Clinically Deployable Devices

Christine P. Hendon, Columbia University

Our Team Spans Disciplines & Schools

Christine Hendon, CU

Electrical Engineering, Imaging, Cardiac Electrophysiology

Arnold Advincula, CU

OB/GYN, Gynecologic Health & Procedures

Christine King, UCI

Biomedical Engineering, Engineering Education, Health Systems

Aaron Kyle, Duke

Biomedical Engineering, Engineering Education, STEM Outreach, Medical Device Design Biomedical Instrumentation and Signal Processing

Joshua Mauney, UCI

Urology, Tissue Engineering, Medical Device Testing

Pamela Moalli, Pitt

OB/GYN, Bioengineering, Uryo/Gyn, Vaginal Mesh Expert, Female Pelvic Floor Health

Kristin Myers, CU

Mechanical Engineering, Mechanics of Soft Tissues, Preterm Birth, Hydrated Biomaterials

Christine O'Brien, WUSTL

Radiology, Raman Spectroscopy, Maternal Hemorrhage, Wearable Devices

Katie Reuther, UPenn

Biomedical Engineering, Development & Translation of Early-Stage Medical Tech., Biomedical Tech. Accelerator

Joy-Sarah Vink, CU

OB/GYN, Preterm Birth Prevention

Yong Wang, WUSTL

OB/GYN, Radiology, Biomedical Engineering, Uterine Functional Imaging, Electrophysiology

Ronald Wapner, CU

OB/GYN, Fetal Genetic Testing

Harry West, CU

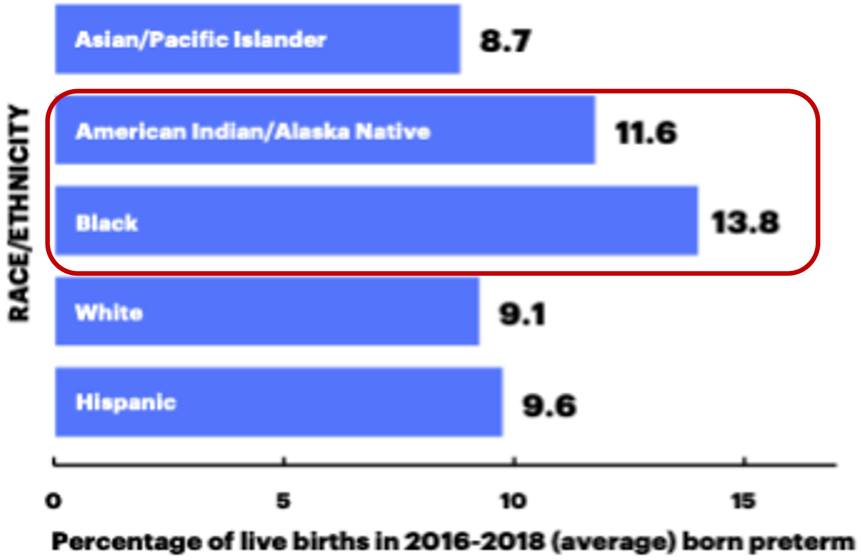
Mechanical Engineering, Industrial Engineering and Operations Research, Product Design Methodology, Service and Experience Design

There is an urgent need for engineering innovation in women's health

HISTORY OF INNOVATION

Who do we invent for? Patents by women focus more on women's health, but few women get to invent

Rembrand Koning[1]*, Sampsa Samila[2], John-Paul Ferguson[3] *Science, 2021*



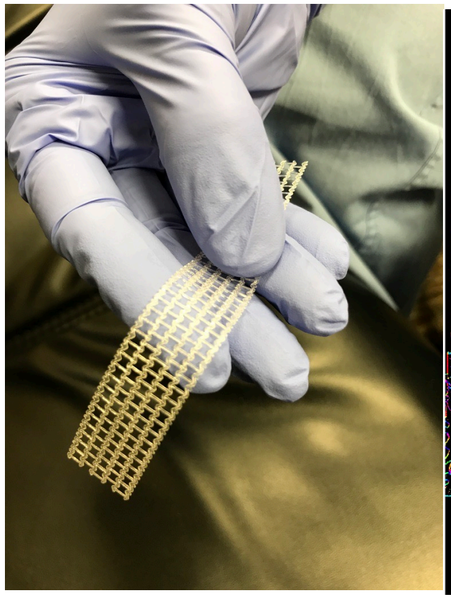
In the United States, the preterm birth rate among Black women is 50% higher than the rate among all other women.

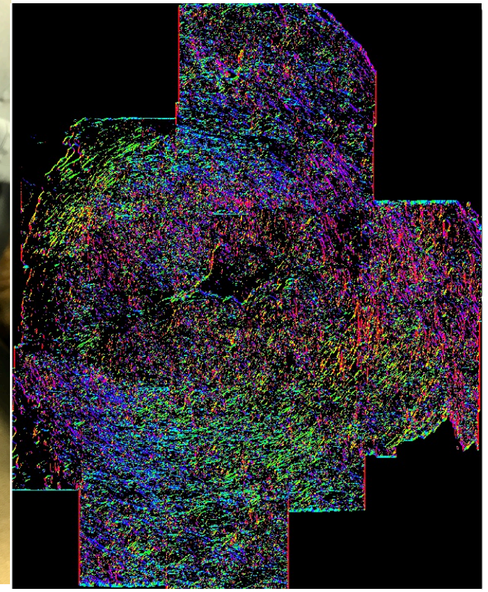
- IMWEL will **make** new biomaterials, sensors, imaging tools, software, and technologies based on mechanobiology to enhance healthcare for women
- IMWEL will emphasize **women-centered design**
- Device development will be driven by
  - Unmet clinical needs identified within the Innovation Ecosystem
  - Fundamental knowledge pursued in Research Thrusts

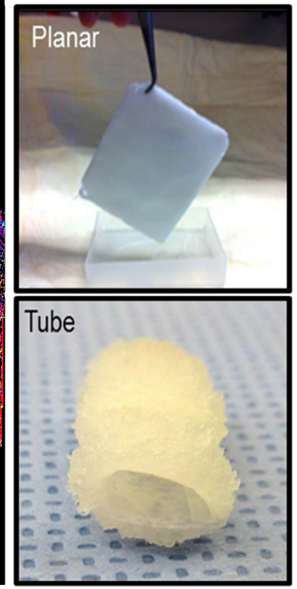
IMWEL's Women-Centered Device Goals

YEARS 1-2	YEARS 3-5	YEARS 5-10
Initiation of clinical device development	Develop prototypes ready for clinical testing	Deploy devices clinically and commercialize

- **Preterm Birth:**
  - Monitor reproductive tissues to alert for urgent events
- **Pelvic floor disorders:**
  - Predict a woman's potential injury from delivery
  - Interventions to minimize injury during delivery
  - Systems to promote muscle-to-bone healing
- **Healthy Aging:**
  - Measure the biomechanics as women exercise
  - Exercises protocols for women







Novel Devices for Pelvic Floor Disorders

Katrina Knight, Pitt

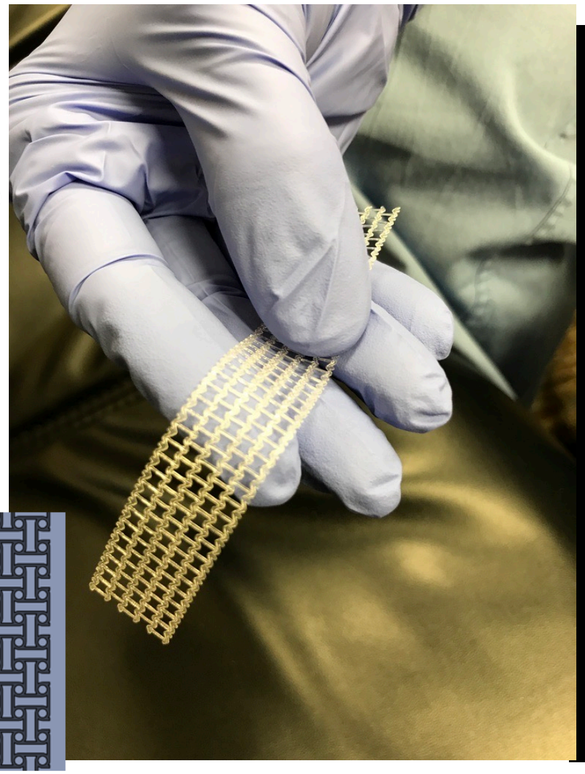
Steven Abramowitch, Pitt

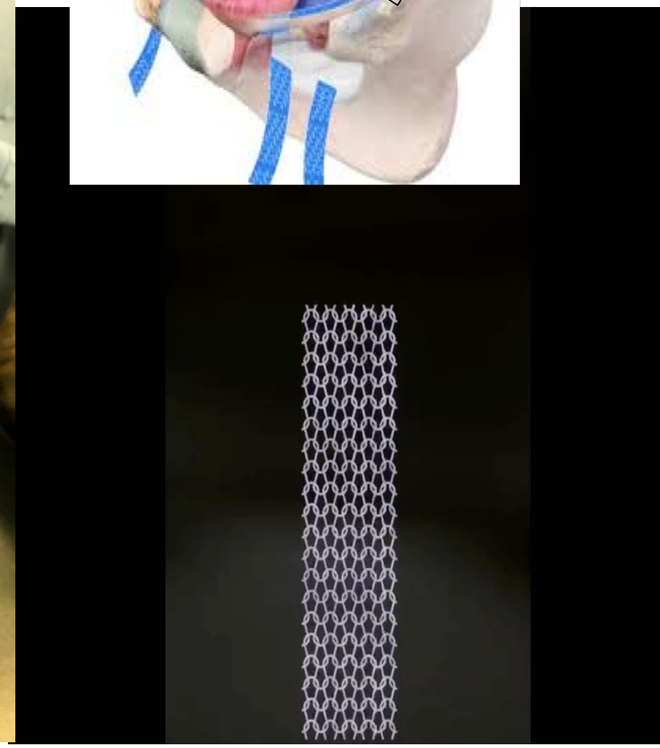
Pamela Moalli, Pitt

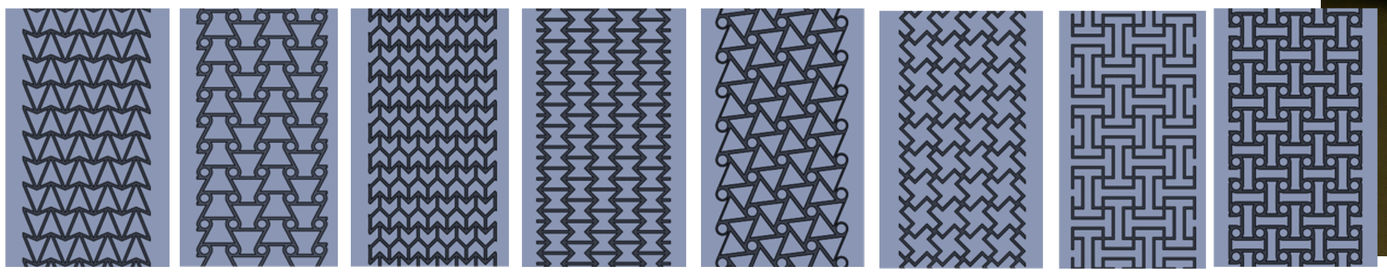
Helen Lu, CU

Elastomer Polymers with tunable mechanical properties to repair prolapse

- Soft polymer that has a material stiffness similar to vaginal tissue
  - Materials that are biostable, biocompatible, compliant, low stiffness and high strength
  - Devices that interact with surrounding tissues to restore original properties
- Pores expand rather than contract with device tensioning
- Repair solutions require fundamental knowledge the soft-tissue to bone interface







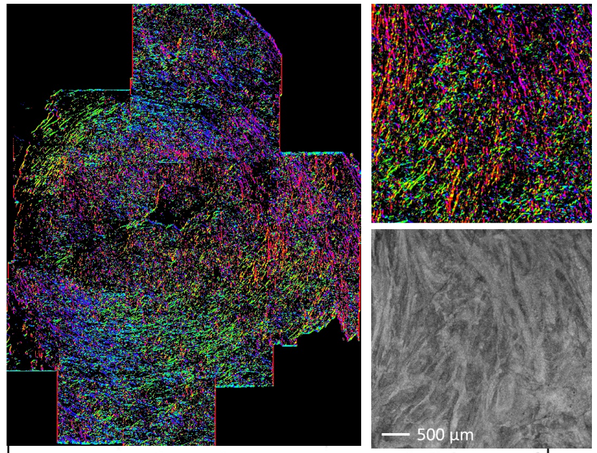
Novel Imaging Endoscopes for Preterm Birth

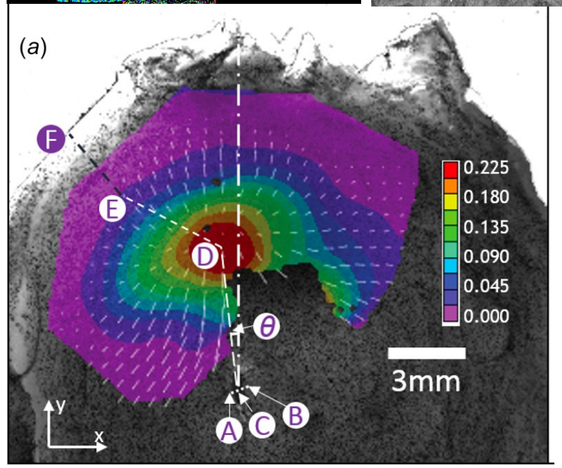
in vivo assessment of structure-function of the cervix

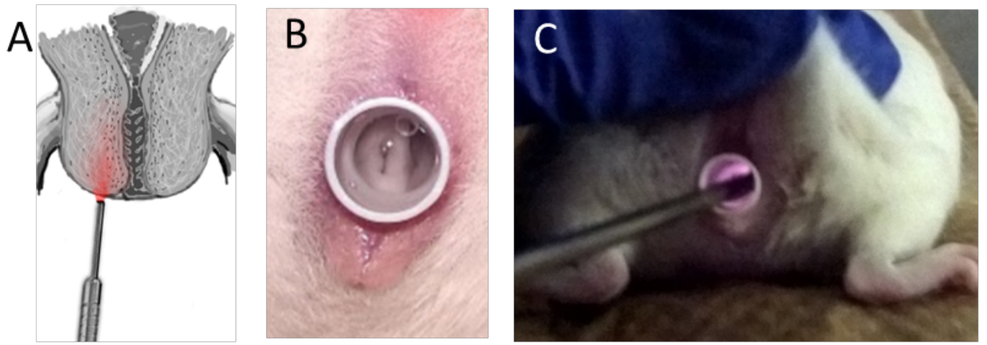
Christine Hendon, CU

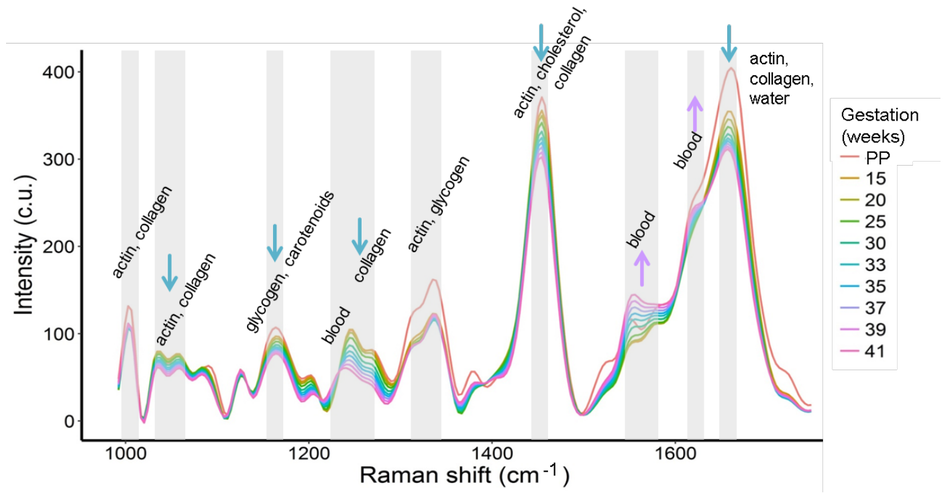
Kristin Myers, CU

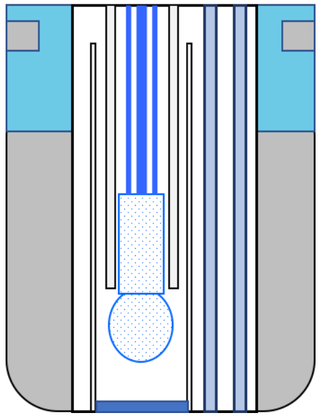
Christine O'Brien, WUSTL

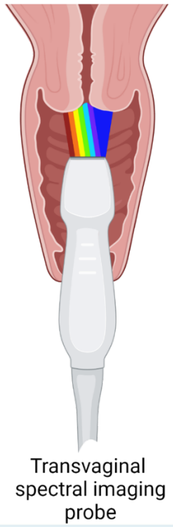


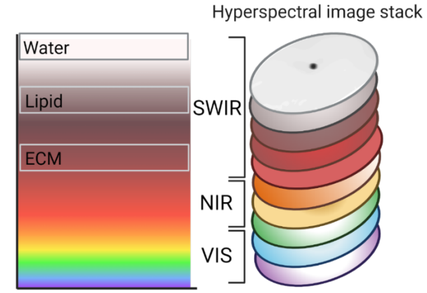


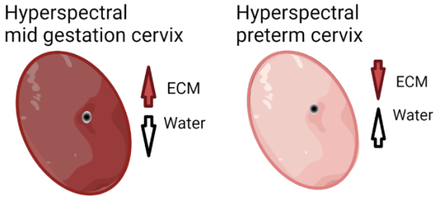












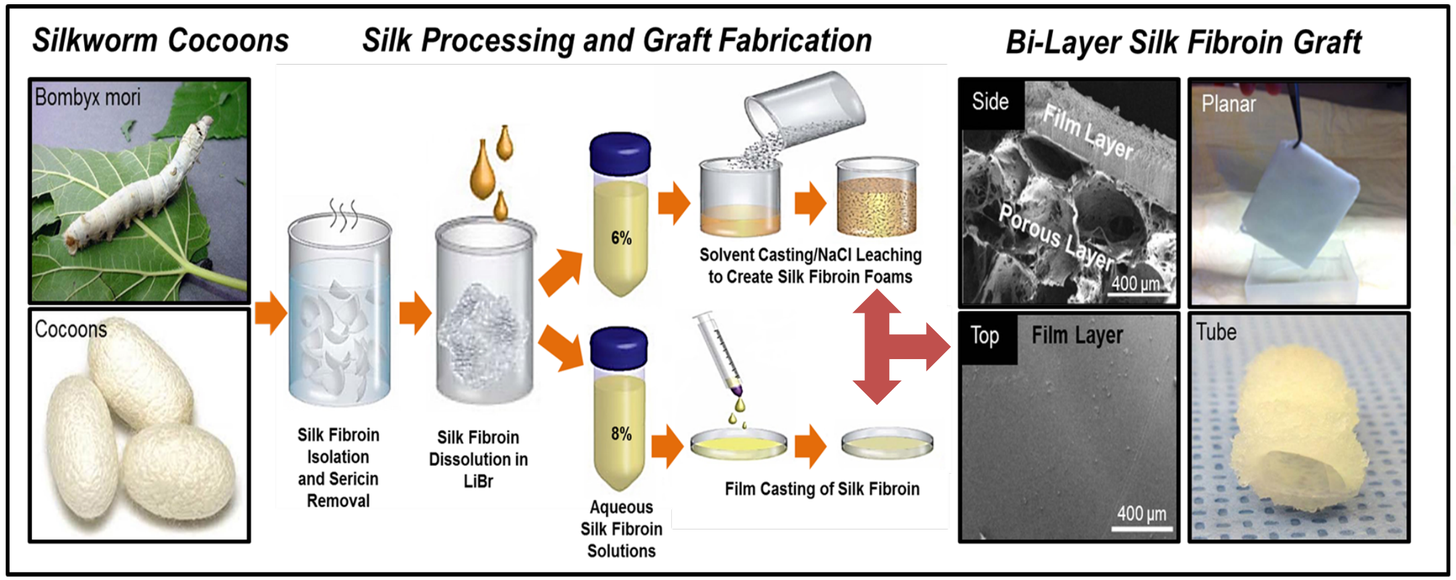
Bi-Layer Silk Fibroin Graft

Platform for Urogenital Organ Reconstruction

Christine King, UCI

Joshua Mauney, UCI

Wendy Liu, UCI

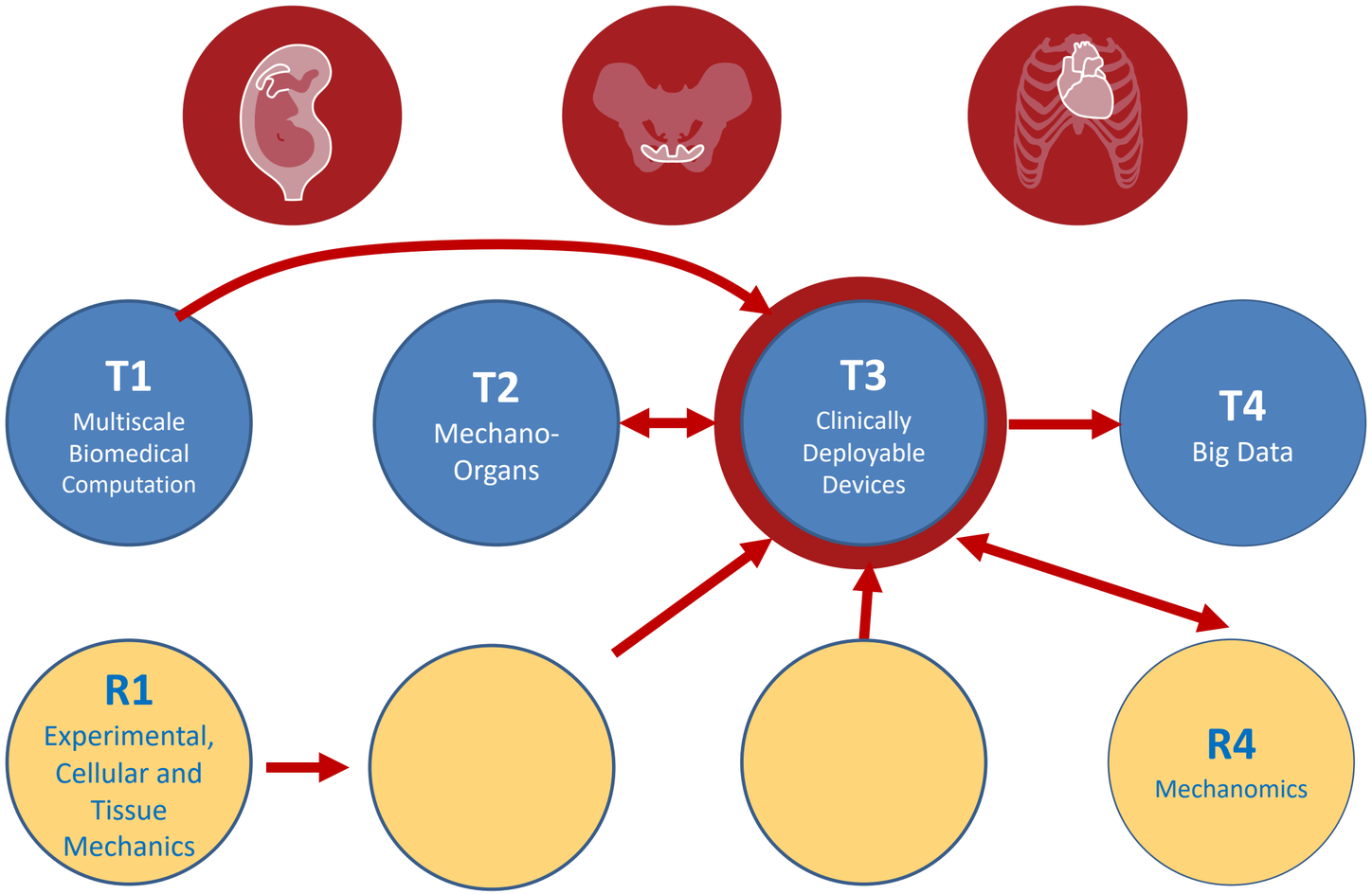


- High structural strength and elasticity
- Low immunogenicity
- Tunable material properties

Restores Organ Integrity

- Uterine Compression Graft for Post-Partum Hemorrhage
- Vaginal Tissue Engineering
- Uterine Tissue Engineering
- Vaginal Fistula Repair
- Stress Urinary Incontinence

Integration (T3)



1. New knowledge gained from research thrusts **Tissue and Organ Mechanobiology (R2)** and **Multiscale Theoretical Mechanics (R3)** will advance **Clinically Deployable Devices (T3)** and treatments for pre-term birth, pelvic floor disorders, and promote healthy cardiovascular and MSK aging.

2. Devices will be tested within **Mechano-Organs (T3)**

3. **Clinically deployable devices (T3)** will enable increase in datasets for the research thrust **Mechanomics (R4)** and enabling technology **Big Data (T4)**.

Goals and Milestones

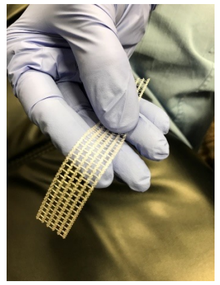
Initial Clinical Device Development

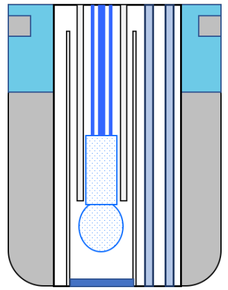
Devices informed by identified needs, measurements and models

R2

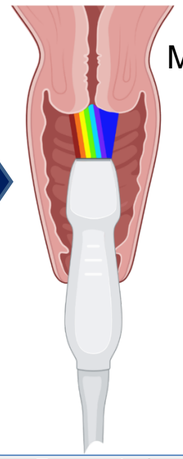
R3

T1

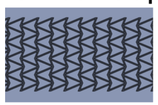


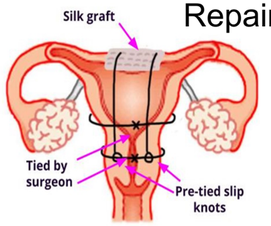


Prototypes ready for clinical testing

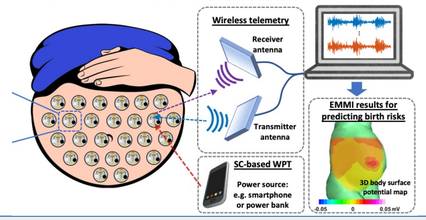


Mechanical Support

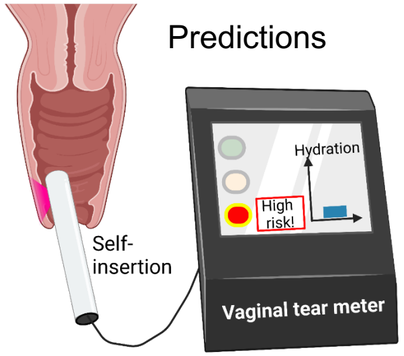




Remote Assessment



Deploy devices and Develop New Protocols



R4

T4

YEARS 1-2

- Initiation of clinical device(s) development informed by research and clinically-defined need

YEARS 3-5

- In vivo pelvic floor strength monitor
- Personalized biomechanical support device
- Wearable tissue stretch contraction monitor
- Optical endoscope and quantitative ultrasound
- Devices to monitor and modify stretch of reproductive tissues
- Sensors to monitor cervical remodeling
- Devices to measure the biomechanics of exercise
- Exercise protocols and equipment design

YEARS 5-10

- Deployment of diagnosis methods and intervention to reduce preterm birth
- Deployment of *in silico* tool to predict a woman's injury potential resulting from vaginal delivery
- Deployment of therapeutics and interventions to minimize risk of maternal injury during delivery
- Protocols for exercise for women at different stages of life and life-events including pregnancy