

# Multiple Agency Fiscal Note Summary

<b>Bill Number:</b> 5388 S SB	<b>Title:</b> 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	321,000	0	0	318,000	0	0	318,000
<b>Total \$</b>	<b>0</b>	<b>0</b>	<b>321,000</b>	<b>0</b>	<b>0</b>	<b>318,000</b>	<b>0</b>	<b>0</b>	<b>318,000</b>

## 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 Social and Health Services	5.0	1,137,000	1,137,000	1,458,000	5.0	1,126,000	1,126,000	1,444,000	5.0	1,126,000	1,126,000	1,444,000
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
Washington State University	In addition to the estimate above, there are additional indeterminate costs and/or savings. Please see individual fiscal note.											
<b>Total \$</b>	<b>8.1</b>	<b>2,584,923</b>	<b>2,584,923</b>	<b>2,905,923</b>	<b>8.2</b>	<b>2,587,009</b>	<b>2,587,009</b>	<b>2,905,009</b>	<b>8.2</b>	<b>2,597,090</b>	<b>2,597,090</b>	<b>2,915,090</b>

## Estimated Capital Budget Expenditures

Agency Name	2023-25			2025-27			2027-29		
	FTEs	Bonds	Total	FTEs	Bonds	Total	FTEs	Bonds	Total
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
<b>Total \$</b>	<b>0.0</b>	<b>0</b>	<b>0</b>	<b>0.0</b>	<b>0</b>	<b>0</b>	<b>0.0</b>	<b>0</b>	<b>0</b>

## Estimated Capital Budget Breakout

<b>Prepared by:</b> Jason Brown, OFM	<b>Phone:</b> (360) 742-7277	<b>Date Published:</b> Final 2/17/2023
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# Individual State Agency Fiscal Note

<b>Bill Number:</b> 5388 S SB	<b>Title:</b> Diversity in clinical trials	<b>Agency:</b> 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	162,000	159,000	321,000	318,000	318,000
<b>Total \$</b>	162,000	159,000	321,000	318,000	318,000

### Estimated Operating Expenditures from:

	FY 2024	FY 2025	2023-25	2025-27	2027-29
FTE Staff Years	4.9	5.0	5.0	5.0	5.0
<b>Account</b>					
General Fund-State 001-1	574,000	563,000	1,137,000	1,126,000	1,126,000
General Fund-Federal 001-2	162,000	159,000	321,000	318,000	318,000
<b>Total \$</b>	736,000	722,000	1,458,000	1,444,000	1,444,000

### 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: 02/09/2023
Agency Preparation: Molli Ragsdale	Phone: 360-902-8182	Date: 02/10/2023
Agency Approval: Dan Winkley	Phone: 360-902-8236	Date: 02/10/2023
OFM Review: Jason Brown	Phone: (360) 742-7277	Date: 02/17/2023

## 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.*

Section 3) (1) The Washington State Institutional Review Board (WSIRB) must establish a diversity in clinical trials program to encourage participation in clinical trials of drugs and medical devices by persons who are members of demographic groups that are underrepresented in clinical trials. In developing this program, the review board may:

- (a) Review the most recent version of "Collection of Race and Ethnicity Data in Clinical Trials — Guidance for Industry and Food and Drug Administration Staff";
- (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; in which the website; (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.

### 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.*

Federal cash receipts are determined by the departments Cost Allocation Plan. Types of federal earned are Title XIX Medicaid, Food Stamp, and Child Support.

### 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 bill assigns a new body of work to the Washington State Institutional Review Board (WSIRB). The administrative staff for the WSIRB are assigned to the Department of Social and Health Services (DSHS) Research and Data Analysis (RDA) section. The WSIRB and RDA have outlined a plan on how to "encourage participation in clinical trials".

In Washington State there are approximately 40-50 Institutional Review Boards (IRB) and likely over 1,000 researchers engaged in clinical research. If there is any expectation of being a resource to encourage greater diversity, then there must be a methodical approach to accomplish that. Some possibilities are listed in the bill as "may include", and we would have to explore the most effective means of providing that consultation/engagement.

Because this is a new direction for WSIRB, DSHS has determined that WSIRB/RDA will need the following staff. The expected start date for these FTEs is September 1, 2023:

One Program Manager, full-time, for the duration of the program (WMS Band 3). This position will be initiating contacts with all IRBs statewide and working to ensure their participation. In addition, this Program Manager will work with state agencies and other entities to create policies in line with the intent of the bill, to create more diversity in clinical trials.

Two Research Associates (WMS Band 1) to create outreach materials, provide training and consultation and to develop and update information on a website that is accessible to all researchers across the state. DSHS anticipates there might be travel for regional or institutional level engagement of IRB staff and researchers around the state, in order to ensure participation.

Two IT staff for technical support in order to provide a report to the legislature on the status and results of the program, DSHS must design/build an application to collect the data on the demographics of those enrolled in clinical trials statewide. DSHS anticipates a larger role for the Information Technology (IT) development in year 1 than in subsequent years and there will be a need for ongoing IT work. DSHS estimates this would require an IT Database Management Developer (Senior level) for 1 year to design, construct, test, and deploy the database needed for the project. There will also be a need for an IT Application Developer (Senior level) to design, create, test, and maintain a web-based application that will permit IRBs and/or researchers to enter the data on their clinical trials. This resource would be needed on an ongoing basis.

One Administrative Assistant - needed for travel support, data entry, coordination of meetings calls, and correspondence.

**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	574,000	563,000	1,137,000	1,126,000	1,126,000
001-2	General Fund	Federal	162,000	159,000	321,000	318,000	318,000
<b>Total \$</b>			736,000	722,000	1,458,000	1,444,000	1,444,000

**III. B - Expenditures by Object Or Purpose**

	FY 2024	FY 2025	2023-25	2025-27	2027-29
FTE Staff Years	4.9	5.0	5.0	5.0	5.0
A-Salaries and Wages	513,000	502,000	1,015,000	1,004,000	1,004,000
B-Employee Benefits	168,000	166,000	334,000	332,000	332,000
C-Professional Service Contracts					
E-Goods and Other Services	32,000	32,000	64,000	64,000	64,000
G-Travel	1,000	1,000	2,000	2,000	2,000
J-Capital Outlays					
M-Inter Agency/Fund Transfers					
N-Grants, Benefits & Client Services					
P-Debt Service	2,000	2,000	4,000	4,000	4,000
S-Interagency Reimbursements					
T-Intra-Agency Reimbursements	20,000	19,000	39,000	38,000	38,000
9-					
<b>Total \$</b>	736,000	722,000	1,458,000	1,444,000	1,444,000

**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
ADMINISTRATIVE ASSISTANT 3	51,889	0.8	1.0	0.9	1.0	1.0
IT APP DEVELOPMENT - SENIOR SPECIALIST	118,721	0.8	1.0	0.9	1.0	1.0
IT DATA MANAGEMENT - SENIO. / SPECIALIST	113,059	0.8		0.4		
WMS BAND 1	99,405	1.7	2.0	1.9	2.0	2.0
WMS BAND 3	133,019	0.8	1.0	0.9	1.0	1.0
<b>Total FTEs</b>		4.9	5.0	5.0	5.0	5.0

**III. D - Expenditures By Program (optional)**

Program	FY 2024	FY 2025	2023-25	2025-27	2027-29
Administration and Support Services - RDA (110)	736,000	722,000	1,458,000	1,444,000	1,444,000
<b>Total \$</b>	736,000	722,000	1,458,000	1,444,000	1,444,000

**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

<b>Bill Number:</b> 5388 S SB	<b>Title:</b> Diversity in clinical trials	<b>Agency:</b> 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: 02/09/2023
Agency Preparation: Sheri Spezze	Phone: (360) 236-4557	Date: 02/10/2023
Agency Approval: Kristin Bettridge	Phone: 3607911657	Date: 02/10/2023
OFM Review: Breann Boggs	Phone: (360) 485-5716	Date: 02/13/2023

## 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 substitute bill adds the requirement for state entities to provide information to trial participants in languages other than English and to provide translation services or bilingual staff for trial screening.

The Department of Health does not participate in any clinical trials, therefore there 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.*

None

### 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

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.*

None

# Individual State Agency Fiscal Note

<b>Bill Number:</b> 5388 S SB	<b>Title:</b> Diversity in clinical trials	<b>Agency:</b> 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
<b>Account</b>					
General Fund-State 001-1	685,865	669,390	1,355,255	1,338,780	1,338,780
<b>Total \$</b>	<b>685,865</b>	<b>669,390</b>	<b>1,355,255</b>	<b>1,338,780</b>	<b>1,338,780</b>

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: 02/09/2023
Agency Preparation: Charlotte Shannon	Phone: 2066858868	Date: 02/14/2023
Agency Approval: Charlotte Shannon	Phone: 2066858868	Date: 02/14/2023
OFM Review: Ramona Nabors	Phone: (360) 742-8948	Date: 02/15/2023

## 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 SUBSTITUTE BILL MAKES THE FOLLOWING CHANGES:

Section 3 (2) adds the following requirements:

- (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.

CHANGES TO FISCAL IMPACTS FROM THE SUBSTITUTE BILL:

The University of Washington (UW) assesses additional fiscal impacts related to providing information for trial participants in a language other than English, and providing translation services for trial screening. The UW has revised its fiscal impacts to include these new requirements which are reflected in the expenditures section.

Overall the Substitute Senate Bill 5388 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 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 SSB 5388 is broader and would require language translation for every clinical trial. Based on the totality of the language in SSB 5388, 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 SSB 5388 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.

SSB 5388 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 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
<b>Total \$</b>			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-					
<b>Total \$</b>	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
<b>Total FTEs</b>		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

<b>Bill Number:</b> 5388 S SB	<b>Title:</b> Diversity in clinical trials	<b>Agency:</b> 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
<b>Account</b>					
General Fund-State 001-1	43,793	48,875	92,668	122,229	132,310
<b>Total \$</b>	<b>43,793</b>	<b>48,875</b>	<b>92,668</b>	<b>122,229</b>	<b>132,310</b>

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: 02/09/2023
Agency Preparation: Chris Jones	Phone: 509-335-9682	Date: 02/13/2023
Agency Approval: Chris Jones	Phone: 509-335-9682	Date: 02/13/2023
OFM Review: Ramona Nabors	Phone: (360) 742-8948	Date: 02/15/2023

## 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.*

5388 S SB would require WSU to ensure there is diversity among the human subjects who participate in clinical trials.

The substitute version of the bill adds the following sections will have additional fiscal impact on WSU.

Section 3.(2).(b) Provide information to trial participants in languages other than English; and (c) 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.*

This fiscal impact of 5388 S SB 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
<b>Total \$</b>			<b>43,793</b>	<b>48,875</b>	<b>92,668</b>	<b>122,229</b>	<b>132,310</b>

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	0.3	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-					
<b>Total \$</b>	43,793	48,875	92,668	122,229	132,310

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
Assistant Director	102,201	0.0	0.0	0.0	0.0	0.0
Clinical Trial Coordinator	65,000	0.1	0.1	0.1	0.1	0.1
Director -DB	75,636	0.0	0.0	0.0		
Director -MK	137,101	0.0	0.0	0.0		
Grants & Contracts Manager	75,000	0.1	0.1	0.1	0.2	0.2
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	59,436	0.0	0.0	0.0	0.0	0.0
<b>Total FTEs</b>		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.*