# **Multiple Agency Fiscal Note Summary**

Bill Number: 5388 SB Title: Diversity in clinical trials

# **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<br>Social and Health<br>Services | 0        | 0           | 321,000 | 0        | 0           | 318,000 | 0        | 0           | 318,000 |
| Total \$                                       | 0        | 0           | 321,000 | 0        | 0           | 318,000 | 0        | 0           | 318,000 |

# **Estimated Operating Expenditures**

| Agency Name                                    |          | 20               | 023-25           |                |            | 2            | 025-27          |               |             |            | 2027-29     |           |
|------------------------------------------------|----------|------------------|------------------|----------------|------------|--------------|-----------------|---------------|-------------|------------|-------------|-----------|
|                                                | FTEs     | GF-State         | NGF-Outlook      | Total          | FTEs       | GF-State     | NGF-Outlook     | Total         | FTEs        | GF-State   | NGF-Outlook | Total     |
| Department of<br>Social and Health<br>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<br>Health                        | .0       | 0                | 0                | 0              | .0         | 0            | 0               | 0             | .0          | 0          | 0           | 0         |
| University of<br>Washington                    | 2.8      | 708,255          | 708,255          | 708,255        | 2.8        | 691,780      | 691,780         | 691,780       | 2.8         | 691,780    | 691,780     | 691,780   |
| University of<br>Washington                    | In addit | ion to the estin | nate above,there | e are addition | al indeter | minate costs | and/or savings. | Please see in | dividual fi | scal note. |             |           |
| Washington State<br>University                 | .3       | 92,668           | 92,668           | 92,668         | .4         | 122,229      | 122,229         | 122,229       | .4          | 132,310    | 132,310     | 132,310   |
| Total \$                                       | 8.1      | 1,937,923        | 1,937,923        | 2,258,923      | 8.2        | 1,940,009    | 1,940,009       | 2,258,009     | 8.2         | 1,950,090  | 1,950,090   | 2,268,090 |

# **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<br>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<br>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**

| Prepared by: Jason Brown, OFM | Phone:         | Date Published: |
|-------------------------------|----------------|-----------------|
|                               | (360) 742-7277 | Final 2/6/2023  |

| Bill Number: | 5388 SB | Title: | Diversity in clinical trials | Agency: | 300-Department of Social and<br>Health Services |
|--------------|---------|--------|------------------------------|---------|-------------------------------------------------|
|              |         |        |                              |         | Ticaltii Scivices                               |

# **Part I: Estimates**

| П | 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 |
|                            | Total \$ | 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       |
| Account                  |          |         |         |           |           |           |
| 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   |
|                          | Total \$ | 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:

| X | 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: 01/23/2023 |
|----------------------|----------------|-----------------------|------------------|
| Agency Preparation:  | Molli Ragsdale | Phone: 360-902-8182   | Date: 02/06/2023 |
| Agency Approval:     | Dan Winkley    | Phone: 360-902-8236   | Date: 02/06/2023 |
| OFM Review:          | Jason Brown    | Phone: (360) 742-7277 | Date: 02/06/2023 |

### 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   |
|         |               | Total \$ | 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-                                   |         |         |           |           |           |
| Total \$                             | 736,000 | 722,000 | 1,458,000 | 1,444,000 | 1,444,000 |

Bill # 5388 SB

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 | 118,721 | 0.8     | 1.0     | 0.9     | 1.0     | 1.0     |
| SPECIALIST                  |         |         |         |         |         |         |
| IT DATA MANAGEMENT - SENIO  | 113,059 | 0.8     |         | 0.4     |         |         |
| / SPECIALIST                |         |         |         |         |         |         |
| 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     |
| Total FTEs                  |         | 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 | 736,000 | 722,000 | 1,458,000 | 1,444,000 | 1,444,000 |
| (110)                                     |         |         |           |           |           |
| Total \$                                  | 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.

| Bill Number: 5388 SB               | Title: Diversity in clinica                                           | l trials                             | Agency: 303-Department of Health            |
|------------------------------------|-----------------------------------------------------------------------|--------------------------------------|---------------------------------------------|
| Part I: Estimates                  | •                                                                     |                                      |                                             |
| X No Fiscal Impact                 |                                                                       |                                      |                                             |
| Estimated Cash Receipts to:        |                                                                       |                                      |                                             |
| NONE                               |                                                                       |                                      |                                             |
| Estimated Operating Expend<br>NONE | litures from:                                                         |                                      |                                             |
| Estimated Capital Budget Im        | pact:                                                                 |                                      |                                             |
| NONE                               |                                                                       |                                      |                                             |
|                                    |                                                                       |                                      |                                             |
|                                    |                                                                       |                                      |                                             |
|                                    |                                                                       |                                      |                                             |
|                                    |                                                                       |                                      |                                             |
|                                    |                                                                       |                                      |                                             |
|                                    |                                                                       |                                      |                                             |
|                                    |                                                                       |                                      |                                             |
|                                    |                                                                       |                                      |                                             |
|                                    |                                                                       |                                      |                                             |
|                                    |                                                                       | e most likely fiscal impact. Factors | impacting the precision of these estimates, |
|                                    | priate), are explained in Part II. follow corresponding instructions: |                                      |                                             |
|                                    |                                                                       | current biennium or in subsequ       | ent biennia, complete entire fiscal note    |
|                                    | nan \$50,000 per fiscal year in the cu                                | rrent biennium or in subsequent      | biennia, complete this page only (Part I)   |
|                                    |                                                                       | irent of misassequent                | ordinia, complete this page only (1 art 1)  |
| Capital budget impact, o           | -                                                                     |                                      |                                             |
| X Requires new rule maki           | ng, complete Part V.                                                  |                                      |                                             |
| Legislative Contact: Kev           | in Black                                                              | Phone: (360) 7                       | 786-7747 Date: 01/23/2023                   |
| Agency Preparation: She            | ri Spezze                                                             | Phone: (360) 2                       | 236-4557 Date: 01/26/2023                   |
| Agency Approval: Kris              | stin Bettridge                                                        | Phone: 360791                        | Date: 01/26/2023                            |
| OFM Review: Brea                   | ann Boggs                                                             | Phone: (360) 4                       | 85-5716 Date: 01/29/2023                    |

### 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 department of Health does not participate in any clinical trials, therefore 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** 

# 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

| <b>Bill Number:</b> 5388 SB          | Title: Diversity in clinica                                                                                   | l trials                 | Age                 | ncy: 360-Universi      | ty of Washington  |
|--------------------------------------|---------------------------------------------------------------------------------------------------------------|--------------------------|---------------------|------------------------|-------------------|
| Part I: Estimates                    | •                                                                                                             |                          | •                   |                        |                   |
| No Fiscal Impact                     |                                                                                                               |                          |                     |                        |                   |
| Estimated Cash Receipts to:          |                                                                                                               |                          |                     |                        |                   |
| NONE                                 |                                                                                                               |                          |                     |                        |                   |
| <b>Estimated Operating Expenditu</b> | ares 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-              | 362,365                                                                                                       | 345,890                  | 708,255             | 691,780                | 691,780           |
|                                      | <b>Total \$</b> 362,365                                                                                       | 345,890                  | 708,255             | 691,780                | 691,780           |
| In addition to the estim             | ates above, there are additional in                                                                           | ndeterminate costs       | and/or savings. Plo | ease see discussion    |                   |
| NONE                                 |                                                                                                               |                          |                     |                        |                   |
| and alternate ranges (if approprie   | e estimates on this page represent the<br>ate), are explained in Part II.<br>llow corresponding instructions: | e most likely fiscal imp | pact. Factors impac | cting the precision of | these estimates,  |
|                                      | an \$50,000 per fiscal year in the                                                                            | current biennium o       | or in subsequent bi | ennia, complete ent    | tire fiscal note  |
| If fiscal impact is less than        | \$50,000 per fiscal year in the cur                                                                           | rrent biennium or i      | n subsequent bieni  | nia, complete this p   | age only (Part I) |
| Capital budget impact, con           | nplete Part IV.                                                                                               |                          |                     |                        |                   |
| Requires new rule making,            | complete Part V.                                                                                              |                          |                     |                        |                   |
| Legislative Contact: Kevin           | Black                                                                                                         | Pł                       | none: (360) 786-77  | 747 Date: 01/          | 23/2023           |
| Agency Preparation: Charlot          | tte Shannon                                                                                                   | Pł                       | none: 2066858868    | Date: 01/              | '27/2023          |
| <u> </u>                             | tte Shannon                                                                                                   |                          | none: 2066858868    |                        |                   |
| OFM Review: Ramon                    | a Nabors                                                                                                      | Pł                       | none: (360) 742-89  | 948 Date: 02/          | 02/2023           |

# 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.

Senate Bill 5388 seeks to improve diversity in clinical trials. 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 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.

# 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, 24.1% benefits rate, Admin Support salary: \$125,000, 31.8% benefits rate).

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 indeterminate at this time, we are not including them in the budget tables.

# 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    | 362,365 | 345,890 | 708,255 | 691,780 | 691,780 |
|         |               | Total \$ | 362,365 | 345,890 | 708,255 | 691,780 | 691,780 |

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     |         |         |         |         |         |
| 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 \$                             | 362,365 | 345,890 | 708,255 | 691,780 | 691,780 |

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 | 85,000  | 1.0     | 1.0     | 1.0     | 1.0     | 1.0     |
| Coordinator                   |         |         |         |         |         |         |
| 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.

| Bill Number: 5388 SB                                                     | Title: Diversity in clinic        | al trials                | Ag                  | ency: 365-Washing<br>University | gton State       |
|--------------------------------------------------------------------------|-----------------------------------|--------------------------|---------------------|---------------------------------|------------------|
| Part I: Estimates                                                        |                                   |                          | •                   |                                 |                  |
| No Fiscal Impact                                                         |                                   |                          |                     |                                 |                  |
| Estimated Cash Receipts to:                                              |                                   |                          |                     |                                 |                  |
| NONE                                                                     |                                   |                          |                     |                                 |                  |
|                                                                          | c.                                |                          |                     |                                 |                  |
| Estimated Operating Expenditur                                           | es from: FY 2024                  | FY 2025                  | 2023-25             | 2025-27                         | 2027-29          |
| FTE Staff Years                                                          | 0.3                               | 0.3                      | 0.3                 | 0.4                             | 0                |
| Account                                                                  | 0.0                               | 0.0                      | 0.0                 | 0.1                             |                  |
| General Fund-State 001-1                                                 | 43,793                            | 48,875                   | 92,668              | 122,229                         | 132,3            |
|                                                                          | <b>Total \$</b> 43,793            | 48,875                   | 92,668              | 122,229                         | 132,3            |
| The cash receipts and expenditure e and alternate ranges (if appropriate |                                   | ne most likely fiscal in | npact. Factors impo | acting the precision of         | these estimates, |
| Check applicable boxes and follo                                         | w corresponding instructions:     |                          |                     |                                 |                  |
| If fiscal impact is greater than form Parts I-V.                         | n \$50,000 per fiscal year in the | e current biennium       | or in subsequent b  | iennia, complete en             | tire fiscal note |
| X If fiscal impact is less than \$                                       | 50,000 per fiscal year in the cu  | urrent biennium or       | in subsequent bier  | nnia, complete this p           | page only (Par   |
| Capital budget impact, comp                                              | lete Part IV.                     |                          |                     |                                 |                  |
| Requires new rule making, c                                              | omplete Part V.                   |                          |                     |                                 |                  |
| Legislative Contact: Kevin Bl                                            | lack                              | F                        | Phone: (360) 786-7  | 7747 Date: 01/                  | /23/2023         |
| Agency Preparation: Brittney                                             | Gamez                             | F                        | Phone: 509-335-54   | 06 Date: 01                     | /27/2023         |
| Agency Approval: Chris Jor                                               | ies                               | F                        | Phone: 509-335-96   | 582 Date: 01                    | /27/2023         |
| OFM Review: Ramona                                                       | Nabors                            | F                        | Phone: (360) 742-8  | 3948 Date: 02                   | /02/2023         |

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

### 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 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 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.

# 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         | 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     |
| 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.