

Multiple Agency Fiscal Note Summary

Bill Number: 1745 2S HB	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	.7	844,701	844,701	844,701	.7	828,226	828,226	828,226	.7	828,226	828,226	828,226
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 \$	2.0	1,163,369	1,163,369	1,227,369	2.1	1,172,455	1,172,455	1,234,455	2.1	1,182,536	1,182,536	1,244,536

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 3/16/2023
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Individual State Agency Fiscal Note

Bill Number: 1745 2S HB	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: Kate Henry	Phone: 360-786-7349	Date: 03/09/2023
Agency Preparation: Karen McArthur	Phone: 360-725-4027	Date: 03/10/2023
Agency Approval: Jason Davidson	Phone: 360-725-5080	Date: 03/10/2023
OFM Review: Gwen Stamey	Phone: (360) 790-1166	Date: 03/13/2023

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 and SHB 1745:

Sections 5 - 8:

- Removes the requirements for the University of Washington, Washington State University, and any hospital or state agency that receives National Institutes of Health Funding for drug and medical device clinical trials to adopt a policy regarding identifying and recruiting members of underrepresented communities and replaces it with a requirement for the entity to provide the requirements that were previously included in the policy.

- Removes the requirement for the University of Washington, Washington State University, and any hospital or state agency that receives National Institutes of Health Funding for drug and medical device clinical trials to provide other strategies of outreach and engagement to increase participating of underrepresented communities in clinical trials of drugs and medical devices.

Section 10 was added that if specific funding for the purposes of this act is not provided by June 30, 2023, this act is null and void.

Summary of 2SHB 1745:

Sections 5 - 8:

Requires the University of Washington, Washington State University and any hospital or state agency that receives National Institutes of Health Funding for drug and medical device clinical trials to increase the recruiting members of underrepresented demographic groups to participate in clinical trials for drugs and medical devices.

Requires the Review Board and the Andy Hill Cancer Research Endowment to consider in their evaluation four factors related to increasing participation of underrepresented communities in clinical trials of drugs and medical devices.

- 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 when not prohibited by other granting entities or federal regulations.

The Department of Commerce (department) does not execute or implement the activities stated in 2SHB 1745; 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.

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 2S HB	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: Kate Henry	Phone: 360-786-7349	Date: 03/09/2023
Agency Preparation: Sue Eckroth	Phone: 360-725-1899	Date: 03/10/2023
Agency Approval: Carl Yanagida	Phone: 360-725-5755	Date: 03/10/2023
OFM Review: Jason Brown	Phone: (360) 742-7277	Date: 03/16/2023

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.

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.

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.

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

HCA Request #: 23-200

Part II: Narrative Explanation

This bill aims to improve diversity in clinical trials by inclusion of underrepresented community or underrepresented demographic group.

This bill:

- Amends RCW 43.348.040 (Andy Hill cancer research endowment program)
- Adds a new section to chapter 28B.20 RCW (University of Washington)
- Adds a new section to chapter 28B.30 RCW (Washington State University)
- Adds a new section to chapter 70.41 RCW (Hospital Licensing and Regulation)
- Adds a new chapter to Title 69 RCW (Foods, Drugs, Cosmetics and Poisons)

The second substitute makes the following changes from the last version:

- Adds new section to Title 69 RCW. Section 10 states if funding for purpose of the act is not provided by June 30, 2023, in the omnibus appropriations act, the act is null and void.

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

Similar to the fiscal note on SHB 1745, this second substitute bill creates no fiscal impact to the Washington State Health Care Authority (HCA).

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 2S HB	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: Kate Henry	Phone: 360-786-7349	Date: 03/09/2023
Agency Preparation: Teresa Elliott	Phone: 360-902-8177	Date: 03/09/2023
Agency Approval: Dan Winkley	Phone: 360-902-8236	Date: 03/09/2023
OFM Review: Arnel Blancas	Phone: (360) 000-0000	Date: 03/09/2023

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. 4. 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) The ability of the agency to offer trial participants information in a language other than English;
- (2) The ability of the agency to provide culturally specific recruitment materials alongside general enrollment materials;
- (3) The ability to provide electronic consent when not prohibited by the granting entity or federal regulation; and
- (4) Any other evidence of outreach and engagement to increase participation of underrepresented communities in clinical trials of drugs or medical devices.

NEW SECTION. Sec. 5. includes the requirements for any state entity that receives funding from the national institutes of health to conduct clinical trials of drugs or medical devices shall adopt a policy concerning the identification and recruitment of persons who are members of underrepresented demographic groups to participate in clinical trials.

- (1) The ability of the agency to offer trial participants information in a language other than English;
- (2) The ability of the agency to provide culturally specific recruitment materials alongside general enrollment materials; and
- (3) The ability to provide electronic consent when not prohibited by the granting entity or federal regulation

Change from previous version:

Deleted: from section 5 (4), 6(1)(d), 7(1)(d), and 8(1)(d) the requirement to 'Provide other strategies of outreach and engagement to increase participation of underrepresented communities in clinical trials of drugs or medical devices.'

Adds: Section 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 as follows: 001-2 Federal Food Stamps

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 estimates there would need to be one additional FTE needed 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.

WSIRB Policies, Procedures and Staff Manuals would need to be updated and changed with new program parameters.

Individual State Agency Fiscal Note

Bill Number: 1745 2S HB	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: Kate Henry	Phone: 360-786-7349	Date: 03/09/2023
Agency Preparation: Donna Compton	Phone: 360-236-4538	Date: 03/13/2023
Agency Approval: Kristin Bettridge	Phone: 3607911657	Date: 03/13/2023
OFM Review: Breann Boggs	Phone: (360) 485-5716	Date: 03/14/2023

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 SHB. This bill clarifies that electronic consent must be provided unless prohibited by the granting entity or federal regulation, and specifies that outreach and engagement to underrepresented communities should be directed at underrepresented communities in clinical trials of drugs or medical devices. 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 any state entity, the University of Washington, Washington State University, and any hospital 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. It outlines minimum policy requirements and defines underrepresented community and underrepresented demographic group.

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.

None

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 2S HB	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	0.8	0.7	0.7	0.7	0.7
Account					
General Fund-State 001-1	430,588	414,113	844,701	828,226	828,226
Total \$	430,588	414,113	844,701	828,226	828,226

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: Kate Henry	Phone: 360-786-7349	Date: 03/09/2023
Agency Preparation: Charlotte Shannon	Phone: 2066858868	Date: 03/14/2023
Agency Approval: Charlotte Shannon	Phone: 2066858868	Date: 03/14/2023
OFM Review: Ramona Nabors	Phone: (360) 742-8948	Date: 03/15/2023

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 second substitute bill makes the following changes:

- Strikes the requirement for the University of Washington to adopt a policy to increase diversity in clinical trials
- Strikes the requirement the University of Washington provide other strategies of outreach and engagement to increase participation of underrepresented communities in clinical trials of drugs or medical devices.
- Adds a null and void clause

FISCAL IMPACTS OF CHANGES TO SUBSTITUTE BILL:

These changes to the underlying bill impact our fiscal analysis of 2SHB 1745, please see the expenditures section below.

Overall 2SHB 1745 seeks to improve diversity in clinical trials. The bill requires that submissions or proposals to the Washington State Institutional Review Board include the ability of the agency to offer trial participants information in a language other than English, the ability of the agency to provide culturally specific recruitment materials alongside general enrollment materials, and the ability to provide electronic consent, to increase participation of underrepresented communities 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.

Any state entity, including University of Washington and Washington State University, and hospitals receiving funding from the National Institutes of Health to conduct clinical trials of drugs or medical devices are required to offer participants information in a language other than English, provide culturally specific recruitment materials with general enrollment materials, and provide electronic consent.

Underrepresented community and underrepresented demographic group are defined as a community or demographic group that is more likely to be historically marginalized and less likely to be included in research and clinical trials represented by race, sex, sexual orientation, socioeconomic status, and age.

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.

The 2S version of this bill strikes the requirement to adopt a policy to recruit individuals from underrepresented groups to participate in clinical trials. While the bill does not require the development of a policy, the changes to requirements for clinical trials require the UW IRB to revise internal policies to integrate these new requirements into existing policies, in addition to ensuring ongoing compliance for all applicable clinical trials. Therefore, the University of Washington (UW) central Institutional Review Board (IRB) office would require an additional 0.25 FTE in FY24 to implement the requirements for translation, electronic consent, and the use of culturally specific materials for all relevant trials required

under this bill, with an ongoing need for 0.15 FTE in FY25 and each year thereafter to manage ongoing compliance (average annual salary: \$125,000; benefits rate: 31.8%).

An additional resource would be required to meet the requirements related to the translation of study documents and provision of culturally appropriate materials in individual trials. The UW would hire additional staff in the Institute for Translational Health Sciences to coordinate the translation of study materials and to oversee the creation of culturally appropriate outreach materials. It will be important to have a resource with appropriate subject matter expertise, including knowledge of different cultural considerations related to trial participation, to be able to meet these requirements. A 0.5 project manager FTE would be needed to support these efforts (annual salary: \$100,000, benefits rate: 31.8%).

In addition to staff required to oversee the translation and creation of culturally appropriate materials, there will be costs associated with the translation of study documents, for which we would contract. The UW assumes all 150 new clinical trials each year will all 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. 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 translation costs associated with the production of culturally appropriate outreach materials. The Institute for Translational Health Sciences, as outlined above, would oversee the creation of these culturally appropriate outreach materials, some of which will require translation. We assume we would use materials across multiple clinical trials when possible, however it would not be possible in all cases. We assume 500 pages of translated materials per year at a cost of \$125 per page, which would cost approximately \$62,500.

While this bill does not require interpreter services for patients with LEP who choose to enroll in trials, given the bill does require offering trial materials in a language other than English, the UW assumes interpreter services would be required for trial participants with LEP, recruited under the requirements of this bill as it would not be feasible or ethical to enroll a study participant with LEP into a trial without providing translation services. For the purposes of this estimate, we have assumed interpreter services would be required for pre-screening and screening services for the 150 new drug and device clinical trials initiated at UW Medicine annually. 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 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. However, these costs are indeterminate since every clinical trial requires a different number of visits. 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.

No additional costs are assumed for the requirement to offer electronic consent for clinical trials because UW already uses electronic consent forms where applicable according to federal granting agencies.

TOTAL DETERMINATE FISCAL IMPACTS:

\$430,588 in FY24
\$414,113 in FY25 and ongoing

INDETERMINATE IMPACTS:

-Additional language translation for trial information and consent forms

- Translation and interpreter services throughout clinical trials (after prescreening/screening)
- Enrollment of 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	430,588	414,113	844,701	828,226	828,226
Total \$			430,588	414,113	844,701	828,226	828,226

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	0.8	0.7	0.7	0.7	0.7
A-Salaries and Wages	81,250	68,750	150,000	137,500	137,500
B-Employee Benefits	25,838	21,863	47,701	43,726	43,726
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 \$	430,588	414,113	844,701	828,226	828,226

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
IRB staff	125,000	0.3	0.2	0.2	0.2	0.2
Project Manager	100,000	0.5	0.5	0.5	0.5	0.5
Total FTEs		0.8	0.7	0.7	0.7	0.7

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 2S HB	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: Kate Henry	Phone: 360-786-7349	Date: 03/09/2023
Agency Preparation: Chris Jones	Phone: 509-335-9682	Date: 03/16/2023
Agency Approval: Chris Jones	Phone: 509-335-9682	Date: 03/16/2023
OFM Review: Ramona Nabors	Phone: (360) 742-8948	Date: 03/16/2023

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 2S HB 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) Update forms and processes to implement the requirements of the bill; 2) Alter the review process to ensure recruitment diversity is considered. In total, this would require approximately 0.1 employee FTEs. 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.