Shirley Ryan AbilityLab

Research 101

A QuickStart Guide for Research at Shirley Ryan AbilityLab

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Introduction

Research and development is hard work. It should be fun and rewarding but is sometimes perceived as intimidating and confusing — especially for those who are just learning how to perform research or have never even tried!

Research and development are very important to our organization: Shirley Ryan AbilityLab's vision is ***"to be the global source of science-driven breakthroughs in Human Ability."*** This vision will only be achieved if our culture collectively embraces its importance. Science itself can be complicated, but being able to contribute to our vision should be straightforward for anyone.

The purpose of this document is to give you a basic overview on how research is performed broadly across Shirley Ryan AbilityLab, hopefully demystifying our research processes. To achieve our vision, we need everyone in the organization to contribute, including you!

Let's Get Started by Bragging a Bit

As you may have heard, Shirley Ryan AbilityLab has been ranked the #1 rehabilitation hospital by U*.S.News & World Report* for an eternity (OK, since 1991). Research remains an essential part of our mission to help people with functional impairments gain as independent and fulfilling lives as possible.

Did you know that Shirley Ryan AbilityLab:

- Is a 1.2 million-square-foot facility with about 800,000 square feet comprised of clinical and research space?
- Has more than 150 ongoing research projects?
- Has more than 200 dedicated researchers on staff?
- Has a large and diverse funding portfolio in rehabilitation of more than $150 million, making it one of the largest rehabilitation research organizations in the world:
  - ~34% of research is funded by the National Institutes of Health
  - ~29% of research is funded by the National Institute on Disability, Independent Living, and Rehabilitation Research
  - ~23% of research is supported by foundations
  - ~12% of research is supported by the Department of Defense
  - The remaining components are supported by industry and other federal agencies
- Has an internal database of more than 6,000 participants, both inpatient and outpatient, who have indicated they are willing to be contacted to participate in our research efforts?

Exterior shot of Shirley Ryan AbilityLab.

How did our research program and passion for science flourish? An excellent video on our history provides a concise overview:

"As soldiers began streaming home from World War II, America faced an unprecedented challenge. More than 600,000 American soldiers were returning home with battlefield injuries, yet in 1945 the science of rehabilitation was in its infancy. Dr. Paul Magnuson, an army orthopedic surgeon from Chicago, who had battlefield experience saving lives and limbs, created the infrastructure for Veterans Affairs to provide rehabilitation services to veterans returning home from battle. In 1951, Dr. Magnuson returned to Chicago with a newfound passion and mission to help the civilian population. Out of a vacant printing building on Ohio Street, Dr. Magnuson created the first freestanding rehabilitation hospital. The Rehabilitation Institute of Chicago opened its doors in 1954. By 1965, Dr. Henry Betts was named medical director and in 1967, he became the chairman of the Department of Physical Medicine and Rehabilitation at Northwestern University Feinberg School of Medicine. This role allowed him to train and develop talent, in turn allowing RIC to grow. Henry's passion and charisma attracted the attention of civic and social leaders and investors, not only from Chicago but from around the nation and the world. Both Dr. Magnuson and Dr. Betts have initiated a pioneering spirit of innovation. Many of RIC's current leaders were in fact trained by Dr. Betts and will march forth with that bright torch of leadership created by those who came before us. RIC's work in integrated research and scientific discovery and the single-minded pursuit of improving patient outcomes has come to define the field of rehabilitation science and medicine around the world."

With history and commitment like that from our past and current leadership, how can you not be excited to contribute to our research efforts? Now, that's just some of the why you should be a part of research. Let's get into the details of ***how research is actually organized at Shirley Ryan AbilityLab***.

What the Heck is an "Ability Lab?"

Maybe you once asked a researcher, "where do you work?" Perhaps they responded with something like, "I work in Neuromodulation & Motor Control Lab, associated with the Harris Family Foundation Arms + Hands Lab, on the 11th Floor of the Shirley Ryan AbilityLab flagship hospital." For goodness sakes, that is so much that you'd need a PhD just to sort it all out!

Let's start with the concept of a "lab." When someone mentions that they are part of a lab, they are probably not referring to just a physical space, but also a team of researchers focusing on a few specialized topics. The lab organization is usually led by a Principal Investigator, or PI for short, and might include graduate students, post-doctoral fellows, and technical and/or clinical staff. The PI is responsible for the general scientific direction and funding of the laboratory. Labs come in a variety of shapes and sizes and operate in an almost infinite number of ways. There are more than 40 PIs within Shirley Ryan AbilityLab that together investigate a broad range of topics.

In research, a center is often thought of as an affiliation of labs or groups that research thematically related topics. For example, the Center for Rehabilitation Outcomes Research is a group of labs that work together to study topics related to rehabilitation outcomes. Admittedly, the difference between a lab and a center can sometimes be confusing. A good rule of thumb is that a center is larger than a lab and has multiple affiliated PIs. Similar to how labs are run by PIs, centers are run by "center directors" who coordinate research priorities.

Research organizations across the world have labs and centers. However, Shirley Ryan AbilityLab's ability labs® are special, which you may have guessed because of the trademark! In the past, the rehabilitation research field has been criticized because it traditionally does not collaborate well with other groups. Clinical care has also been criticized because it is sometimes performed in outdated therapy gyms that don't incorporate the most recent technology or research findings. To address both of these issues, Shirley Ryan AbilityLab developed the concept of an ability lab: a modern inviting space where research and clinical care are intended to occur simultaneously. Individual labs and centers all work together to achieve both their independent research goals as well as the overarching research and clinical goals of SRAlab. Again, from the research perspective, ability labs have leadership structures, with Scientific Chairs at the helm working to define the science that is incorporated into each ability lab.

Shirley Ryan AbilityLab is the name of our organization as a whole, with the 355 E. Erie flagship hospital being our largest location. The idea and philosophy behind the ability lab (clinical care and science being performed side by side in a shared space) is so important to our institution that we even incorporated it into our name! The ability lab system in its entirety requires leadership at the highest level, with Rick Lieber, PhD, our Chief Scientific Officer, overseeing our translational research model.

Whew! Now I totally understand the explanation "I work in the Neuromodulation & Motor Control Lab, associated with the Harris Family Foundation Arms + Hands Lab, on the 11th Floor of the Shirley Ryan AbilityLab flagship hospital." This information may have been a bit more than you wanted to hear, but we hope it provides more clarity on how our research enterprise is organized. Now though, let's learn more about how you can get involved in research here at SRAlab yourself!

I’m Ready! How Can I Get Involved?

At Shirley Ryan AbilityLab, we have an awesome initiative called the **Research Accelerator Program**, which is filled with ways to learn about or get involved in research even if you haven’t ever done any before! Starting at the very beginning? That’s okay! We will go over some basics of research in later sections, but for now let’s talk about some of the ways you can learn more about research — both at Shirley Ryan AbilityLab and beyond — and how you can start getting involved or even performing your own project!

Want to know more details about the Research Accelerator Program? Contact Melissa Briody for detailed information (her contact information is at the end of this document). As you will soon see, we have dozens of experts here at Shirley Ryan AbilityLab who are ready and eager to help you with whatever questions about research you may have! Here are a few of these programs:

IN A NUTSHELL

The “In a Nutshell” monthly publication is a great way to start getting familiar with research, especially if scientific papers with all their jargon seem daunting to read. Don’t worry — they still sometimes seem like jargon to research pros too! Each month, a Shirley Ryan AbilityLab employee finds a scientific paper from a peer-reviewed journal (more on the peer-review process later) on a cool finding relevant to the research we do or patients we serve here at Shirley Ryan AbilityLab. Then, they write up a summary on what the researchers found and why it’s important and/or interesting. “In a Nutshell” is emailed to the entire organization on the 15th of each month with both the summary and the original paper attached as files. This allows you to learn a bit and take a stab at reading the paper yourself if you find it interesting!

IDEALAB

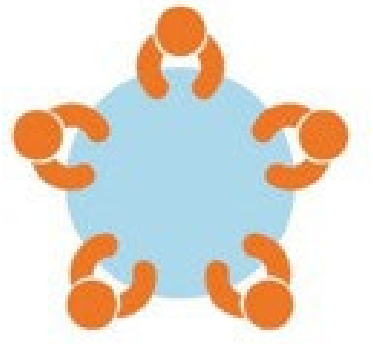
The IdeaLab is a collaborative way to get feedback on early-stage research ideas/topics and connect with more experienced researchers and other professionals at Shirley Ryan AbilityLab. They happen one to two times per month and consist of a participant who has a research idea they’re still developing, along with attendees composed of researchers, physicians, nurses, therapists, engineers and more. In the IdeaLab, the participant gives a brief presentation on their research project idea to everyone. Then, the attendees ask questions, provide feedback, help develop the idea and assist in finding the participant a potential mentor and/or funding opportunity.

Integrated team collaborating in an IdeaLab.

BUZZLAB

The BuzzLab is sort of like a follow up to the IdeaLab: it’s the next step in a research discussion. It consists of the same set up but, instead of a new, early-stage research idea, the presenter brings a research project they’re currently working on. The attendees then provide feedback and input which help provide clarity for next steps in the project. The BuzzLab can be helpful for people looking for ways to address reviewer feedback (more on reviewers later), who want to understand how a certain technology could be translated into the clinic, or who want to know if a new intervention might help another patient population, among many other uses. Once you’ve begun working on your research, the BuzzLab creates an inclusive space to share that work with others at Shirley Ryan AbilityLab.

ROUNDTABLES



Once per quarter, Roundtables bring together Shirley Ryan AbilityLab clinicians and researchers to talk about a common area of interest, such as spinal cord injury or stroke. While clinicians and researchers often work together, sometimes our viewpoints on situations or needs for our patients can be very different, so it's important to come together and share ideas. During Roundtables, Shirley Ryan AbilityLab clinicians and researchers learn from each other and potentially form new collaborations for research projects. Clinicians present current clinical treatments while researchers present new, state-of-the-art research findings and future possibilities related to these clinical treatments or the patient population they treat. Together, the clinicians and researchers then discuss how we might be able to bring some of these new research ideas to clinical care and what clinical questions are still being overlooked in research. These types of discussions are often how an entirely new research project begins and thus uphold the collaborative spirit that is at the core of Shirley Ryan AbilityLab!

PRESENTATIONS AND AWARDS

Already in research and doing some awesome stuff? Know someone else in research you think is really going above and beyond in their work? Below are ways to share your research findings or have your work recognized for its success by Shirley Ryan AbilityLab leaders.

Sarah Baskin Outstanding Research Awards

Sarah Baskin Awards are given each year for outstanding research in many different categories. Anyone involved in research can submit a manuscript that demonstrates the awesome research they are doing here at Shirley Ryan AbilityLab to win a Sarah Baskin Award.

Kabiller Humanitarian Prize

The Kabiller Humanitarian Prize is an annual award to honor a nominated individual who personifies our organization's compassionate culture in their work and interactions.

Magnuson Award

Magnuson Awards are given every year to recognize nominated employees' contributions to ensuring high-quality patient care, demonstration of organizational values and commitment to going above and beyond in their roles.

Quality Fest

Quality Fest is an annual event where you can share a quality improvement project you and your team have worked on over the past year. The process involves submitting a poster and recording a presentation on the project.

We've talked about some ways to discuss and share research, but now let's talk about ways you can get money to perform your own research here at Shirley Ryan AbilityLab!

ALLIED HEALTH FELLOWSHIPS

Allied Health Fellowships are one of the many exciting ways you can fund your own independent research project here at Shirley Ryan AbilityLab! Each one-year project includes a research mentor to help guide your work. The final part of the selection process involves a presentation on your project to a review committee (talking about your project in one of those "IdeaLabs" we mentioned earlier would come in handy for this presentation!). We have two Allied Health Fellowships that are open to different types of Shirley Ryan AbilityLab staff members:

James Brown IV Fellowship

This fellowship is open to allied health, social work, chaplaincy and therapeutic recreation professionals and is an approximately $25,000 project award.

Buchanan Family Fellowship

This fellowship is open to occupational therapists and is an approximately $20,000 project award.

NURSING FELLOWSHIPS & GRANTS

Registered Nurses and Advanced Practice Registered Nurses may apply for funding to support nurse-led research and quality improvement projects through a Prince Nurse Fellowship or Whirlpool Grant. Project applications are reviewed by the Director of Nursing Research and Chief Nursing Officer. Projects with the potential to result in measurable quality and safety improvements for SRAlab patients, improvements in the work environment for nursing staff, or new knowledge on an underexplored topic in the field of rehabilitation nursing are prioritized. Proposals are reviewed on a rolling basis throughout the year. The number of projects and total amount funded each year will vary.

CATALYST GRANT PROGRAM

The Catalyst Grant Program is our biggest internal opportunity for getting involved in research and getting money for it: a win-win! Catalyst Grants are an opportunity open to all employees at Shirley Ryan AbilityLab, whether in a research position or not. If you have a good idea that could help our patients or improve the way Shirley Ryan AbilityLab does things, you should consider applying! All applications must include a researcher and either a clinician or non-research employee. You do not have to have research experience to participate — that is what the researcher on your team is for!

There are four types of Catalyst Grants, all with different funding amounts: a Project Grant, Quality Grant, Mentorship Grant and Foundational Grant. Here's a brief overview of each:

Project

These grants are for inexpensive projects that are easy to implement and can have an immediate impact on our patients or Shirley Ryan AbilityLab itself. These grants are typically for $10,000 or less. While the project grant budget is the smallest of the four grant options, there's no limit on what the project can be! Your project can range from building a new medical device to modifying a patient care protocol to even refining/updating a general process of how we do things here.

Quality

Quality grants specifically focus on a quality improvement project. This project can be a change in infrastructure, a process or a procedure that helps with efficiency and/or accessibility at Shirley Ryan AbilityLab. These grants are for up to $25,000; however, do not apply for a quality grant just because your budget requires $25,000. Quality improvement projects are a bit more specialized and, although not required, it is a good idea to use a quality improvement model such as the four-stage Plan, Do, Study, Act Model.

Mentorship

Mentorship grants are a great starting place for new researchers and are the "bread and butter" of really diving into the world of research. These are grants for projects started by people with limited research experience but who want to develop their research skills and expertise. These grants focus on translational research, meaning that they should address a clinical problem you see or develop a new tool that we can further evaluate before putting it into the clinic. Although a goal of mentorship grants is to support innovative ideas that impact clinical care, their main purpose is to develop the research expertise of the mentee and serve as a "catapult" for their research career. For instance, the mentorship grant would be perfect for a clinician who wants to gain experience in order to apply for a research position in the future. These grants are for up to $25,000; again, don't apply for this grant just because your budget is $25,000. It is a good idea in mentorship grants to provide an explicit section in your proposal to detail your mentorship goals and plans for future research involvement.

Foundational

Foundational grants are the largest amount of money available from the Catalyst Grant Program, with a maximum amount of $50,000 per project. These are grants for collaborations between an experienced scientist and clinician to get pilot data that they can then use to apply for a larger research grant from funding agencies like the National Institutes of Health (NIH) or Department of Defense (DOD).

As an example of just how important the Catalyst Grant Program has been, consider this success story:

Mitra Lavasani, PhD, was a young scientist with big dreams. As with many of her peers, however, she had yet to translate her early research success into significant federal funding. In a previous study, Dr. Lavasani used stem cells to double the lifespan of aged mice, delaying the onset of several common diseases. However, to obtain meaningful external funding for fueling continued studies, she couldn't just present this observation; she had to come up with a plausible basis for the finding. Everything changed when Dr. Lavasani secured $50,000 through the internal Catalyst Grant program. She finally got her chance. The funding paid for sophisticated proteomic analysis, a method used to identify the exact type of proteins made by her stem cells. Through this process, she pinpointed candidate

Mitra Lavasani, PhD, at work in the Biologics Lab.

proteins that might be responsible for the anti-aging effect being spurred in mice. She now had her testable hypothesis and the basis for a solid grant proposal. Then, instead of simply injecting stem cells into tissues of need, such as joint cartilage or muscle — which is considered the traditional approach — Dr. Lavasani's team injected the cells in a manner that allowed them to circulate systemically in aged mice. The result: inflammation decreased, regenerative cells flourished and cartilage regrew — lending hope that osteoarthritis can be reversed. Following this discovery, made possible in part by funding from private donors, Dr. Lavasani subsequently has secured sizable foundation and government grants totaling more than $4 million. "My story is a perfect example of how early funding not only spurs discoveries, but also leads to more funding," she said. "Without the seed money I received, it would have been almost impossible to secure the significant multi-year grants I've received since. The early funding provided the jump start to accelerate my research." Dr. Lavasani hopes one day to translate her research by testing it in humans — the ultimate goal to optimize and individualize treatments. She's convinced Shirley Ryan AbilityLab's translational hospital, where she has direct access to willing patients and research participants, is the perfect setting. "Shirley Ryan AbilityLab is a goldmine for stem cell biologists like me," she said. "We have ready access to state-of-the-art tools and technology through our Biologics Lab — the only one located in a rehabilitation hospital. Additionally, we are surrounded by patients, and have access to samples and data on a scale not possible elsewhere. Importantly, we are more connected to those who will benefit from our research. There is no greater inspiration."

Are you excited to prepare one of these proposals but don't know where to start? Maybe you have no research experience at all but really want to learn? Maybe you're just a little like, "This is kind of overwhelming! Can we take a step back?!" Well, whatever you're feeling, we've got you covered. So keep on reading!

Time to Learn the Basics …

Science, engineering, research and development: what do these words even mean? Let's get a good understanding with some definitions before we dive into more details.

Science
Knowledge or a system of knowledge covering general truths, or the operation of general laws especially as obtained and tested through the scientific method.

Engineering
The application of science and mathematics by which the properties of matter and the sources of energy in nature are made useful to people.

Research
The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions.

Development
To create or produce, especially by deliberate effort over time.

THE SCIENTIFIC METHOD
You can see that most of these definitions require two major components: a systematic method and careful planning (which, honestly, we should be applying to many things that we do day to day already!). At some point in your life, you may have also heard the term "Scientific Method." But what exactly is the Scientific Method? How is it used? And what does it have to do with what we do here at Shirley Ryan AbilityLab?

The **Scientific Method** is a logical problem-solving approach used to create our system of scientific knowledge. It is used in all fields of science, from chemistry to geology to psychology. Although scientists in each field ask different questions and perform different experiments, they each use the same core approach to find answers that are logical and supported by evidence. The Scientific Method has five basic steps plus an iterative feedback step. These six steps are listed below with an example experiment to go along:

1. **Make an observation:** The powered wheelchair is not running.
2. **Ask a question:** Why is the powered wheelchair not running?
3. **Form a hypothesis:** The powered wheelchair is not running because its battery is dead.
4. **Make a prediction:** If the powered wheelchair's battery is replaced, then it will run again.
5. **Test the prediction:** Replace the powered wheelchair's battery and see if it now runs. If the powered wheelchair runs after replacing its battery, the hypothesis is supported and likely correct. If the powered wheelchair does not run after replacing its battery, the hypothesis is not supported and likely incorrect.
6. **Iterate:**
   If the hypothesis is supported, perform additional tests to confirm it or revise the hypothesis to be more specific. For example, if the battery died quicker than expected, you could ask what was wrong with the battery to make it unable to run the powered wheelchair. Then, you can form a new hypothesis based on the question and continue researching!
   If the hypothesis is not supported, come up with a new hypothesis. For example, perhaps the powered wheelchair is not running because the wires are loose and therefore not transmitting electricity adequately. You've formed a new hypothesis which you can now test!

In most cases, the Scientific Method is an **iterative process**, which means the result of one round of it becomes feedback to improve the next round of questioning. Every time we answer a question in research, new ones inevitably pop up to keep the Scientific Method cycle going!

HYPOTHESIS-DRIVEN VS. NEEDS-DRIVEN RESEARCH

You may be asking yourself if you even need a hypothesis to perform research. Why can't we just dive right in and start trying things out?! That sounds easiest, after all! Let's be clear: a hypothesis is a very important part of the Scientific Method. It is a proposed explanation or outcome that is scientifically testable and usually based on at least a little bit of evidence. However, the good news is that you can contribute to our research goals even if you don't have a hypothesis! Wait, though … but didn't we JUST say that a hypothesis is a very important part of the Scientific Method? How can we do research without a hypothesis then?! Well, let's talk about that now!

Let's define a new, broad category of research so that we can answer the question of whether or not you need a hypothesis: **needs-driven research**. We often use this term interchangeably with developmental research. Let's look at an example: modern motorized prosthetic legs are only rated for users that weigh 250 pounds or less, but what about those with amputations who are heavier than this weight limit? Are they limited to only passive prosthetic legs? Well, now we've identified a need: make a motorized prosthetic leg that supports heavier people. With this identified need in mind, we will build a new type of leg that supports those up to 400 pounds. Notice, we don't have an explicit hypothesis going into the work, but instead focus on development to address this specific need. This type of research usually also relies on engineering support (remember, engineers are the ones who apply science and mathematics to build something).

Some of the best projects include both need- and hypothesis-driven components and include a team of engineers and scientists (and clinicians, students, etc.). For example, we hypothesize that heavier people will improve their performance on a six-minute walk test when wearing a motorized leg that fits their weight. Well, to even test this hypothesis, we first need to build the specialized leg (needs-driven) and then afterward perform our six-minute walk test (hypothesis-driven).

This is Interesting, Tell Me More!

ALRIGHT, TELL ME THE TRUTH THEN: WHAT'S MORE IMPORTANT, SCIENCE OR ENGINEERING?

Let's reframe your thinking here: neither science nor engineering is "more important" than the other — both are equally important and usually complement each other! To create truly groundbreaking work, research teams often need a combination of scientists, engineers, clinicians, mathematicians and other experts. Most good research is interdisciplinary in nature, which means it explores multiple different subjects at the same time. When research explores multiple different subjects at the same time, it needs multiple types of experts from many different fields! Imagine an operating room: you need a surgeon, multiple skilled nurses and an anesthesiologist all performing different roles for the surgery to be successful. You wouldn't want to be on the operating table with just one surgeon in the room trying to do everything by themself! It's the same with research: skilled teams of people from different fields are what make for a successful project. Alright now though, back to talking about scientists and engineers!

Engineers can perform science and scientists can perform engineering: everyone can cross disciplines, and some are even trained in their formal education to do so. However, scientists and engineers still have specialized skills that they are specifically trained in that make them a scientist or engineer in the first place. For instance, a scientist might know how to use a microscope to identify different types of neurons, but not know where to even begin using a sensor system that tracks movement. On the other hand, an engineer might not know the first thing about how a microscope works but can use a sensor system that tracks movement easily. This phenomenon is just like how a physical therapist is an expert at rehabilitating a patient's ability to move their body and manage their pain, while an occupational therapist is an expert at rehabilitating a patient's ability to perform activities of daily living. Despite different roles, both physical therapists and occupational therapists are equally important in a patient's recovery. Different types of experts complementing each other and filling in each other's gaps in knowledge is what makes great research teams successful in the first place!

WHAT IS THE DIFFERENCE BETWEEN QUANTITATIVE AND QUALITATIVE RESEARCH?

You may have heard of different terms like quantitative and qualitative research. Quite a few of our studies use both types. Maybe you are wondering what the difference is.

Quantitative research is research that deals with numerical or measurable data. Something quantitative is something that gives you an exact, or objective, answer.

Examples of quantitative research include:

- Recording how many steps a person can take in a given time period
- Recording how much the temperature of Lake Michigan changes from day to day
- Administering a survey with close-ended questions which can be turned into quantifiable data (e.g., "on a scale of 1–5, how much did you enjoy using our product?" will give an average value between one and five as a quantitative, measurable result)
- Counting the number of different types of cell colonies on a petri dish

Qualitative research is research that deals with non-numerical or non-measurable data. Qualitative data are those which are subjective, like how you feel about a new movie.

Examples of qualitative research include:

- Interviewing a patient about their experiences or symptoms
- Interviewing musicians to gain insight on the particular music scene that they are participating in
- Performing a literature review to put forward a new philosophical theory
- Recovering and analyzing historical records of a certain population of people

COOL! HOW ELSE CAN RESEARCH BE CATEGORIZED?

There are probably infinity plus one ways (okay, maybe not quite that many) to categorize research. For instance, there is human-subject research, animal research, behavioral research and much more. Let's talk about three quite common and useful ways we can categorize research that interests our researchers here at Shirley Ryan AbilityLab.

Laboratory research

Laboratory research is research that is performed in a very controlled laboratory with lots of technical equipment. If you are thinking of a geeky-looking scientist in a lab coat examining slides under a microscope, you are on the right track. Did you know we have a huge biologics laboratory with microscopes, centrifuges and other equipment up on the 26th floor? We also have some other very specialized labs in the hospital, such as a biomechanics gait lab that can very precisely measure how people move. We even have some equipment that can be used to measure how strong people are or that can examine how their muscles fire when they try to generate specific movements! Shirley Ryan AbilityLab hasn't been the number one rehabilitation hospital since 1991 for nothing, after all! The following are research activities that might take place in a laboratory:

Biologics Lab

- Testing what level of radiation kills the most cancer cells in a petri dish
- Synthesizing a new drug to target the immune system
- Examining the motor unit firing rates of individuals after stroke

Clinical research

Clinical research is research involving human participants, usually performed in an environment such as a hospital or clinic. Maybe you have seen a person wearing an exoskeleton in the Strength + Endurance Lab being monitored by some physical therapists or a scientist. Have you ever thought about what they might all be doing? Perhaps they were evaluating how the exoskeleton improved the patient's recovery, asking the patient about their feelings on the exoskeleton's safety and comfort, or testing a newly developed Iron Man-esque super suit (okay, it's probably not that last one, but that would be pretty cool too, right?). Clinical research, by definition, is done in a less-controlled environment and often involves ideas that are a bit more mature. Clinical research can take the form of clinical trials, which help to determine the safety and effectiveness of medications, devices, diagnostic products, treatment regimens, etc., for human use.

Legs + Walking Lab

Examples of clinical research include:

- Developing and testing a new prosthetic arm for an individual with an upper-limb amputation
- Testing if a new stimulation therapy is safe for use in individuals with spinal cord injury
- Examining if increased gait training helps improve walking ability for individuals after experiencing a stroke

Community research

Community research is performed in and about the community at large. While clinical research outcomes can give us some interesting answers, there are limitations to what we can interpret from them. Just because someone improved their walking score on a clinical test after wearing an exoskeleton does not necessarily mean the project was a success. Can the person put the exoskeleton on by themselves? If so, do they choose to use it on their own or is it too uncomfortable to wear every day? Does the exoskeleton provide increased community access and/or home mobility, or is it too bulky for doorways in a typical home? These are questions that can only be answered by performing community-based research.

Examples of community research include:

- Looking at community ambulation before and after intensive gait training using step counters
- Evaluating spontaneous communication in a community setting after aphasia treatment
- Assessing how well a new prosthetic arm improves social activities for an individual with an upper-limb amputation

Just like science and engineering, none of these types of research are more important than any other. Laboratory, clinical and community research all form a continuum that leads to science that can actually be translated into the clinic or a person's daily life. Here is a good illustration of a success story:

In the 1980s, Dr. Todd Kuiken was a PhD student researching how electromyographic (EMG) control of bionic arms might be improved, and read a research article that suggested a "grafting technique might allow for the recording of EMG signals directly from a mosaic of cross-reinnervated muscles, thus taking advantage of the signal amplification properties inherent in the neuromuscular system." The article then went on to discuss all the problems that might prevent this from being a practical idea. Dr. Kuiken first performed careful experiments within a laboratory environment by examining how muscles reinnervated in rats, and reported his results in 1994. After promising findings, he performed this new technique on the first person in 2002. Between 2002 and 2009, he completed several clinical research studies showing that the technique was safe and that it improved outcomes on a set of clinical evaluations. From 2009 to 2016, he monitored patients in the community using a bionic limb controlled with targeted muscle reinnervation (TMR) signals. Dr. Kuiken's research spanned the laboratory to the clinic and finally to the community. The result of this work? Now, thousands of people with amputations around the world have had the surgery Dr. Kuiken invented!

Jesse Sullivan, the first patient to receive Dr. Todd Kuiken's TMR-controlled bionic limb, along with Clinician-Researcher Kristi Turner!

How Do We Recruit Patients?

As part of our recruitment strategy, we use tools called “registries.” Ours is called the Clinical Research Registry (CRR). The CRR is housed in REDCap, a browser-based research electronic data-capturing system. The data analytic staff and REDCap administrators have been able to develop a system to extract specific demographic and medical history information from Cerner, Shirley Ryan AbilityLab’s EMR system. The pre-population process provides a consenter with the most up-to-date and accurate information in the consenter’s workflow tool of the REDCap database. This information is only to be accessed once the participant agrees to be consented into the CRR. Each repository of the CRR has specific data dictionaries which have been developed by a collaboration of principal investigators in those specialized areas of research. The CRR is a non-public database exclusively available to researchers with active studies from Shirley Ryan AbilityLab and/or Northwestern University’s Physical Therapy or Physical Medicine Departments. Participants within the CRR reflect a large diversity of individuals. The CRR currently has more than 2,000 active participants ranging from birth to 90 years old; inclusion criteria consist of individuals with a history of stroke, spinal cord injury, cerebral palsy, traumatic brain injury and/or a history of amputation/limb difference. The pool of participants in each repository has been consented from varying settings (e.g., inpatient, outpatient and DayRehab, in addition to online submissions). Access to this ready pool of potential subjects will help us efficiently meet our recruitment goals.

Non-invasive brain stimulation.

What Sort of Safety Regulations Are There?

It is important that our research is **ethical and safe**. Just like in the clinic, our researchers are trained to use specialized equipment, perform routine maintenance, properly dispose of hazardous materials and use personal protective equipment (PPE). We sometimes even consult with our friends at the **Donnelley Ethics Program** to discuss the ethical implications of studies that we are planning. All these procedures are performed not only to keep ourselves safe, but also our patients.

Speaking of which, at Shirley Ryan AbilityLab a lot of our research involves human research participants (or subjects). Just as there are clinical guidelines that we must follow to keep our patients safe and healthy, we also have necessary and important steps to ensure that our human-subject research is safe. A big part of this safety process is that participants must be fully informed of the risks and benefits to participating in the research as well as their rights as research participants. So, how do we do ensure research participants' rights and who makes sure we (and others) are following safe and ethical procedures? Well, let's break it down a little bit.

THE INSTITUTIONAL REVIEW BOARD (IRB)

The **IRB** is a group whose job it is to make sure all studies that involve human participants or human samples (blood, tissue samples, etc.) are safe and protect the rights of each person involved. Each research institution has their own IRB group, but all IRB groups must be approved by the United States Food and Drug Administration (FDA). The IRB must approve all studies involving humans before the research can even begin. At Shirley Ryan AbilityLab, we don't have our own IRB — we submit our IRB documents to the IRB at Northwestern University for approval. IRB documents cover all aspects of the study, including how the study will be performed, what the potential risks and benefits are to a participant, and how any data will be kept confidential or safe. Some good news about IRB documents: if you've thought through your project for a grant proposal, you've probably simultaneously already thought through a lot of these IRB pieces and just need to restructure them and get more specific on certain points!

IRB documents can often seem daunting with how much detail they require, but it is an important step to keeping everyone, especially our participants, safe. Don't worry though, you don't need to tackle IRB documents alone! There are lots of people here at Shirley Ryan AbilityLab who have gone through the IRB process many times and can help you. If you've never performed the IRB process before, you will most likely be paired with an experienced researcher who can help you prepare the documents.

One final little note while we are on the topic of ways to work safely with participants: To ensure a team has appropriate training to work with human research participants, our IRB requires that designated study personnel have taken Collaborative Institutional Training Initiative courses (CITI Training courses). The basic CITI Training courses are free, can be taken online, and typically require ~4-8 hours in total to complete.

WHAT ABOUT ANIMAL RESEARCH?

Whenever we involve animals, such as mice, primates or even fish in research, we want to make sure these critters are treated humanely and safely throughout our research studies. Just as it's important to keep our human research participants safe, we have regulations in place to ensure research involving animals is performed in a humane manner as well. Animal research is not reviewed by the IRB. Instead, all animal research gets reviewed by Northwestern's Institutional Animal Care and Use Committee **(IACUC)** Office, which is basically the IRB for animals. Again, specialized training is required for working with animals, and the documentation needed to have a study approved and monitored is extensive. Due to Illinois state law, Shirley Ryan AbilityLab is not allowed to have live research animals in the hospital building, so most of our animal work is performed in facilities housed at Northwestern University right across the street.

Who Pays for Research?

We all do (but, let's be clear, none of us could afford the cost of research projects out-of-pocket — that's what taxes are for)! Research is funded in a few different ways, but money to do research at Shirley Ryan AbilityLab primarily comes from research grants.

A **research grant** is a financial award given to complete a project or goal. This award can include money for equipment and supplies, staff salaries, travel, research participant reimbursement and much more. When you hear someone talking about "writing a proposal" or "writing a grant," they are referring to the process of obtaining a grant to fund their research. Preparing a research grant proposal is like telling a story on the hows and whys of your proposed project (keep this in mind as you write your Catalyst Grants!). Research costs money and, to get money for your research, you must get other people to believe in your idea too! For now, though, let's just focus on a breakdown of the major types of research grants.

TYPES OF RESEARCH GRANTS

Research grants come in a few different flavors. Here's just a quick sampling of some broad categories of grants:

Federal Grant

These are the most common type of research grants. These grants come from many different government agencies. Some major federal funding agencies that you may have heard about are the National Institutes of Health (NIH), the National Science Foundation (NSF), the National Institute on Disability, Independent Living and Rehabilitation Research (NIDILRR), and the Department of Defense (DOD). Federal grants also come in many different types and can range from smaller project or mentorship grants all the way up to large-scale clinical trial grants or even multimillion-dollar grants that help establish a new research center.

Foundation/Philanthropic Grant

Foundation grants are given by a foundation, nonprofit organization or philanthropist. These funders will often have a special interest that they focus on and want to see research performed in. For example, the Neilsen Foundation awards grants related to research on spinal cord injury. These grants are usually less money than government grants but can be a great place to start for new researchers to get funding! Similarly, sometimes these foundations provide research funding as donations, but more often than not researchers must still write a proposal to explain what they want to accomplish with said donation.

Industry/Company Grant

Company/industry grants are money given by a company to a researcher, often to do research on one of their devices. Usually, these grants are given to more established researchers, where the company will be the one to reach out rather than the researcher contacting them. However, this is not always the case. For example, Medtronic has a small grant program where clinicians or researchers can apply for money to perform research studies relating to their products.

Internal Research Grant

These are smaller grants from the place you work or do research. Many of these internal grants are funded by generous philanthropists or large fundraising campaigns. Internal research grants are probably the best place to dip your toes into research! At Shirley Ryan AbilityLab, we have a few different ways to get your research project funded through our Research Accelerator Program, as we discussed in more detail in a previous section of this document.

How Do I Know How Much Money to Ask For?

Listen, in a perfect world we would just get a "take all the money you need!" response from funding agencies for our awesome research projects. But unfortunately, budgets are a thing. Money is limited, so a funding agency wants to make sure they know where every penny they give you is going and why you need it. Some obvious costs are your equipment and supplies. But what else do you need to think about when asking for that money?

There are two main categories of costs. Equipment and supplies, for example, fall under the umbrella of **direct costs**. Direct costs are what you are directly budgeting for in your grant application and are usually explicitly stated in your budget as line items. Let's cover some typically budgeted direct costs in more depth.

DIRECT COSTS

Equipment and Supplies

There are generally two types of budgeted equipment on a grant: major and minor equipment. Major equipment, sometimes referred to as capital equipment, is categorized as equipment that costs more than $5,000. There are tax implications in how major equipment is depreciated, so we treat it separately. Minor equipment costs less than $5,000 and does not require separate treatment. Finally, you may also have materials and supplies. These are generally disposables or consumables like medical tape, adhesive electrodes, syringes, etc.

Labor Expenses

A big part of understanding how much money a project might need is knowing your staff. What type of experts do you need to make your project successful? For example, if you are trying to see if a new therapy training helps improve walking, you would want to make sure to have a physical therapist on your staff who is able to perform the training. Another example is that if you think a new device may be useful during therapy or at home, you will want to make sure an engineer is on board to help you develop the device and fix it if it stops working. Thinking through all the possible people you want to work on your project is a big step in your budget and planning, so take your time on this!

When you apply for funding to pay for a research project, the funding agency giving you the money will ask for a list of staff and what their expected effort on the project is. **Effort** is how much time out of the calendar year each person expects to be working on the research project. That amount may be as low as 1% of the time or as high as 100% of the time — it just depends on what needs to be done. In other words, are you going to be working on your project for only 1–2 hours per work week or closer to 20 hours per week? For grants, we often calculate this time in terms of "calendar months," (e.g., if you think a research project will require 50% of your time, that would be six calendar months). A handy table on converting percent effort to calendar months can be found here. A final thing to remember is that labor expenses also include covering all eligible benefits like health insurance, retirement planning and paid time off. These "fringe" costs are around 25% of salary, which can add quite a bit to your overall budget.

If you can, it's always best to err on the side of caution and budget a bit more time than you think you might need. You never know what unexpected twists and turns could pop up along the way, and you want to make sure you have the money to pay your staff to address them when they do. It's better to come in under budget and request additional scope be added to your proposal than to run out of money just when things are getting interesting!

Travel

Hearing about others' research or talking about your own is an awesome way to get new ideas or feedback on your project (hey, remember those **IdeaLabs** and **BuzzLabs** we talked about earlier?). One of the most impactful ways to share research ideas more broadly is through conferences, where you can present on your work and listen to other researchers talk about similar work. Conferences can get expensive, but you don't need to pay for these yourself! You can budget for conference travel in your grant,

including registration fees, hotel and flight costs, and (for some grants) a per diem for your expenses while you travel. You may also need travel money to visit another researcher to collaborate. Some grants might even require you to travel to certain conferences to talk about your project, so always make sure to check for travel in the grant instructions!

Participant Reimbursement

Time is money as they say, right? When we do research with human participants, they are often taking time out of their day to help us. Because of this, we want to be able to compensate our participants. How much money do we give them, though? The amount of money given is very dependent on what the participant is doing. For instance, is the participant completing surveys, performing assessments (like a six-minute walk test) or taking a device home to use in their community? Each of these types of participation will have a different stipend amount. The key factor is that the amount must not be so high that it coerces people to be involved in a study that they might not otherwise take part in. To figure out these amounts, it's best to speak with other researchers to discover what standard reimbursement amounts for different types of studies look like. ***Note:*** you'll also need to know what these amounts are before submitting your IRB documents!

Publication Costs

Publishing your research (most often in an academic journal) is a huge part of the research process — it's how we share our results with others! When your research is all said and done, you're going to want to be able to share your findings with the world. As with all things, the publication process costs money, so you'll want to make sure you budget for how much it might cost to publish.

Those are some common categories of direct costs associated with research proposals. You may be asking, ***"What about expenses like rent, power, internet, human resource management, insurance, etc.?"*** Researchers need to contribute money to offset these sorts of costs; we have a lot of space in the hospital and don't expect to use it for free! However, researchers generally don't have specific line items in their budget for each of these items. Rather, these items all get grouped together into our second category of expense: **indirect costs**.

INDIRECT COSTS

To simplify things, the large federal granting agencies will negotiate a reasonable indirect cost rate that can be used for all proposals. This changes periodically but the Shirley Ryan AbilityLab indirect rate is 64%. This means that if you had a budget of $100,000 in direct costs, you would have to add an additional $64,000 to cover indirect costs for a total of $164,000. Some foundation or industry grants limit indirect costs. If this is the case, there is a process to request lower values. For example, our Catalyst Grant Program allows for a 10% indirect cost rate. There are some other more complicated subtleties that go into indirect cost calculations, but don't worry too much about that now. We have an entire department here at Shirley Ryan AbilityLab to help you with indirect costs and all other administrative issues that may arise during the grant process (but more on that later!).

Like we said before, it would be awesome to have all the money we could ever ask for. But even if it loves every project, a funding agency can't fund everything that's submitted to it. So how do funding agencies decide which projects get funded and which don't? The full decision process is a little different for every agency, but there's one common piece between them all: **the peer review process**. Let's talk about exactly what that is now.

How Do Funding Agencies Decide Who Gets Money?

THE PEER REVIEW PROCESS

Peer review is how a funding agency critically evaluates a proposed project and all its moving parts (the budget, the safety for participants, the staff, etc.). The funding agency will send out proposals to other researchers within the field who then act as **reviewers** who read and evaluate the project. These reviewers provide written feedback and scores for the agency. They may comment on multiple aspects of the grant such as: Is the project designed in a way that makes sense? Can the project be accomplished in the time allotted? Is the project safe? Does the project have the proper staff working on it? Will the project make an impact on its field?

Each proposal is usually sent out to three to five peer reviewers who provide comments and scores. Then all the reviewers for all proposals meet to discuss each proposal. This session allows reviewers who have not evaluated a certain proposal in depth to provide feedback based on an overview and comments from the other reviewers. At this meeting, a score for each project is finalized. Those with the highest scores are then usually recommended for funding by the review panel. Ultimately, it's up to the higher-ups like a program officer or an advisory council to decide which projects to actually fund, but these peer review comments are critical components in their final decision.

While it would be nice and easy if all funding agencies had the same criteria (which never seems to be the case for anything!), each agency has its own individual review criteria that peer reviewers follow. Thus, it's important to look these criteria up on the funding agency's website while working on the grant so you know to hit every topic the agency will look for.

ARE CATALYST GRANTS PEER-REVIEWED TOO?

Yes! You likely put a lot of effort into preparing your proposal, and you can rest assured that it will be carefully considered through an internal peer-review process. Research project managers organize all received proposals and send them out to a peer review committee. At Shirley Ryan AbilityLab, the peer review committee includes representatives from our various research and clinical departments. After carefully reading each proposal and reviewing the budgets, the reviewers all meet to discuss the proposals and make recommendations. These recommendations are then discussed by our council (Dr. Lieber, Dr. Sliwa and Shirley Ryan AbilityLab executive leadership) to make funding recommendations. You might even be asked to reduce your budget, just so you get the full research experience!

What Happens if I am Recommended for Funding?

HOW DO FUNDING AGENCIES KNOW IF I'M EVEN QUALIFIED TO DO THE WORK?

Well, you need a way to tell them. For grants, the document that shows how great you are is called a **biosketch**. A biosketch is a streamlined version of your resume or curriculum vitae (CV). A biosketch shows your qualifications to take on whatever role you are performing in the proposed research project. Reviewers require biosketches so that they can assess whether or not each person on the project can properly handle the research proposed based on their education, past achievements and experience. Think of it like when you are hiring someone for a new job. If you need to hire someone for a nurse position, you will look at their resume to make sure they have the proper licensing as well as experience being a nurse. However, you would not hire a person for a nurse position if their entire background was in administration, they had never worked with a patient before and they were not licensed as a nurse. A biosketch is that same idea, but for researchers. In research, it's okay if you don't have the exact experience needed to perform your role on the project, but your biosketch should clearly show how your background in everything else relates to your role and makes you qualified to perform it in some way.

A standard biosketch is composed of degrees and licenses earned, a personal statement, past positions/appointments/honors and past contributions to science (oftentimes in the form of publications, conference presentations, etc.). However, depending on the grant, some biosketch sections may be added or subtracted. See the attachments at the end of this document for an example of one of our scientific chair's biosketches and an example "new researcher" biosketch, both formatted for an NIH-style proposal. For further information, please also see the NIH Grants webpage on biosketches.

Assuming that the funding agency determines your project is within scope and you have a favorable peer review, you will be recommended for funding. Receiving a letter letting you know your project will be funded is one of the most exciting days in any researcher's career! However, there are a few additional steps that must be taken to actually get to spending. It is possible that the program officer or advisory council will request some minor changes to your proposal, like reducing your budget. They may also ask you to verify a few things, like a quote for equipment or the labor costs associated with your budget. It's a good idea to get this information to the funding agency as quickly as possible — you're on their good side, after all!

I THOUGHT MY PROPOSAL WAS PRETTY GOOD, BUT I DID NOT GET IT. WHY NOT?

Rejected!! We feel your pain, but don't take it personally. Researchers quite often need to submit proposals four or five times before they are recommended for funding. Don't get discouraged! There are a wide variety of reasons why your proposal may not be selected for funding. The likely reason is that your proposal was excellent, but there were other excellent proposals too and not enough money to go around. This is certainly the case for many Catalyst Grants that we review. The number of outstanding proposals is increasing each year, and the competition for funding is becoming more intense.

I DIDN'T GET MUCH FEEDBACK, IS THIS NORMAL?

Sorry to be the bearer of bad news but receiving little or poor feedback is quite normal. It stinks that you spend so much time preparing the proposal and receive so little in return. Remember that the review panel is likely reviewing dozens of proposals, and they are often volunteering their time. The best course of action to take is to call the program manager and discuss your proposal individually, and they can often fill in some additional gaps as to what can be done to improve your proposal for the next application round.

Here are two absolute deal-breakers that will limit the amount of feedback you get:

- You didn't follow the instructions in the application: For example, if the application has a page limit of one, and you submit a two page proposal, it likely won't even be read. Similarly, if the application said include a mentorship plan and you didn't, then the reviewer might not even read the rest of your proposal.
- The reviewer didn't understand your idea: You might have the response, of 'what a stupid reviewer,' but, sorry, this is the wrong attitude. It is on you to explain your ideas really clearly and prevent confusion.

This Seems Very Overwhelming. I Need Help!!

Good news — we have you covered! There is an entire department within Shirley Ryan AbilityLab that helps people prepare, submit and administer proposals: the Office of Research Administration (ORA), led by Amneh Kiswani. Fortunately, our research administrators are pros and have experience working with all the major funding agencies. Need a template to help you prepare a budget? Ask ORA! Need to know how much money is remaining on your project? Ask ORA! Don't know where to begin with all this administrative stuff related to grants and research? Ask ORA! They can help all researchers make sure they are following the rules, tracking effort and costs correctly, and getting any sort of needed progress reports to the appropriate officials in a timely fashion.

Need help actually writing the proposal or want a second set of eyes to make sure it's in the best shape possible? We also have two scientific writers on staff who can assist you (their contact information is on the following page).

Who Can I Talk to About All This Cool Research Stuff?

Don't know where to start? **Talk to research leaders** either during Third Thursday Office Hours or by reaching them via the contact information below.

Levi Hargrove, PhD
Scientific Chair, Center for Bionic Medicine
lhargrove@sralab.org

Leora Cherney, PhD, CCC-SLP, BC-ANCDS
Scientific Chair, Think + Speak Lab
lcherney@sralab.org

Monica Perez, PT, PhD
Scientific Chair, Arms + Hands Lab
mperez04@sralab.org

Katherine Earnest, RN, MSN, CRRN, CNML
Director, Nursing Research
kearnest@sralab.org

José Pons, PhD
Scientific Chair, Legs + Walking Lab
jpons@sralab.org

Allen Heinemann, PhD
Director, Center for Rehabilitation Outcomes Research
aheinemann@sralab.org

Rick Lieber, PhD
Chief Scientific Officer
rlieber@sralab.org

DID YOU KNOW WE HAVE A TEAM OF SCIENTIFIC WRITERS HERE TO HELP YOU?

Helping you prepare, write and edit successful grant applications is what these people are experts at!

Meghan O'Connell, PhD
Senior Scientific Writer
moconnell@sralab.org

Dylan Schellenberg
Scientific Writer
dschellenb@sralab.org

NEED HELP WITH A LITERATURE SEARCH?

Shirley Ryan AbilityLab's medical librarian is a great resource if you need advice on your search strategy or require assistance to obtain full text resources.

Andrew Wahl, MSLS
Medical Librarian
awahl@sralab.org

WANT MORE INFORMATION ON THE RESEARCH ACCELERATOR PROGRAM?

We have an employee at Shirley Ryan AbilityLab to help answer all your questions or get you involved!

Melissa Briody, MOT, OTR/L, MS, HSM
Senior Project Manager, Research
mbriody@sralab.org

BIOSKETCH EXAMPLES

The following two biosketches have been used in recent grant submissions.

- The first was used by Levi Hargrove to obtain a large NIH grant to evaluate osseointegration with implanted electrodes to improve ability for individuals with upper-limb amputation.
- The second was used by Kristi Turner to apply for a Department of Defense grant to evaluate outcomes when using a prosthetic limb.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Levi J. Hargrove**

eRA COMMONS USER NAME (credential, e.g., agency login): **lhargrove**

POSITION TITLE: **Director & Scientific Chair, Regenstein Foundation Center for Bionic Medicine**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of New Brunswick, Fredericton, Canada	BSc Eng	05/2003	Electrical and Computer Engineering
University of New Brunswick, Fredericton, Canada	MSc Eng	09/2005	Electrical and Computer Engineering (Biological Signal Processing)
University of New Brunswick, Fredericton, Canada	PhD	08/2008	Electrical and Computer Engineering, (Biological Signal Processing

A. Personal Statement

I have more than 20 years of experience in the field of electrical engineering, focusing on the development of technology for individuals with amputation. My works include development of control systems for powered prosthetic arms and legs, implantable sensors, and overseeing clinical trials to evaluate new approaches. Over the past decade, I have been independently directing a large laboratory and directly managing and mentoring engineers, scientists, clinicians, fellows, and students. I have significant experience completing research to evaluate neural interfaces for both upper and lower limb devices. My first experience in this topic, completed during my Master's work, was in evaluating how intramuscular EMG signals could be used to with pattern recognition myoelectric control system, including how many channels should be used, and where channels should be placed. We have since extended this work to evaluate how these types of signals can allow for simultaneous and proportional control of multiple degree of freedom devices. A consistent struggle with this work was in how to evaluate performance with a chronic implant. While we are actively developing fully wireless solutions, there are many challenges associated with wireless power transfer, and transmission of full-bandwidth signals. The e-OPRA system is a compelling solution to this problem for transhumeral amputees. I also have extensive experience working with individuals with targeted muscle reinnervation, including performing a year-long home-trial with an innovative pattern recognition system. This prior trial was of a similar complexity to our proposed work and was also completed with 8 subjects. Finally, I have prior experience in successfully translating technology from the lab to the clinic. The pattern recognition control system that I helped develop as part of my PhD work was translated to Coapt, LLC and has resulted in 3 Class II FDA Cleared medical devices. I believe that I have the necessary education and experience to act as PI on this proposal.

1. **Hargrove L.**, Miller LA, Turner K, and Kuiken TA, "Myoelectric Pattern Recognition Outperforms Direct Control for Transhumeral Amputees with Targeted Muscle Reinnervation: A Randomized Clinical Trial" *Scientific Reports*, 7:13840, 2017.
2. L. Smith, T. Kuiken, and **L. Hargrove**, "Evaluation of linear regression simultaneous myoelectric control using intramuscular EMG", *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, 63(4):737-746, 2015.

3. **L. Hargrove**, K. Englehart, and B. Hudgins. “A Comparison of Surface and Intramuscular Myoelectric Signal Classification” IEEE Transactions on Biomedical Engineering, 54:847-853, 2007. PMID:17518281
4. L. Smith, T. Kuiken, and **L. Hargrove**. “Intramuscular EMG Allows for Real-Time, Simultaneous and Proportional Myoelectric Control”, *Journal of Neural Engineering*, 11(6), 066013, 2014. PMC4268782

B. Positions, Scientific Appointments, and Honors

Positions, Employment, and Scientific Appointments

Shirley Ryan AbilityLab

2017–present	Director and Scientific Chair, Center for Bionic Medicine
2016–2017	Associate Director, Center for Bionic Medicine
2008-present	Research Scientist, Shirley Ryan AbilityLab (previously RIC)

Northwestern University

2016–present	Associate Professor, Biomedical Engineering
2016–present	Associate Professor, Physical Medicine & Rehabilitation
2015–2016	Assistant Professor, Biomedical Engineering
2014–2016	Assistant Professor, Physical Medicine & Rehabilitation
2008–2014	Research Assistant Professor, Physical Medicine & Rehabilitation

Other Experience and Professional Memberships

2018–present	Associate Editor, *IEEE Transactions on Medical Robotics and Bionics*
2012–present	Founding Partner, Coapt LLC
2012–present	CDMRP Program Grant Peer Reviewer – PROP Program
2012–2013	Associate Editor, *IEEE Transactions on Biomedical Engineering*
2011–present	Member, IEEE
2011–present	Member, International Society of Electrophysiology and Kinesiology
2008–present	Registered Professional Engineer, Association of Professional Engineers and Geoscientists of New Brunswick

Honors

2021	Medical Design Excellence Awards, Silver Winner
2019	Brian and Joyce Blatchford Team Prize for Innovation (ISPO)
2019	Research Award, AAOP
2017	AOPA Presidential Papers Award
2017	Collaboration Award, Chicago Innovation Awards
2015	US Army Military Health System Research Symposium TEAM Award for Outstanding Research Accomplishment by Academic collaborators
2014	Young Professional Achievement Award, Association of Professional Engineering and Geoscientists of New Brunswick
2003	Valedictorian, University of New Brunswick

C. Contributions to Science

1. As I was beginning my academic career, a clinically feasible implantable myoelectric sensor had just been proposed. While this type of sensor had many potential benefits, it was unclear if it would improve myoelectric signal classification for use with pattern recognition controlled upper-limb prostheses. In

fact, the focal nature of the intramuscular EMG signal recording could result in reduced performance if the motor unit pool was only sparsely sampled. I completed a set of experiments to show that the system performed equivalently to a system which used surface EMG signals. More recently, we have shown that we can alter our control approaches to take advantage of the more focal recordings and to produce a simultaneous multifunction control system, which is an advance in the field.

a. **L. Hargrove**, K. Englehart, and B. Hudgins. "A Comparison of Surface and Intramuscular Myoelectric Signal Classification" *IEEE Transactions on Biomedical Engineering,* 54:847-853, 2007. PMID:17518281
b. J. Birdwell, **L. Hargrove**, T. Kuiken, and R. Weir. "Isolated Activation of the Extrinsic Thumb Muscles and Compartments of the Extrinsic Finger Muscles*", Journal of Neurophysiology*, 110 (6):1385-1392, 2013. PMC3763151
c. L. Smith, T. Kuiken, and **L. Hargrove**. "Intramuscular EMG Allows for Real-Time, Simultaneous and Proportional Myoelectric Control", *Journal of Neural Engineering*, 11(6), 066013, 2014. PMC4268782
d. J. Birdwell, **L. Hargrove**, R. Weir, T. Kuiken. "Extrinsic Finger and Thumb Muscles Command a Virtual Hand to Allow Individual Finger and Grasp Control", *IEEE Transactions on Biomedical Engineering*, 62(1), 218-226, 2015. PMC4501427

2. While attempting to quantify the performance of pattern recognition myoelectric control systems, it became apparent that classification error, the accepted method of characterizing system performance, was inadequate. As a result, I first worked to create a virtual limb to evaluate real-time control when the user could use visual feedback and subsequently implemented the controller on physical prostheses. The results of this research showed a nebulous relationship between offline error and real-time control, which has since been replicated by other groups. Now, impactful research has been refocused supplementing classification error with results from testing with the user in the loop.

    a. **L. Hargrove**, E. Scheme, K. Englehart and B. Hudgins. "Multiple Binary Classifications via Linear Discriminant Analysis for Improved Controllability of a Powered Prosthesis", *IEEE Transactions of Neural Systems and Rehabilitation Engineering*, 18(1):49-57, 2010
    b. A. Simon, **L. Hargrove**, B. Lock, T. Kuiken. "The Target Achievement Control Test: Evaluating real-time myoelectric pattern recognition control of a multifunctional upper-limb prosthesis", *Journal of Rehabilitation Research and Development,* 48(6):619-628, 2011, PMC4232230
    c. A. Young, **L. Hargrove**, and T. Kuiken. "Improving Myoelectric Pattern Recognition Robustness to Electrode Shift by Changing Interelectrode Distance and Electrode Configuration", *IEEE Transactions on Biomedical Engineering,* 59(3):645-652, 2012, PMC4234037
    d. S Wurth, and **L. Hargrove**. "A Real-time Comparison between Direct Control, Sequential Pattern Recognition Control and Simultaneous Pattern Recognition Control using a Fitts' Law Style Assessment Procedure", *Journal of NeuroEngineering and Rehabilitation*, 11(1), 91, 2014, PMC4050102

3. Powered lower-limb prostheses are now becoming commercially available. Their impact is substantially limited by the quality of the control. We have been working to improve the control of these devices by combining prior knowledge of gait, sensor readings from sensors inherent to the mechanical design of the device, and EMG signals from the user. This approach has led to the development of a control system that allows for seamless and automatic transitions when the user ambulates over a variety of terrains.

    a. **L. Hargrove**, A. Simon, R. Lipschutz, S. Finucane and T. Kuiken. "Real-time Myoelectric Control of Knee and Ankle Motions for Transfemoral Amputees", ***Journal of the American Medical Association,*** 305(15):6-8, 2011, PMID: 21505133
    b. **L. Hargrove**, A. Simon, A. Young, R Lipschutz, S. Finucane, D. Smith, and T. Kuiken. "Robotic Leg Control with EMG Decoding by an Amputee with Nerve Transfers", ***New England Journal of Medicine***, 369(13):1237-1242, 2013
    c. A. Young, T. Kuiken, and **L. Hargrove**. "Analysis of using EMG to enhance intent recognition in powered lower limb prostheses", *Journal of Neural Engineering,* 11(5), 056021, 2014

d. N. Fey, A. Simon, A. Young, and **L. Hargrove**. “Controlling knee swing initiation and ankle plantarflexion with an active prosthesis on level and inclined surfaces at variable walking speeds”, *Journal of Translational Engineering in Health and Medicine*, 2, pp 1-12, 2014.

4. It is possible to use signal processing and engineering principles to create the movements that prostheses make. However, if we have a better understanding of the dynamical properties of human limbs, and how users actually control them, then it is likely that we can create more lifelike prosthetics. Towards this end, we have been investigating natural joint impedances of the leg, and used computational motor control theory to understand how we should better provide feedback to users as they change their activities.
    a. E. Rouse, **L. Hargrove**, E Perreault, and T. Kuiken. “Estimation of human ankle impedance during the stance phase of walking.” IEEE Transactions on Neural Systems and Rehabilitation Engineering, 22(4):870-878, 2014. PMID: 24760937
    b. R. D. Gregg, E. J. Rouse, **L. Hargrove**, and J. W. Sensinger. “Evidence for a time-invariant phase variable in human ankle control,” *Public Library of Science ONE*, 9(2): e89163, 2014, PMC3928429
    c. R. Johnson, K. Kording, **L. Hargrove**, and J. Sensinger. “Does EMG control lead to distinct motor adaptation”, *Frontiers in Neuroscience*, 8:302, PMC4179747

5. It is very important to me that positive developments and findings be translated to a clinical population. This is partially achieved through publication in high-quality peer reviewed journals. However, it is equally important that intellectual property is protected and all efforts are made to find an appropriate partner to take suitable technologies to market. Toward this end, I have submitted, received and out-licensed several patents to leading prosthetics and orthotics manufacturers (e.g., Willowood Global, Ossur). I also cofounded company, Coapt LLC, to commercialize myoelectric pattern recognition control systems available for upper-limb amputees. Coapt now employees nearly 30 people, has three 510(k) approved medical devices, and has sold nearly 1,000 control systems across the world.
    a. Systems and Methods of Myoelectric Prosthesis Control, U.S Patent Application No: 13/587,755
    b. Systems and Methods for Hierarchical Pattern Recognition for Simultaneous Control of Multiple Degree of Freedom Movements for Prosthetics, U.S. Provisional Patent Application No: 61/659,887
    c. Autoconfiguration of Pattern-Recognition Controlled Myoelectric Prostheses, US Provisional Patent Application 61/675,147
    d. Ambulation Prediction Controller for Assistive Device invention, U.S. Patent Application No. 13/925,668

Complete List of Published Work in MyBibliography
https://www.ncbi.nlm.nih.gov/myncbi/levi.hargrove.1/bibliography/public/

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Turner, Kristi L

eRA COMMONS USER NAME (credential, e.g., agency login): KTURNER2

POSITION TITLE: Research Occupational Therapist, Shirley Ryan AbilityLab

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Saginaw Valley State University	B.S.	12/1999	Occupational Therapy
University of Indianapolis	M.S.	5/2017	Health Science
University of Indianapolis	D.H.S.	8/2019	Health Science

A. Personal Statement

I have more than 20 years of experience as an occupational therapist with an emphasis on individuals with limb absence and individuals with burn injury. I have continued to contribute to education and training to both the clinicians and individuals in these populations in clinical departments throughout my career. As one of a small number of occupational therapists globally that work with individuals with upper limb absence, I provide clinical guidance on the design, function, control, and evaluation of new advanced prosthetic systems in the Center for Bionic Medicine.

I have played a critical and leading role in several prior research grants within the Center for Bionic Medicine. I am primarily responsible for overcoming clinical challenges associated with the application of advanced pattern recognition myoelectric control systems for individuals with upper limb absence, including training and evaluation of functional change and outcome improvement. I took responsibility for ensuring all outcome measures were professionally administered and systematically analyzed. I have published on the influence of pattern recognition myoelectric control systems on the controllability of upper limb prostheses and have been involved as this technology moved from research to clinical availability. Additionally, I co-managed and was the occupational therapist for a complex multi-site NIH study involving surgical services and a home trial as well as was the project manager of an international multi-center phantom limb study, which required additional collaboration and coordination with multisite study teams. I have expanded my involvement in research in pursuit of my Doctor of Health Sciences, completing a study of individuals with unilateral upper limb absence to evaluate the relationship of prosthesis use and embodiment with balance confidence, fear of falling, and falls. All these experiences have prepared me to be the principal investigator on this grant, and my co-investigators provide excellent additional strengths that will allow for successful completion of the project.

Research projects that I would like to highlight include:
Award Number HT9425-23-1-0162 (Co-I: Turner)
Comparison of Upper Limb Virtual Outcome Measures and Control Accuracy to Physical Outcome Measures with a Prosthetic Hand and Wrist System
6/1/2023-5/31/2027
Our overall objective is to accurately predict the control performance of a physical upper limb prosthesis using a virtual reality (VR) environment. To achieve this, we will compare accuracy and performance outcome results in an immersive VR environment with accuracy and performance outcomes of a physical upper limb prosthesis for individuals with transradial upper limb absence.

1R44HD110334-01A1 Subaward (Co-I: Turner)
User-centered Design of Digital Health Technology for Clinicians Treating Upper-Limb Myoelectric Prosthesis Wearers
5/17/2023 – 4/30/2025The goal of this study is to improve the design and implementation of digital health technology in real-world clinical settings for upper-limb prosthesis users and their clinical care providers. The information gathered will be used to design a web-based digital health portal that will contain data and analyses related to upper-limb prosthesis users' daily prosthesis use and performance in their home and community. The web portal will be to assist prosthetists/occupational therapists providing clinical care and provide extended telehealth support to upper-limb prosthesis users.

B. Positions, Scientific Appointments, and Honors

Positions and Employment

2012 -	Research Occupational Therapist, Shirley Ryan AbilityLab, Chicago, IL
2012 -	Occupational Therapist, Outpatient Allied Health, Shirley Ryan AbilityLab, Chicago, IL
2007-2012	Program Specialist/Lead Occupational Therapist, Rehabilitation Institute of Chicago, Chicago, IL
2003-2007	Lead/Senior Occupational Therapist III, Medically Complex Unit, Rehabilitation Institute of Chicago, Chicago, IL
2001-2003	Occupational Therapist, Meadow Park Care Center, Prescott, AZ
2001-2003	Occupational Therapist, Prescott Pediatrics, Prescott, AZ
2000-2003	Occupational Therapist, Northern Arizona Veterans Affairs Health Care System, Prescott, AZ
2000-2003	Occupational Therapist, Prescott Valley Samaritan Center, Prescott Valley, AZ
1999-2000	Activity Director, Prescott Valley Samaritan Center, Prescott Valley, AZ

Clinical Licensures and Board Certifications

2015-2019	Maryland Licensed Board of Occupational Therapy Practice
2005-2014	Michigan Occupational Therapy License
2003 -	Illinois State Board of Occupational Therapy Examiners – License # 056.007023
2000 -	National Board for Certification in Occupational Therapy Certification # 143260

Other Experience and Professional Memberships

2020	Scientific and Medical Advisory Board, Amputee Coalition
2020	Co-chair, Skills for Life Workshop
2019	Upper Limb Outcomes Research Committee, Academy of Orthotists and Prosthetists
2016	Handsmart group, established Berlin, Germany
2015 -2019	Professional Member, American Occupational Therapist Association
2013	Professional Member, American Academy of Orthotists and Prosthetists
2013	Professional Member, International Society of Prosthetics and Orthotics
2013	Assessment of Capacity for Myoelectric Control Certification, Örebro University Hospital
2009	Clinical Cancer Exercise Specialist, University of Northern Colorado Cancer Rehabilitation Institute
2007	Multiple Sclerosis Certified Specialist, Consortium of Multiple Sclerosis Centers
2006	Certified Kinesio Taping Practitioner, Kinesio Taping Association International®
2006	Clinical Ladder Level III, Rehabilitation Institute of Chicago

Honors

2021	Five year service award for contributions to the Occupational Therapy Program, University of Illinois Chicago
2005	Custom Care Award Nomination, Rehabilitation Institute of Chicago
2005	MVP Award on Inpatient Medically Complex Floor, Rehabilitation Institute of Chicago

2002-2003 Four Special Contribution Awards, Northern Arizona Veterans Health Care System

C. Contributions to Science

1. Though outcome measures are needed to evaluate the new control and devices developed in the CBM, I have also been involved in efforts to identify the best outcomes and to refine existing outcomes. In 2019, I was part of an international team to refine the training and evaluation materials for one of the widely used functional measures, the ACMC. We continue to refine the measure to be appropriate to properly evaluate new prosthetic components, such as multifunction hands. I continue to work to explore new ways to train prosthetic users, with both body- powered and externally-powered systems, and assess and improve prosthetic function and control.

    a. Hermansson, L. N., and **Turner, K.** (2017). Occupational Therapy for Prosthetic Rehabilitation in Adults with Acquired Upper-Limb Loss: Body-Powered and Myoelectric Control Systems. *Journal of Prosthetics and Orthotics* (12).
    b. L. Hargrove, L., Miller, L., **Turner, K.**, and Kuiken, T. (2018). Control within a virtual environment is correlated to functional outcomes when using a physical prosthesis. *Journal of NeuroEngineering and Rehabilitation*, 15(1).
    c. Hermansson LN, Lindner HY, Hill W, and **Turner, K**. (2019). Assessment of Capacity for Myoelectric Control Manual v3.1.
    d. **Turner, K**., Simon, A., Miller, L., and Hargrove, L. Myoelectric prosthesis control testing demonstrates correlation between outcome measurement scores. *American Orthotic and Prosthetic Association National Assembly*, Boston, MA, September 9-11 and Virtual, September 16-18, 2021.

2. Pattern recognition (PR) is a recently developed method for controlling powered prosthetic devices by utilizing more of the EMG signal from the entire arm. Though early work done on PR was done offline, as an OT in CBM, I provided clinical feedback regarding training and implementation of this new control paradigm, first in the research setting and as it progressed to clinical care.

    a. **Turner K**, Stubblefield KA, Finucane S, Miller LA, and Lock BA. Training Pattern Recognition Control to Upper Limb Prosthetic Users. *American Academy of Orthotists and Prosthetist 40th Annual Meeting*, Chicago, IL, February 26-March 1, 2014.
    b. Kuiken, TA**, Turner K**, Soltys N, and Dumanian G. First Clinical Fitting of an Individual After Bilateral TMR with Intuitive Pattern Recognition Control. *Myoelectric Controls Symposium*, Fredericton NB Canada, August, 2014, p. 117-121
    c. Kuiken TA, Miller LA, **Turner, K**, Hargrove, L "A comparison of pattern recognition control and direct control of a multiple degree-of-freedom transradial prosthesis." *IEEE Journal of Translational Engineering in Health and Medicine*, 4:1-8, 2016
    d. Hargrove, L. J., Miller, L.A., **Turner, K.**, & Kuiken, T. A. (2017). Myoelectric Pattern Recognition Outperforms Direct Control for Transhumeral Amputees with Targeted Muscle Reinnervation: A Randomized Clinical Trial. *Scientific Reports*, *7*(1). https://doi.org/10.1038/s41598-017-14386-w

3. In addition to evaluating new control methods, CBM has developed new body-powered and externally powered upper limb components. My role as the OT on these development projects is to work with our research participants to ensure they understand the devices and can use the functions of the system in a manner beneficial and designed for them. I also work with the prosthetist to evaluate fit, control, and performance and to provide feedback to the engineering team to refine the technology.

    a. Sensinger J, Lipsey J, Sharkey T, Thomas A, Miller L, **Turner K**, Ochoa J, and Idstein T. Initial Experiences with The RIC Arm. *Myoelectric Controls Symposium*, Fredericton NB Canada, August, 2014, p. 227-229.

b. Sensinger, J., Lipsey, J., Thomas, A., and **Turner, K**. (2015*).* “Design and evaluation of voluntary opening and voluntary closing prosthetic terminal device”. *Journal of Rehabilitation Research & Development*, 52(1), pp.63-76.

c. Swartz, A.Q., **Turner, K.,** Miller, L., & Kuiken, T. (2017). Custom, rapid prototype thumb prosthesis for partial-hand amputation: A case report. *Prosthetics and Orthotics International*. https://doi.org/10.1177/0309364617706421

d. Pizza, C., Simon, A., **Turner, K**, Miller, L., Catalano, M., Bicchi, A., and Hargrove, L. (2020). Exploring Augmented Grasping Capabilities in a Multi-Synergistic Soft Bionic Hand. *Journal of NeuroEngineering and Rehabilitation*, 17, 116.