tests → Their rules only apply to living animals. Dead tissue must be ethically sourced (supermarket meat fits into this definition).
 - Verified with Dr. Puccinelli that we can use meat in the teaching lab. We can as long as we dispose of it in a sealed container.
 - Found pH sensor in the teaching lab and downloaded its manual to learn about calibration techniques. We will have this probe as a backup in case something goes wrong with our other probes.
 - Verified that the teaching lab has buffers at pH 7 and 4 to calibrate our probes for testing.
- Looked into FDA approved ISFET devices
 - One sensor is produced by Sentron, a Dutch company. Their sensor has been incorporated into multiple FDA-approved devices. I contacted the company to learn more, but haven't heard back.

- Found other ISFET devices used to measure pH in the cardiovascular system and in the gastric system (none of them are penetrating). It might be hard to find a predicate device that involves piercing.
- Met with the team to put together our ordering list and design preliminary tests (see Alex's section above)
- We selected the DeltaTrak Water Resistant pH Meter, so I looked into its specs and requested more materials information from the company.
 - Probe materials: Steel, ABS, PEEK
 - Steel and PEEK have previously been approved by the FDA for *in vivo* use
 - ABS is cytotoxic. If the body is exposed to it, we will have to replace this material in the downsized probe.
- Met with Dr. Doro to discuss our plan going forward and submit our orders to Brad Brugger, the orthopedic surgery department's financial person (See Alex's section above).
- Our orders should be here within two weeks.

Problems/ To Do

• Research miniaturizing ISFETs and find out how surface area affects their usefulness