



# House of Representatives

General Assembly

**File No. 59**

January Session, 2023

Substitute House Bill No. 6672

*House of Representatives, March 14, 2023*

The Committee on Public Health reported through REP. MCCARTHY VAHEY of the 133rd Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

## ***AN ACT CONCERNING ENDOMETRIOSIS.***

Be it enacted by the Senate and House of Representatives in General Assembly convened:

- 1 Section 1. (NEW) (*Effective July 1, 2023*) (a) As used in this section:
- 2 (1) "Biorepository" means a facility that, for laboratory research,  
3 collects, catalogs and stores samples of biological material from humans,  
4 including, but not limited to, urine, blood, tissue, cells, DNA  
5 (deoxyribonucleic acid), RNA (ribonucleic acid) and protein, that is  
6 coded without individual identifiers and linked with phenotypic data;  
7 and
- 8 (2) "Phenotypic data" means clinical information about a person,  
9 coded without individual identifiers, that includes disease history,  
10 symptoms and demographic data including, but not limited to, age, sex,  
11 race and ethnicity.
- 12 (b) Not later than January 1, 2024, The University of Connecticut

13 Health Center, in collaboration with a research laboratory in the state,  
14 shall establish an endometriosis data and biorepository program in the  
15 state to enable and promote research regarding (1) early detection of  
16 endometriosis in adolescents and adults, and (2) the development of  
17 therapeutic strategies to improve clinical management of endometriosis.

18 (c) The endometriosis data and biorepository program established  
19 pursuant to subsection (b) of this section shall:

20 (1) (A) Design a comprehensive longitudinal sample and clinical data  
21 collection protocol to characterize endometriosis and cellular functions  
22 of individuals with endometriosis, and (B) collect from patients with  
23 endometriosis and control patients without endometriosis and code (i)  
24 endometrial tissue specimens, (ii) fluids, including, but not limited to,  
25 blood and urine, and (iii) clinical and demographic data and  
26 questionnaires regarding symptoms of endometriosis and quality of life;

27 (2) (A) Develop standard operating procedures concerning samples  
28 of biological material, including, but not limited to, transportation,  
29 coding, processing, long-term retention and storage of such samples,  
30 and (B) establish data transmission and onboarding operations  
31 necessary for institutions in the state to participate in banking with and  
32 accessing data from the data and biorepository program;

33 (3) Curate biological samples of endometriosis from a diverse cross-  
34 section of communities in the state to ensure representation of all groups  
35 affected by endometriosis, including such under-represented  
36 populations as African American and black persons, Latino, Latina and  
37 Latinx persons, Puerto Rican persons, other persons of color,  
38 transgender and gender diverse persons, and persons with disabilities;

39 (4) Raise awareness regarding endometriosis in such under-  
40 represented populations and promote research of better diagnostic and  
41 therapeutic options, including through communications with health  
42 care providers and persons impacted by endometriosis concerning  
43 information about the latest therapeutic options for persons diagnosed  
44 with endometriosis;

45 (5) Create opportunities for collaborative research among institutions  
46 in the state focused on the pathogenesis, pathophysiology, progression,  
47 prognosis and prevention of endometriosis and the discovery of  
48 noninvasive diagnostic biomarkers, novel targeted therapeutics and  
49 improved medical and surgical interventions;

50 (6) Serve as a centralized resource for endometriosis information and  
51 a conduit to promote education and raise public awareness regarding  
52 endometriosis;

53 (7) Facilitate collaboration among researchers and health care  
54 providers, educators, students, patients and other individuals impacted  
55 by endometriosis through conferences and continuing medical  
56 education programs regarding best practices for the diagnosis, care and  
57 treatment of endometriosis;

58 (8) Collect information on the impact of endometriosis on residents  
59 of the state, including, but not limited to, its impact on health and  
60 comorbidity, health care costs and overall quality of life; and

61 (9) Apply for and accept grants, gifts and bequests of funds for the  
62 purpose of performing its functions pursuant to subdivisions (1) to (8),  
63 inclusive, of this subsection.

64 Sec. 2. (NEW) (*Effective July 1, 2023*) (a) There is established an  
65 Endometriosis Data and Biorepository Program Oversight Committee  
66 to (1) oversee the governance and operation of the endometriosis data  
67 and biorepository program established pursuant to section 1 of this act,  
68 (2) develop processes and guidelines for scientific review of research  
69 projects and data-sharing processes within such program, (3) ensure the  
70 integrity of data and biorepository specimens within such program, and  
71 (4) facilitate access to and distribution of data and biorepository  
72 specimens within such program. The committee shall be within the  
73 Legislative Department.

74 (b) The committee shall consist of the following members:

75 (1) The chairpersons and ranking members of the joint standing

76 committee of the General Assembly having cognizance of matters  
77 relating to public health, or their designees;

78 (2) Two appointed by the speaker of the House of Representatives;

79 (3) Two appointed by the president pro tempore of the Senate;

80 (4) One appointed by the majority leader of the House of  
81 Representatives;

82 (5) One appointed by the majority leader of the Senate;

83 (6) One appointed by the minority leader of the House of  
84 Representatives;

85 (7) One appointed by the minority leader of the Senate;

86 (8) The Commissioner of Public Health, or the commissioner's  
87 designee;

88 (9) The executive director of the Office of Health Strategy, or the  
89 executive director's designee;

90 (10) The Healthcare Advocate, or the Healthcare Advocate's  
91 designee; and

92 (11) The executive director of the Commission on Women, Children,  
93 Seniors, Equity and Opportunity, or the executive director's designee.

94 (c) Any member of the committee appointed under subdivisions (1)  
95 to (7), inclusive, of subsection (b) of this section may be a member of the  
96 General Assembly.

97 (d) Any vacancy shall be filled by the appointing authority.

98 (e) The Commissioner of Public Health, or the commissioner's  
99 designee, and a member of the General Assembly selected jointly by the  
100 speaker of the House of Representatives and the president pro tempore  
101 of the Senate from among the members serving pursuant to subdivision  
102 (1) of subsection (b) of this section shall be cochairpersons of the

103 committee. Such cochairpersons shall schedule the first meeting of the  
104 committee, which shall be held not later September 1, 2023.

105 (f) Members of the committee shall serve without compensation,  
106 except for necessary expenses incurred in the performance of their  
107 duties.

108 (g) Not later than January 1, 2025, and annually thereafter, the  
109 committee shall report, in accordance with section 11-4a of the general  
110 statutes, to the joint standing committee of the General Assembly  
111 having cognizance of matters relating to public health regarding the  
112 endometriosis data and biorepository program.

This act shall take effect as follows and shall amend the following sections:		
Section 1	July 1, 2023	New section
Sec. 2	July 1, 2023	New section

**PH** Joint Favorable Subst.

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

**OFA Fiscal Note**

**State Impact:**

Agency Affected	Fund-Effect	FY 24 \$	FY 25 \$
UConn Health Ctr.	GF - Cost	220,000 - 468,000	225,000 - 735,000
Legislative Mgmt.	GF - Cost	500,000	500,000

Note: GF=General Fund

**Municipal Impact:** None

**Explanation**

The bill results in an annual cost to the University of Connecticut (UConn) Health Center associated with developing an endometriosis data and biorepository program, and an annual cost to the Office of Legislative Management (OLM) associated with the newly established Endometriosis Data and Biorepository Program Oversight Committee.

**Section 1** of the bill results in a cost to the UConn Health Center of approximately \$220,000 in FY 24 and \$225,000 in FY 25 (and annually thereafter), associated with establishing an endometriosis data and biorepository program, including research. Costs for FY 24 include: 1) \$124,000 in additional staff costs and fringe benefits, 2) \$88,000 in indirect facility and administrative costs, and 3) \$8,000 in materials and supplies. Staff costs and indirect costs increase slightly in FY 25, for a total of \$225,000.

The bill requires the UConn Health Center to establish the program in collaboration with a research laboratory within Connecticut. The bill is unclear how the costs to the private laboratory would be covered. If the cost were borne by the UConn Health Center, it is estimated that an

additional state cost of \$248,000 in FY 24 and \$510,000 in FY 25 would be incurred. The additional costs in FY 24 would include: 1) \$115,000 in indirect costs, 2) \$68,000 in materials and expenses, and 3) \$65,000 in staff costs. In FY 25, the additional costs would include: 1) \$201,000 for materials, supplies and sample collection, 2) \$195,000 in facility and administrative costs, and 3) \$114,000 in staff costs. UConn Health's costs could be offset by any grants, gifts, or other funding secured for the purposes contained within the bill.

**Section 2** establishes an Endometriosis Data and Biorepository Program Oversight Committee within OLM resulting in an estimated cost of \$500,000 per year beginning in FY 24. To meet the requirements of the bill,<sup>1</sup> it is anticipated that OLM will need to contract with an institution of higher education to provide the oversight.

### ***The Out Years***

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

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<sup>1</sup> The committee is required to oversee the program, develop guidelines for scientific review of research, ensure integrity of data and biorepository specimens, and facilitate access to and distribute data.

**OLR Bill Analysis****sHB 6672*****AN ACT CONCERNING ENDOMETRIOSIS.*****SUMMARY**

This bill requires UConn Health Center, by January 1, 2024, and in collaboration with a research laboratory, to develop an endometriosis data and biorepository program to enable and promote research on (1) early detection of endometriosis in adolescents and adults and (2) the development of therapeutic strategies to improve clinical management of the condition.

The bill also establishes a 16-member Endometriosis Data and Biorepository Program Oversight Committee within the Legislative Department to do the following:

1. oversee the program's governance and operation;
2. develop processes and guidelines for scientific review of the program's research projects and data-sharing processes; and
3. ensure the integrity of, and facilitate access to and distribution of, the program's data and biorepository specimens.

Under the bill, the oversight committee must annually report on the program to the Public Health Committee, starting by January 1, 2025.

EFFECTIVE DATE: July 1, 2023

**ENDOMETRIOSIS DATA AND BIOREPOSITORY PROGRAM*****Duties***

Under the bill, the endometriosis data and biorepository program must do the following:



1. design a comprehensive longitudinal sample and clinical data collection protocol to characterize endometriosis and cellular functions of those with endometriosis;
2. collect from patients with endometriosis and control patients without the condition and code (a) endometrial tissue specimens; (b) fluids, including blood and urine; and (c) clinical and demographic data and questionnaires on endometriosis symptoms and quality of life;
3. develop standard operating procedures for biological material samples, including for their transportation, coding, processing, and long-term retention and storage;
4. establish data transmission and onboarding operations necessary for institutions in the state to participate in banking with and accessing data from the program;
5. curate biological endometriosis samples from a diverse cross-section of communities in the state to ensure they represent all groups affected by endometriosis, including African American, black, Latino, Latina, Latinx, and Puerto Rican persons; other persons of color; transgender and gender diverse persons; and persons with disabilities;
6. raise awareness on endometriosis in these underrepresented populations and promote research on better diagnostic and therapeutic options, including through communications with health care providers and those impacted by endometriosis on information about the latest therapeutic options for people diagnosed with the condition;
7. create opportunities for collaborative research among institutions in the state focused on the pathogenesis, pathophysiology, progression, prognosis, and prevention of endometriosis and the discovery of noninvasive diagnostic biomarkers, new targeted therapeutics, and improved medical

- and surgical interventions;
8. serve as a centralized resource for endometriosis information and a conduit to promote endometriosis education and raise its public awareness;
  9. facilitate collaboration among researchers and health care providers, educators, students, patients, and others impacted by endometriosis through conferences and continuing medical education programs on best practices for endometriosis diagnosis, care, and treatment;
  10. collect information on endometriosis's impact on Connecticut residents, including health and comorbidity, health care costs, and overall quality of life; and
  11. apply for and accept grants, gifts, and funds bequested to perform its functions.

### ***Definitions***

Under the bill, "biorepository" means a facility that collects, catalogs, and stores human samples of biological material, including urine, blood, tissue, cells, DNA, RNA, and protein for laboratory research. These samples are coded without individual identifiers and linked with phenotypic data.

"Phenotypic data" means non-individually identifiable clinical information on a person's disease history and symptoms and his or her demographic data, including age, sex, race, and ethnicity.

## **ENDOMETRIOSIS DATA AND BIOREPOSITORY PROGRAM OVERSIGHT COMMITTEE**

### ***Membership***

Under the bill, committee members include the following individuals:

1. the chairpersons and ranking members of the Public Health Committee, or their designees;

2. two members each appointed by the House speaker and Senate president pro tempore;
3. one member each appointed by the House and Senate majority and minority leaders;
4. the Department of Public Health (DPH) commissioner, or her designee;
5. the Office of Health Strategy executive director, or her designee;
6. the healthcare advocate, or his designee; and
7. the Commission on Women, Children, Seniors, Equity and Opportunity executive director, or his designee.

Under the bill, appointed members may be legislators, and appointing authorities must fill any vacancies. Committee members are not compensated but may be reimbursed for necessary expenses incurred in performing their duties.

**Leadership and Meetings**

Under the bill, the committee co-chairpersons are (1) the DPH commissioner, or her designee, and (2) a legislator jointly selected by the House speaker and Senate president pro tempore from among the committee members.

The co-chairpersons must schedule the first meeting, which must be held by September 1, 2023.

**COMMITTEE ACTION**

Public Health Committee

Joint Favorable Substitute  
 Yea 35 Nay 0 (03/03/2023)