Female childhood cancer survivors are a growing patient population developing premature ovarian insufficiency (POI). This is due to toxicities associated with cancer treatments that adversely affect hormone levels and ovarian functionality before puberty, leading to delayed physical and psychosocial development in young girls and to chronic health issues later in life.

Currently, the only available treatment is hormone replacement therapy, which is not designed for adolescent girls and is inadequate for physiological puberty induction.

The Solution

University of Michigan researcher, Ariella Shikanov, Ph.D., Associate Professor in Biomedical Engineering, is developing a novel polymer capsule that will contain functioning ovarian tissue from a healthy donor and transplant it into adolescent girls with POI. This will restore the patient’s ovarian endocrine function and return physiological balance without using synthetic hormones.

The immuno-isolation capsule can be easily placed under the skin, and is designed to accommodate structural and functional changes in the encapsulated ovarian tissue during the menstrual cycle, support follicle growth and expansion, and allow for the exchange of hormones. It prevents the patient’s immune cells from infiltrating the implant, which minimizes the chance of tissue rejection while still allowing the diffusion of nutrients.

The University of Michigan Translational Research and Commercialization (MTRAC) for Life Sciences Innovation Hub is supported by the U-M Medical School, U-M Tech Transfer Office, and the Michigan Economic Development Corporation and works to “fast forward” projects that have a high potential for commercial success, with the ultimate goal of positively impacting human health. The ovarian tissue implant technology is one of 45 projects funded since the program was launched in 2014.
Polymer capsule has the potential to deliver donor ovarian tissue to adolescent girls with POI

Significant Need
Hormone Replacement Therapy (HRT), the current treatment for POI, was designed to treat postmenopausal symptoms and is inadequate for physiological puberty induction. It only delivers two of the approximately dozen hormones normally secreted from the ovary and can affect the rate of bone development, insulin, and fat storage regulation. There is also a lack of data in regards to long-term safety use of HRT in children.

Compelling Science
The design of the immuno-isolating device is tuned to the unique physiology of ovarian tissue. It uses an optimized dual-layer biomaterial capsule to deliver natural ovarian tissue which secretes hormones that interact with endocrine organs and control muscular-skeletal development at physiological rates.

Competitive Advantage
This new device would provide an easy-to-remove method of transplanting donor ovarian tissue that would deliver all the hormones present in the ovary and help restore physiological balance without using synthetic hormones. The capsule accommodates structural and functional changes in ovarian tissue associated with development, providing a crucial advantage over rigid encapsulation systems.

MTRAC Project Key Milestones

Capsule design — Optimize the biomaterial formulation and geometry to support implantation of human tissues in animal models

Optimize the amount of donor tissue delivered to support implant efficacy and longevity

First-in-human enabling GLP animal studies to assess safety in animal preclinical model

Conduct an FDA Pre-Submission meeting to determine path to first-in-human clinical trials

Overall Commercialization

Commercialization Strategy
Develop technology through start-up formation, with the goal of acquisition by a strategic when the technology is mature.

Regulatory Pathway
Conducting FDA Pre-Submission meeting to determine regulatory strategy for this product.

Product Launch Strategy
Initial indication for female childhood cancer survivors with POI. Potential for expansion to perimenopausal women, transgender patients, and fertility preservation.