

# UConn HEALTH

## UConn HEALTH & THE JACKSON LABORATORY FOR GENOMIC MEDICINE REPORT TO THE PUBLIC HEALTH COMMITTEE TO DEVELOP A PLAN TO ESTABLISH AN ENDOMETRIOSIS DATA AND BIOREPOSITORY PROGRAM

Pursuant to Connecticut Public Act 22-33, Section 3  
December 26, 2022

**Presented to:**

The Connecticut General Assembly Public Health Committee

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## Executive Summary

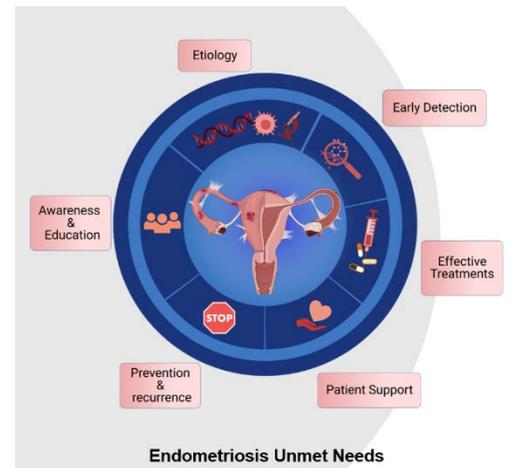
This document contains a blueprint for a Connecticut Endometriosis Data and Biorepository Program in accordance with Public Act No. 22-33, Sec 3 (*Effective July 1, 2022*).

The act requires the UConn Health Center, in consultation with a research laboratory, to develop a plan to establish an Endometriosis Data and Biorepository Program in the State of Connecticut.

**The proposed Program, hereafter referred to as the Endo-DBR, represents a pioneering, state-driven initiative that will be the first public, multi-institution biorepository of its kind in the nation.** The ultimate goal of the Endo-DBR is to address a highly invasive, under-diagnosed and under-researched disease in order to improve awareness and health outcomes in Connecticut, while driving research breakthroughs that will impact women across the nation and beyond. It is critical to the success of this effort that we work closely with the state, healthcare providers and across diverse stakeholder groups to successfully advance the aims of this proposed program.

Seeking to address the unmet clinical needs of a female dominant disease, the Endo-DBR will place the State of Connecticut at the forefront of work that will:

- foster **basic research** and **clinical collaborations** designed to help understand the pathology, drivers and impact of endometriosis;
- allow for curation of information from a diverse cross-section of communities to ensure **representation of all ethnic groups**;
- support the identification of **biomarkers of the disease** to provide earlier diagnosis;
- catalyze the advancement of **new therapeutic strategies**, along with early access for Connecticut residents to the latest therapeutic options as they are developed;
- support **better care management of the disease** that has an estimated current cost of over \$78 billion a year in the U.S. in healthcare dollars and loss of work/school; and
- serve as a centralized resource to disseminate information, educate the public, and raise awareness in order to promote **early detection** in adolescents and adults.



Success in this endeavor will improve the early detection of endometriosis in adolescents and adults, yield potential therapeutic strategies to treat and better manage the condition, and broaden early access to the latest therapeutic options for patients.

We look forward to working with the Legislature, and all stakeholders statewide, to develop innovative and lasting infrastructure that will improve the lives of women affected by this common and devastating disease.

## Background

### **What Is Endometriosis?**

Endometriosis is a chronic inflammatory gynecologic condition that affects 10% of female-born individuals. It is characterized by the abnormal growth of endometrium-like cells outside of the uterus, generally in the peritoneal cavity, but also in more distant extra pelvic organs such as lung, liver or spinal cord.

Endometriosis presents most prominently in individuals during reproductive age (15–49 years) and symptoms include chronic debilitating pain, severe menstrual cramping, severe bleeding and painful intercourse. As a systemic disease, however, it cannot be considered solely a gynecologic disorder, nor should its symptoms be minimized to pain only. Endometriosis causes systemic inflammation, anxiety, depression, and bladder and bowel dysfunction. It is a leading cause of hysterectomy among women of reproductive age, and is associated with infertility, cancer and cardiovascular diseases.

While the pathology of endometriosis was described almost a century ago, the pathogenesis and drivers of the disease remain largely unknown. As a result, endometriosis is often misdiagnosed or missed altogether. By the time it is properly diagnosed, patients have been symptomatic for seven-10 years, on average, and many display features of advanced disease. We therefore have a poor understanding of the conditions that foster disease initiation, progression and recurrence. We also lack any disease-modifying therapeutics, leaving doctors few options other than invasive surgical procedures to remove diseased tissue—procedures that carry significant risks of side effects and compound the risk of infertility. Even worse, these procedures rarely provide long-term relief and often do not prevent disease recurrence, estimated at 58% at five years post-surgery.

### **Rationale for an Endometriosis Data and Biorepository Program**

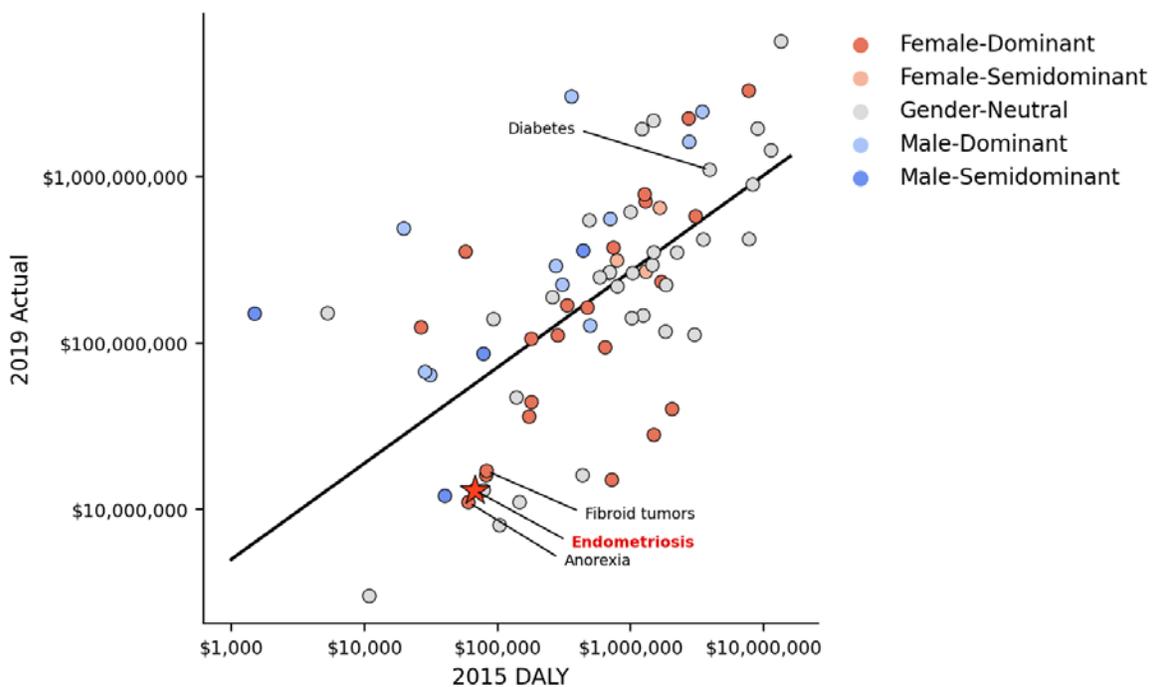
Endometriosis affects 200 million people with uteruses worldwide, 6.5 million women in the United States, and one in 10 women in Connecticut. At an impact rate of 10% of women and girls, endometriosis has an estimated cost of management (in the U.S.) of greater than \$20 billion a year (Falcone and Flyckt 2018).

The dearth of diagnostic and treatment options results from the lack of fundamental knowledge of the precise pathophysiology of the disease. The length to which the disease progresses undiagnosed is due to an absence of biomarker-based diagnostics and reliable non-invasive non-surgical diagnostic tools. Additionally, endometriosis symptoms often do not correlate with surgical presentation, and endometriosis lesions can adopt a wide variety of locations and shapes. Such complexity and heterogeneity can further complicate its detection and study.

Despite the huge prevalence and associated burden, and profound lack of mechanistic insight into the disease, endometriosis research remains under-supported at the federal level. It is one of several female-dominant diseases that receives significantly less NIH funding compared to gender-neutral or male-dominant diseases (Mirin 2021) (Fig. 1). The Department of Defense's Congressionally Directed Medical Research Program (CDMRP) only started to list endometriosis as a topic area for the Peer Reviewed Medical Research Program in 2018, but it is one of dozens of topic areas competing for the same scarce grant dollars. The CDMRP funded zero endometriosis grants in 2021, underscoring this issue.

The creation of the Endo-DBR will position Connecticut as a leader in the endometriosis field and in addressing the disparity in funding and resources for improving women’s health. As a core piece of this State-driven endometriosis program, the Endo-DBR will be the first public, multi-institution biorepository in the United States, and will foster basic research and clinical collaborations designed to help understand the impact of endometriosis on Connecticut residents. It will also promote early detection in adolescents and adults, catalyze the development of initiatives aimed at developing new therapeutic strategies and better management of the disease, and provide early access to the latest therapeutic options as they are developed – all of which are desperately needed. The impact on healthcare, healthcare costs, quality of life and economic potential for endometriosis patients could be transformative.

### NIH Funding Level of Various Diseases Normalized to Their Disease Burden



**Figure 1. Gender Disparity in the funding of diseases by the National Institutes of Health.** This plot represents the NIH funding level of various diseases, colored according to their female or male dominance, and normalized to their disease burden. The black line represents funding commensurate with disease burden. The majority of female dominant diseases can be found below the line, and endometriosis stands as one of the most underfunded female-dominant diseases. Figure adapted from Mirin et al, 2021, *Gender Disparity in the funding of diseases by the National Institutes of Health*.

As a core piece of this state-driven endometriosis program, the data and biorepository initiative will be the **first** public, multi-institution biorepository in the United States, and will foster basic research and clinical collaborations designed to help understand the impact of endometriosis on Connecticut residents. It will also promote early detection in adolescents and adults, catalyze the development of initiatives aimed at developing new therapeutic strategies and better management of the disease, and provide early access to the latest therapeutic options as they are developed – all of which is desperately needed to treat this complex pathology.

Finally, at an impact rate of 10% of women and girls, endometriosis has an estimated cost of management (in the U.S.) of greater than \$20 billion a year (Falcone and al., 2018, “Clinical Management of Endometriosis”). This effort will therefore have significant impact on healthcare, healthcare costs and quality of life for Connecticut residents.

## **UConn Health and The Jackson Laboratory - A Unique Partnership**

UConn Health (UCH) and The Jackson Laboratory (JAX) have a long history of partnership that provided the foundation for development of this plan and will serve to support success in this collaborative effort. Further, partnership between UConn Health and The Jackson Laboratory will enable these institutions to powerfully link clinical data to advanced molecular and tissue mapping technologies and continue to develop the infrastructure and experience to support network buildout statewide and beyond (Fig. 2).

### **CT Endometriosis Data And Biorepository**

#### *Initiating Partners*

UCH & The Jackson Laboratory for Genomic Medicine (JAX) have a long history of partnership that will serve as a foundation for successful collaboration in the creation and support of a Center. The partnership of JAX and UConn Health will permit the link of clinical data with advanced molecular biotechnology, and support network buildout, in Connecticut and beyond.



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| <ul style="list-style-type: none"> <li>✓ Center of Excellence in Minimally Invasive Gynecology</li> <li>✓ Referral center for endometriosis</li> <li>✓ Extensive clinical research experience on endometriosis</li> <li>✓ Teaching institution with a record of teaching trainees, community physicians and health care providers about endometriosis</li> <li>✓ Designated institution for graduate medical education for central Connecticut, with academic associations in all neighboring community hospitals including St. Francis Medical Center, Hartford Hospital and the Hospital of Central Connecticut</li> <li>✓ Connecticut's only public hospital, providing health access to diverse and underserved populations</li> </ul> | <ul style="list-style-type: none"> <li>✓ Unique setting for human disease research, at the intersection of molecular biology, immunology and human disease</li> <li>✓ Connecticut-licensed and CLIA-registered clinical laboratory</li> <li>✓ Proven ability to build-out a significant statewide hospital network through direct clinical partnerships in support of state COVID testing</li> <li>✓ Strong expertise in cutting-edge molecular technologies</li> <li>✓ Over nine decades of research breakthroughs have helped lay the foundation of modern medicine including bone &amp; organ transplants, stem cell therapy and in-vitro fertilization</li> <li>✓ 26 Nobel Prizes are associated with JAX research, resources and educational programming</li> </ul> |
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**Figure 2.** UCH and JAX are the initiating partners for the Connecticut endometriosis clinical data and tissue biorepository.

UCH has extensive clinical and clinical research experience in endometriosis. It is the first and largest designated Center of Excellence in Minimally Invasive Gynecologic Surgery in Connecticut. It is a referral center for the treatment of endometriosis in Connecticut and neighboring states, and as the state's only public hospital, it reaches diverse and underserved communities. At the Center of Excellence, UCH surgeons see hundreds of endometriosis patients annually and conduct over 150 endometriosis surgeries per year. They bring invaluable expertise in patient selection and enrollment, diagnosis of endometriosis, study of clinical symptoms, surgical evaluation of disease burden, and collection of endometriosis tissues.

UCH has renowned experts in endometriosis who do significant research, have participated in multiple multicenter trials and have written several authoritative papers on endometriosis (Luciano and Luciano 2006, Luciano and Luciano 2011, Exacoustos, Luciano et al. 2013, Lindsay, Luciano et al. 2015, Thorne, Kwait et al. 2015, Newmark, Luciano et al. 2021). The gynecologic surgeons at UCH have lectured nationally and internationally on the treatment of gynecologic diseases including endometriosis.

UCH is also a teaching institution with a long track record of teaching trainees, community physicians and healthcare providers about endometriosis. It is a designated institution for graduate medical education for central Connecticut, with academic affiliations with all the neighboring community hospitals, including Hartford Hospital, The Hospital of Central Connecticut, and St. Francis Medical Center.

The Jackson Laboratory is an independent, nonprofit research institution who seeks to discover the genetic and genomic mechanisms of human disease. It has a Connecticut-licensed and CLIA-certified clinical laboratory with a tested ability to build out a significant statewide hospital network through direct clinical partnerships, as seen in its support of the state’s COVID testing programs. JAX is a pioneer in the application of innovative genomic and tissue mapping technologies such as single cell and spatial transcriptomic sequencing to define the molecular features of a range of human cell types and tissues (Li, Courtois et al. 2017, Elyada, Bolisetty et al. 2019, Podojil, Glaser et al. 2020, Johnson, Anderson et al. 2021, Tan 2022). Exploiting these technologies, JAX serves as a tissue mapping center for multiple NIH funded programs. It brings significant analytic expertise in the analysis of these complex data to illuminate the cellular signatures underpinning specific diseases. This experience is essential to ensure optimal preservation, banking and management of tissues deposited in the repository for research.

Drs. Luciano and Courtois, who are leading the development of the Endo-DBR at UCH and JAX respectively, are longstanding collaborators with a track record of research productivity in endometriosis. In 2018 they were awarded a Peer-Reviewed Medical Research Program Discovery Award from the Department of Defense to study the endometriosis microenvironment in patient tissues using state-of-the-art single cell technology. The outcome of this study, recently published in *Nature Cell Biology*, shows for the first time unique endometriosis-specific markers, cell types, transcriptomic profiles and cell type compositions in the endometrium and in pelvic lesions (Tan 2022, Tan, Flynn et al. 2022). Data generated from this pioneering study seeded research collaborations with national and international research institutions such as Dartmouth (U.S.), Warwick Institute (U.K.), and Leuven University (Belgium) and with pharmaceutical companies such as GlaxoSmithKline.

The Endo-DBR would be a natural extension of this collaboration between UCH and JAX, and will build upon each institution’s efforts to provide resources and expertise to the endometriosis research community and to raise awareness on endometriosis.

<b>Legislative Directives and Execution</b>
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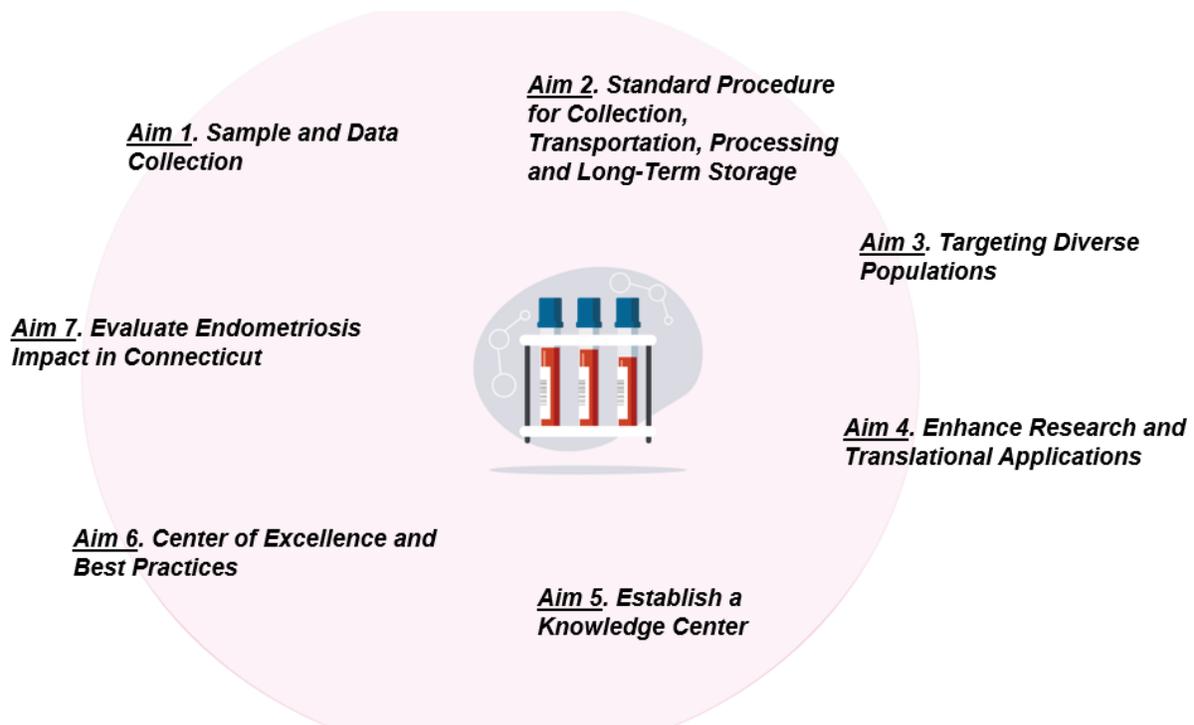
**Requirements under Public Act No. 22-33**, *An Act Concerning Intimate Examinations, Continuing Medical Education in Screening for Endometriosis and the Effects of Systemic Racism, Bias, Racial Disparities, and Experiences of Transgender and Gender Diverse Persons on Patient Diagnosis, Care and Treatment, the Establishment of An Endometriosis Data and Biorepository Program, and Cervical Cancer Early Detection and Treatment Referral Program.*

As established by the Public Act No 22-33, the endometriosis data and biorepository program must do the following:

- 1) collect standardized phenotypic data along with biological samples of a person's endometriosis and control samples to improve the characterization of the condition and the person with it;
- 2) develop standard operating procedures for retaining and storing biological endometriosis samples and control samples, including for their collection, transportation, processing and long-term storage;
- 3) curate biological endometriosis samples from a diverse cross-section of communities to ensure they represent all groups affected by the condition, including black and Latino persons, other persons of color, transgender and gender diverse persons, and persons with disabilities;
- 4) research the pathogenesis, pathophysiology, progression and prognosis of endometriosis and the development of noninvasive diagnostic biomarkers, novel targeted therapeutics, curative therapies and preventive interventions for the condition, including medical and surgical interventions;
- 5) serve as a centralized resource for endometriosis information;
- 6) facilitate collaboration among researchers and health-care professionals, educators and students on best practices for the diagnosis, care and treatment of endometriosis; and
- 7) research the impact of endometriosis on Connecticut residents, including its effect on health and comorbidity, health-care costs and overall quality of life.

### **Seven-Point Plan**

The seven point plan below illustrates the effort to support each of the legislatively defined charge areas (Fig. 3). Together, the resulting Endometriosis Program coalesces around three core pillars: endometriosis research, awareness and resources.



**Figure 3.** Strategic planning and proposed aims for the Connecticut endometriosis biorepository program

**Aim 1: Collect standardized phenotypic data and samples from endometriosis and non-endometriosis patients.** The CT Endo-DBR will prospectively collect endometriosis tissue, clinical and phenotypic data, symptom questionnaires, and blood and urine samples from patients with endometriosis. Tissue, fluid and data collection will be done following the standardized protocols of the WERF- EPHect, as a conduit to the global project.

Execution methods include:

- Enrolling endometriosis patients and control patients undergoing laparoscopic surgery for collection of tissue and fluids, and design longitudinal sample and data collection processes;
- Using the World Endometriosis Research Foundation standardization (WERF)- Endometriosis Phenome and Biobanking Harmonization Project ([EPHect](#)) for tissue sample and fluid collection and processing;
- Using the WERF-EPHect for surgical phenotyping (data collection sheet) and clinical phenotyping (standard questionnaire).

The purpose of WERF-EPHect is to enable large-scale, cross-center epidemiologically robust research into the causes of endometriosis, novel diagnostic methods and better treatments through the development of an international consensus on:

- Standardized detailed clinical and personal phenotyping (phenome) data to be collected from women with endometriosis and controls, to improve patient and disease characterization; and
- Standard Operating Procedures (SOPs) for banking biological samples from endometriosis patients and controls, to include collection, transportation, processing and long-term storage.



The WERF-EPHect collaboration is a landmark in endometriosis research worldwide. The tools are designed to facilitate the design and interpretation of collaborative studies across the entire endometriosis research field, including those into its pathogenesis and identification of disease subtypes; biomarker and targeted treatment discovery; and assessment of treatment outcome/effectiveness in clinical trials. To date, [50 institutions in 22 countries](#) are registered users of the tools.

While Connecticut's engagement in efforts to collect endometriosis specimen and data would be a significant advancement for endometriosis research in the state, coordinating this with the larger international effort would: 1) provide Connecticut research institutions with access to international information and resources; 2) provide a workable, standardized initiating collection template that could be further adapted for specialized study in Connecticut, along with emerging/future technologies; and 3) align Connecticut's actions with global efforts toward significantly greater scientific impact in the field worldwide.

**Aim 2: Develop standard operating procedures for retention and storage of biological samples of endometriosis and control samples, including, but not limited to, collection, transportation, processing and long-term storage of such samples.** In addition to traditional biobanking approaches, the current knowledge and use of state-of-the-art tissue mapping technologies at JAX, ensures patient samples will be preserved in a fashion that enables interrogation by these advanced technologies.

Execution methods include:

- Documenting surgically collected tissues and fluids;

- Processing samples and storage SOPs: WERF-[EPHect](#) (Endometriosis phenome and biobanking) Harmonization Project) SOPs + JAX's technology-oriented SOPs; and
- Providing sample transportation
  - UCH-JAX on Year 1
  - Other sites to JAX Year 2.

In addition to the use of WERF-EPHect SOPs, JAX/UCH will offer the following expertise in coordination of data collection and a centralized biorepository:

- IRB protocol & Informed Consent;
- SOP templates for collection, transportation/transmission and adaptations for novel/innovative technologies established at JAX;
- Pilot collection, resource and data housing site;
- Networking and onboarding for Connecticut institutions interested in joining the Center Collection Network;
- Technical guidance to Connecticut institutions interested in banking and accessing data from the Center; and
- Ongoing data and materials warehousing.

**Aim 3: Curate biological samples of endometriosis from a diverse cross-section of communities to ensure representation of all groups affected by endometriosis, including but not limited to black and Latino persons, other persons of color, transgender and gender diverse persons and persons with disabilities.** As endometriosis is a health issue that affects female-born individuals independent of socio-cultural status or race, it would be an important aim of any endometriosis program to curate from a diverse cross-section of communities to ensure representation of all ethnic groups and under-represented populations affected by the disease. Further, efforts would run in parallel to disseminate information and raise awareness toward improving understanding of endometriosis in an unbiased way, while promoting investigation for better diagnostic and treatments.

Execution methods include:

- Leveraging UCH's status as a Center for Excellence in Minimally Invasive Gynecologic Surgery, and a referral center for endometriosis, to support the treatment of underserved and uninsured patients and increase access to care for a diverse population of patients with endometriosis;
- Collaborating between sites, statewide, to allow for curation from a diverse cross-section of communities to ensure representation of all ethnic groups affected by the disease; and
- Using WERF-EPHect questionnaire translated into many languages and validated so it can be used to gather information easily and more accurately from patients in their native languages.

**Aim 4: Study the pathogenesis, pathophysiology, progression and prognosis of endometriosis, towards development of noninvasive diagnostic biomarkers, novel targeted therapeutics, curative therapies and preventive interventions with regard to endometriosis, including medical and surgical interventions.** Creating an endometriosis clinical data and biospecimen repository that is assessable to researchers investigating the disease would promote research and the advancement of diagnostics and treatments of this complex human-specific disease. Curated resources would allow for studies that, among other things, combine surgical phenotypes, clinical symptoms and biological sample information and have sufficient power through extensive and representative datasets of all patient backgrounds and communities.

Further, due to the centralized insight into prospective reach interests, the program can create opportunities for collaborative research among Connecticut institutions.

Execution methods include:

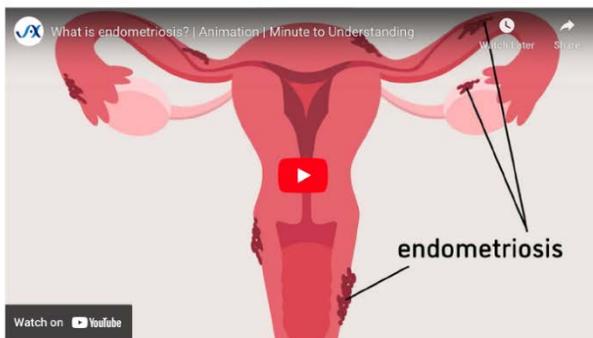
- Performing longitudinal collection of samples and clinical data (survey);
- Establishing an oversight committee to establish processes and guidelines for review of research projects and biorepository sample distribution to interested researchers;
- Establishing research data sharing policies;
- Validating the sample collection process for cutting-edge technology through a validation cohort; and
- Collaborating between sites with a larger and more diverse population to allow for larger and more significant research projects, increasing ability to apply for federally funded research grants.

**Aim 5: Serve as a centralized resource for endometriosis information.** The Endo-DBR by its very nature will serve as a centralized resource for endometriosis information. Beyond the research components discussed, the program will serve as an external interface, providing a centralized in-state resource lead for endometriosis information and conduit to collaboration among endometriosis stakeholders, public promotion and educational efforts for Connecticut residents and organizations.

Execution methods include:

- Creating a program webpage;
- Developing a list of endometriosis “experts” and other resources for patients;
- Creating infographics (Fig. 4), videos and descriptive materials for recruited patients and family, to inform about the goals of this program;
- Disseminating information to patients through the press, pamphlets in offices, advertisements; and
- Coordinating an annual conference for all endometriosis stakeholders.

## MINUTE TO UNDERSTANDING: WHAT IS ENDOMETRIOSIS?



**Figure 4.** Educational video for endometriosis awareness. This one-minute animation was created by the JAX creative department following the UCH/JAX research program development.

What is Endometriosis?  
Learn all about endometriosis in this Minute to Understanding from the Jackson Laboratory.

**Aim 6: Facilitate collaboration among researchers and health-care professionals, educators and students regarding best practices for the diagnosis, care and treatment of endometriosis.**

As the first multi-institutional statewide public biorepository for endometriosis tissue we will be able to share data for multiple studies both clinical and basic science. To bring healthcare providers and scientists throughout the state together, we will organize conferences to bring together researchers and use the oversight committee to coordinate multicenter longitudinal studies.

Execution methods include:

- Coordinating healthcare provider conferences with continuing education credits – CMEs and midlevel Practitioners, MD/DO and RN;
- Organizing meeting series for endometriosis awareness and education to cover several topics, targeting students, scientists, healthcare professional and educators in these areas: clinical, treatment, basic biology, basic research and translational research;
- Sharing samples and data with endometriosis researchers through the oversight committee; and
- Writing scientific publications highlighting the Connecticut state effort to promote research and education on endometriosis.

**Aim 7: Investigate the impact of endometriosis on residents of the state, including, but not limited to, its impact on health and comorbidity, health care costs and overall quality of life.** By being a centralized resource and collecting data for the state, the Endo-DBR will be able to accurately determine the number/percentage of patients with endometriosis and will pursue impact reporting related to curation activities.

Execution methods include:

- Evaluating health care costs, lost work time and effects on QOL through FMLA and questionnaires;
- Providing outreach to relevant state agencies to seek opportunities to generate reporting tied to state healthcare programs; and
- Promoting epidemiological studies, scientific publications.

## **Conclusion**

**Impact and significance of the proposed program.** Compared to other diseases with similar healthcare and societal burden, endometriosis has been comparatively ignored and remains poorly diagnosed and managed. Without additional investigation, it will remain a disease of invasive diagnostics, with no definitive treatment or cure, and will continue to rob up to one in 10 women of their physical and mental health and economic potential. This legislative initiative is therefore an unprecedented opportunity to turn the tide towards improved research investment, awareness-building, and clinical impact in this disease, and will position Connecticut as a trailblazer in endometriosis collaboration and research.

With this infrastructure, we will place Connecticut as a national and international center for endometriosis research, that will bring in important federal funding that will benefit economically the state and its citizens. It will encourage increased funding for research on the pathogenesis, pathophysiology, progression and prognosis of the disease and the development of non-invasive diagnostic biomarkers, novel targeted therapeutics, curative therapies, and preventive endometriosis interventions both medical and surgical.

## Timeline & Budget

### Endo-DBR Timeline

The CT Endometriosis Program will be rolled out in two phases comprised of a JAX/UCH year one pilot, to develop infrastructure and in preparation for the year two expansion to partner sites. Foundational elements and deliverables are outlined below.

**Year 1:** Establish a pilot program between UCH and JAX (targeted enrolled patients = up to 50), including:

- DIRB and Informed Consent forms for UCH/JAX;
- Setting up necessary IT infrastructure UCH/JAX;
- Determining key personnel, including Clinical Head and Lab Director(principal investigator), and Clinical Research Coordinator;
- Establishing sample processing and storage procedures; and
- Building internal infrastructure at JAX for sample receipt
  - Sample accessioning room
  - Cold storage for long-term storage.

### **Deliverables:**

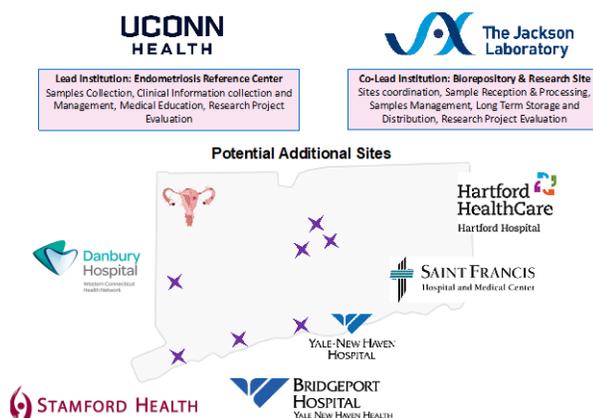
- Website;
- Validated Clinical bio-banked samples;
- Versatility of the biobanked samples for novel and cutting edge assays; and
- Plan for additional sites.

**Year 2:** Expand to other clinical sites in Connecticut (target = 4 external partner sites, Fig. 5) and:

- Be the **first** state-initiated, statewide, public, multi-institutional biorepository that is part of the World Endometriosis Research Foundation -WERF-EPHect Biorepository;
- Enroll sites with academic affiliation that will cover different demographic and geographic areas of CT (central, south, western);
- Foster collaborative projects across all institutions in Connecticut;
- Establish data sharing policies with WERF-EPHect; and
- Apply for federal funding for research grants.

### **Deliverables:**

- Endometriosis conference for healthcare providers and researchers;
- Collaborative research projects; and
- Quality-of-life data collection.



**Figure 5.** Year two expansion program and potential additional sites

## Endo-DBR Budget

<b>Endo-DBR Two Year Budget</b>			
	<b>Year 1 - Pilot</b>	<b>Year 2 - Expansion</b>	<b>Total</b>
<b>A. Total Salaries &amp; Fringe Benefits</b>	189,491	241,370	430,861
<b>C. Other Direct Costs</b>			-
Materials & Supplies	61,700	50,750	112,450
Publication Costs	7,000	-	7,000
Consultant Services	5,000	5,000	10,000
Computer Services REDCap data base set up	1,000	-	1,000
Sample Collection for Expansion Sites	-	100,000	100,000
Other Expenses	1,120	53,120	54,240
<b>Total Other Direct Costs</b>	75,820	208,870	284,690
<b>D. Total Direct Costs</b>	265,311	450,240	715,551
<b>E. Indirect Costs (F&amp;A) @ 66.5% UCHC 86% JAX</b>	202,436	274,749	477,185
<b>F. Total Costs</b>	<b>\$ 467,747</b>	<b>\$ 724,989</b>	<b>\$ 1,192,736</b>
<b>Indirect Cost Base (MTDC)</b>	<b>\$ 265,311</b>	<b>\$ 350,240</b>	<b>\$ 615,551</b>

## Appendix

### Public Act 22-33 Sec. 3

Sec. 3. (Effective July 1, 2022) (a) As used in this section:

(1) "Biorepository" means a facility that collects, catalogs and stores samples of biological material, including, but not limited to, urine, blood, tissue, cells, DNA, RNA and protein, from humans for laboratory research; and

(2) "Phenotypic data" means clinical information regarding a person's disease symptoms and relevant demographic data regarding the person, including, but not limited to, the person's age, sex, race and ethnicity.

(b) The University of Connecticut Health Center, in consultation with a research laboratory, shall develop a plan to establish an endometriosis data and biorepository program in the state to promote (1) early detection of endometriosis in adolescents and adults, (2) new therapeutic strategies for treatment and better overall management of endometriosis, and (3) early access to the latest therapeutic options for persons diagnosed with endometriosis.

(c) In developing the plan pursuant to subsection (b) of this section, The University of Connecticut Health Center shall require the endometriosis data and biorepository program to have the following functions:

(1) Collecting standardized phenotypic data along with the collection of biological samples of a person's endometriosis and control samples to improve the characterization of endometriosis and of the person with endometriosis;

(2) Developing standard operating procedures for retention and storage of biological samples of endometriosis and control samples, including, but not limited to, collection, transportation, processing and long-term storage of such samples;

(3) Curating biological samples of endometriosis from a diverse cross-section of communities to ensure representation of all groups affected by endometriosis, including, but not limited to, black persons, Latino persons, other persons of color, transgender and gender diverse persons and persons with disabilities;

(4) Researching the pathogenesis, pathophysiology, progression and prognosis of endometriosis and the development of noninvasive diagnostic biomarkers, novel targeted therapeutics, curative therapies and preventive interventions with regard to endometriosis, including medical and surgical interventions;

(5) Serving as a centralized resource for endometriosis information;

(6) Facilitating collaboration among researchers and health care professionals, educators and students regarding best practices for the diagnosis, care and treatment of endometriosis; and

(7) Researching the impact of endometriosis on residents of the state, including, but not limited to, its impact on health and comorbidity, health care costs and overall quality of life.

(d) Not later than January 1, 2023, the chairman of the board of directors of The University of Connecticut Health Center shall report, in accordance with the provisions of section 11-4a of the general statutes, regarding the plan developed pursuant to subsections (b) and (c) of this section and the anticipated timeline for establishing the endometriosis data and biorepository program to the joint standing committee of the General Assembly having cognizance of matters relating to public health.

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