

Multiple Agency Fiscal Note Summary

Bill Number: 1745 HB 1745-S2 AMS HLTC S2471.1	Title: Diversity in clinical trials
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Estimated Cash Receipts

Agency Name	2023-25			2025-27			2027-29		
	GF-State	NGF-Outlook	Total	GF-State	NGF-Outlook	Total	GF-State	NGF-Outlook	Total
Department of Social and Health Services	0	0	64,000	0	0	62,000	0	0	62,000
Total \$	0	0	64,000	0	0	62,000	0	0	62,000

Estimated Operating Expenditures

Agency Name	2023-25				2025-27				2027-29			
	FTEs	GF-State	NGF-Outlook	Total	FTEs	GF-State	NGF-Outlook	Total	FTEs	GF-State	NGF-Outlook	Total
Department of Commerce	.0	0	0	0	.0	0	0	0	.0	0	0	0
Washington State Health Care Authority	.0	0	0	0	.0	0	0	0	.0	0	0	0
Department of Social and Health Services	1.0	226,000	226,000	290,000	1.0	222,000	222,000	284,000	1.0	222,000	222,000	284,000
Department of Health	.0	0	0	0	.0	0	0	0	.0	0	0	0
University of Washington	2.8	1,355,255	1,355,255	1,355,255	2.8	1,338,780	1,338,780	1,338,780	2.8	1,338,780	1,338,780	1,338,780
University of Washington	In addition to the estimate above, there are additional indeterminate costs and/or savings. Please see individual fiscal note.											
Washington State University	.3	92,668	92,668	92,668	.4	122,229	122,229	122,229	.4	132,310	132,310	132,310
Total \$	4.1	1,673,923	1,673,923	1,737,923	4.2	1,683,009	1,683,009	1,745,009	4.2	1,693,090	1,693,090	1,755,090

Estimated Capital Budget Expenditures

Agency Name	2023-25			2025-27			2027-29		
	FTEs	Bonds	Total	FTEs	Bonds	Total	FTEs	Bonds	Total
Department of Commerce	.0	0	0	.0	0	0	.0	0	0
Washington State Health Care Authority	.0	0	0	.0	0	0	.0	0	0
Department of Social and Health Services	.0	0	0	.0	0	0	.0	0	0
Department of Health	.0	0	0	.0	0	0	.0	0	0
University of Washington	.0	0	0	.0	0	0	.0	0	0
Washington State University	.0	0	0	.0	0	0	.0	0	0
Total \$	0.0	0	0	0.0	0	0	0.0	0	0

Estimated Capital Budget Breakout

NONE

Prepared by: Breann Boggs, OFM	Phone: (360) 485-5716	Date Published: Final 4/ 5/2023
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Individual State Agency Fiscal Note

Bill Number: 1745 HB 1745-S2 AMS HLTC S2471.1	Title: Diversity in clinical trials	Agency: 103-Department of Commerce
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Part I: Estimates

No Fiscal Impact

Estimated Cash Receipts to:

NONE

Estimated Operating Expenditures from:

NONE

Estimated Capital Budget Impact:

NONE

The cash receipts and expenditure estimates on this page represent the most likely fiscal impact. Factors impacting the precision of these estimates, and alternate ranges (if appropriate), are explained in Part II.

Check applicable boxes and follow corresponding instructions:

- If fiscal impact is greater than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete entire fiscal note form Parts I-V.
- If fiscal impact is less than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete this page only (Part I).
- Capital budget impact, complete Part IV.
- Requires new rule making, complete Part V.

Legislative Contact: Kevin Black	Phone: (360) 786-7747	Date: 03/23/2023
Agency Preparation: Karen McArthur	Phone: 360-725-4027	Date: 03/27/2023
Agency Approval: Jason Davidson	Phone: 360-725-5080	Date: 03/27/2023
OFM Review: Gwen Stamey	Phone: (360) 790-1166	Date: 03/30/2023

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Significant provisions of the bill and any related workload or policy assumptions that have revenue or expenditure impact on the responding agency by section number.

The difference between 2SHB 1745 AMS HLTC S2471.1 and 2SHB 1745:

Section 3 was previously section 5 and removed the requirement for entities which receive NIH funding for clinical trials of drugs or medical devices to provide for electronic consent when not prohibited by the granting entity or federal regulation.

Section 4 was previously section 2 relating to the Andy Hill Cancer Research Endowment Program.

Section 5 was previously section 9 stating that section 1 through 3 of this act constitute a new chapter in Title 69 RCW.

There are no differences between 2SHB 1745 AMS HLTC S2471.1 and 2SHB 1745 that affect the fiscal impact to the Department of Commerce (department).

Summary of 2SHB 1745 AMS HLTC S2471.1:

Section 3 directs the Washington State Institutional Review Board to establish a Diversity in Clinical Trials Program with duties including providing assistance to research entities in identifying and recruiting members of underrepresented demographic groups to participate in clinical trials, to establish a website, and to consider publication of a biannual report. Requires any state entity which receives National Institutes of Health (NIH) funding for clinical trials of drugs or medical devices to adopt a policy concerning identification and recruitment of underrepresented demographic groups, to collaborate with community-based organizations, and to use methods to recruit members of underrepresented groups which are recognized by the United States Food and Drug Administration.

Section 4 amends RCW 43.348.040 and explains the Andy Hill Cancer Research Endowment Program.

The department does not execute or implement the activities stated in 2SHB 1745 AMS HLTC S2471.1; therefore, this legislation does not affect the department.

II. B - Cash receipts Impact

Cash receipts impact of the legislation on the responding agency with the cash receipts provisions identified by section number and when appropriate, the detail of the revenue sources. Description of the factual basis of the assumptions and the method by which the cash receipts impact is derived. Explanation of how workload assumptions translate into estimates. Distinguished between one time and ongoing functions.

II. C - Expenditures

Agency expenditures necessary to implement this legislation (or savings resulting from this legislation), with the provisions of the legislation that result in the expenditures (or savings) identified by section number. Description of the factual basis of the assumptions and the method by which the expenditure impact is derived. Explanation of how workload assumptions translate into cost estimates. Distinguished between one time and ongoing functions.

There is no fiscal impact associated with this legislation. The department does not execute or implement the activities stated in 2SHB 1745 AMS HLTC S2471.1.

Part III: Expenditure Detail

III. A - Operating Budget Expenditures

NONE

III. B - Expenditures by Object Or Purpose

NONE

III. C - Operating FTE Detail: *FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part I and Part IIIA.*

NONE

III. D - Expenditures By Program (optional)

NONE

Part IV: Capital Budget Impact

IV. A - Capital Budget Expenditures

NONE

IV. B - Expenditures by Object Or Purpose

NONE

IV. C - Capital Budget Breakout

Acquisition and construction costs not reflected elsewhere on the fiscal note and description of potential financing methods.

NONE

IV. D - Capital FTE Detail: *FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part IVB.*

NONE

Part V: New Rule Making Required

Provisions of the bill that require the agency to adopt new administrative rules or repeal/revise existing rules.

Individual State Agency Fiscal Note

Bill Number: 1745 HB 1745-S2 AMS HLTC S2471.1	Title: Diversity in clinical trials	Agency: 107-Washington State Health Care Authority
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Part I: Estimates

No Fiscal Impact

Estimated Cash Receipts to:

NONE

Estimated Operating Expenditures from:

NONE

Estimated Capital Budget Impact:

NONE

The cash receipts and expenditure estimates on this page represent the most likely fiscal impact. Factors impacting the precision of these estimates, and alternate ranges (if appropriate), are explained in Part II.

Check applicable boxes and follow corresponding instructions:

- If fiscal impact is greater than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete entire fiscal note form Parts I-V.
- If fiscal impact is less than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete this page only (Part I).
- Capital budget impact, complete Part IV.
- Requires new rule making, complete Part V.

Legislative Contact: Kevin Black	Phone: (360) 786-7747	Date: 03/23/2023
Agency Preparation: Alexa Price	Phone: 360-725-0000	Date: 03/29/2023
Agency Approval: Carl Yanagida	Phone: 360-725-5755	Date: 03/29/2023
OFM Review: Jason Brown	Phone: (360) 742-7277	Date: 03/29/2023

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Significant provisions of the bill and any related workload or policy assumptions that have revenue or expenditure impact on the responding agency by section number.

Please see attached narrative.

II. B - Cash receipts Impact

Cash receipts impact of the legislation on the responding agency with the cash receipts provisions identified by section number and when appropriate, the detail of the revenue sources. Description of the factual basis of the assumptions and the method by which the cash receipts impact is derived. Explanation of how workload assumptions translate into estimates. Distinguished between one time and ongoing functions.

Please see attached narrative.

II. C - Expenditures

Agency expenditures necessary to implement this legislation (or savings resulting from this legislation), with the provisions of the legislation that result in the expenditures (or savings) identified by section number. Description of the factual basis of the assumptions and the method by which the expenditure impact is derived. Explanation of how workload assumptions translate into cost estimates. Distinguished between one time and ongoing functions.

Please see attached narrative.

Part III: Expenditure Detail

III. A - Operating Budget Expenditures

NONE

III. B - Expenditures by Object Or Purpose

NONE

III. C - Operating FTE Detail: *FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part I and Part IIIA.*

NONE

III. D - Expenditures By Program (optional)

NONE

Part IV: Capital Budget Impact

IV. A - Capital Budget Expenditures

NONE

IV. B - Expenditures by Object Or Purpose

NONE

IV. C - Capital Budget Breakout

Acquisition and construction costs not reflected elsewhere on the fiscal note and description of potential financing methods.

NONE

IV. D - Capital FTE Detail: *FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part IVB.*

NONE

Part V: New Rule Making Required

Provisions of the bill that require the agency to adopt new administrative rules or repeal/revise existing rules.

HCA Fiscal Note

Bill Number: 1745 2SHB AMS HLTC S2471.1

HCA Request #: 23-218

Part II: Narrative Explanation

These changes do not create a fiscal impact that differs from the fiscal note on the second substitute.

AN ACT Relating to improving diversity in clinical trials.

II. A - Brief Description of What The Measure Does That Has Fiscal Impact

Similar to the fiscal note on 2SHB 1745, this bill creates no fiscal impact to the Washington State Health Care Authority.

II. B - Cash Receipts Impact

None.

II. C – Expenditures

No fiscal impact. The requirements of this bill can be absorbed using existing resources.

Part IV: Capital Budget Impact

None.

Part V: New Rule Making Require

None.

Individual State Agency Fiscal Note

Bill Number: 1745 HB 1745-S2 AMS HLTC S2471.1	Title: Diversity in clinical trials	Agency: 300-Department of Social and Health Services
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Part I: Estimates

No Fiscal Impact

Estimated Cash Receipts to:

ACCOUNT	FY 2024	FY 2025	2023-25	2025-27	2027-29
General Fund-Federal 001-2	33,000	31,000	64,000	62,000	62,000
Total \$	33,000	31,000	64,000	62,000	62,000

Estimated Operating Expenditures from:

	FY 2024	FY 2025	2023-25	2025-27	2027-29
FTE Staff Years	1.0	1.0	1.0	1.0	1.0
Account					
General Fund-State 001-1	115,000	111,000	226,000	222,000	222,000
General Fund-Federal 001-2	33,000	31,000	64,000	62,000	62,000
Total \$	148,000	142,000	290,000	284,000	284,000

Estimated Capital Budget Impact:

NONE

The cash receipts and expenditure estimates on this page represent the most likely fiscal impact. Factors impacting the precision of these estimates, and alternate ranges (if appropriate), are explained in Part II.

Check applicable boxes and follow corresponding instructions:

- If fiscal impact is greater than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete entire fiscal note form Parts I-V.
- If fiscal impact is less than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete this page only (Part I).
- Capital budget impact, complete Part IV.
- Requires new rule making, complete Part V.

Legislative Contact: Kevin Black	Phone: (360) 786-7747	Date: 03/23/2023
Agency Preparation: Teresa Elliott	Phone: 360-902-8177	Date: 04/02/2023
Agency Approval: Dan Winkley	Phone: 360-902-8236	Date: 04/02/2023
OFM Review: Arnel Blancas	Phone: (360) 000-0000	Date: 04/04/2023

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Significant provisions of the bill and any related workload or policy assumptions that have revenue or expenditure impact on the responding agency by section number.

This bill relates to improving diversity in clinical trials. RCW 43.348.040 and 2018 c 4 s 4 are each amended to include that the endowment must solicit requests for grant funding and evaluate the requests by reference to factors such as: the ability to offer trial participants information in a language other than English; (j) the ability to provide culturally specific recruitment materials alongside general enrollment materials; (k) the ability to provide electronic consent; and (l) other evidence of outreach and engagement to increase participation of underrepresented communities in clinical trials.

NEW SECTION. Sec. 3. includes the responsibilities for the Washington State Institutional Review Board (WSIRB). The administrative staff for the WSIRB are assigned to RDA. These responsibilities include establishing a plan to ensure that all submissions or proposals submitted to the WSIRB board shall include, and the review board shall consider a list of requirements for underrepresented populations, including:

(1)(b) Collaborate with medical facilities, health authorities, and other local governmental entities, nonprofit organizations, and scientific investigators and institutions that are performing research relating to drugs or medical devices to assist such investigators and institutions in identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials;

(c) Establish and maintain a website that:

(i) Provides information concerning methods recognized by the United States food and drug administration for identifying and recruiting persons who are members of underrepresented demographic groups to participate in clinical trials; and

(ii) Contains links to websites maintained by medical facilities, health authorities, and other local governmental entities, nonprofit organizations, and scientific investigators and institutions that are performing research relating to drugs or medical devices in this state;

(d) Apply for grants from any source including, without limitation, the federal government, to fund the diversity in clinical trials program; and

(e) Beginning July 1, 2024, and every even-numbered year thereafter, submit a report concerning the status and results of the diversity in clinical trials program to the health care committees of the legislature.

(2) Any state entity that receives funding from the national institutes of health to conduct clinical trials of drugs or medical devices must:

(a) Adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials. This policy must include requirements that investigators who are conducting clinical trials collaborate with community-based organizations and use

methods recognized by the United States food and drug administration to identify and recruit such persons to participate in those clinical trials;

(b) Provide information to trial participants in languages other than English; and

(c) Provide translation services or bilingual staff for trial screening.

(3) For the purposes of this section, demographic groups that are underrepresented in clinical trials may include persons who are underrepresented by race, sex, sexual orientation, socioeconomic status, and age.

Adding "when not prohibited by the granting entity or federal regulation" to the ability to provide electronic consent.

Clarifying clinical trials by adding "of drugs or medical device."

Sec. 10

Added: NEW SECTION. Sec. 10. If specific funding for the purposes of this act, referencing this act by bill or chapter number, is not provided by June 30, 2023, in the omnibus appropriations act, this act is null and void."

II. B - Cash receipts Impact

Cash receipts impact of the legislation on the responding agency with the cash receipts provisions identified by section number and when appropriate, the detail of the revenue sources. Description of the factual basis of the assumptions and the method by which the cash receipts impact is derived. Explanation of how workload assumptions translate into estimates. Distinguished between one time and ongoing functions.

It is assumed that the provisions of this bill would be eligible for federal funding based on the DSHS cost allocation plan for program 110.

II. C - Expenditures

Agency expenditures necessary to implement this legislation (or savings resulting from this legislation), with the provisions of the legislation that result in the expenditures (or savings) identified by section number. Description of the factual basis of the assumptions and the method by which the expenditure impact is derived. Explanation of how workload assumptions translate into cost estimates. Distinguished between one time and ongoing functions.

The Department of Social and Health Services, Research Data and Analysis (RDA) division will need one FTE for the duration of the program (WMS Band 1, Research Associate). Initially, this staff will lead efforts to create policies in line with the intent of the bill, to create more diversity in these trials. This would require the new FTE to create outreach materials to provide training and consultation on the delineated required review items, and to develop and update information on a website that is accessible to all submitters to all agencies for whom Washington State Institutional Review Board (WSIRB) reviews and for RDA/WSIRB. Ongoing, there will be increased workload across all staff to review and ensure that all clinical trial submissions include the four items delineated above and adequately meet the new requirements.

In consultation with the Institutional Review Board (IRB) Administrator, the staff will evaluate research submissions under the jurisdiction of five Washington state agencies for compliance with state and federal regulatory requirements for conducting human subject research. The position will evaluate, investigate, and determine the extent to which individual research proposals comply with a multitude of complex state and federal laws and regulations, and state agency policies regarding the use and disclosure of confidential records. They will determine the extent to which the risk of the proposed research (including risks to state agency clients, wards, patient, and employees or their personal records), are outweighed by the benefits of the proposed research. The staff will review study methods to ensure compliance with standards for sound research design, and exercise judgment in identifying and resolving problematic issues. The staff will communicate clear and concise regulatory determinations and advise on problem resolution. They will provide professional and technical advice to those submitting applications. This advice can involve complex, multi-dimensional issues impacting diverse departments, programs, policies, organizations, and/or jurisdictions.

Part III: Expenditure Detail

III. A - Operating Budget Expenditures

Account	Account Title	Type	FY 2024	FY 2025	2023-25	2025-27	2027-29
001-1	General Fund	State	115,000	111,000	226,000	222,000	222,000
001-2	General Fund	Federal	33,000	31,000	64,000	62,000	62,000
Total \$			148,000	142,000	290,000	284,000	284,000

III. B - Expenditures by Object Or Purpose

	FY 2024	FY 2025	2023-25	2025-27	2027-29
FTE Staff Years	1.0	1.0	1.0	1.0	1.0
A-Salaries and Wages	99,000	99,000	198,000	198,000	198,000
B-Employee Benefits	33,000	33,000	66,000	66,000	66,000
C-Professional Service Contracts					
E-Goods and Other Services	6,000	6,000	12,000	12,000	12,000
G-Travel					
J-Capital Outlays	6,000		6,000		
M-Inter Agency/Fund Transfers					
N-Grants, Benefits & Client Services					
P-Debt Service					
S-Interagency Reimbursements					
T-Intra-Agency Reimbursements	4,000	4,000	8,000	8,000	8,000
9-					
Total \$	148,000	142,000	290,000	284,000	284,000

III. C - Operating FTE Detail: *List FTEs by classification and corresponding annual compensation. Totals need to agree with total FTEs in Part I and Part IIIA*

Job Classification	Salary	FY 2024	FY 2025	2023-25	2025-27	2027-29
WMS BAND 1 - RESEARCH ASSOCIATE		1.0	1.0	1.0	1.0	1.0
Total FTEs		1.0	1.0	1.0	1.0	1.0

III. D - Expenditures By Program (optional)

Program	FY 2024	FY 2025	2023-25	2025-27	2027-29
Administrative and Support Services (110)	148,000	142,000	290,000	284,000	284,000
Total \$	148,000	142,000	290,000	284,000	284,000

Part IV: Capital Budget Impact

IV. A - Capital Budget Expenditures

NONE

IV. B - Expenditures by Object Or Purpose

NONE

IV. C - Capital Budget Breakout

Acquisition and construction costs not reflected elsewhere on the fiscal note and description of potential financing methods.

NONE

IV. D - Capital FTE Detail: *FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part IVB.*

NONE

Part V: New Rule Making Required

Provisions of the bill that require the agency to adopt new administrative rules or repeal/revise existing rules.

Individual State Agency Fiscal Note

Bill Number: 1745 HB 1745-S2 AMS HLTC S2471.1	Title: Diversity in clinical trials	Agency: 303-Department of Health
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Part I: Estimates

No Fiscal Impact

Estimated Cash Receipts to:

NONE

Estimated Operating Expenditures from:

NONE

Estimated Capital Budget Impact:

NONE

The cash receipts and expenditure estimates on this page represent the most likely fiscal impact. Factors impacting the precision of these estimates, and alternate ranges (if appropriate), are explained in Part II.

Check applicable boxes and follow corresponding instructions:

- If fiscal impact is greater than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete entire fiscal note form Parts I-V.
- If fiscal impact is less than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete this page only (Part I).
- Capital budget impact, complete Part IV.
- Requires new rule making, complete Part V.

Legislative Contact: Kevin Black	Phone: (360) 786-7747	Date: 03/23/2023
Agency Preparation: Donna Compton	Phone: 360-236-4538	Date: 03/27/2023
Agency Approval: Kristin Bettridge	Phone: 3607911657	Date: 03/27/2023
OFM Review: Breann Boggs	Phone: (360) 485-5716	Date: 03/31/2023

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Significant provisions of the bill and any related workload or policy assumptions that have revenue or expenditure impact on the responding agency by section number.

The fiscal impact has not changed from the previous fiscal note on 1745 2SHB. This striker amendment requires the Washington State Review Board to establish a diversity in clinical trials program to encourage participation of underrepresented demographic groups in clinical trials for drugs and medical devices. It removes the requirement for entities that receive National Institutes of Health funding for clinical trials of drugs or medical devices to provide the ability for electronic consent unless prohibited, and the definitions of underrepresented community and underrepresented demographic group. Changes in the bill do not change the fiscal impact for the Department of Health (department).

This bill requires the Andy Hill Cancer Research Endowment and the Washington State Institutional Review Board to consider an entity's ability to engage underrepresented communities and demographic groups as part of grant submissions. It requires the Washington State Review Board to establish a diversity in clinical trials program to encourage participation of underrepresented demographic groups in clinical trials for drugs and medical devices, and requires any state entity that receives funding from the National Institutes of Health to conduct clinical trials of drugs or medical devices to adopt policies concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials.

This bill does not create any new work for the department and therefore is no fiscal impact.

II. B - Cash receipts Impact

Cash receipts impact of the legislation on the responding agency with the cash receipts provisions identified by section number and when appropriate, the detail of the revenue sources. Description of the factual basis of the assumptions and the method by which the cash receipts impact is derived. Explanation of how workload assumptions translate into estimates. Distinguished between one time and ongoing functions.

II. C - Expenditures

Agency expenditures necessary to implement this legislation (or savings resulting from this legislation), with the provisions of the legislation that result in the expenditures (or savings) identified by section number. Description of the factual basis of the assumptions and the method by which the expenditure impact is derived. Explanation of how workload assumptions translate into cost estimates. Distinguished between one time and ongoing functions.

Part III: Expenditure Detail

III. A - Operating Budget Expenditures

NONE

III. B - Expenditures by Object Or Purpose

NONE

III. C - Operating FTE Detail: *FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part I and Part IIIA.*

NONE

III. D - Expenditures By Program (optional)

NONE

Part IV: Capital Budget Impact

IV. A - Capital Budget Expenditures

NONE

IV. B - Expenditures by Object Or Purpose

NONE

IV. C - Capital Budget Breakout

Acquisition and construction costs not reflected elsewhere on the fiscal note and description of potential financing methods.

NONE

IV. D - Capital FTE Detail: *FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part IVB.*

NONE

Part V: New Rule Making Required

Provisions of the bill that require the agency to adopt new administrative rules or repeal/revise existing rules.

Individual State Agency Fiscal Note

Bill Number: 1745 HB 1745-S2 AMS HLTC S2471.1	Title: Diversity in clinical trials	Agency: 360-University of Washington
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Part I: Estimates

No Fiscal Impact

Estimated Cash Receipts to:

NONE

Estimated Operating Expenditures from:

	FY 2024	FY 2025	2023-25	2025-27	2027-29
FTE Staff Years	2.9	2.8	2.8	2.8	2.8
Account					
General Fund-State 001-1	685,865	669,390	1,355,255	1,338,780	1,338,780
Total \$	685,865	669,390	1,355,255	1,338,780	1,338,780

In addition to the estimates above, there are additional indeterminate costs and/or savings. Please see discussion.

Estimated Capital Budget Impact:

NONE

The cash receipts and expenditure estimates on this page represent the most likely fiscal impact. Factors impacting the precision of these estimates, and alternate ranges (if appropriate), are explained in Part II.

Check applicable boxes and follow corresponding instructions:

- If fiscal impact is greater than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete entire fiscal note form Parts I-V.
- If fiscal impact is less than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete this page only (Part I).
- Capital budget impact, complete Part IV.
- Requires new rule making, complete Part V.

Legislative Contact: Kevin Black	Phone: (360) 786-7747	Date: 03/23/2023
Agency Preparation: Charlotte Shannon	Phone: 2066858868	Date: 03/28/2023
Agency Approval: Charlotte Shannon	Phone: 2066858868	Date: 03/28/2023
OFM Review: Ramona Nabors	Phone: (360) 742-8948	Date: 03/29/2023

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Significant provisions of the bill and any related workload or policy assumptions that have revenue or expenditure impact on the responding agency by section number.

The Senate Amendment to HB 1745 strikes the majority of the bill, and inserts the language and requirements from SSB 5388. Therefore the University of Washington is submitting the same fiscal note as SSB 5388.

Overall 1745 HB 1745-S2 AMS HLTC S2471.1 seeks to improve diversity in clinical trials for drugs and medical devices. It would require the Washington State Institutional Review Board to establish a program to encourage the participation of members of underrepresented groups in clinical trials. Through this program, the Washington State Institutional Review Board would collaborate with researchers to support efforts in identifying and recruiting underrepresented study participants, establish and maintain a website with best practices related to diversity in clinical trials, and report on the status of diversity in clinical trials.

The Andy Hill Cancer Research Endowment Program is also required to evaluate grant funding requests by the ability to offer trial participants information in a language other than English, the ability to provide culturally specific recruitment materials alongside general enrollment materials, the ability to provide electronic consent, and other evidence of outreach and engagement to increase participation of underrepresented communities in clinical trials.

The bill would also require any state entity that receives funding from the National Institutes of Health to conduct clinical trials on drugs and medical devices to adopt a policy concerning the identification and recruitment of individuals who are members of underrepresented groups. The policy must include requirements that investigators who are conducting clinical trials collaborate with community-based organizations and use methods recognized by the US Food and Drug Administration (FDA) to increase diversity in clinical trials, provide information to trial participants in languages other than English, and provide translation services or bilingual staff for trial screening.

II. B - Cash receipts Impact

Cash receipts impact of the legislation on the responding agency with the cash receipts provisions identified by section number and when appropriate, the detail of the revenue sources. Description of the factual basis of the assumptions and the method by which the cash receipts impact is derived. Explanation of how workload assumptions translate into estimates. Distinguished between one time and ongoing functions.

II. C - Expenditures

Agency expenditures necessary to implement this legislation (or savings resulting from this legislation), with the provisions of the legislation that result in the expenditures (or savings) identified by section number. Description of the factual basis of the assumptions and the method by which the expenditure impact is derived. Explanation of how workload assumptions translate into cost estimates. Distinguished between one time and ongoing functions.

To comply with the requirement to adopt a new policy to recruit individuals from underrepresented groups to participate in clinical trials, the UW central Institutional Review Board (IRB) office would require an additional 0.25 FTE in FY24 to generate and communicate the new policy, with an ongoing need for 0.15 FTE in FY25 and each year thereafter to manage compliance with the policy (average annual salary: \$125,000; benefits rate: 31.8%).

To comply with the legislation's requirement that investigators conducting clinical trials collaborate with community-based organizations and use FDA-recognized methods to increase clinical trial diversity, the UW would hire additional staff in the Office of Health Care Equity to coordinate with investigators to support efforts to enroll members of underrepresented communities. An additional 1.0 FTE would be needed to expand community engagement work (Community Engagement Research Coordinator, annual salary: \$85,000 FTE, benefits 31.8%), and an additional 1.0 FTE would be needed to support a project manager (annual salary: \$75,000, benefits rate: 31.8%). Faculty and administrative support would also be required (0.1 FTE faculty and 0.5 FTE staff administrative support, Faculty lead annual salary: \$225,000, Benefits rate: 24.1%).

Investigators at the UW engage in approximately 600 active clinical trials for drugs or medical devices per year. Approximately 150 new clinical trials for drugs or medical devices begin each year. Existing federal requirements require translation only when clinical trial enrollment is targeting populations with Limited English Proficiency. The language in this

legislation is broader and would require language translation for every clinical trial. Based on the totality of the language in this legislation, we are assuming these requirements apply to clinical trials for drugs or medical devices only. We assume all 150 new clinical trials for drugs or medical devices each year will require translation into at least one language.

For the purposes of this fiscal note, the UW assumes translation into one language for all applicable clinical trials, which is displayed in the expenditures table. In reality, translation into additional languages would likely be necessary but would be dependent on each individual trial. Individual investigators must procure translation services independently; no central translation purchasing exists at UW. To comply with the requirement to offer clinical trial information in a language other than English and assuming an average translation cost of \$600 for a five-page consent form, the cost of translation would be \$90,000. We have provided a determinate baseline for translation expenses; the needs will vary by trial, length of written clinical trial materials, and targeted populations, and are likely to be significantly higher. We also assume the Office of Health Care Equity would create some translated outreach materials for outreach to underrepresented communities that could be used for multiple clinical trials. We assume 500 pages of translated materials per year at a cost of \$125 per page, which would cost approximately \$62,500.

The language in this legislation limits the translation and interpreter services to the screening portion of the clinical trial. UW is assuming that translation or interpreter services are needed for both pre-screening and screening portions of clinical trial recruitment. Pre-screening involves the work done to determine the interest of an individual to participate in a research study and their initial eligibility. It typically happens before informed consent. Screening occurs after informed consent and requires the completion of initial tests and procedures to fully determine eligibility. For the purposes of this estimate, we are assuming translation or interpreter services required by this bill would apply both to pre-screening and screening services for the 150 new drug and device clinical trials initiated at UW Medicine annually. In reality, UW would not limit translation services to the pre-screening and screening processes of clinical trials. The need for translated documents and interpreter services for individuals with Limited English Proficiency is necessary for the entirety of the study, not just during the recruitment and screening processes. These costs are indeterminate since every clinical trial requires a different number of visits, but for illustrative purposes, if you assumed six one-hour visits per year, the interpretation cost would be \$360 per enrollee with Limited English Proficiency per year of a clinical trial, or \$54,000 per year.

This legislation does not specify a threshold or number of persons of limited English proficiency that need to be screened for a particular trial. For purposes of this fiscal note, we estimate the additional costs required to recruit one person of limited English proficiency to every clinical trial. However, we would consider this a baseline estimate; ideally, trial participation of limited English speakers would match the percentage in the greater population. The numbers we provide could be scaled to estimate the translation costs required to recruit additional individuals with limited English proficiency. We assume that enrollment of one person with Limited English Proficiency will require the pre-screening of ten individuals with Limited English Proficiency and the screening of three individuals with Limited English Proficiency. We assume ten people will need to be pre-screened for one hour, and three people will need to be screened for approximately three hours for every one person enrolled in each clinical trial. Interpretation is estimated to cost up to \$60 per hour based on the current contracted vendor cost of in-person interpreter services. This will cost \$1,140 per individual with Limited English Proficiency enrolled in a clinical trial, or \$171,000 if we assume one individual with Limited English Proficiency enrolls in each clinical trial. This is the number reflected in the expenditures table.

In line with UW Medicine policies and best practices, and in order to reasonably implement this legislation, significant community engagement would be necessary to increase clinical trial diversity as directed by the policy. Additional initiatives in this area could include creating a new program to improve overall outreach to community organizations (e.g., hiring a project manager), additional funding to support honoraria for 20 community participants (estimates include approximately \$15,000 per community champion each year), funding to support professional service contracts with community-based organizations, and funding for goods and services to support community outreach meetings and education sessions. These additional initiatives would likely be needed in order to achieve desired outcomes, but because they are not specifically prescribed by this legislation and are therefore indeterminate at this time, we are not including them in the budget tables.

TOTAL DETERMINATE FISCAL IMPACTS:

\$685,865 in FY24
 \$669,390 in FY25 and ongoing

INDETERMINATE IMPACTS:

- Community engagement and outreach
- Additional language translation for trial information and consent forms
- Translation and interpreter services throughout clinical trials (after prescreening/screening)
- More than 1 Limited English Proficiency participant per trial

Part III: Expenditure Detail

III. A - Operating Budget Expenditures

Account	Account Title	Type	FY 2024	FY 2025	2023-25	2025-27	2027-29
001-1	General Fund	State	685,865	669,390	1,355,255	1,338,780	1,338,780
Total \$			685,865	669,390	1,355,255	1,338,780	1,338,780

In addition to the estimates above, there are additional indeterminate costs and/or savings. Please see discussion.

III. B - Expenditures by Object Or Purpose

	FY 2024	FY 2025	2023-25	2025-27	2027-29
FTE Staff Years	2.9	2.8	2.8	2.8	2.8
A-Salaries and Wages	276,250	263,750	540,000	527,500	527,500
B-Employee Benefits	86,115	82,140	168,255	164,280	164,280
C-Professional Service Contracts	323,500	323,500	647,000	647,000	647,000
E-Goods and Other Services					
G-Travel					
J-Capital Outlays					
M-Inter Agency/Fund Transfers					
N-Grants, Benefits & Client Services					
P-Debt Service					
S-Interagency Reimbursements					
T-Intra-Agency Reimbursements					
9-					
Total \$	685,865	669,390	1,355,255	1,338,780	1,338,780

In addition to the estimates above, there are additional indeterminate costs and/or savings. Please see discussion.

III. C - Operating FTE Detail: *List FTEs by classification and corresponding annual compensation. Totals need to agree with total FTEs in Part I and Part IIIA*

Job Classification	Salary	FY 2024	FY 2025	2023-25	2025-27	2027-29
Administrative Support Staff	125,000	0.5	0.5	0.5	0.5	0.5
Community Engagement Research Coordinator	85,000	1.0	1.0	1.0	1.0	1.0
Faculty	225,000	0.1	0.1	0.1	0.1	0.1
IRB staff	125,000	0.3	0.2	0.2	0.2	0.2
Project Manager	75,000	1.0	1.0	1.0	1.0	1.0
Total FTEs		2.9	2.8	2.8	2.8	2.8

III. D - Expenditures By Program (optional)

NONE

Part IV: Capital Budget Impact

IV. A - Capital Budget Expenditures

NONE

IV. B - Expenditures by Object Or Purpose

NONE

IV. C - Capital Budget Breakout

Acquisition and construction costs not reflected elsewhere on the fiscal note and description of potential financing methods.

NONE

IV. D - Capital FTE Detail: *FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part IVB.*

NONE

Part V: New Rule Making Required

Provisions of the bill that require the agency to adopt new administrative rules or repeal/revise existing rules.

Individual State Agency Fiscal Note

Bill Number: 1745 HB 1745-S2 AMS HLTC S2471.1	Title: Diversity in clinical trials	Agency: 365-Washington State University
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Part I: Estimates

No Fiscal Impact

Estimated Cash Receipts to:

NONE

Estimated Operating Expenditures from:

	FY 2024	FY 2025	2023-25	2025-27	2027-29
FTE Staff Years	0.3	0.3	0.3	0.4	0.4
Account					
General Fund-State 001-1	43,793	48,875	92,668	122,229	132,310
Total \$	43,793	48,875	92,668	122,229	132,310

Estimated Capital Budget Impact:

NONE

The cash receipts and expenditure estimates on this page represent the most likely fiscal impact. Factors impacting the precision of these estimates, and alternate ranges (if appropriate), are explained in Part II.

Check applicable boxes and follow corresponding instructions:

- If fiscal impact is greater than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete entire fiscal note form Parts I-V.
- If fiscal impact is less than \$50,000 per fiscal year in the current biennium or in subsequent biennia, complete this page only (Part I).
- Capital budget impact, complete Part IV.
- Requires new rule making, complete Part V.

Legislative Contact: Kevin Black	Phone: (360) 786-7747	Date: 03/23/2023
Agency Preparation: Brittney Gamez	Phone: 509-335-5406	Date: 03/29/2023
Agency Approval: Chris Jones	Phone: 509-335-9682	Date: 03/29/2023
OFM Review: Ramona Nabors	Phone: (360) 742-8948	Date: 03/31/2023

Part II: Narrative Explanation

II. A - Brief Description Of What The Measure Does That Has Fiscal Impact

Significant provisions of the bill and any related workload or policy assumptions that have revenue or expenditure impact on the responding agency by section number.

1745 HB 1745-S2 AMS HLTC S2471.1 would require WSU to ensure there is diversity among the human subjects who participate in clinical trials for drugs and medical devices.

II. B - Cash receipts Impact

Cash receipts impact of the legislation on the responding agency with the cash receipts provisions identified by section number and when appropriate, the detail of the revenue sources. Description of the factual basis of the assumptions and the method by which the cash receipts impact is derived. Explanation of how workload assumptions translate into estimates. Distinguished between one time and ongoing functions.

II. C - Expenditures

Agency expenditures necessary to implement this legislation (or savings resulting from this legislation), with the provisions of the legislation that result in the expenditures (or savings) identified by section number. Description of the factual basis of the assumptions and the method by which the expenditure impact is derived. Explanation of how workload assumptions translate into cost estimates. Distinguished between one time and ongoing functions.

This fiscal impact of 1745 2S HB would require WSU Office of Research to 1) Draft a policy that addresses diversity in trials, including a requirement for working with community-based organizations to develop recruitment strategies; 2) Update forms and processes to implement the new policy once drafted; 3) Alter the review process to ensure recruitment diversity is considered. In total, this would require approximately 0.1 employee FTE, with costs slightly higher in FY 2024 and FY 2025 to draft the policy and update forms. The Elson S. Floyd College of Medicine estimates additional staff time of a Grants & Contracts Manager to track and manage the requirements of the bill (e.g., maintaining a website and report submissions). The College of Nursing and the College of Pharmacy and Pharmaceutical Sciences each estimate 0.05 FTE of a Clinical Trial Coordinator's time to collaborate with community partners and records management to ensure the requirements of the bill are met. Personal service contract costs are for collaboration with community-based organizations that may consult on the development and implementation of the diversity requirements and aid in recruitment efforts. Goods and services costs are for additional records management services and further collaboration with community partners.

WSU estimates it will incur costs to offer translation services if needed and to provide documentation in languages other than English. Total costs are indeterminate since they will vary based on the number of trial participants, number of languages needed for translation from English, and also the clinical trial location and what translation services may or may not already be available. Costs per trial could be minimal or as much as \$10,000 for larger trials where professional translation services will be required.

Part III: Expenditure Detail

III. A - Operating Budget Expenditures

Account	Account Title	Type	FY 2024	FY 2025	2023-25	2025-27	2027-29
001-1	General Fund	State	43,793	48,875	92,668	122,229	132,310
Total \$			43,793	48,875	92,668	122,229	132,310

III. B - Expenditures by Object Or Purpose

	FY 2024	FY 2025	2023-25	2025-27	2027-29
FTE Staff Years	0.3	0.3	0.3	0.4	0.4
A-Salaries and Wages	19,068	22,818	41,886	52,632	56,382
B-Employee Benefits	6,725	8,057	14,782	18,597	19,928
C-Professional Service Contracts	10,000	10,000	20,000	35,000	40,000
E-Goods and Other Services	8,000	8,000	16,000	16,000	16,000
G-Travel					
J-Capital Outlays					
M-Inter Agency/Fund Transfers					
N-Grants, Benefits & Client Services					
P-Debt Service					
S-Interagency Reimbursements					
T-Intra-Agency Reimbursements					
9-					
Total \$	43,793	48,875	92,668	122,229	132,310

III. C - Operating FTE Detail: *List FTEs by classification and corresponding annual compensation. Totals need to agree with total FTEs in Part I and Part IIIA*

Job Classification	Salary	FY 2024	FY 2025	2023-25	2025-27	2027-29
Assistant Director (JC)	102,201	0.1	0.1	0.1	0.2	0.2
Director (DB)	75,636	0.0	0.0	0.0		
Director (MK)	137,101	0.0	0.0	0.0		
IRB Co-chair/Faculty (AL)	185,751	0.0	0.0	0.0	0.0	0.0
IRB Co-chair/Faculty (CB)	97,068	0.0	0.0	0.0	0.0	0.0
Manager (MJ)	59,436	0.1	0.1	0.1	0.1	0.1
Total FTEs		0.3	0.3	0.3	0.4	0.4

III. D - Expenditures By Program (optional)

NONE

Part IV: Capital Budget Impact

IV. A - Capital Budget Expenditures

NONE

IV. B - Expenditures by Object Or Purpose

NONE

IV. C - Capital Budget Breakout

Acquisition and construction costs not reflected elsewhere on the fiscal note and description of potential financing methods.

NONE

IV. D - Capital FTE Detail: *FTEs listed by classification and corresponding annual compensation. Totals agree with total FTEs in Part IVB.*

NONE

Part V: New Rule Making Required

Provisions of the bill that require the agency to adopt new administrative rules or repeal/revise existing rules.