

**SAN JOSE STATE UNIVERSITY ACADEMIC SENATE**

**2017/2018**

**Agenda**

**October 23, 2:00 pm – 5:00 pm**

**Engineering 285/287**

- I. Call to Order and Roll Call –**
- II. Approval of Minutes:**  
Senate Minutes of October 9, 2017
- III. Communications and Questions:**
  - A. From the Chair of the Senate
  - B. From the President of the University
- IV. Executive Committee Report:**
  - A. Minutes of the Executive Committee
    - Executive Committee Minutes of September 11, 2017
    - Executive Committee Minutes of September 25, 2017
    - Executive Committee Minutes of October 2, 2017
  - B. Consent Calendar –
  - C. Executive Committee Action Items –
    - AS 1663, Sense of the Senate Resolution, On the Timelines and Content of Executive Orders 1100 and 1110 (Final Reading)***
- V. Unfinished Business: None**
- VI. Policy Committee and University Library Board Action Items (In rotation)**
  - A. Organization and Government Committee (O&G):
    - AS 1667, Sense of the Senate Resolution, Faculty Trustee Report for Academic Senate (Final Reading)***
    - AS 1669, Policy Recommendation, Amendment to Senate Constitution Regarding Administrative Representatives (First Reading)***
    - AS 1656, Policy Recommendation, Modification to Bylaw 1.10 Pertaining to Academic Deans (First Reading)***
    - AS 1668, Policy Recommendation, Rescind S88-7, Conditional Admissions (Final Reading)***
  - B. University Library Board (ULB):
  - C. Curriculum and Research Committee (C&R):
    - AS 1664, Sense of the Senate Resolution, Guidance on Implementation of EO 1064 Student Internships, Service Learning, and Off-Campus Learning Experiences (Final Reading)***
    - AS 1665, Policy Recommendation, Rescinds S08-7 - Policy for Protection of Human Research Subjects (First Reading)***
  - D. Instruction and Student Affairs Committee (I&SA):

- E. Professional Standards Committee (PS):  
***AS 1666, Policy Recommendation, Amendment F to S15-7,  
Retention, Tenure and Promotion for Regular Faculty Employees  
(First Reading)***

**VII. State of the University Announcements:**

- A. Statewide Academic Senators
- B. AS President
- C. Provost
- D. Vice President for Administration and Finance
- E. Vice President for Student Affairs
- F. Chief Diversity Officer

**VIII. Special Committee Reports:**

**IX. New Business:**

**X. Adjournment:**

**2017/2018 Academic Senate**

**MINUTES  
October 9, 2017**

**I. The meeting was called to order at 2:00 p.m. and roll call was taken by the Senate Administrator. Forty-five Senators were present.**

**Ex Officio:**

Present: Frazier, Van Selst, Manzo,  
Lee, J.

**CASA Representatives:**

Present: Schultz-Krohn, Shifflett, Grosvenor, Chin  
Absent: Sen

**Administrative Representatives:**

Present: Feinstein, Faas,  
Wong(Lau), Willey  
Absent: Papazian

**COB Representatives:**

Present: Rodan, Bullen, He  
Absent: None

**Deans:**

Present: Jacobs, Elliott, Stacks  
Absent: None

**EDUC Representatives:**

Present: Marachi, Mathur  
Absent: None

**Students:**

Present: De Guzman, Gill, Hospidales,  
Tran, Busick, Donahue  
Absent: None

**ENGR Representatives:**

Present: Chung, Sullivan-Green  
Absent: Hamed-Hagh

**Alumni Representative:**

Present: Walters

**H&A Representatives:**

Present: Ormsbee, Khan, Riley, Bacich, McKee  
Absent: None

**Emeritus Representative:**

Present: Buzanski

**SCI Representatives:**

Present: White, Kim, Rangasayee  
Absent: Cargill

**Honorary Representative:**

Absent: Lessow-Hurley

**SOS Representatives:**

Present: Peter, Wilson, Curry, Liu  
Absent: Hart

**General Unit Representatives:**

Present: Trousdale, Higgins,  
Kauppila  
Absent: Matoush

**II. Approval of Academic Senate Minutes–**

The minutes of September 18, 2017 were approved with no objection.

**III. Communications and Questions –**

**A. From the Chair of the Senate:**

Chair Frazier welcomed Senators and announced this was a special Senate meeting devoted solely to budget presentations.

Chair Frazier announced that the fires in Sonoma had caused mass evacuations and that our former Dean of the College of Humanities and the Arts, Lisa Vollendorf, who is now Provost at Sonoma State University, had been evacuated from her home. However, the President of Sonoma State University, Judy Sakaki, lost her home in the fire.

Chair Frazier congratulated former Senator Romey Sabalius on being appointed the Faculty Trustee. Professor Sabalius thanked the President, Provost, and Senators for all their support. Senator Buzanski asked Professor Sabalius if he would be willing to come to the Senate meetings and give the Senate information about issues before the Board of Trustees? Senator Shifflett announced that the Organization and Government Committee would be bringing a resolution to address this at the next Senate meeting.

**B. From the President of the University – Not present.**

**IV. State of the University Announcements. Questions. In rotation.**

**A. Chief Diversity Officer (CDO) – No report.**

**B. Provost: No report.**

**C. Vice President of Finance and Administration (VPAF): No report.**

**D. CSU Statewide Senators – No report.**

**E. Associated Students President (AS) – No report.**

**V.**

**Executive Committee Report:**

**A. Minutes of the Executive Committee:** No minutes for review.

**B. Consent Calendar:**

There was no dissent to the consent calendar of October 9, 2017.

**C. Executive Committee Action Items:**

**VI. Policy Committee and University Library Board Action Items. In rotation.**

**A. Curriculum and Research Committee (C&R) – No report.**

**B. University Library Board (ULB) – No report.**

**C. Organization and Government Committee (O&G) – No report.**

**D. Instruction and Student Affairs Committee (I&SA) – No report.**

**E. Professional Standards Committee (PS) – No report.**

**VII. Special Committee Reports –**

Vice President for Administration and Finance, Charlie Faas, gave a presentation on the state of the university budget for 2017-2018. (See PowerPoint slides attached.)

## Questions:

Q: How much of the IT Operating Fund expenditure is for hardware versus software?

A: It might be worthwhile for Bob Lim to come in and talk to the Senate about what his vision is. Part of Bob's increase this year was to fund the new Peoplesoft initiatives.

Q: Over the summer the restroom in the Engineering Building was redone. However, nothing was done to the restrooms in the old building. What method was used to determine what restrooms got updated? For the past year, one or the other stalls has been out of order in the bathroom in the old building on the first floor.

A: It will be taken care of now.

Q: Is there discussion in University Advancement about tracking donor behavior at SJSU, such as in finding out if there is a drain of donations from other areas on campus in order to fund athletic renovations?

A: The main donor we had on South campus this year donated close to \$10 million. They weren't given a dime from the university, so there is no redirection of their money to anywhere else. About ½ a billion dollars in construction efforts is going on right now on campus compared to a few million going in construction at South Campus.

Q: Many years ago lottery funds were allocated largely by a committee. Over the last decade or so, all the lottery funds have gone to the library. My concern is whether these funds are being used to replace regular funding for the library. The Lottery Act states that the net revenue of the lottery funds shall not be used as substantive funds but shall supplement the total amount of money allocated, and no program shall have the amount appropriated to support that program reduced as a result of funds allocated. If these funds are being used to support our acquisitions budget, what's left of the acquisitions budget other than lottery funds? Have we reduced the library's acquisitions budget as a result of having the lottery funds, and if we've done that, wouldn't we be vulnerable to some kind of audit about how we are using these lottery funds?

A: VP Faas will look into this and get back to the Senate with an answer.

Q: This relates to slide number 4. We receive an alert almost every single day about some crime being committed. For instance, this morning when walking to my office on campus I almost got hit by someone on a skateboard, then a bicycle, and then by a car. I'm hoping we have some budget for police to patrol, especially at night, to increase security? Also, a nice job was done on the S2 locks, but are they going to be finished soon?

A: I want our police staff to be way more visible than they are. Skateboarders are hard to control. We spent a lot of time redoing the Chavez arch and every morning when I come in I see skateboard and bike marks on it. It's a shame.

Q: Can you talk about the upcoming capital campaign and where would that money go?

A: What I've asked the VP of University Advancement to do is to come talk about the plan and where it goes to, how long it takes to collect it, how it gets distributed, how

much we are looking to raise, what levels do you spend, and what the plans are for those funds.

Q: Where is the increased tuition money being directed?

A: In general, it goes to those four categories I talked about for student success, and they include safety, capital improvements, etc. It's not anything in particular. It is everything in general.

Q: On the 16<sup>th</sup> sheet of the budget report you have a comparison of the large campuses. I find this very helpful in terms of where we compare with other campuses in terms of expenditures. There is one thing that stands out and that is our student financial aid and that is very low compared to the other campuses. Is that just a reflection of the socioeconomic standing of our students, or are our students not applying for financial aid as much as they should?

A: Good question. The Provost and VP of Administration and Finance will look into this.

Q: Where are many of the resource centers and where does their funding come from?

A: For many of our resource centers, most of the funding is going to come from Student Affairs for staffing. We added a number of resource centers this year and we still have the DACA area that is coming online. Provost Feinstein announced he contributed to several of the resource centers last year as part of his student success efforts.

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Dr. Bradley Olin, Interim AVP of Academic Budgets and Planning, gave a presentation on the Academic Affairs Budget for AY 2017-2018. (See PowerPoint slides attached.)

### **Questions:**

Q: On last year's spending down college reserves, line 24, some items there look to be ongoing costs and not one-time costs. If it is spending down money, how do you sustain the ongoing costs?

A: A lot of these can be treated as one-time expenses. AVP Olin agrees some of these should be ongoing expenses in principle, but to some extent the colleges do have some control over the financial levers and to the extent there are ever salary savings in the vacant positions or ongoing recruitment, this is what generates surplus at the end of the year.

Q: A few years ago there was no report from Academic Affairs and we requested that a report be given and this has been wonderful. Thank you. A few years ago we asked that something be done about tenure density and only recently has something being done about tenure density. We complained there wasn't anything being done about bottleneck courses and only recently has anything been done about bottleneck courses. Then we complained that there wasn't any money for Research, Scholarship, and Creative Activity (RSCA) and only recently have funds been allocated for RSCA. The Senate should applaud our leadership for granting these requests that have been made for years and

have only recently been fulfilled. Now if we could look at the marginal cost of instruction by college, I'm representing the COSS. There was a time that faculty-student ratios were used to allocate funds to colleges. At that time COSS was tied with COB, but now we are at the bottom of the barrel. What do we need to do to crawl out of our hole so that we are not so far behind the other colleges in the amount of resources for our students? Wouldn't it be in the best interest of the university to admit many more COSS majors, since each one of them brings far more resources than they are costing us?

A: In terms of raising the marginal cost of instruction, three things come to mind. One is that the more that you concentrate the classroom density, the more your marginal cost of instruction goes up. The same would be said about increasing faculty salaries. During the RTP process as faculty salaries are increased, certainly through the collective bargaining process as well, general salary increases, those all have an impact on the marginal cost of instruction. Then any increases in assigned time also have an impact. The way we calculate it, assigned time is actually part of the cost of instruction and adds to that cost. These levels are at your disposal.

Q: Is there a chance that the COSS is being punished for being very, very efficient in 2012?

A: To go back to that remember that no college pierced the ceiling of what we call the marginal cost of instruction. The 2012-2013 actuals are what established that baseline. Since that time everyone has pretty much fell below that mark. However, I don't think the COSS is at the bottom of the barrel any longer, but I don't have the information with me.

A: If you recall back in 2012-2013 and 2013-2014, first there was a drop in resources in 2012-2013, and then a restoration of those resources in 2013-2014. What we have basically done is as the absorption of the base funding back to the colleges occurred, colleges have not actually spent all of the money that they are requiring. Also, we retired 180 faculty members over the last three years. We have not actually reached that ceiling where we are spending more than we've allocated.

Q: What is the number of actual tenured faculty we have at the university?

A: It is close to 700 tenure/tenure-track and 1,200 lecturers.

Q: Of those 700 tenure/tenure-track, about how many of those actually do have tenure?

A: We will do some research and report back to the Senate.

Q: In terms of figuring out the ratio, you mentioned 1,200 lecturers and are they full-time?

A: They are all across the board. The FTEF of the lecturers is equivalent to the FTEF of the tenure/tenure-track faculty. There is about 680 FTEF for lecturers.

Q: Over a four-year period you have the same proportion for everyone and that seems like an impossibility.

A: I wouldn't say impossible. We have experienced some changes, but we certainly are back at our original state except for our international numbers. Also, this is just the Frosh. We have had tremendous growth at the graduate level with international students, just not at the undergraduate level. About 11% of our students are graduate students.

Q: In slide 11, advising is at 3.7 million, but if you look at number two and three together that is about 1.4, so I'm curious if you can explain this huge difference and if you think of advising as being the main problem in access to classes? Why is advising so much more than restructuring and tutoring?

A: The four pillars are not necessarily exclusive of each other. I think advising had a deeper hole to climb out of than some of these other initiatives. When we talk about hiring 50 advisors over a number of years those costs, including salary and benefits, those are not going to be taken lightly. Advising was clearly identified as a way to improve student success outcomes, but that is not to say it is at the expense of other things. However, you can only throw so much money at Math or English restructuring at one time to change the course of it.

Q: What does our net gain of tenure/tenure-track faculty look like?

A: Our average net faculty gain per year over the last three years has been 20. We hire 50 faculty members a year, but the net increase is only 20.

Q: What are the outcomes of advising?

A: We are working on a final draft of that right now.

Q: As far as the library acquisitions, some things are beyond our control as part of the CSU and others are not. The library didn't add any resources this year, but saw a 5% increase in cost. Trying to keep up with that is difficult. The library is trying to look for more stable funding. Also, the Provost is working on a new model for the library to allow for flexibility when their FTES increases. The problem is the way the vendors bundle the resources. It really is more about the copyright and not the cost of the materials.

Q: We invested a lot of advisors and that took care of students being able to get an advising appointment, but do you know how much was spent on the quality of the advising versus the quantity of advisors? It is one thing to have an advising appointment, but what money is being spent on training the advisors?

A: Yes, we make sure our advisors have the training they need, and also that their caseloads are manageable. In partnership with Student Affairs, Academic Affairs is not only hiring new advisors, but also purchasing a whole suite of new technological tools to assist students to help themselves.

Q: Years ago, there was only the School of Humanities and the Arts. The Provost, at the time, divided the College of Humanities and the Arts into Humanities and the Arts and Social Sciences. The idea was to divide them equally. It turned out it was just about equal except for the History Department and the department had to make a choice where they wanted to go. Unfortunately, History made the wrong choice. I'm just wondering how much better off the History Department would be today if we had made a different choice?

A: [laughter]



Q: I think it is great we are tracking advisors, but I've received complaints from students that say that the advisors are not very welcoming, and that the students feel that the advisors feel it is a burden to help them.

A: We want to know about that. That is unacceptable.

Q: We give faculty ratings on classes, is there something along those lines we could give to the advisors?

A: There should be some way to provide evaluation of advisors. We don't want students to feel this way. The Provost will address this.

**VIII. New Business – None**

**IX. Adjournment – The meeting adjourned at 4:02 p.m.**

# 2017/18 Annual Budget Report



## SPARTANS

SAN JOSÉ STATE UNIVERSITY

Charlie Faas

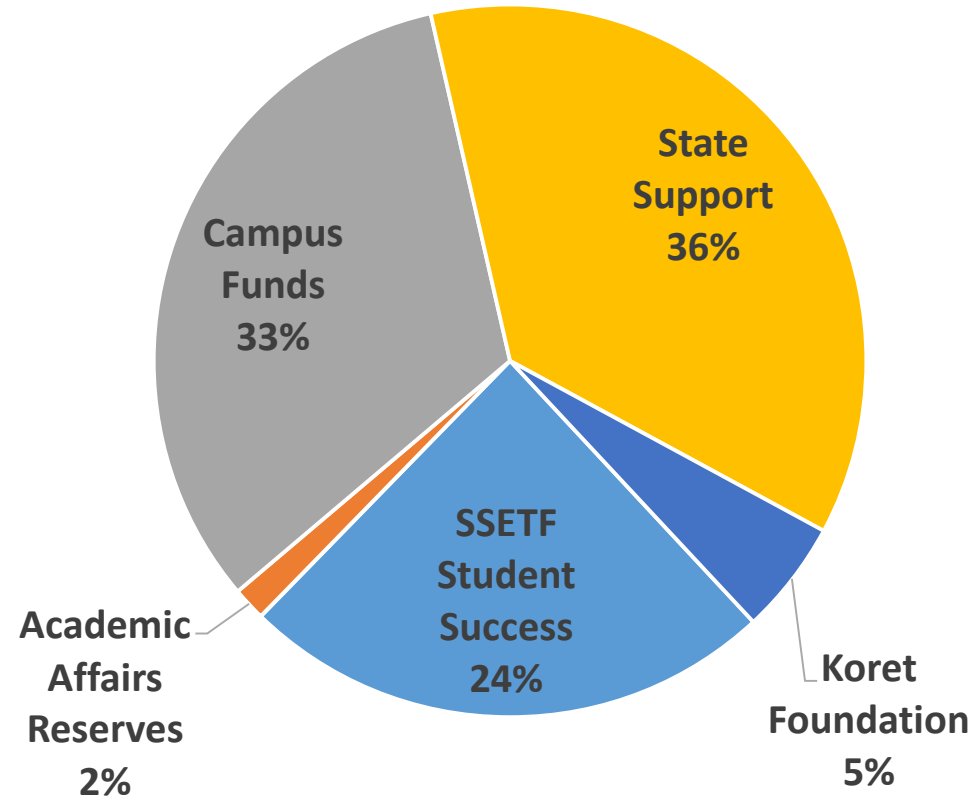
VP Administration & Finance/CFO

- Increase in tuition and General Fund appropriation
  - Tuition rate increase (\$270, 4.9% increase)
  - +240 funded FTES
- CSU Budget Adjustments \$20M
  - Funded enrollment growth \$2.6M
  - GI 2025 \$3.5M
  - Student Aid \$2.2M
  - Mandatory Costs, Compensation, & Benefits \$12.0M
- Operating base budget \$357M
  - +\$22M over FY1617 budget of \$335M
- SJSU Total Operating Budget \$625M
  - +\$25M over FY1617 budget of \$601M
- Internal budget process: base vs. one-time, three-year outlook

## ■ Graduation Initiative 2025 - \$10.8M

- Advising (\$5M)
- Clearing Bottlenecks (\$2M)
- College Readiness (\$2M)
- Student Engagement (\$1M)

GI 2025 Support Sources  
2015/16 -2017/18 (\$25M)



- **Campus Safety and Security Enhancements**
  - University Police Department staffing and operations (\$913K)
  - MLK Library atrium project (\$1.5M)
  - Housing fire life safety projects (\$4.5M)
  - Parking cameras (\$310K)
  - Classroom clocks (\$600K)

- **Planning and Economic Development**
  - New Interdisciplinary Science and Innovation Building (\$1.5M)
  - Space management and planning (\$400K)
  - Campaign staffing and operations (\$600K)
  - Hammer Theatre (\$1.35M)
  - Welcome Center (\$145K)

- **Continually Funding Deferred Maintenance and Capital Improvements**
  - Continued focus on aging infrastructure (\$2.3M)
    - DMH
    - HGH restrooms (\$150K)
    - Concrete repairs (\$760K)
  - Engineering Building Restroom, Elevator (\$1.1M)
  - Fire alarm upgrades (\$600K)

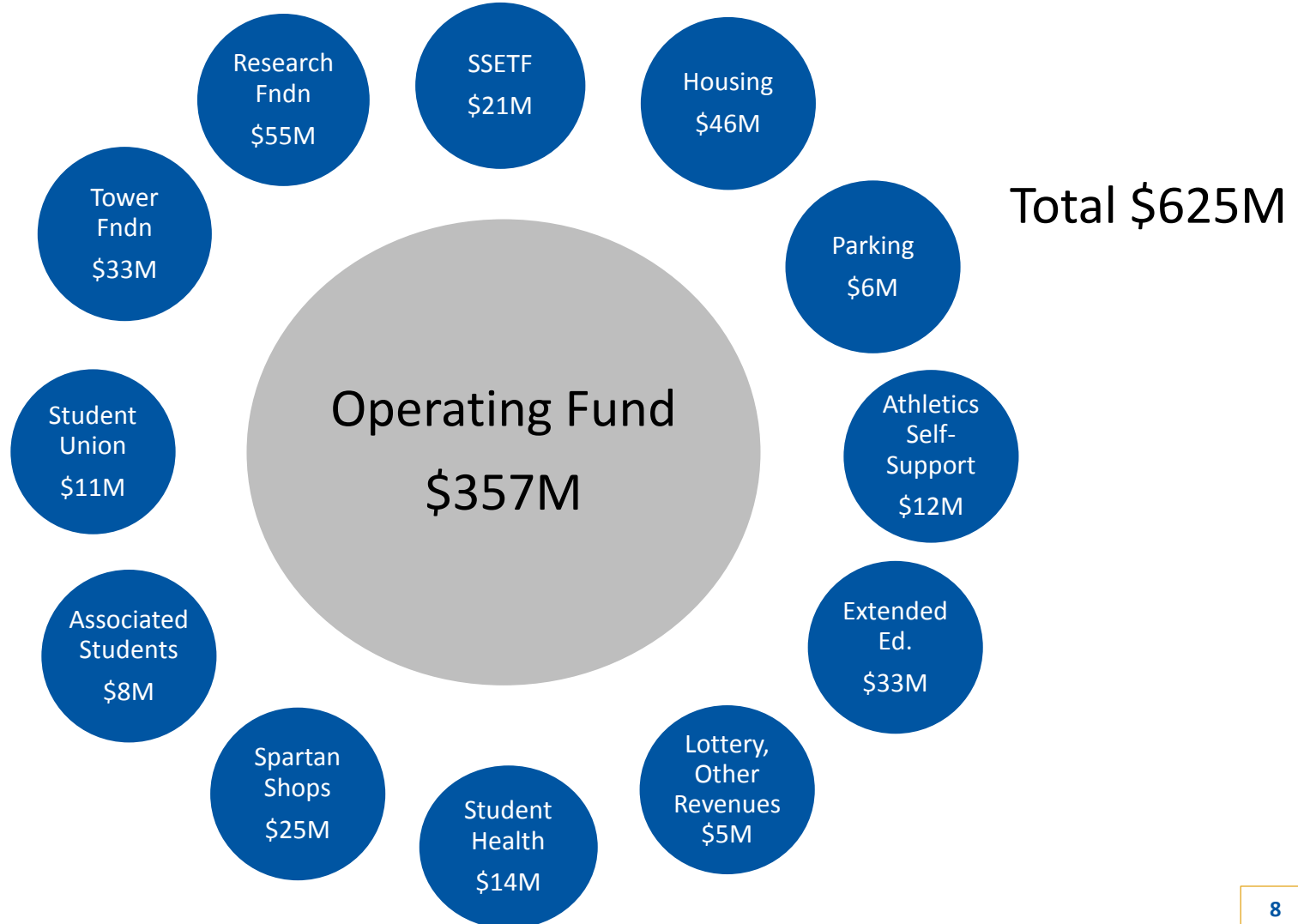
- **Externally Funded Projects**

- CIES Space in Student Union
  - Non General Fund
- Spartan Golf Complex
  - Donor funded
- South Campus Plan: Softball, Tennis Complex, Track and Field
  - Donor / Student Union funded

- **Ongoing Major Capital Projects**

- Student Recreation & Aquatic Center (\$132M)
  - Student Union fees
- Interdisciplinary Science and Innovation Building (\$148M)
  - CSU funded with campus contribution required





# Operating Fund Expenditures by Division

## FY17/18 Budget

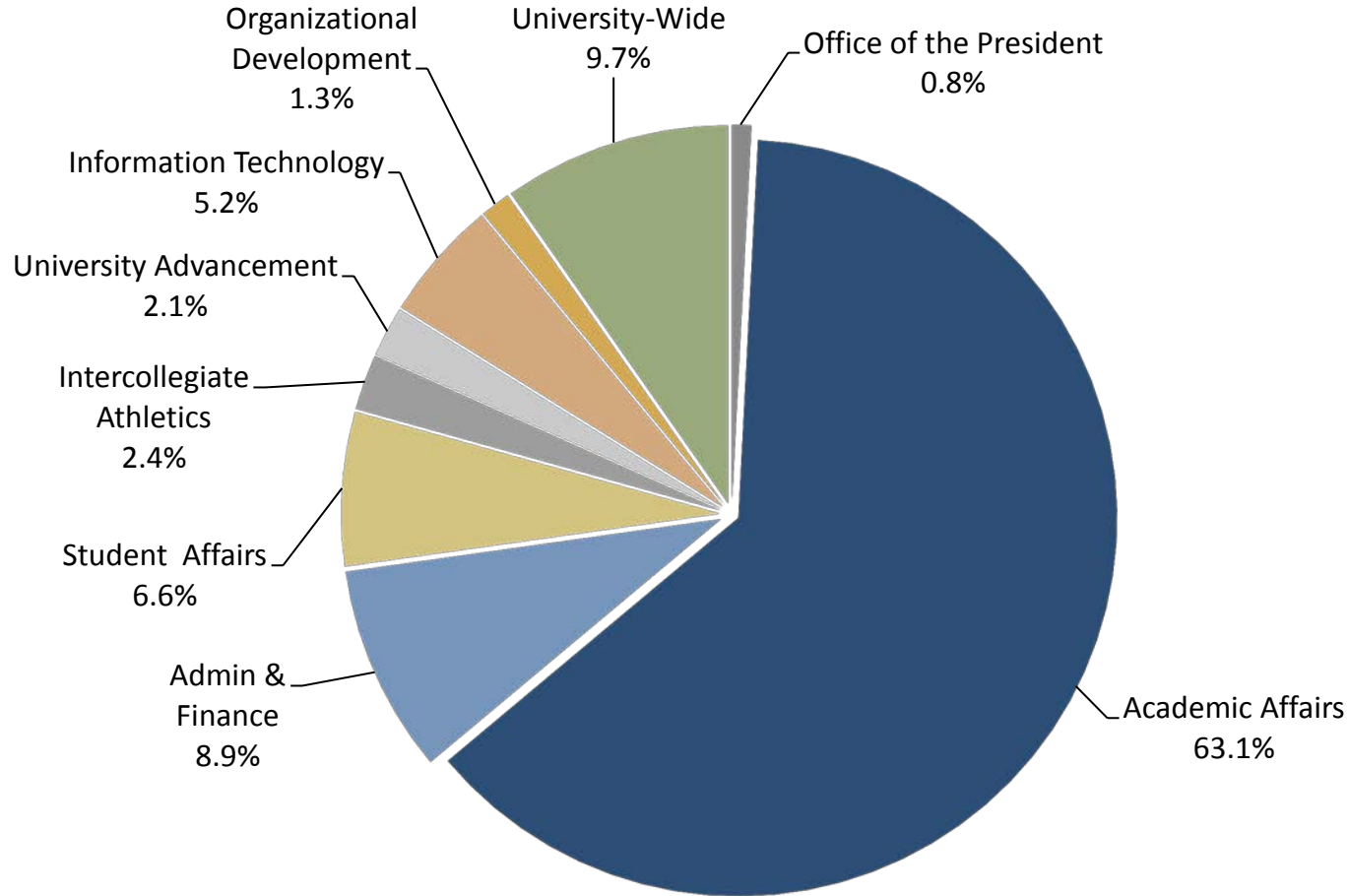
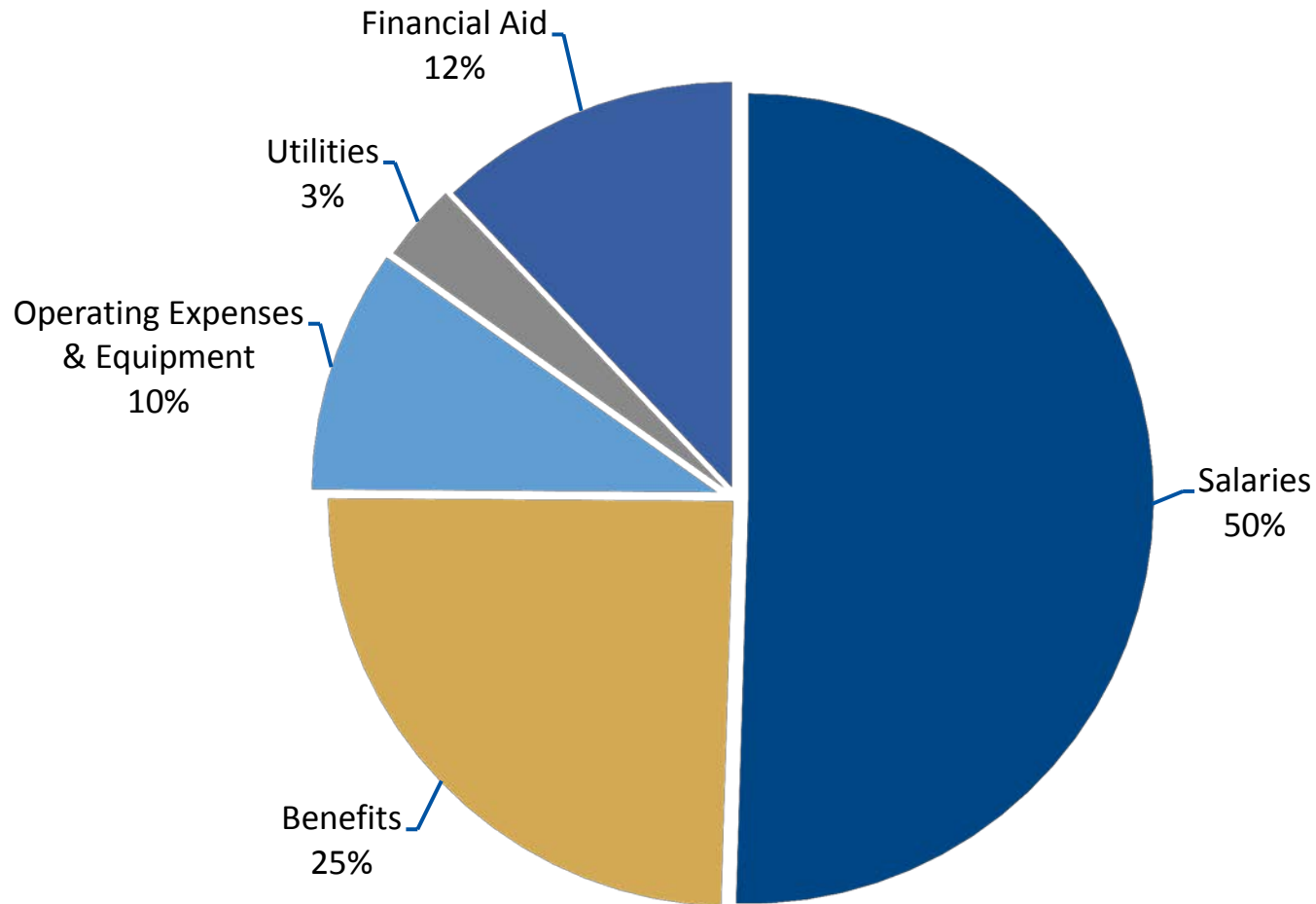


Chart above displays the breakdown of the Operating Fund Base expenditure budget. Budget excludes Restricted Student Aid (primarily a U-Wide tuition discount). Consistent with FY16/17 chart, the benefits are distributed across Divisions. Intercollegiate Athletics does not include one-time funding as reported last year. More details are available in the Annual Budget Report (p. 8).





For more information, visit:

[http://www.sjsu.edu/finance/about\\_us/budget/budget\\_reports/](http://www.sjsu.edu/finance/about_us/budget/budget_reports/)

[http://www.sjsu.edu/adminfinance/about/budget\\_central/](http://www.sjsu.edu/adminfinance/about/budget_central/)

<http://www.sjsu.opengov.com>

**SAN JOSÉ STATE UNIVERSITY** *powering* **SILICON VALLEY**





# Appendix



# SPARTANS

SAN JOSÉ STATE UNIVERSITY



## ■ Revenue Sources

- Operating Funds, SSETF-IRA, Ticket sales, conference distribution, game guarantees, NCAA distribution and development

## ■ Functions

- Supports operating and travel costs for all sports
- Grants in Aid for student-athletes

## ■ Highlights / Accomplishments

- Spartan Golf Complex facility on South Campus
- Establish on the University's tradition of academic & athletic excellence
- Recruit and retain top athletes by providing financial incentives through scholarship

## Revenue Sources

- Student Health & Health Facility Fees
- Fee-for-service

## Functions

- Support and provide student health & mental health services
- Promote health and well-being of student community

## Highlights / Accomplishments

- Student Health & Wellness Center
- Increased Counseling & Preventative Health support



## Revenue Sources

- Housing Rent and Fees
- Other Lodging and Conference Fees
- Rent for Dining Commons and Village Market

## Functions

- Support housing operations & programs

## Highlights / Accomplishments

- Over 4,000 residents
- Campus Village II opened in Fall 2016
- Renovations in Washburn Hall, Joe West Hall
- Housing Feasibility Study to be initiated in Fall 2017

## Revenue Sources

- Parking permit sales and parking citation fines

## Functions

- Parking operations and enforcement costs
- Maintenance and repair to existing facilities
- Alternative transportation program

## Highlights / Accomplishments

- Parking garage cameras, security improvements underway
- Parking permits available online
- Provide Park & ride courtesy shuttle
- Updated bus fleet (2 buses in FY16/17, 1 expected FY17/18)

## Revenue Sources

- Tuition and fees from for-credit & noncredit programs

## Functions

- Extended ed. operations and program/curriculum development

## Highlights / Accomplishments

- New Programs: Master of Criminology with Concentration in Global Criminology, Masters in Nursing with Concentration in Family Nurse Practitioner, among others.
- New CIES space in the Student Union - Summer 2017
- Partnership with College of Science to build out part of new Interdisciplinary Science and Innovation Building



## Revenue Sources

- Student Success, Excellence & Technology Fee
- Expenditures reviewed by CFAC & Approved by President

## Functions

- Instructionally Related Activities
- Course Support
- Student Success

## Supported Initiatives

- Spartan Scholars Program
- SASS Programs (Task Forces)
- Academic Technology Improvements

## Revenue Sources

- Fees, program revenues, grants and contracts
- Fee changes must be approved by student referendum

## Student fees support AS programs

- Student Leadership and governance
- Child Care Center
- Campus Life
- Transportation

## Revenue Sources

- Federal and state grants and contracts, fees, investment income, and other revenues

## Restrictions

- Most funding tied to grants or specific programs

## Highlights / Accomplishments

- The Research Foundation also provides employment support to more than 1,800 individuals, including faculty, students, research affiliates, and staff.
- Program sites are located on the SJSU main campus, Moss Landing Marine Laboratories, NASA-Ames Moffett Field, and several other locations.



## Revenue Sources

- Dining, event, retail, and real estate services, commissions, interest and other income

## Division Functions

- Writing Request for Proposal to outsource operations
- Retail Services operates the Barnes & Noble Bookstore; the current contract extends through June 30, 2026
- Event Services division provides concessions and retail to Event Center Arena, Hammer Theatre, and Spartan Stadium
- Real Estate Services to SJSU faculty and staff

### Revenue Sources

- Mandatory Student Union Fee

### Functions

- Supports Student Union Operations
- Capital Construction (SU Expansion & New SRAC)

### Highlights / Accomplishments

- Student Union Spaces booked for entire year
- Construction progress on the new Student Recreation & Aquatic Center (SRAC)



## Revenue Sources

- Gifts, pledges, investment income

## Functions

- As a 501(c)(3) auxiliary organization, Tower Foundation directly manages all financial aspects of funds donated to San Jose State University
- Tower Foundation Board approves the annual endowment distribution rate (4% for FY17/18)

## Highlights / Accomplishments

- \$140+ million endowment comprised of over 600 individual funds
- Tower Foundation supporting the expansion of South Campus



# 2017-18 Presentation to the Academic Senate

October 9, 2017

Bradley Olin, Ed.D.

Interim AVP of Academic Budgets and Planning  
Office of the Provost

# Presentation Overview

1. Incoming Class Profile
2. 2017/18 Budget Planning Priorities
3. Looking Ahead

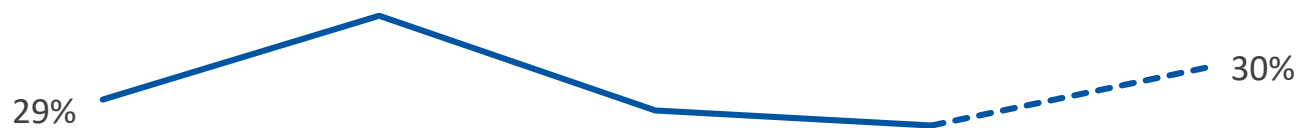




# Incoming Class Profile

# First Generation

## Share of New Freshmen Who Were First Generation to Attend College



Fall 2013

Fall 2014

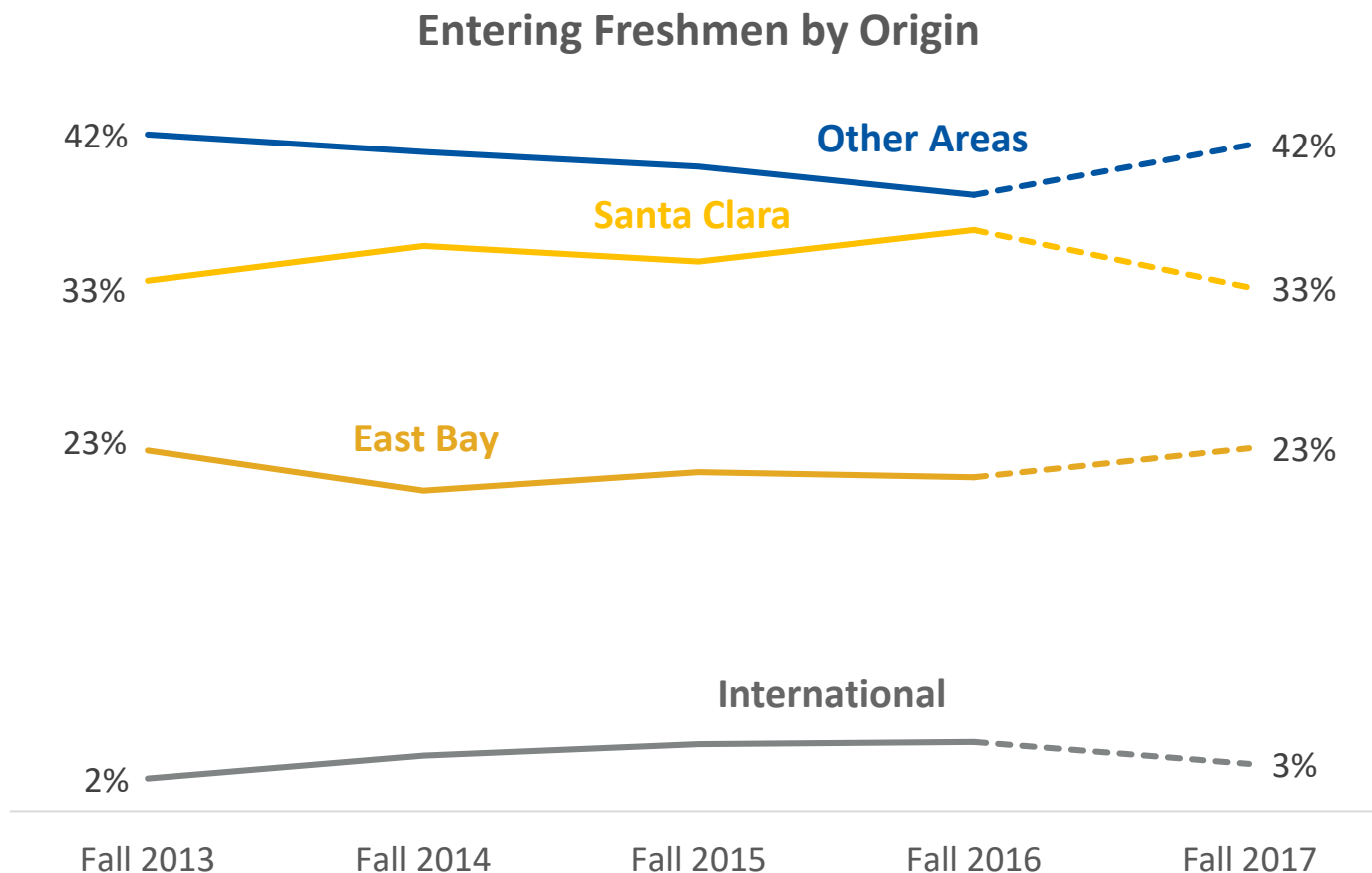
Fall 2015

Fall 2016

Fall 2017

*Dashed line represents a preliminary figure*

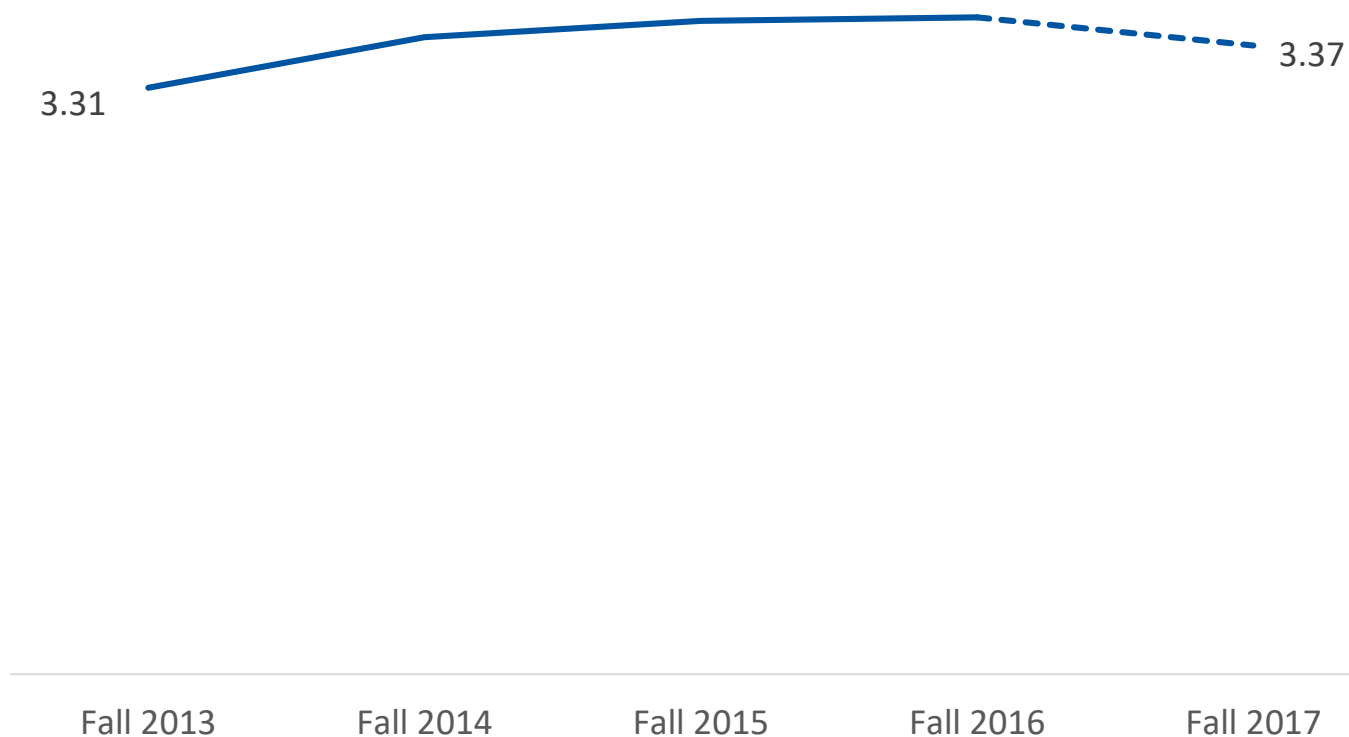
# Incoming Frosh Origins



*Dashed line represents a preliminary figure*

# Incoming GPA

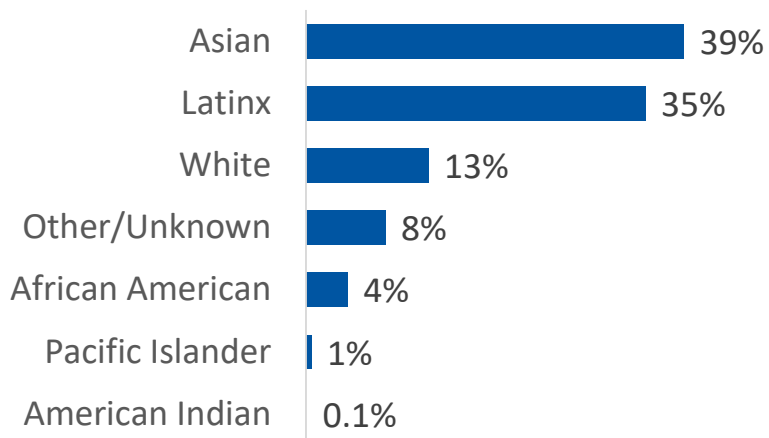
## Incoming Freshman High School GPA



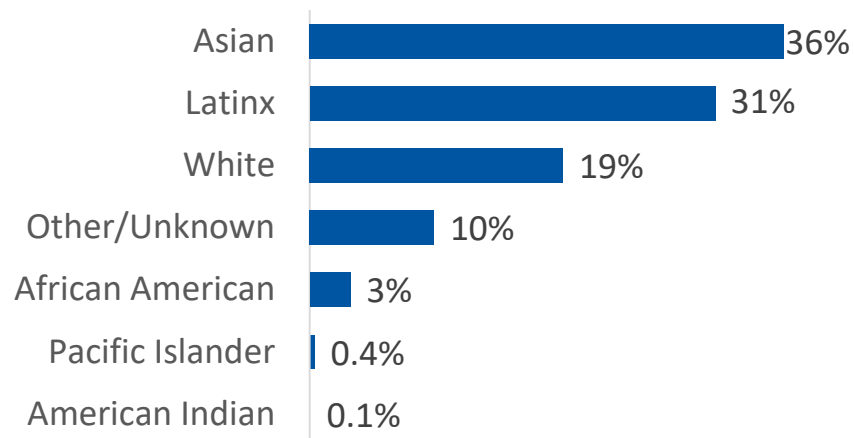
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# Demographic Profile

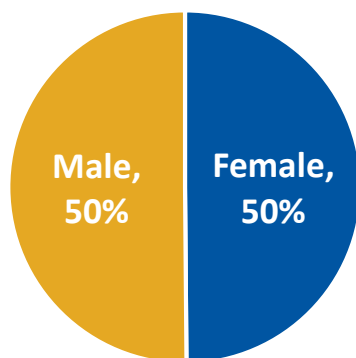
## Freshmen Class by Ethnicity



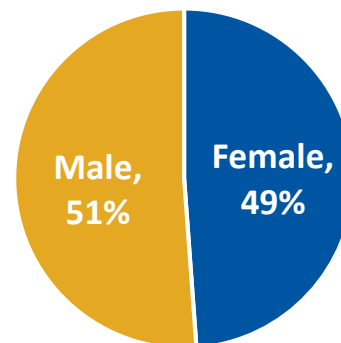
## Transfer Class by Ethnicity



## Freshmen by Gender



## Transfers by Gender



*All figures are preliminary for Fall 2017*





# 2017-18 Budget Planning Priorities

# 2017-18 Budget Planning Priorities

1. Four Pillars of Student Success
2. No Limits Enrollment Plan
3. Continue Improving Tenure Density
4. RSCA Expansion



# Four Pillars of Student Success

# Notable Investments

**\$ 3.7M** Advising

**\$ 0.9M** English & Math Restructuring\* /  
Tutoring (College Readiness)

**\$ 0.5M** Support for Students in High  
Failure Rate Courses (Elimination of  
Bottlenecks)

**\$ 0.3M** Student Data Warehouse (multiple)

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**\$ 5.4M** TOTAL

*\* The CSU provided \$140K for this initiative*

# Advising Progress

30

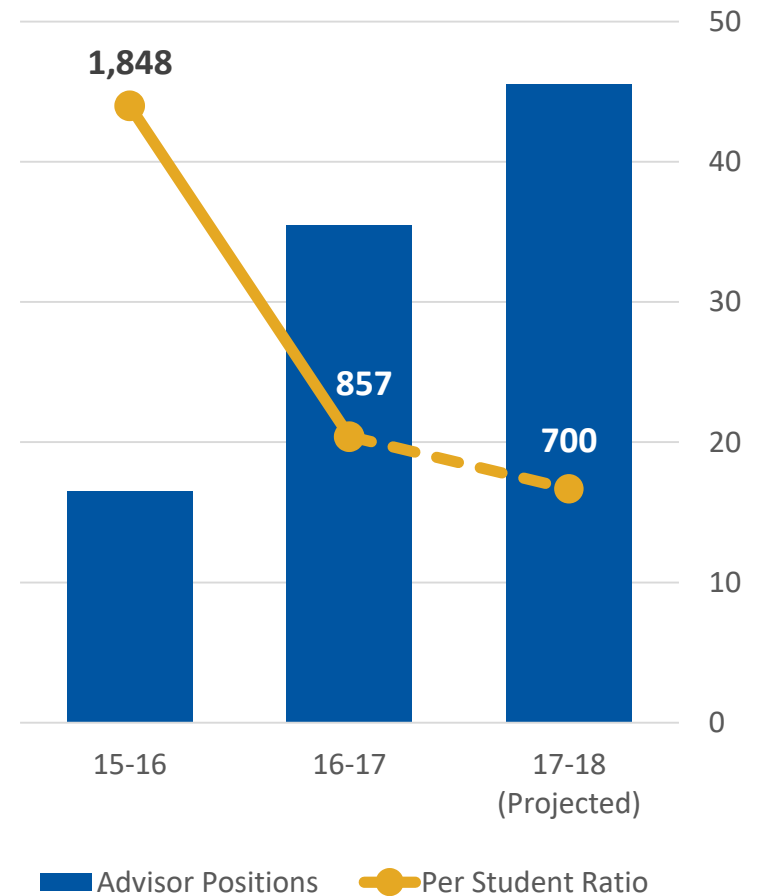
Additional Positions

Added in 16-17	Planned and Budgeted in 17-18
20	10

1:857

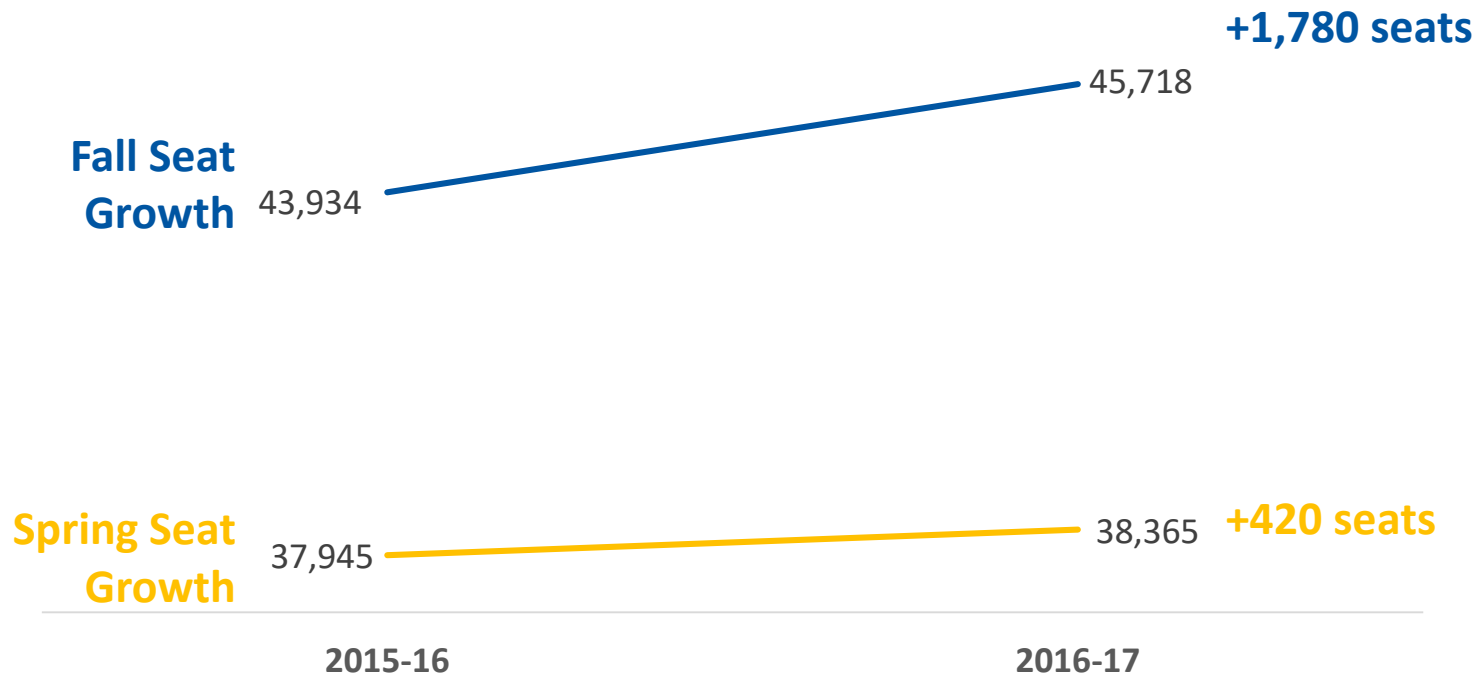
16/17 Staff Advisors/Student  
Ratio

Down from 1:1,848 in 15/16



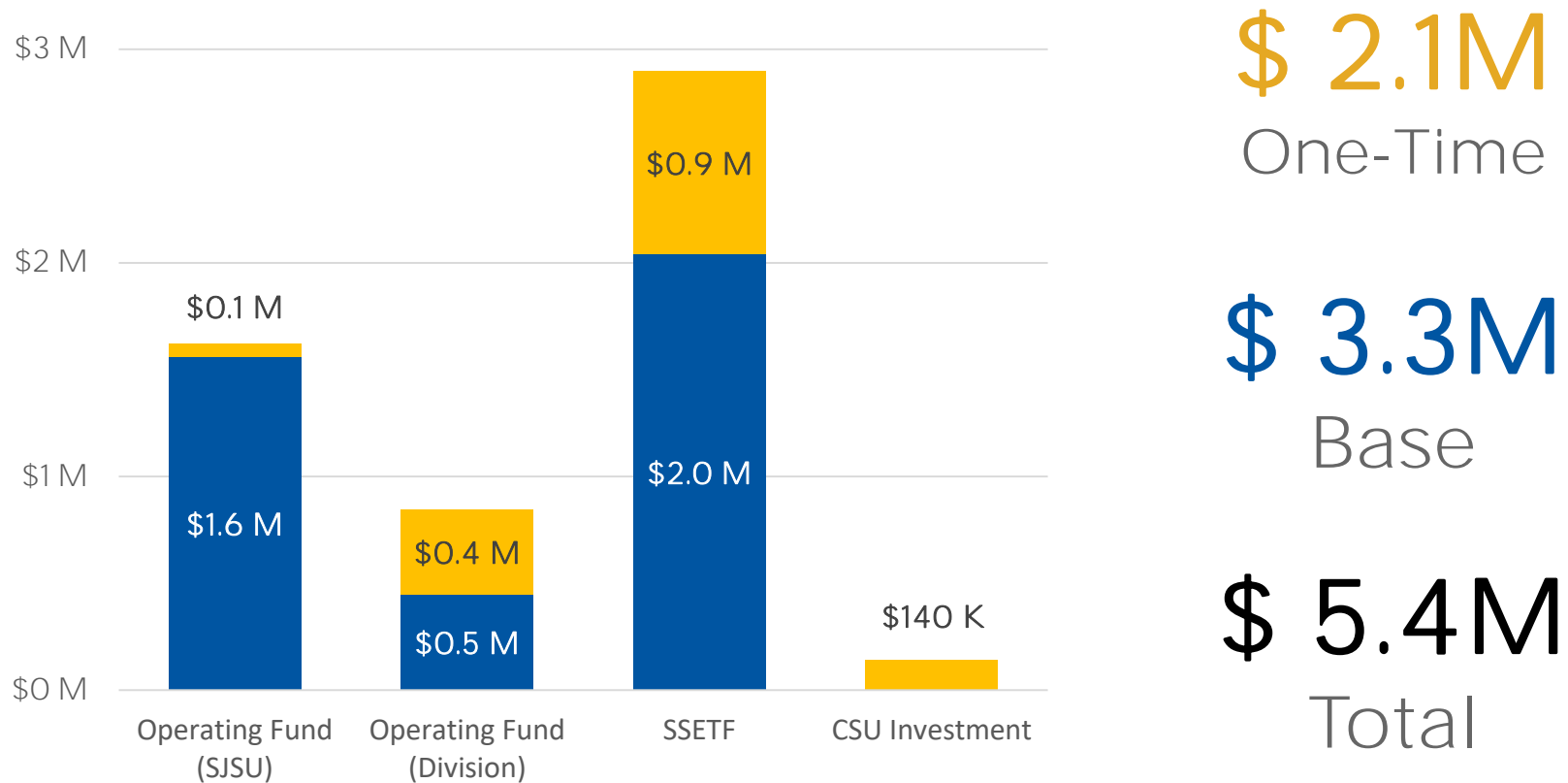
# Bottleneck Elimination Progress

Additional Seats Filled in High Wait List / High Demand  
Courses  
2016-17 vs. 2015-16



# Base vs. One-Time Investments

(excludes enrollment funding)







# College Based Funding Model



# Budget Model and FTES

TARGET FTES  
(Base Funding)

Funding Rate  
Marginal Cost of  
Instruction

17-18 Target  
24,911

GOAL FTES  
(1x Funding)

Funding Rate  
\$ 2,600 / FTES

17-18 Goal  
664

# College Enrollment Target (Annualized)

College	2017-18	2016-17	Change	New Enrollment Funding
Applied & Sciences & Arts	3,764	3,664	100	\$ 365,700
Business	2,925	2,825	100	\$ 336,600
Education	1,409	1,409		
Engineering	3,624	3,624		
Humanities & the Arts	4,597	4,597		
Science	4,077	4,077		
Social Sciences	4,515	4,515		
Totals	24,911	24,711	200	\$ 702,300

# Fall Goal Enrollment Update (Actual FTES)

College	Fall Funded per ICLM	Fall Actual	Change
Applied & Sciences & Arts	3,939	4,209	270
Business	3,168	3,322	154
Education	1,518	1,617	99
Engineering	3,800	4,177	377
Humanities & the Arts	4,904	5,253	349
Science	4,565	4,730	165
Social Sciences	4,874	5,038	164
Totals	26,768	28,347	1,579

# Marginal Cost of Instruction Calculation

## Marginal Cost of Instruction

Total Cost of Instruction / FTES = Marginal Cost of Instruction

# Marginal Cost of Instruction by College

College	Marginal Cost of Instruction Rate
Applied Sciences & Arts	\$ 3,657
Business	\$ 3,366
Education	\$ 3,489
Engineering	\$ 3,527
Humanities & the Arts	\$ 3,157
Science	\$ 3,325
Social Sciences	\$ 2,710

- ❖ Colleges receive funding for Target FTES adjustments based on individual Marginal Cost of Instruction rates.
- ❖ Current rates were established using the 2012-13 instructional cost data.
- ❖ Actual rates have since declined due to a change in the instructional FTEF definition, increased research activities, and fluctuation in instructional tenure density.
- ❖ The division is upholding the 2012-13 rates for new enrollment funding until they are exceeded.



# University Library New Budget Model

- ❖ Closely aligns to the college based budget model.
- ❖ Aims to bring stability and address incremental costs as enrollment expands.
- ❖ Address inflationary costs for library acquisitions.

# University Library New Budget Model

## Funding Methodology

Budget Category	Basis for Adjustments	2017-18 Adjustments
Librarian (enrollment bearing)	Changes in target and goal FTES based on Marginal cost rate, currently at \$77 / FTES.	\$ 18K
Staff and Operating Expense	Allocate when funds are available. Typically a flat percentage increase.	\$0
Library Acquisitions	Inflationary adjustments will be given using the Higher Education Price Index (HEPI). The current rate is 1.8%.	\$ 56K
Total Adjustments		\$ 74K

# SSETF Course Support

- ❖ Funding will remain the same as 2016/17
- ❖ Allocations are based on enrollment
- ❖ Structural Deficit from “unbundling”
- ❖ Operating Fund & Other Resource Supplements
- ❖ Extra enrollment-based allocation

# College Expenditure Plan Summary

## Reserve Balance Spend Down

Category	Amount
Capital Projects - Health Building, Building Safety, 21 <sup>st</sup> Century Teaching Spaces and Classroom Upgrades	\$ 3.2M
Faculty Recruitment and Start-Up Packages	\$ 1.9M
RSCA Expansion	\$ 1.8M
Program Development	\$ 2.7M
Faculty and Staff Professional Development	\$ 0.2M
<b>Total Planned Use</b>	<b>\$ 9.8M</b>

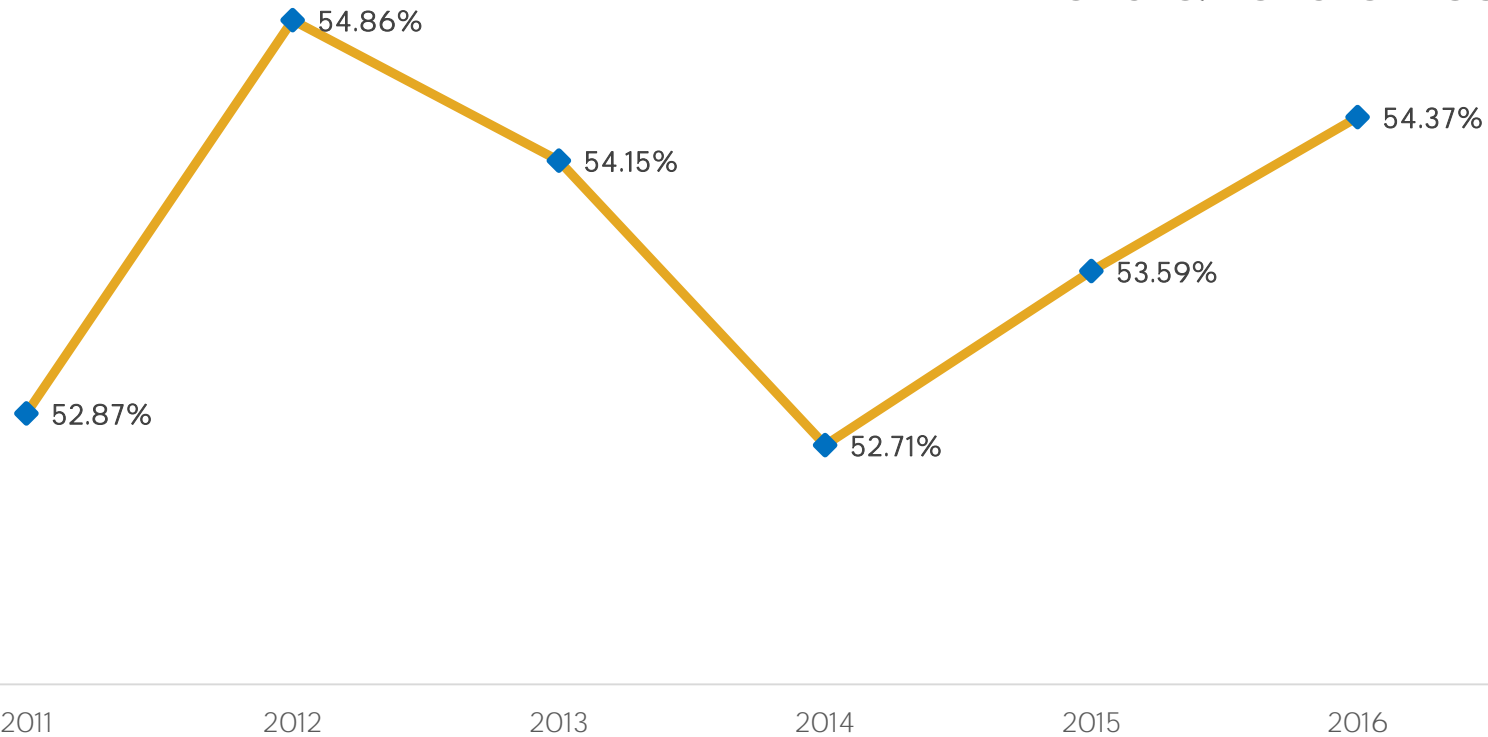


# Tenure Density



# Tenure Density

12% Increase in the number of  
Tenure/Tenure Track Faculty

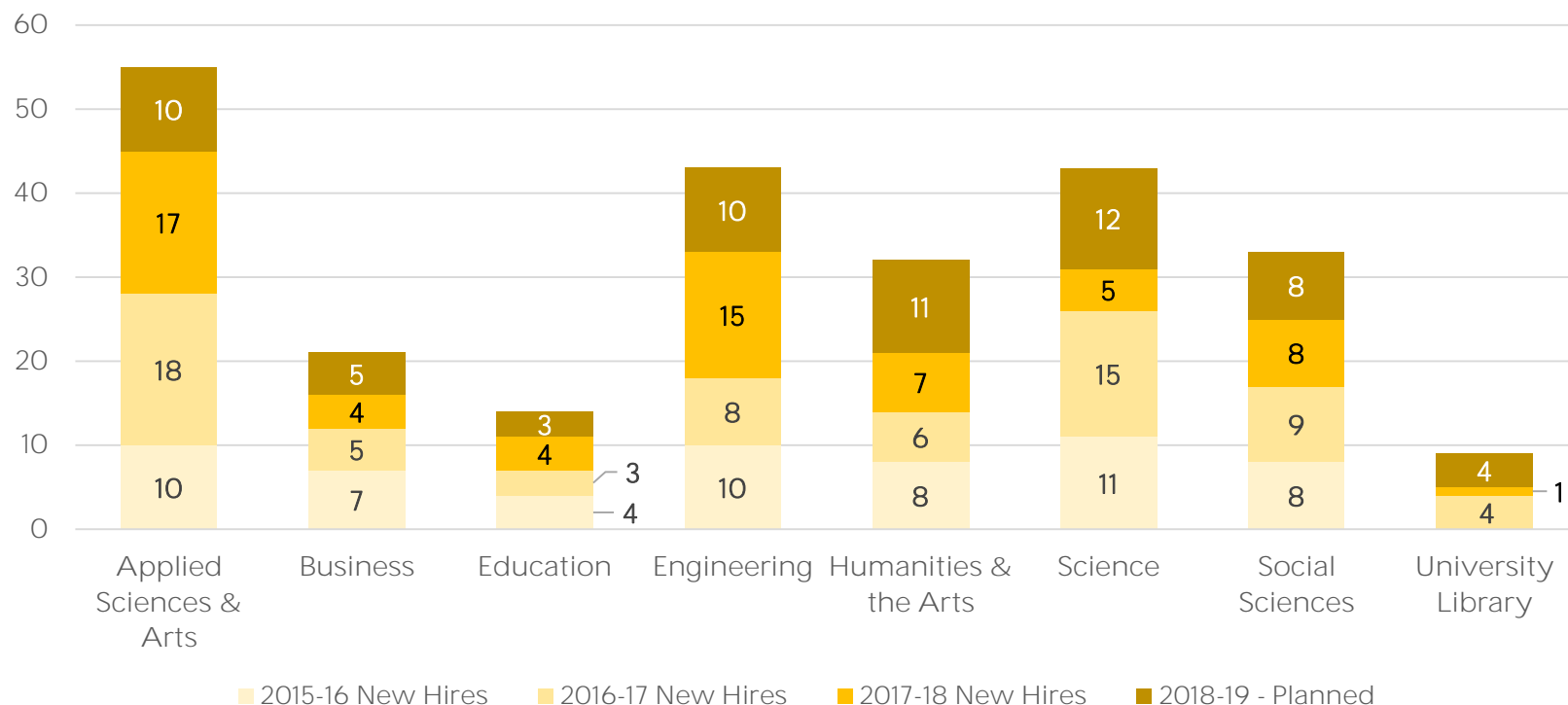


# Tenure Track Faculty Increases

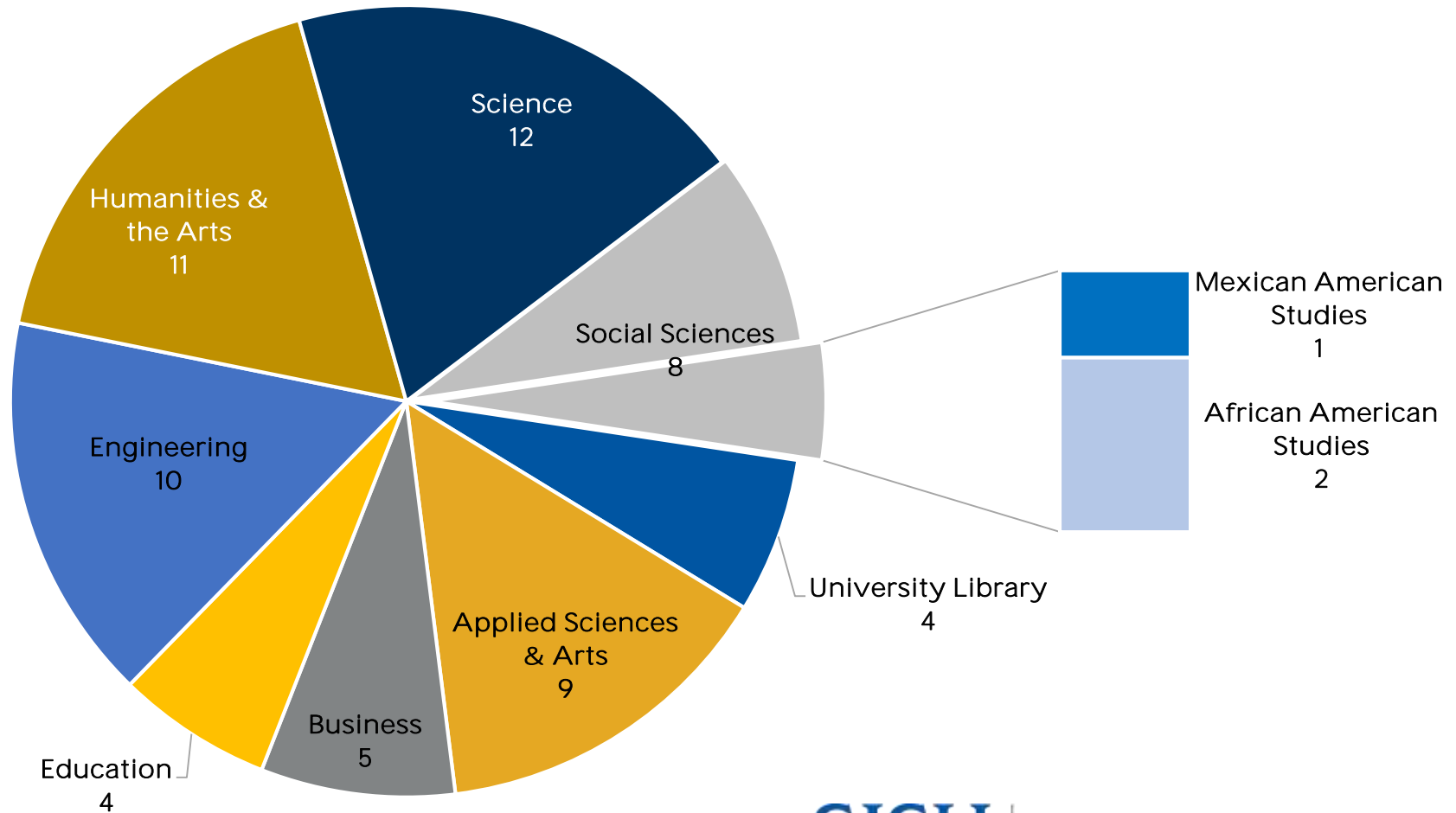
**188** New Tenured/Tenure Track Faculty since 2015-16

**63** Recruitments underway

**20** Avg. Net New Faculty Lines/Yr. since 14/15



# 63 Authorized Tenure Track Searches for 2017-18





# RSCA Investment

# RSCA Funding in 2017/18 and Beyond

**\$1M**

CSU/SJSU RSCA  
PROGRAM

## Sources

\$ 166K – CSU

\$ 250K – Division

\$ 584K – Division Roll Forward

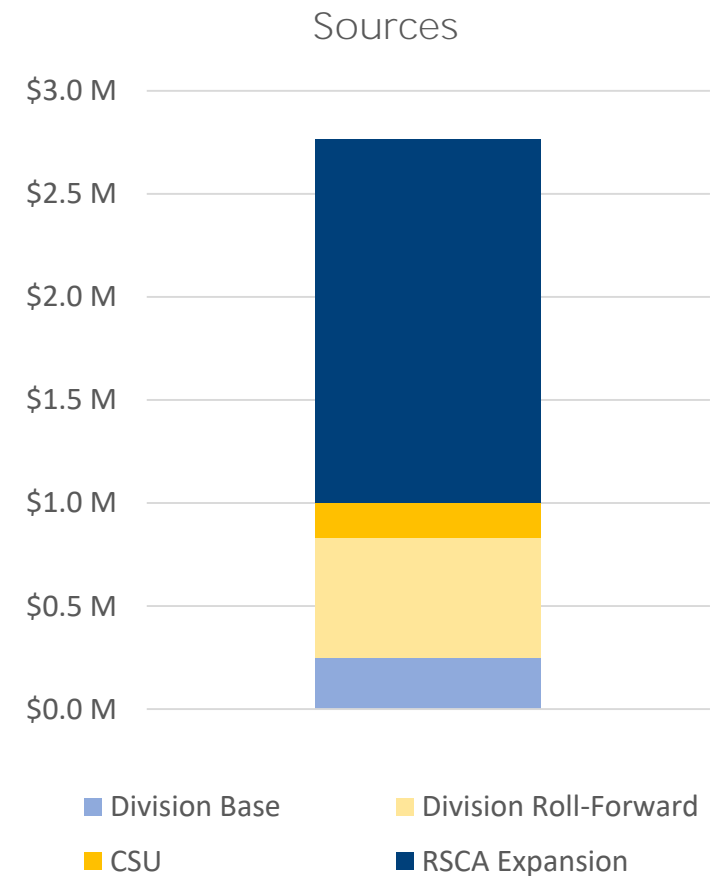
## Uses

\$ 500K – SJSU RSCA (Office of Research)

\$ 500K – College RSCA Infusion

**\$1.76M** RSCA EXPANSION

**\$2.76M** TOTAL RSCA  
FUNDING





# RSCA Expansion

- ❖ Framework in development
- ❖ Desired Outcomes:
  - ✓ Further engage faculty in RSCA
  - ✓ Enhance student learning outcomes
  - ✓ Expand recognition and reputation for the institution and faculty
  - ✓ Recognize RSCA with a reduced teaching load  $\leq 9$  WTUs (Three 3-Unit Courses) of teaching/sem.

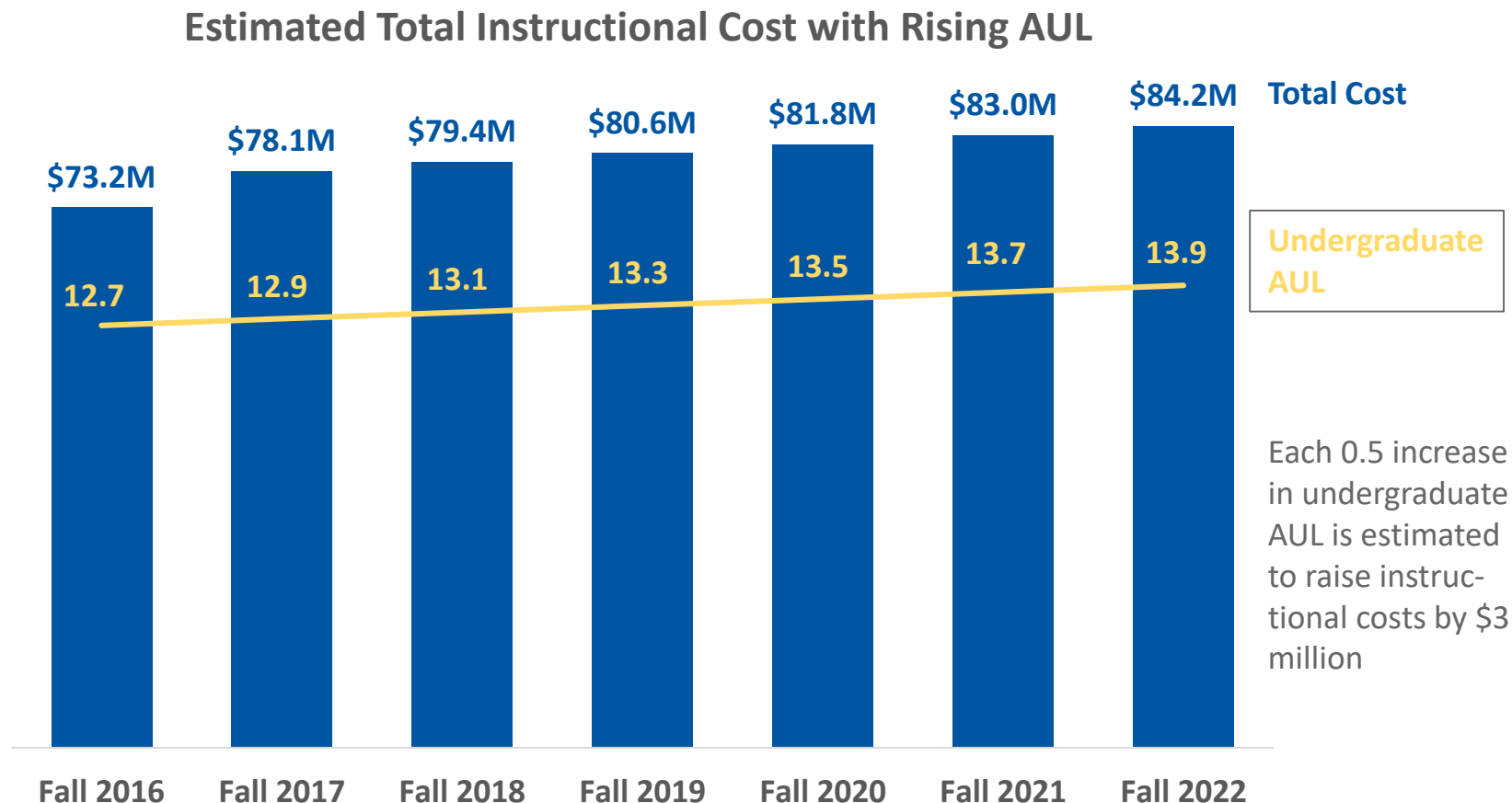


Looking Ahead

# CSU Tenure Density Model

- ❖ Represented as a Percentage
  - ✓  $\text{T/TT Faculty} \div \text{All Instructional Faculty}$
- ❖ Limitations Looking Forward
  - ✓ T/TT Faculty Assigned Time
  - ✓ RSCA Expansion
  - ✓ New TT Hires
- ❖ An Internal Measure Makes Sense
  - ✓ Adjusted Model
  - ✓ Percentage Increase in T/TT Faculty

# Estimated Cost of AUL Increases



*Estimates assume that marginal cost of instruction and undergraduate headcount are held constant at Fall 2017 rates.*

# Exploring New Allocation Models

Looking beyond ICLM for other college needs

- ❖ RSCA
- ❖ Course Support
- ❖ Interdisciplinary Curriculum and ICLM Limitations
- ❖ Realigning funding in light of increased student unit loads



# Additional Resources

- ❖ [2017/18 Academic Affairs Budget Report](#)
- ❖ [2017/18 College Resource Allocation Memo](#)
- ❖ [ICLM Explained](#)



# 2017-18 Presentation to the Academic Senate

October 9, 2017

Bradley Olin, Ed.D.

Interim AVP of Academic Budgets and Planning  
Office of the Provost

**Executive Committee Minutes**  
**September 11, 2017**  
**Noon – 1:30 p.m., ADM 167**

Present: Frazier, Shifflett, Wong(Lau), Manzo, Peter, Feinstein, Willey, Faas, Schultz-Krohn, Riley, Mathur, Papazian

Guest: Sullivan-Green

Absent: Van Selst

1. The minutes of August 28, 2017 were approved.
2. There was no dissent to the consent calendar of September 11, 2017.
3. The committee discussed and selected Faculty-at-Large members for the Student Success, Budget Advisory, and Accreditation Review Committees.
4. The committee discussed and selected a Faculty-at-Large nominee to recommend to the President for the Athletics Board.
5. The committee discussed a referral to the Organization and Government Committee to consider adding the AVP of Faculty Affairs as an ex officio member of the Senate. The Executive Committee offered suggestions along the lines of greater flexibility rather than adding a specific seat/position to the Senate. O&G will take this into consideration as it discusses the issue.
6. Updates:

From the President:

The President discussed her concerns with several policies sent to her for signature. The Registration Priority policy does not follow a logical order. Categories A and D are redundant. Also, the President questioned why Summa Cum Laude was raised from 3.85 to 3.90 in the new Honors Policy. The President would like the appropriate committee (IS&A) to review the language and revise of these policies.

Regarding Amendment C to S15-6, the Appointment of Regular Faculty Employees: This amendment restores a practice allowed under the old RTP policy that previously tenured faculty from other institutions could be considered for early tenure at SJSU. This was inadvertently made far more difficult under the revised RTP policies of 2015. The President has concerns about having different standards for faculty who join us vs. faculty that start with us. She will discuss further with the Provost and decide later.

On the Privacy of Electronic Information Policy, the President wondered about what problem we were trying to solve with this policy. We already have a CSU policy. A member commented that information privacy is a minor concern in the CSU policy and that is not sufficient. Our old campus policy (F97-7) is out of date and needs replacement. Some faculty will not use SJSU email, because they are concerned about whether their privacy can be protected. The President is not convinced that faculty are not protected by CSU policy. However, she will review the policy again. The President noted that sometimes the best action is just to get rid of a policy.

7. The Executive Committee approved a ***Sense of the Senate Resolution in Opposition to Ending the Deferred Action for Childhood Arrivals Program (Final Reading) (12-0-0)***.
8. The meeting adjourned at 1:38 p.m.

These minutes were taken and transcribed by the Senate Administrator, Eva Joice, on September 11, 2017. The minutes were reviewed and edited by the Senate Chair, Stefan Frazier, on September 18, 2017. The minutes were approved by the Executive Committee on September 25, 2017.

Executive Committee Meeting  
September 25, 2017  
12-1:30 p.m., ADM 167

Present: Frazier, Feinstein, Riley, Schultz-Krohn, Shifflett, Manzo, Peter, Wong(Lau), Mathur, Van Selst, Willey, Faas, Lee, Sullivan-Green

Absent: Papazian

1. The Executive Committee minutes of September 11, 2017 were approved.
2. Senators Peter and Shifflett presented edits to the legislative history and rationale of AS 1660 approved by the Academic Senate on September 18, 2017 (Honors Policy). A motion was made to adopt the edits. The motion was seconded. The Executive Committee voted and the motion was approved (14-0-0).
3. There was no dissent to the consent calendar of September 25, 2017.
4. Updates:

a. **From the Vice President for Student Affairs (VPSA) –**

Over 200 people attended the Student-Parent Weekend and brunch at Gordon Biersch. In addition, over 200 people attended the tailgate party before the football game and parents and students got to run onto the field before the players.

We are getting ready for Homecoming week. There are a number of events coming up including the Fire in the Fountain.

The average GPA of incoming Frosh is 3.34. The average GPA of transfer students is 3.08.

There were 50 American Indian students last year, and that number has grown to 112 this year due to recruiting efforts.

All frosh required to be in housing were housed by June 1, 2017.

Fall admission opens October 1, 2017.

b. **From the Associated Students President (AS):**

AS has a number of events planned for Homecoming week. There will be a door decorating contest.

AS has donated \$150,000 in the form of scholarships to be given to students that need assistance with the renewal application for Deferred Action for Childhood Arrivals (DACA).

AS is having difficulty getting enough students to serve on committees. They continue to work on this.

AS is working on getting students to vote in elections.

AS approved their recent audit due to fraud uncovered in connection with a previous employee. There were no significant findings.

The AS President urged Senators to come to see the community garden next week on October 6, from 4 to 6 p.m. across from the Dining Commons.

The Tommy Smith and John Carlos statues are being restored.

There is a full week of activities planned for "Rush" week.

c. **From the CSU Statewide Senate:**

The Chancellor's Office will be holding a webinar on EO 1100 and EO 1110 this Friday (9/29/17) from 2 to 4 p.m. Some changes include upper division GE that can be completed at any CSU. It is designed to maximize student progress. There was no news on the Faculty Trustee. [Note: Since this meeting, the Governor announced the selection of Senator Sabalius as the Faculty Trustee.]

d. **From the Provost:**

The Provost spoke about visiting other universities where they have both a faculty and staff Senate. Provost Feinstein would really like to see the SJSU Academic Senate include staff in its membership. The Provost does not see the administrators as staff, and the General Unit is limited to faculty that are not part of a college and staff that are either SSP III's or SSP IV's. There is currently no mechanism in place for staff to give input on resolutions in the Senate. Senator Shiflett stated that she was waiting for a referral on this matter.

Questions:

Q: A member asked why we have moved to requiring two library cards for the MLK Library? It is as if we are no longer a joint city-university library. The committee discussed how beautiful the new atrium looks. Kudos to VPAF Faas.

A: The Provost will look into the library card issue.

Q: Is there any movement towards a 3/3 teaching load?

A: The Provost had Marc d'Alarcao look into what we would have to do to move to a 3/3 teaching load. Incoming faculty are already teaching a reduced load. The Provost has a plan and is committed to the 3/3 load. However, \$4 million is needed in base funding and right now it is a matter of priorities.

Q: What is the status of the VP of Research and Innovation position?

A: The Provost still believes we have a need for this position, but it is currently on hold. The Provost announced that we did just hire an Executive Director for the Research Foundation.



Q: About 2,000 students did not received their books on time this semester. Are there any plans to address this?

A: The Provost commented that there are issues with this on every campus. However, we had over 1,000 unexpected students this year. A member commented that the bookstore does not order the amount you indicate you need to begin with.

e. **From the Chief Diversity Officer (CDO):**

Faculty facilitator training is continuing throughout the semester. The CDO is looking for faculty and staff to attend an on campus intergroup/facilitator training that includes four 8-hour sessions. This is professional training normally offered through the University of Michigan that is being offered on our campus for free as a favor for the CDO.

The CDO will be working closely with Student Affairs to assist DACA students.

f. **From the Vice President of Administration and Finance (VPAF):**

The MLK Library glass is up. The best compliment the VPAF received is that you can't tell the difference, but it is way safer than it was.

We have had ridiculously high temperatures this month with no cool-down at night and high humidity. The VPAF committed last Monday to some short-term fixes including the rental of air conditioning units for each classroom in DMH and a couple in HGH for one month.

The additional volume of students is causing parking problems as well. Even South Campus is getting full very early. Until noon faculty can park in the 4<sup>th</sup> Street garage. The VPAF is looking for solutions. He may consider converting the first floor of the 10<sup>th</sup> Street garage to parking and moving those people elsewhere. That would free up 400 spots.

The Cleary Report on crime doesn't show any trends for SJSU. There is no increase in specific crimes in the dorms. If a crime is reported quickly, the cameras may be able to identify the person. There is better reporting of incidents in the dorms with the increased security efforts.

BART has decided to go with the West Station because they wanted to be in the central part of the city and be attached to the subway entrance.

g. **From the Instruction and Student Affairs Committee (I&SA):**

I&SA is working on Priority Registration, Academic Qualifications for Students, and the Academic Integrity policies/resolutions.

h. **From the Organization and Government Committee (O&G):**

O&G is approaching the end of dealing with the policy clean-up.

O&G will be considering the requested bylaw amendment to the description of academic deans. A constitutional amendment may be necessary.

i. **From the Curriculum and Research Committee (C&R):**

C&R will be working on the Internship, Human Subjects, Curriculum, and BOGS policies.

- j. **From the Professional Standards Committee (PS):**  
The PS Committee will be working on the Chairs and Directors Policy, and continuing work on previously reported policies.
- 5. The meeting adjourned at 1:24 p.m.

These minutes were prepared by the Senate Administrator on September 25, 2017. The minutes were edited by Chair Frazier on October 2, 2017. The Executive Committee approved the minutes on October 2, 2017.

**Executive Committee Minutes**  
**October 2, 2017**  
**Noon – 1:30 p.m., ADM 167**

Present: Frazier, Shifflett, Wong(Lau), Manzo, Peter, Willey, Schultz-Krohn, Riley, Mathur, Lee, Van Selst

Absent: Papazian, Feinstein, Faas, Sullivan-Green

1. The minutes of September 25, 2017 were approved.
2. There was no dissent to the consent calendar of October 2, 2017.
3. The committee discussed the Board of Academic Freedom and Professional Responsibility (BAFPR). The members of this committee have to be full professors elected by the college that serve four-year terms. We have five college vacancies right now and are having much difficulty in getting them filled. Chair Frazier emphasized how important this committee is to the university.
4. The President and Provost are at a golf tournament today. The VPAF is at a P3 Conference (Public, Private, Partnerships) for campus projects.
5. The committee reviewed and suggested members for the faculty award selection committees (Distinguished Service, President's Scholar, Outstanding Lecturer, Outstanding Professor). The Chair will follow up with the suggestions, keeping in mind the guiding principle of fair representation across colleges.
6. Updates from the policy committees:
  - a. From the Professional Standards Committee (PS):  
PS is working on the Chairs and Directors policy.
  - b. From the Instruction and Student Affairs Committee (I&SA): Not present, no report.
  - c. From the Organization and Government Committee (O&G):  
O&G is continuing its work on a proposal related to the administration's representatives on the Senate. Feedback from the executive committee included keeping membership in the constitution and process in the bylaws. O&G will discuss further at today's meeting.

O&G is preparing a proposal to allow the Faculty Trustee to report to the Senate. The committee discussed this unique situation and whether it might be better to have the Chair issue an invitation to the Faculty Trustee to address the Senate at each meeting.

A clarification was made regarding O&G's review of university policies: the focus of any proposals brought to the senate will be those that clean up problems. If they find a policy in which there appears to be a concern with compliance, they will refer it to the Senate Chair.

- d. From the Curriculum and Research Committee (C&R):  
C&R is working on a revision to the Human Subjects Policy that has to do with compliance issues.

C&R is also working on the Sense of the Senate Resolution pertaining to Internships.

## 7. University Updates:

- a. From the Vice President for Student Affairs (VPSA):  
SJSU has 48 students in Nevada and 20 from Las Vegas. Student Affairs has been reaching out to these students. They have heard from 3 of them.

There are a number of events set for homecoming week and some of those events are as follows:

- Golf Cart Parade
- Open House at the Student Services Center
- Fire in the Fountain
- Fall 2018 Spartan Speakers Series

Census has passed. Fall enrollment was at 33,415 students. This is 1,245 more than last fall. Special session adds another 2,500 students.

Forty-seven percent of all frosh are taking 15+ units. However, only 20% of transfer students are taking 15 or more units. We have more work to do with transfer students.

- b. From Associated Students (AS):

In honor of homecoming week AS is wearing gold and blue.

Tomorrow there will be a golf cart decorating contest for the parade on October 4, 2017.

The Child Development Center is at 90% enrollment.

The DACA post on facebook is the most liked of any items on the AS webpage.

Three fix-it bike repair stations have been opened.

AS is having difficulty recruiting students for committees.

AS is working on a resolution in honor of Don Ryan, a previous Financial Aid Director at SJSU that recently passed away.

AS would like a list of committees that still have student vacancies. AVC Riley will forward to her.

c. From the Statewide Senate:

Some CSU campuses have all of their CSU Statewide Senators on the Executive Committee.

With Romey Sabalius being selected as a Faculty Trustee, he will have to be removed from the SJSU Senate as a Statewide Senator. A cross-campus call for nominations will be initiated in the near future.

The committee discussed a possible referral to C&R to look into having completion of a category R,S,V class on equality/inequality as a graduation requirement separate from the general education requirements.

d. From the Provost: Not here.

e. From the Vice President for Administration and Finance (VPAF): Not here.

f. From the Chief Diversity Officer (CDO):

WASC said that the diversity training should be supported. The CDO is preparing to start training for staff.

The CDO has asked the Chancellor to host a meeting of all campus CDOs.

The CDO has just completed faculty search committee training with the AVP of Faculty Affairs.

8. The meeting adjourned at 1:36 p.m.

These minutes were taken and transcribed by the Senate Administrator, Eva Joice, on October 2, 2017. The minutes were reviewed and edited by the Senate Chair, Stefan Frazier, on October 5, 2017. The minutes were approved by the Executive Committee on October 16, 2017.

		Consent Calendar	23-Oct-17		
	Committee	Last Name/First Name	Term	Phone	Seat/College
ADD:					
	Program Planning Committee	Gregg, Jennifer	2018		Seat T General Unit
	University Library Board	Khavul, Susanna	2018		Seat K (CoSci now at large)
REMOVE:					
	University Library Board	Kim, Youngsoo	2020		Seat I (Eng--gone at large)



San José State University  
Academic Senate  
Organization and Government Committee  
October 23, 2017  
First Reading

AS 1656

## Policy Recommendation

### Modification of Bylaw 1.10 Pertaining to Academic Deans

Legislative History: This proposal would Modify bylaw 1.10 which pertained to the definition of the term 'academic dean'.

Whereas: Administrative changes and reporting lines have changed in the academic affairs division with the appointment of a deputy provost, and

Whereas: The language in bylaw 1.10 presently conveys that AVPs report directly to the provost, which is no longer the case, therefore be it

Resolved That bylaw 1.10 be modified as follows:

1.10 ~~The phrase "academic deans" as used in~~ With regard to Article II, Section 2 of the constitution, means college deans within Academic Affairs will select their two representatives for staggered two-year terms; and Associate Vice Presidents within Academic Affairs will select their representative for a two-year term; reporting directly to the Provost. and one Associate Vice President from a division outside of Academic Affairs will be selected by the President in consultation with the Senate Executive Committee for a two-year term. Elections of representative deans shall be conducted and reported by The Provost will report the selection of representative Deans and Associate Vice Presidents from Academic Affairs to the Senate Chair. The President will report the selection of the AVP representative from the division outside Academic Affairs to the Senate Chair. and Any vacancies arising before the end of a term shall be filled for the balance of that term by selection as outlined above. special elections

Rationale: In conjunction with changes to the constitution being considered concurrently with this bylaw change, the bylaw now appropriately focuses on process.

Approved: 10/16/17

Vote: 7-0-0

Present: Curry, Grosvenor, Hart, Higgins, Rajkovic, Shifflett, Ormsbee

Absent: Ramasubramanian, Bailey, Tran, Rangasayee

Financial Impact: None

Workload Impact: None

**SENSE OF THE SENATE RESOLUTION**  
**On the Timelines and Content of**  
**Executive Orders 1100 and 1110**

**Background and Rationale:** In August 2017, Executive Order (EO) 1100 (Revised) and Executive Order 1110 were issued. Concerns about shared governance, the timeline, and the content of the resolutions existed both before distribution and are continuing. The Academic Senate CSU, the Chancellor's General Education Advisory Committee, and many individual campuses have asked for deferrals of the new requirements, withdrawal of one or both of the new executive orders, and/or more campus autonomy in achieving and defining student success. Additional concerns have been expressed about campus autonomy (e.g., Upper Division GE), negative impacts on diversity requirements, and on the implementation of the Quantitative Reasoning Task Force recommendations regarding what constitutes adequate and appropriate levels of quantitative reasoning proficiency in a baccalaureate degree (e.g., QRTF writing group statement [Oct 11, 2017]). A specific burden imposed by the EOs on SJSU is in curricular development. The EOs require us to revamp our curricular offerings to accommodate changes in expectations for quantitative reasoning capabilities at the point when many of our students will enter CSU GE B4 coursework (potentially with a co-requisite developmental support course). Part of the unreasonable time pressure is that the required changes in course structures and content need to be done in time to meet catalog deadlines.

Whereas, Many of the principles contained in Executive Orders 1100 (Revised) and 1110 are sound and welcome (for example, the principle of providing additional academic development for those frosh in need of it, in order for them to succeed better and in a more timely fashion); and be it further

Whereas, There has been widespread outcry over the development process, the content, and the timeline of EO 1100 (Revised) and of EO 1110; and be it further

Whereas, San José State University, although less impacted by these changes than many of our sister campuses, is nevertheless having to spend considerable efforts to accommodate these EOs; thus be it

Resolved, That the Academic Senate of San José State University find the development process, elements of the content, and the timeline of EO

44 1100 (Revised) and of EO 1110 to have violated normal processes of  
45 shared governance in curricular development; and,  
46  
47 Resolved, That the SJSU Senate endorse the statewide Academic Senate CSU  
48 resolution [AS-3304-17, On the Development and Implementation of](#)  
49 [Executive Orders 1100 \(Revised\) and 1110](#) and align ourselves with the  
50 spirit and intent of the various campus-based resolutions issued across  
51 the CSU system addressing the process that led to, and content of, the  
52 recent revision to EO 1100 and the new EO 1110.  
53  
54 Approved: October 16, 2017  
55 Vote: 9-0-4  
56 Present: Manzo, Feinstein, Frazier, Peter, Shifflett, Sullivan-Green,  
57 Wong(Lau), Faas, Papazian, Lee, Schultz-Krohn, Van Selst,  
58 Mathur  
59 Absent: Willey, Riley  
60 Curricular impact: None  
61 Financial impact: None  
62 Workload impact: None  
63  
64

**Sense of the Senate Resolution**  
**Guidance on Implementation of EO 1064 Student Internships,**  
**Service Learning, and Off-Campus Learning Experiences**

**Rationale** CSU Executive Order 1064 "...recognizes the beneficial educational purpose of student internships, as well as the need to maximize the educational experience while mitigating the risks to participants and minimizing the university's liability exposure;" and requires each campus "to develop, implement, maintain and publish a student internship policy governing internships where the university makes the placement". In response to this executive order, SJSU developed S16-14: University Policy, Internships, Service Learning, and Off-Campus Experiences. This policy refers to internships, service learning, and off-campus experiences used for university credit. In spring 2017, S16-14, was amended, Amendment A, to allow student self-placement for internships, service learning and off-campus experiences bypassing the University-Organization Agreement process which could delay students' progress towards their degree and prevent access to valuable learning experiences. Amendment A, developed in consultation with the Chancellor's Office, was passed at the Academic Senate meeting on March 13, 2017. Following the passage of Amendment A, the Chancellor's Office Risk Manager informed the Curriculum and Research Committee that the vendor for the insurance coverage for students and the CSU campuses (SAFECLIP) would ONLY cover students engaged in internships where a UOA was fully executed.

**Whereas** During the Summer of 2017 the Chancellor's Office informed the SJSU community that all internships must have a University Organization Agreement (UOA) in place in advance of enrollment or students will not be covered by SAFECLIP; and

**Whereas** Progress to degree for students in programs with internship/observation requirements can be significantly delayed by the recent interpretation from the Chancellor's Office regarding the timing of the UOA; and

**Whereas** The Academic Senate of San José State University acknowledges the importance of internships, service learning, and other off-campus experiences as educational "high impact practices";

**Whereas** EO 1064 embraces this spirit but San José State University is now severely hampered in its ability to offer this high impact educational method; therefore be it

43 Resolved That the Academic Senate of San José State University requests Chancellor's  
 44 Office provide flexibility and options that will allow students to enroll in  
 45 internship/experiential coursework once a UOA is in progress; and be it further

46 Resolved That Chancellor's Office allow students to obtain SAFECLIP or equivalent  
 47 packages without a UOA in place or allow students to submit a waiver; and be it  
 48 further

49 Resolved That the Academic Senate of San José State University requests the  
 50 Chancellor's Office clarify if a UOA is needed for SJSU students completing  
 51 internships at other California campuses of Higher Education; and be it further

52 Resolved That the Academic Senate of San José State University requests that the  
 53 Chancellor's Office work with the Statewide Academic Senate to coordinate and  
 54 support the process used among the CSU campuses to comply with EO 1064,  
 55 such as maintaining a list of approved sites and government agencies; and be it  
 56 further

57 Resolved That the Academic Senate of San José State University requests financial  
 58 support from the Chancellor's Office to implement and maintain UOAs on the  
 59 San José State University campus; and be it further

60 Resolved That this Sense of the Senate resolution be distributed to the California State  
 61 University Chancellor, to all campus Academic Senates, the Chair of the  
 62 Academic Senate of the CSU, the California Faculty Association, and SJSU  
 63 Faculty.

64

65 Approved: 10/02/2017  
 66 Vote: 9-0-0  
 67 Present: Anagnos, Bacich, Cargill, Heil, Liu, Matoush, Rodan, Schultz-Krohn,  
 68 Stacks  
 69 Absent: Buzanski, Chung, De Guzman  
 70

71 Curricular Impact: The current CSU requirement that SAFECLIP is only available to students  
 72 completing an internship where a current UOA is in place severely  
 73 compromises the use of this best practice educational method

74 Financial Impact: Very closely tied to the Workload Impact. If the current requirement for a  
 75 UOA to be in place for every internship site, SJSU will need additional  
 76 workforce to implement and maintain this requirement

77 Workload Impact: Workload impact is closely tied to the following factors (from S16-14):

78 • the number of students enrolled in a given department's internship  
 79 program (*the more students, the greater the workload*)  
 80 • the total number of organizations at which the department's  
 81 students are interning (*the more organizations involved, the greater*  
 82 *the workload*)  
 83 • what percentage of the organizations that a department is working  
 84 with already have a nonexpired UOA on file (*the more new UOAs*  
 85 *that have to be secured, the greater the workload*)

86  
87  
88  
89  
90

- to what extent new organizations in the process of signing a UOA request changes/amendments to their agreements (*the more changes required, the greater the workload*)



1 **San José State University**  
2 **Academic Senate**  
3 **Curriculum & Research Committee**  
4 **October 23, 2017**  
5 **First Reading**

**AS 1665**

6  
7 **Policy Recommendation**  
8 **Rescinds S08-7 - Policy for Protection of**  
9 **Human Research Subjects**  
10

11 Legislative History: The policy recommendation would rescind S08-7 and provide a  
12 Human Research Subjects policy that is in compliance with the Federal Government  
13 requirements. Federal regulatory changes were passed in January 2017 with the  
14 requirement that institutions have a policy reflecting these new regulations as of  
15 January 2018.

16  
17 Whereas: San José State University recognizes the need to address the ethical  
18 issues concerning human research subjects; and  
19

20 Whereas: San José State University must have a current policy that complies with  
21 the Federal Regulations; and  
22

23 Whereas The San José State University Institutional Review Board has reviewed  
24 the current Federal Policy regulating Human Research Subjects (HRS);  
25 and  
26

27 Whereas: The San José State University HRS Policy S08-7 does not comply with  
28 the current Federal requirements; and  
29

30 Whereas: The suggested policy submitted by the SJSU Institutional Review Board to  
31 the Curriculum and Research Committee was reviewed and disseminated  
32 to the SJSU community for comment; therefore be it  
33

34 Resolved: That S08-7 be rescinded, and be it further  
35

36 Resolved: That the attached policy be implemented  
37

38 Approved: 12-0-1

39 Vote: 10-16-2017

40 Present: Anagnos, Bacich, Buzanski, Cargill, Chung, Gilles (for Stacks) De  
41 Guzman, Liu, Matoush, Rodan, Schultz-Krohn

42 Absent: None  
43

44 Workload Impact: Minimal; as needed, additional training for new members of the  
45 SJSU IRB Committee  
46

47 Financial Impact: Minimal; cost for additional training as needed  
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## 141 **LIST OF ACRONYMS**

142 IRB – Institutional Review Board

143 LAR – Legally Authorized Representative

144 OHRP – Office of Human Research Protections

145 PI – Principal Investigator

## 146 **0.0 Intention**

147 San Jose State University acknowledges and accepts responsibility for protecting the rights and welfare  
 148 of human subjects in research. SJSU shall comply with all appropriate statutes governing human  
 149 research. In addition, non-federally funded or unfunded research shall undergo the same review as if it

were federally funded. This policy shall apply to all protocol submissions, including active protocols submitted prior to the 2018 effective date of this policy.

## **1.0 Definitions**

**1.1 Engaged Institution** – SJSU is considered engaged in human subjects research when its employees or agents obtain informed consent, collect and analyze data, and/or obtain private individually identifiable data for the purposes of contributing to generalizable knowledge under the auspices of SJSU. Such activities trigger either the need for SJSU IRB review or entering into a reliance agreement with another engaged institution whose IRB will review the research instead of the SJSU IRB. The following are examples of scenarios describing the types of institutional involvement that would make SJSU not engaged in human subjects research:

- When an SJSU employee or agent consults on research but does not receive or possess identifiable and private information about persons participating in the study.
- When an SJSU employee or agent is engaged in research as a consultant through a non-institutional contract. In this case, research activities must occur outside of his/her institutional employment and he/she may not reference the institution in documents or publications associated with any reported outcomes.
- When an SJSU employee or agent performs commercial or other services for external investigators, provided that the services performed do not merit professional recognition or publication privileges; the services performed are typically performed for non-research purposes; or SJSU employees or agents do not administer any study intervention being tested or evaluated under the protocol.
- When SJSU employees or agents inform prospective subjects about the availability of research; provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB approved materials) but do not obtain subjects' consent for the research or act as representatives of the investigators; provide prospective subjects with information about contacting investigators for information or enrollment; and/or seek to obtain the prospective subjects' permission for investigators to contact them.
- When SJSU permits use of campus facilities for recruitment, intervention, or interaction with subjects by investigators from another institution.

**1.2 Exclusion** – Activities that do not meet the definition of human subjects research as outlined in both sections 1.3 and 1.6 are excluded from oversight by the IRB and the Office of Research. Investigators may self-determine whether their work qualifies for exclusion by using a decision tool developed by the Office of Research for this purpose. Exclusion should not be confused with exemption, as described in section 4.2.1, a category of human subjects research for which there is limited oversight and which must be registered with the Office of Research.

**1.3 Human Subject** – A living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Although an activity may be considered research, it may not involve human subjects. Except for the populations as defined in (i) and (ii) above, persons involved in a research activity are not considered to be human subjects when the following apply:

- The information collected is not about the individual. That is, the person interviewed/surveyed is asked to provide information specific to his/her expertise or profession as opposed to personal information about him/herself (opinions, thoughts, or perceptions). For example, a welder asked to describe the composite of shielding gas, shielding gas flow rate, and formation of the weld bead is not disclosing information about him/herself and, as such, is not a research subject. Likewise, an entomologist who describes the varieties of pesticide used to control a specific pest and to identify the types of pesticides that are used most frequently is contributing his/her expertise rather than information about him/herself.
- The information must be about a living individual to qualify as a human subject. Review of death records does not involve human subjects. However, analyses of identifiable biological specimens or identifiable private records of living individuals do require review and approval before analysis may begin.
- When an activity uses diagnostic or classification data for epidemiologic and analytic purposes that are not identifiable by individual or group and when such data are not proposed for a use that conflicts with the conditions under which the data were originally obtained.
- When research data are taken from the public domain and may include data traceable to known individuals or social groups who have clearly made both the information and their identities available for any forms of scrutiny and analysis within the limitations set by statutes concerning libel.
- When observed behavior takes place in a public arena or locale and is observed as aggregate behavior in such a way as to preclude any post-facto identification of individuals.

**1.4 Identifiable Private Information** – Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Private information is identifiable when the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**1.5 Minimal Risk** – The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.



**1.6 Research** – A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. The following activities are deemed not to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or a court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- Studies conducted for the purpose of program evaluation, needs assessment, or quality control in which findings are solely intended for use in internal program planning and development and are not designed to contribute to generalizable knowledge.
- Student classroom work intended as research practicum (see Section 2.3.2 for restrictions).

## **2.0 Scope of Policy**

### **2.1 Federal Regulations**

SJSU human research activities are to be conducted according to the requirements of the code of federal regulations [TITLE 45, PUBLIC WELFARE: DEPARTMENT OF HEALTH AND HUMAN SERVICES, PART 46: PROTECTION OF HUMAN SUBJECTS](#) as if all SJSU research were federally supported. The federal regulations represent the minimum compliance requirements for human research activities

### **2.2 Other Applicable Regulations and Guidelines**

**2.2.1 State, Federal, and Tribal Law** – Where state, federal , or tribal laws require more stringent principles, those will be applied.

**2.2.2 Professional Associations** – Where professional representative organizations such as the American Medical Association, the American Nursing Association, or the American Psychological Association, have established more stringent principles, investigators are encouraged to consider those principles when designing or submitting research proposals for review.

**2.2.3 Foreign Countries** – Where research takes place in foreign countries, comparable foreign statutes which provide additional protections for human subjects will also apply.

## **2.3 Applicability to Research When SJSU is an Engaged Institution**

**2.3.1 To Whom Does SJSU Policy Apply?** Policies and procedures presented here are applicable to all research that, in whole or in part, involves human subjects if the research is sponsored by SJSU, or the research is conducted by or under the direction of SJSU employees, auxiliary employees, and/or students (including student/faculty collaborative research) under the auspices of SJSU. Student research must be supervised by a member of the faculty.

**2.3.2 Student Research vs. Classroom Activities** – Policies and procedures presented here are applicable to any student-initiated and/or student conducted work that meets the definitions outlined in both sections 1.3 and 1.6.

Policies and procedures presented here are explicitly not applicable to courses that deal with established research methodology and which have been identified by faculty supervisors as research practicum. Numerous departments offer courses that require students to undertake small projects in which people are interviewed, observed, or otherwise serve as human subjects. The primary purpose of providing training in research methods is for the student to become more knowledgeable about the research process. Instructors may assign a project, in conjunction with the course, in which students design a study, recruit participants, collect and analyze data, and report their findings in the form of a final paper. Since the intent of the project/assignment is to train students, the assignment is not considered to be research as defined within the federal regulations and section 1.6 of this policy and is not subject to IRB review. The course instructor is responsible for including information about ethical research practices and providing direct supervision of each project. Projects conducted for this purpose should not exceed minimal risk, target special populations, or include sensitive subject matter. The instructor of such a course is required to assure that procedures associated with, and data collected from, human subjects within these settings conforms to the ethical principles and guidelines established within the discipline and any other related rules.

If the course assignment produces results that may be of interest to the academic community, the IRB recommends that the student replicate the study under an IRB-approved protocol. The IRB does not have the authority to approve research retrospectively. If the primary intention of the student and faculty supervisor is to contribute to generalizable knowledge, then IRB approval is needed prior to commencement of the research.

**2.3.3 Collaborative Research and Reliance Agreements** – SJSU will abide by the single IRB mandate outlined in the federal regulations at [45 CFR 46.114 \(b\)\(1\)](#). When both SJSU and another domestic institution are engaged in collaborative research, only one IRB need review the IRB proposal. The non-reviewing institution will establish a reliance agreement with the reviewing institution. The reviewing

IRB will be identified either by the funding agency, by the lead institution, or by consensus between the institutions.

## **2.4 Applicability to Research When SJSU is not an Engaged Institution**

**2.4.1 External Investigators with External IRB Approval** – SJSU IRB approval is not needed in cases where a non-SJSU investigator conducts research at SJSU or recruits SJSU students or employees as research participants, provided that the investigator has obtained IRB approval from a supporting institution. The external investigator should register their IRB-approved work with the Office of Research using a form developed for this purpose. Nothing in this policy prevents SJSU department heads from declining to assist external investigators with their research endeavors.

**2.4.2 External Investigators from Institutions Lacking IRBs** – Federal regulations give common rule departments and agencies authority to enforce compliance directly against IRBs. For this reason, SJSU does not require its IRB to review research projects by external investigators who either come from an institution lacking an IRB or who are conducting research independent of any institutional support. SJSU will not take responsibility for or provide institutional support for external investigators' research activities.

## **3.0 SJSU Personnel Responsibilities and Authority**

**3.1 Principal Investigator** —The principal investigator (PI) is responsible for conduct consistent with the ethical treatment of research participants and data. A PI is the individual in charge of a research project and must be qualified in the area of the proposed human subjects research. The PI must assume responsibility for compliance with the present policy. A student may not serve as PI but may be supervised by a faculty member to be a student investigator. PI responsibilities include:

- Completing the training requirement for the protection of human subjects in research as outlined on the Office of Research website and ensuring all research personnel are adequately trained.
- Submitting a complete proposal that is clearly written for a general audience.
- Adhering to all proposed actions that have been approved.
- Informing the IRB of any modifications to the proposed research.
- Informing the IRB of unanticipated problems, adverse events, or injuries within no more than one week (7 calendar days).
- Carefully monitoring research by students, staff, or associates conducted under the guidance and supervision of the PI.
- Complying with an SJSU IRB decision to suspend or withdraw its approval for the project.
- Applying all relevant professional standards.

**3.2 Institutional Review Board (IRB) Members** – The SJSU IRB is responsible for the appropriate review and oversight of human research activities. The IRB is a 13 to 15-member operating committee that is appointed by the Academic Senate and reports to the Curriculum and Research policy committee.

The IRB shall be comprised of persons from diverse backgrounds to promote complete and adequate review of research proposals involving human subjects, shall include both male and female members, at least one member whose primary expertise is in a nonscientific area, and at least one community member who is not affiliated in any way with SJSU. The IRB shall include one physician or licensed health professional, and may include an additional consultant for specific protocol reviews as needed.

Membership shall provide for one faculty member from each senate representative unit with an additional faculty member from each of the Colleges of Education, Social Sciences, and Applied Sciences and Arts

When research involving a category of vulnerable subjects (e.g., prisoners, children) or individuals with impaired decision making ability is to be reviewed, the IRB shall consider the inclusion in its reviewing body of one or more individuals who have as a primary concern the welfare of these subjects. In addition, federal Department of Education regulations require that when an IRB reviews research for one of its programs that purposefully requires inclusion of handicapped children or mentally disabled persons as research subjects, the IRB must include at least one person primarily concerned with the welfare of these subjects [\[34 CFR 97.107\(a\)\]](#).

IRB members from SJSU receive three-year appointments, which are renewable. Community members and students serve for one year. The Associate Dean and a qualified IRB staff person for the Office of Research serve as ex-officio members of the IRB, maintain IRB files, and process protocol reviews. The qualified staff member has voting status as an ex officio member of the IRB and may carry out administrative reviews for minimal risk research.

Recruitment of faculty and student members to serve on the IRB will be done through the normal Committee on Committees process for the seats designated for faculty and student members. All applicants will submit a one-page written statement describing their qualifications to serve on the board. When there are multiple applications for any seat, the Executive Committee of the Academic Senate will select individuals to serve. In considering potential IRB members, attention should focus on the person's research skills and experience and careful consideration of the balance of new and continuing members so the board retains experienced members yet also brings on new members.

IRB member responsibilities and authority include:

- Evaluating discipline-specific research proposals submitted by SJSU PIs to ensure that research involving human subjects is conducted ethically and according to institutional, state, and federal policies.
- Approving, requiring modifications, or disapproving (under convened committee) research involving human subjects conducted at SJSU or in the name of SJSU.
- Suspending or terminating (under convened committee) approval of research that is not being conducted in accordance with this policy and federal regulations or that has resulted in unanticipated serious harm to human subjects.

The IRB shall have access to all information and records necessary to conduct an adequate review of all proposed research involving human subjects to safeguard their rights and welfare.

The IRB shall require that information that it deems necessary to protect the rights and welfare of human subjects be given to the subjects as part of the informed consent process.

The IRB shall apply the criteria for approval outlined in the federal regulations at [45 CFR 46.111](#).

**3.3 Institutional Officer (IO)** – SJSU’s Institutional Officer, the Associate Vice President for the Office of Research, has administrative authority for the protection of human subjects. The IO responsibilities and authority include:

- Maintaining federal wide assurance with the Office of Human Research Protections (OHRP) at the Department of Health and Human Services.
- Reporting unanticipated harms to OHRP, when applicable.
- Proposing actions for various compliance issues, including suspension and termination of research. The IO may suspend research; only the convened committee may terminate research.

**3.4 Other Institutional Officials** – Research that has received IRB approval may be subject to further review by officials of the University; however, no official (including the IO) may approve and authorize research that has not been approved by the IRB.

## **4.0 Description of Procedures**

### **4.1 Protocol Submission Procedures**

**4.1.1 Training Requirements** – Prior to submission of a research protocol to the IRB, any SJSU employee planning to perform or to supervise student research involving human subjects must complete and file with the Office of Research an affirmation attesting to the successful completion of all training courses required of PIs. The nature of the training and access to it is provided on the IRB website.

IRB members are required to complete a training requirement within one month of joining the committee. The nature of the training and access to it is provided on the IRB website.

**4.1.2 Protocol Documents** – The protocol shall provide a complete description of the purpose and background of the research, the methods and procedures used to recruit participants and obtain data, the data management plan, and the risks and benefits of the research. In the protocol, the PI shall make provisions for the adequate protection of the rights and welfare of prospective research participants, delineate the research team’s responsibilities toward the subjects involved in the research, and ensure that pertinent regulations are observed.

For all research, the PI is required to provide adequate information about the research to potential subjects so that an informed decision can be made regarding participation. The procedures for providing this information must be outlined in the protocol. The expectations for the consent process for both exempt and expedited research are outlined in section 5.0.

Regardless of the type of review that is applied to a research protocol (exempt, expedited, convened committee), all protocol submissions must be complete, written in a manner that is comprehensible to a general audience, and apply relevant professional standards and best practices, including the minimization of risk to participants and a plan to mitigate conflicts of interests and/or situations that present undue influence.

**4.1.3 Protocol Routing** – Protocols that present minimal risk to subjects, if not found to be exempt under an administrative review by a qualified IRB staff member for the Office of Research, shall be assigned to individual IRB members on a rotating basis by a qualified IRB staff member. IRB staff may screen protocols to ensure they are complete and coherent before routing them an IRB member.

Protocols that present greater than minimal risk to subjects, as determined by a qualified IRB staff member who is also a member of the IRB or by an individual IRB member, must be reviewed by the convened committee.

Subsequent modifications to approved protocols shall undergo an administrative review by a qualified IRB staff member for the Office of Research, unless the modifications increase the risks to subjects. Modifications that increase the risks to subjects shall be reviewed by an IRB member or by the convened committee.

## **4.2 Review Categories**

**4.2.1 Exempt Review and Registration** – The federal regulations exempt several classes of research from IRB review. SJSU bases recognition of these exemptions on two assumptions: (1) the risk to participants in research is so minimal that requiring an IRB review represents unwarranted intrusion into the research process; and (2) investigators (faculty, students, staff) understand, accept, and will implement the principles of informed consent contained in this policy.

Table 1 lists the categories of research that qualify for exemption from IRB review under the federal regulations at [45 CFR 46.104](#). The table also shows how these categories apply to the regulatory subparts protecting certain vulnerable subjects (pregnant women, human fetuses, and neonates; prisoners; and children). SJSU has adopted the application of the exemption categories to these protected groups according to the federal regulations. Table 1 outlines the type of consent process which SJSU requires of research qualifying for exemption. In most cases, a written consent notice is provided to subjects but documentation of consent (i.e., a signature on a consent form) is not required. The expectations for the consent process for all review categories are outlined in greater detail in section 5.0.

Exemption is not the same as exclusion. Investigators may not self-determine exempt status and must register a complete protocol with the Office of Research for activities that may qualify for exemption. Protocols shall be screened by a qualified IRB staff member and those protocols that are determined to be exempt from IRB review will undergo an administrative review by the Office of Research only. Registration is not complete until confirmation from the Office of Research has been received by the investigator. The Office of Research reserves the right to evaluate the risk to human subjects in research

identified as exempt and to require formal IRB review if the risk is greater than minimal or if it is deemed that expedited or full review is required.

The federal regulations identify the concept of “limited IRB review” for some categories of exempt research at [45 CFR 6.111\(a\)\(8\)](#). For the purposes of SJSU policy, the limited IRB review is akin to an administrative review conducted by the Office of Research which takes into consideration the privacy and confidentiality protections afforded to subjects as well as the consent procedures outlined in the protocol (when applicable).

An administrative review can be conducted by a qualified staff member for the Office of Research. In cases where the work is also subject to a limited IRB review under the federal regulations, the review can be conducted by a qualified staff member who is also a member of the IRB or through an expedited review by an IRB member.

**4.2.2 Expedited Review** – An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson or a qualified staff member from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#). In reviewing the research, the reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. Only a convened committee may disapprove research protocols. IRB members are informed of initial review, continuing review, and protocol modifications using expedited procedures via a tracking system provided by the Office of Research.

Research is eligible for an expedited review if it presents no more than minimal risk to human subjects and involves procedures or activities outlined by OHRP and listed in Table 2.

The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, or reputation, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk.

The expedited review procedure may not be used for classified research involving human subjects.

Federal regulations describe the general requirements for informed consent and allowable waivers at [45 CFR 46.116](#) and [45 CFR 46.117](#) respectively. The fundamentals of informed consent are discussed in greater detail in section 5.0 of this policy.



**4.2.3 Convened Committee / Full Review** – If the research is not eligible for an exempt or expedited review because it involves more than minimal risk to subjects, the protocol must be reviewed by the convened IRB membership at the monthly meeting. Full review will take place with a quorum of the IRB, defined as a majority of the total membership, including at least one member whose primary concerns are in a nonscientific area. Research protocols shall be distributed to the full membership at least one week in advance of the scheduled meeting. A protocol shall be approved if it receives the approval of a majority of those members present at the meeting. A primary reviewer is identified to present a specific protocol to other members in attendance. Following presentation and discussion, the committee will vote on a motion to either: 1) approve the protocol as it stands; 2) request revisions to the protocol to secure approval; 3) request that additional information be provided prior to further review by the convened committee; or 4) disapprove the protocol.

The IRB shall apply the criteria for approval outlined in the federal regulations at [45 CFR 46.111](#) and shall approve the research if:

- Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits from the research.
- Selection of subjects is equitable, considering the purpose of the research, the setting, and the population from which subjects will be recruited, with special consideration for vulnerable populations and/or subjects who may be vulnerable to undue influence or coercion.
- Subjects are fully informed of their rights and of the potential risks and benefits of participation in the research.
- Informed consent will be obtained from each prospective subject, as needed, and appropriately documented unless a waiver of documentation of consent is granted.
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, protecting the privacy of subjects, and maintaining the confidentiality of data.

**4.2.4 Continuing Review** – Continuing annual review for approved protocols that qualified for exemption or expedited review is not required unless modifications to the ongoing research significantly change the risks to subjects or the IRB has documented the need for continuing review for a specific protocol.

Protocols approved under a convened committee must undergo a continuing review at least annually. Investigators are responsible for submitting an extension request for continuing review prior to the expiration date of the protocol approval.

Regardless of the type of initial review (exempt, expedited, convened committee) or whether continuing review is needed, investigators are responsible for communicating any changes or modifications to the approved research protocol to the IRB. Submitting modification requests to an approved protocol and

obtaining approval for the modification is required before the modification can be implemented except where the modification is necessary to eliminate apparent immediate hazards to subjects.

#### **4.3 Communication between the IRB and Investigators**

**4.3.1 Written Communication to Investigator** – Protocol forms, including consent templates, shall be provided on the IRB website.

Approvals, recommendations, restrictions, conditions, or disapprovals shall be communicated to the PI in written form. Reasons for disapproval shall be set forth in detail with IRB recommendations for modification of the proposal.

**4.3.2 Written Communication from Investigator** – All changes to a protocol in response to IRB recommendations must be made in writing.

**4.3.3 Appeal Procedures** – If an investigator believes that his/her protocol has been disapproved because of incorrect, unfair, or improper evaluation by the IRB, s/he may appeal to the IRB chairperson. Likewise, if an investigator believes requests made by an IRB member are unfair or improper, s/he may appeal to the IRB chairperson. If the IRB chairperson upholds the disapproval or the IRB request made by an individual IRB member, the investigator shall show cause in writing within 3 weeks after the negative decision as to why the IRB decision should be reversed. The appeal shall be considered by a full convened committee review.

**4.3.4 Compliant Procedures** – Complaints about failure to protect human subjects participating in research activities covered by this policy shall be made in writing to the IRB chairperson and to the Associate Vice President for the Office of Research.

Upon receipt of a complaint, the IRB Chairperson and one IRB member shall investigate the complaint and shall make a report with a recommended action to the full IRB and to the AVP for the Office of Research. If the report includes recommendations to modify or terminate approval for the activity, the chairperson shall convene the IRB no later than the next scheduled meeting to discuss the complaint and all other pertinent information. After reviewing all the evidence and addressing all appropriate questions, the IRB may decide to affirm the appropriateness of the activity, to request modification(s), or to terminate approval for the activity. The IRB decision shall be communicated to the complainant, the PI, and the AVP for the Office of Research in writing.

**4.3.5 Reporting Procedures for Unanticipated Problems, Adverse Events or Injuries** — Any unanticipated problems, adverse events or injuries to human subjects during the course of the research must be reported to the IRB via the Office of Research promptly, within no more than one week (7 calendar days), by the principal investigator, using a form designated for this purpose that is posted on the IRB website.

An unanticipated problem is characterized as being:

- (1) Unexpected (in terms of nature, severity, or frequency) in relation to the IRB-approved research procedures described in protocol documents;
- (2) Related or possibly related to participation in research; and
- (3) Suggests that the research places subjects or others at greater risk of harm than was previously known.

An adverse event or injury is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign, symptom, or disease temporally associated with the subject's participation in the research. Adverse events encompass both physical and psychological harms.

A qualified IRB staff member shall triage such reports and any follow up information to the AVP for the Office of Research and the IRB chair. The IRB chair shall determine whether any corrective actions or substantive changes are required to the protocol with the assistance of at least one other IRB member or a sub-committee designated by the chair. The AVP for the Office of Research shall determine whether further reporting to other institutional officials or to OHRP is required.

The PI shall be notified by the Office of Research of any corrective actions or changes the IRB has determined are needed. These may include, but are not limited to: modification to selection criteria; modification to consent documents; provision of additional information to previously enrolled subjects; implementation of additional procedures for monitoring subjects; suspension of enrollment of new subjects; suspension of research procedures.

#### **4.4 IRB Records and Reports**

**4.4.1 IRB Documentation** – The IRB shall prepare and maintain adequate documentation of IRB activities. Records of specific human subjects research activity shall be maintained for three years after termination of the last IRB approval period for the activity. Records shall include the following:

- Current IRB membership and operating procedures.
- Copies of all human subjects research proposals reviewed, with all pertinent materials that accompany the proposals, progress reports, and any reports of unanticipated or adverse events.
- Minutes of IRB meetings in sufficient detail to show names of attendees, actions taken with the votes specified, basis for requiring changes in or disapproving human subjects research, summaries of discussions of controverted issues and their resolution. If any member has a conflicting interest regarding any research, the minutes shall show that this member did not participate in the review, except to provide information requested by the IRB.
- Reports of continuing review activities, including the rationale for conducting continuing review of research that would otherwise not require it.
- Copies of all IRB correspondence.

**4.4.2 IRB Reporting** – The IRB shall report promptly to OHRP these matters of information:

- Any serious or continuing noncompliance by research investigators, SJSU, or its agencies with the requirements of this policy.

- Any unanticipated problems or adverse events that meet the OHRP reporting criteria.
- Suspension or termination of IRB approval (with a statement of reasons for the IRB action), when required by OHRP.

**4.4.3 Audits of Research Activities** – The Office of Research and the IRB have the authority to obtain any original research records from the PI for the purposes of auditing the research activity for compliance; records that may be requested include, but are not limited to, signed consent documents and raw data.

## **5.0 Fundamentals of Informed Consent**

OHRP states that “informed consent is one of the primary requirements underpinning research with human subjects; it reflects the basic principle of respect for persons.” Informed consent is the knowing consent of an individual or his/her legally authorized representative (LAR) which is obtained without undue influence or coercion. Obtaining informed consent is a process in which an individual is given enough information about a study to make a decision about whether to participate in the research. The consent process involves discussing the details of study participation with a knowledgeable member of the research team, as well as reading and signing a consent form to document that the process has occurred. The consent process must be conducted in a way that facilitates the comprehension of prospective subjects.

**5.1 Investigator Responsibilities** – It is the responsibility of the research team to provide complete information about a study and to obtain meaningful informed consent from the subject or his/her LAR prior to enrolling them in the study. Guided by the federal regulations at [45 CFR 46.116](#), SJSU requires investigators to maximize the meaningfulness of the consent process by:

- Providing complete information about the study, including beginning with a focused and concise presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons one might or might not want to participate in the research. The standard elements of consent outlined in section 5.3.2 can be considered to satisfy the key information that must be communicated to subjects at the outset of the consent process.
- Facilitating comprehension by using layman’s language and text that is well-written and has been proofread.
- Using a clean and clutter free presentation in written consent documents.
- Describing and following alternatives to written consent for subjects with limited reading skills, who are illiterate, or who are members of a distinct cultural group or community for whom signing documents is not the norm.
- Conducting the consent process in the primary language of subjects and providing them with translations of written documents.
- Providing information about the limits to confidentiality, such as mandated reporting, when appropriate.
- Conducting the consent process under circumstances that offer the subject or the LAR sufficient opportunity to consider whether the subject should or should not participate, including minimizing the possibility of undue influence or coercion, and refraining from the use of exculpatory language.

Where documentation of consent is required or utilized by the research team, the PI is required to maintain such documentation for three years.

Consent is not required for access to identifiable private information from stored records or directly via oral or written communication with prospective subjects for the purposes of recruitment, screening, and determining eligibility for participation as long as there are adequate confidentiality and privacy safeguards for these preparatory-to-research activities.

## **5.2 SJSU-Specific Requirements**

**5.2.1 Exempt Research** – Investigators must utilize the most appropriate consent option discussed in section 5.3 for their research. SJSU requires a consent process for research that is granted exempt status by the Office of Research. However, documentation of consent is waived for most exempt research except where the subjects are minors or where other laws or regulations require a participant's written authorization. Table 1 summarizes the type of consent process which SJSU requires of research qualifying for exemption.

**5.2.2 Parental Permission** – Parental permission is required when recruiting children or minors as subjects in research. In California, a minor is identified as a person under the age of 18 years. Parental permission must be obtained in advance of enrolling a minor subject into a study even if the research qualifies for exemption. The exception to the requirement for parental permission is for college students providing their consent for participation in school-based research, such as enrolling in a business or psychology department subject pool for extra credit.

The standard elements of consent, as outlined in section 5.3.2, are used when developing a parental permission form. Text should reflect the activities that the child (and the parent, if they are also considered a subject) will be asked to participate in as a research subject.

**5.2.3 Assent** – The assent of children is required in cases where obtaining assent is appropriate, regardless of whether the protocol undergoes an administrative review for exemption or an IRB review. In determining whether a child is capable of assenting, reviewers shall take into account the age, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol or for each child, as is deemed appropriate during the review. If the reviewer determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under the same circumstances in which consent may be waived in accordance with section 5.4. The PI is required to provide an explanation in the IRB protocol of how assent will be obtained or a justification for why it would not be appropriate to obtain assent in a specific case.

**5.2.4 Translations** – Non-English speaking persons must be presented with a consent form and other written materials in their primary language. The investigator must provide the IRB with translations for review and approval prior to recruiting subjects. It is recommended that the investigator secure preliminary IRB approval of the English documents prior to having them translated. The IRB does not require that a certified translator perform the document translation, but the IRB does require a verification of the accuracy of the translation(s). The verification may be provided by a member of the Department of World Languages, an individual who has the equivalent of a bachelor's degree in that language, an individual who has received an education through secondary school with that language as the language of instruction, or from a certified translator. Research team members may translate their research documents if they are fluent in the language, but they may not verify their own translations.

### **5.3 Types of Informed Consent**

The Office of Research shall provide templates for all consent options discussed below, including consent notice, a standard consent form for adults, and a parental permission form.

**5.3.1 Consent Notice** – This type of document or script can be used for research that qualifies for exemption. It includes all of the information needed to help prospective adult participants make an informed decision about whether or not to participate in the research, but this document does not include a place for participants to indicate with a signature that they agree to take part in the research. This means that the reviewer is asked to waive the requirement for documented (signed) consent. This option can be used when the study is either:

- (1) No greater than minimal risk and involves no procedures for which written consent is normally expected, or
- (2) The only record linking the participants to the research would be the consent document and the primary risk would be potential harm resulting from a breach of confidentiality (e.g., an anonymous survey).

At a minimum the consent notice should include:

- (1) The investigator's name, institutional affiliation, academic status, and contact information.
- (2) The purpose of the study.
- (3) A brief description of what subjects will be asked to do and the time involved.
- (4) That participation is voluntary and that the person may withdraw at any point.
- (5) How data will be recorded and maintained as well as who will have access.
- (6) A description of incentives/compensation offered or costs that may be incurred.

The signature line on the standard consent form is replaced with a statement such as "your completion of the survey indicates your willingness to participate. Please keep this information for your records and do not write any information that could identify you on the survey."

The consent notice must be in the primary language of the participants.

The consent notice option may not be used with parents or legal guardians consenting for participants in their care – written consent is needed in those cases from the LAR.

**5.3.2 Standard Elements of Consent** – This form includes all of the required information designed to help prospective participants make an informed decision about whether or not to participate in the research. This form can also be used to seek permission from parents of minors and other types of guardians who are LARs. The form must be in the primary language of the participants or their LARs and must include a signature line and date line for the consenting individual to sign. The form must also be signed by the primary investigator and a copy provided to the participant and/or LAR.

The standard elements of informed consent as outlined in the federal regulations at [45 CFR 46.116\(b\)](#) are:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without



additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

**5.3.3 Additional Elements of Consent** – The following elements of information, when appropriate, shall also be provided to each subject or their LAR:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**5.3.4 Verbal Consent (Standard Consent Short Form and Script)** – This method may be used in circumstances where oral presentation of consent information is necessary (e.g., participants are illiterate in their primary language or they come from an oral rather than written tradition). The standard consent form is presented as a "short form" document stating that the required elements of informed consent have been presented orally to the participant. When the short form method is used, a script of the information that is presented to the participant must also be provided to the IRB for approval and there must be an impartial witness to the oral presentation. The witness and the PI must sign both the script and the short form, while the participant must sign the short form only and is given a signed copy for his/her records. The short form usually contains appropriate contact information in addition to the statement that the elements of informed consent have been presented orally. The oral

presentation and short form must be provided in the primary language of the participant.

**5.3.5 Broad Consent** –In accordance with the recommendations of the CSU IRB Working Group, SJSU chooses not to apply the broad consent option and the corresponding exemption categories at [§II.104\(d\)\(7\)](#) and [§II.104\(d\)\(8\)](#). The broad consent option enables the creation of data repositories that are primarily of interest to institutions that support biomedical research and clinical trials. Apart from potentially being a source of confusion for PIs in the social and behavioral sciences, the broad consent option raises questions about data ownership, security concerns, and burdensome tracking requirements that have yet to be addressed by regulatory guidance.

## **5.4 Waivers**

**5.4.1 Waiver of Documentation of Consent** – An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- (1) The only record linking the subject and the research would be the consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject or LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- (2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- (3) If the subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or LARs with a written statement regarding the research.

**5.4.2 Waiver of Some or All Consent Elements** – The IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in sections 5.3.2 and 5.3.3, provided the IRB finds and documents all of the following:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The research could not practicably be carried out without the requested waiver or alteration;
- (3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- (4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (5) Whenever appropriate, the subjects and/or LARs will be provided with additional pertinent information after participation.

**Table 1. Exemption Review Categories**

Exemption Category	Application to Subparts and to Consent at SJSU
<p><b>(1)</b> Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</p>	<p><b>Pregnant women Human Fetuses and Neonates (subpart B):</b> exemption applies.</p> <p><b>Prisoners (subpart C):</b> exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p><b>Children (subpart D):</b> exemption applies.</p> <p><b>Consent:</b> Notice for adults except when other policies require participant written authorization (e.g., FERPA). Written parental consent required except for college students providing consent for their participation in school-based research.</p>
<p><b>(2)</b> Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:</p> <p><b>(i)</b> The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;</p> <p><b>(ii)</b> Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or</p> <p><b>(iii)</b> The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by <a href="#">§II.111(a)(7)</a>.</p>	<p><b>Pregnant women Human Fetuses and Neonates (subpart B):</b> exemption applies.</p> <p><b>Prisoners (subpart C):</b> exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p><b>Children (subpart D):</b> (i) and (ii) exemption applies if PI does not participate in the activity being observed; (iii) exemption does not apply.</p> <p><b>Consent:</b> Notice for adults except when other policies require participant written authorization (e.g., FERPA, HIPAA). Written parental consent required except for college students providing consent for their participation in school-based research.</p>

<p><b>(3)(i)</b> Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:</p> <p><b>(A)</b> The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;</p> <p><b>(B)</b> Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or</p> <p><b>(C)</b> The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by <a href="#">§11.111(a)(7)</a>.</p> <p><b>(ii)</b> For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no interventions that are offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.</p> <p><b>(iii)</b> If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed</p>	<p><b>Pregnant women Human Fetuses and Neonates (subpart B):</b> exemption applies.</p> <p><b>Prisoners (subpart C):</b> exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p><b>Children (subpart D):</b> exemption does not apply.</p> <p><b>Consent:</b> Notice for adults except when other policies require participant written authorization (e.g., FERPA, HIPAA).</p>
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<p>that he or she will be unaware of or misled regarding the nature or purposes of the research.</p>	
<p><b>(4)</b> Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:</p> <p><b>(i)</b> The identifiable private information or identifiable biospecimens are publicly available;</p> <p><b>(ii)</b> Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;</p> <p><b>(iii)</b> The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA at <a href="#">45 CFR parts 160 and 164</a>, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or</p> <p><b>(iv)</b> The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 <i>et seq</i></p>	<p><b>Pregnant women Human Fetuses and Neonates (subpart B):</b> exemption applies.</p> <p><b>Prisoners (subpart C):</b> exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p><b>Children (subpart D):</b> exemption applies.</p> <p><b>Consent:</b> Not applicable unless another policy applies (e.g., FERPA). [Note: SJSU PIs who have access to individually identifying health info are not covered by (iii) of this exemption, unless the covered entity providing the access is a collaborator in the research and there is a business associate contract between the covered entity and the SJSU PI].</p>

<p><b>(5)</b> Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.</p> <p><b>(i)</b> Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.</p>	<p><b>Pregnant women Human Fetuses and Neonates (subpart B):</b> exemption applies.</p> <p><b>Prisoners (subpart C):</b> exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p><b>Children (subpart D):</b> exemption applies.</p> <p><b>Consent:</b> (i) of this exemption covers the SJSU notice requirement.</p>
<p><b>(6)</b> Taste and food quality evaluation and consumer acceptance studies:</p> <p><b>(i)</b> If wholesome foods without additives are consumed, or</p> <p><b>(ii)</b> If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level</p>	<p><b>Pregnant women Human Fetuses and Neonates (subpart B):</b> exemption applies.</p> <p><b>Prisoners (subpart C):</b> exemption does not apply except for research aimed at involving a broader subject population that only incidentally includes prisoners.</p> <p><b>Children (subpart D):</b> exemption applies.</p>

found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.	<b>Consent:</b> Notice for adults. Written parental consent required except for college students providing consent for their participation in school-based research.
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<p><b>(1)</b> Clinical studies of drugs and medical devices only when condition (a) or (b) is met.</p> <p>(a) Research on drugs for which an investigational new drug application (<a href="#">21 CFR Part 312</a>) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)</p> <p>(b) Research on medical devices for which (i) an investigational device exemption application (<a href="#">21 CFR Part 812</a>) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.</p>
<p><b>(2)</b> Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:</p> <p>(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or</p> <p>(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.</p>
<p><b>(3)</b> Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.</p>
<p><b>(4)</b> Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to</p>



<p>evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.</p>
<p><b>(5)</b> Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the regulations for the protection of human subjects. This listing refers only to research that is not exempt.)</p>
<p><b>(6)</b> Collection of data from voice, video, digital, or image recordings made for research purposes.</p>
<p><b>(7)</b> Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the regulations for the protection of human subjects. This listing refers only to research that is not exempt.)</p>
<p><b>(8)</b> Continuing review of research previously approved by the convened IRB as follows:</p> <p>(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or</p> <p>(b) where no subjects have been enrolled and no additional risks have been identified; or</p> <p>(c) where the remaining research activities are limited to data analysis.</p>
<p><b>(9)</b> Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.</p>

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823 \* Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

824 \* Children are defined in the regulations as "persons who have not attained the legal age for consent to  
825 treatments or procedures involved in the research, under the applicable law of the jurisdiction in which  
826 the research will be conducted." [45 CFR 46.402\(a\)](#).

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## 2018 Revised Common Rule for Human Subjects Research

Prepared by Alena Filip, Human Protections Analyst, Office of Research

### Summary of Revisions

#### Compliance Date

January 2018. The new regs leave it up to the institution to decide whether they should be applied to pre-2018 active protocols.

#### Definition of Research

Remains the same as previous rule but includes examples of activities that are not considered research:

- Journalistic and scholarly activities -- includes oral history, journalism, literary criticism, legal research, historical scholarship, and collection and use of data that focuses on specific individuals.
- Public health surveillance activities.
- Criminal investigations.
- National security.

#### Exempt Research

- Adds 3 new categories (benign interventions under certain conditions, storage and maintenance of identifiable secondary data and biospecimens, use of identifiable secondary data and biospecimens); omits 1 current category (public officials).
- Expands and clarifies existing categories, including clarifications on which exemptions can be applied to subparts B (pregnant women), C (prisoners), and D (children).
- Introduces concept of "limited IRB review" for certain categories. Limited IRB review only evaluates privacy, confidentiality, and consent – can be conducted under expedited review or administrative review by a qualified staff member.
- Introduces concept of "broad consent" for storage, maintenance, and use of identifiable private information and identifiable biospecimens in secondary research such as that covered by exemption categories 7 and 8. Broad consent may not be used for any other research except secondary research, which involves identifiable private information or identifiable biospecimens that are collected originally for another research activity or for a non-research activity.

[Refer to the Table of Exemption Categories for a list of the exemption categories under the revised rule, info on how the exemptions apply to the subparts under the revised common rule, and my recommendations on how consent should be applied under SJSU policy:](http://www.sjsu.edu/research/docs/2018-Table-Exemption-Categories.pdf)  
<http://www.sjsu.edu/research/docs/2018-Table-Exemption-Categories.pdf>

## 2018 Revised Common Rule for Human Subjects Research

Prepared by Alena Filip, Human Protections Analyst, Office of Research

### Continuing Review

Omits requirement for continuing review of research that qualified for expedited review (i.e., approval does not have an expiration date but PIs must continue to inform IRB about modifications); otherwise IRBs must provide and document justification for requiring a continuing review of each protocol.

### Single IRB Mandate

- Only one IRB review for cooperative research that involves multiple study sites – to be determined either by the federal sponsor of the research or by consensus between institutions.
- Reliance agreements for cooperative research should list the allocated responsibilities of each institution.

### Consent

- Requirement that consent forms include essential info first (e.g., elements of informed consent) and are designed to facilitate understanding.
- Addition to basic elements of informed consent: whether or not research data involving identifiable secondary data or biospecimens will be shared for use in future research even if identifiers are removed.
- Expanded additional elements of informed consent (used when applicable) to include whether biospecimens will be used for commercial profit and whether subject will share in that profit.
- No consent required for access to secondary data from records or directly from subjects for the purposes of recruitment, screening, and determining eligibility for participation as long as confidentiality and privacy safeguards are in place.
- Outlines conditions under which broad consent may be used -- only for secondary research involving identifiable private information or identifiable biospecimens.
- Outlines the elements of broad consent – are more extensive than typical consent.
- Waivers of informed consent and documentation of informed consent under standard IRB review remain the same.
- Revision of terminology "mental disability" to "individuals with impaired decision making ability"
- Expansion of the concept of vulnerability to include coercion and undue influence.

Prepared by Alena Filip, Human Protections Analyst, Office of Research

[illegible]

## 2018 Revised Common Rule for Human Subjects Research

Prepared by Alena Filip, Human Protections Analyst, Office of Research

### SJSU Policy Recommendations

#### Compliance Date

Apply 2018 regulations to pre-2018 active protocols at the time that investigators submit an extension request. At that time, a continuing review will be conducted to determine whether the protocol needs to be revised in any way to accommodate the new regs; after this continuing review the investigator will no longer have to seek additional continuing reviews for protocols that underwent an expedited or exempt review.

#### Definition of Research

- Continue to include the definition of research, but add these examples to others already included in the policy (needs assessment, program evaluation, quality control, SJSU employee consultants, student classroom work intended as research practicum).
- Omit current reference that equates publication with generalizable knowledge.

#### Exempt Research

- Revise exemption categories accordingly.
- Apply the exemption categories to pregnant women (subpart B) and prisoners (subpart C) in the same way as the revised common rule does.
- Remove publication as a condition for not exempting research involving minors and apply exemption categories to minors (subpart D) in the same way as the revised common rule does. (See Section VI.C.1b of current SJSU policy).
- Merge the revised common rule concept of “limited IRB review” and the current SJSU policy of “IRB registration” for exempt research. Conduct an administrative review of all research qualifying for exemption that takes into consideration privacy and confidentiality protections and consent procedures (when applicable). The administrative review can be conducted by a qualified staff person. In cases where the work is also subject to a limited IRB review under the revised common rule, the review can be conducted by a qualified staff person or through an expedited review by an IRB member.
- Add language to the policy that all research proposals, regardless of whether they qualify for exemption, must be 1) complete, 2) written in a manner that is comprehensible to a general audience, and 3) apply relevant professional standards and best practices, including the minimization of risk to participants and a plan to mitigate conflicts of interests or situations that present undue influence.
- Continue to require some form of consent for applicable exempt research. For research involving minors, whether exempt or not, require written parental consent except if participants are college students and are providing consent for their participation in school-based research. For exempt research involving adults only, require consent notice but not signed consent, except when other policies require participant written authorization (e.g., FERPA, HIPAA). The Office of Research will provide templates for all required consent documents, including the standard consent form for adults, parental authorization form, consent notice, and broad consent form.

[Refer to the Table of Exemption Categories for a list of the exemption categories under the revised rule, info on how the exemptions apply to the subparts under the revised common rule, and my recommendations on how consent should be applied under SJSU policy:](http://www.sjsu.edu/research/docs/2018-Table-Exemption-Categories.pdf)  
<http://www.sjsu.edu/research/docs/2018-Table-Exemption-Categories.pdf>

## 2018 Revised Common Rule for Human Subjects Research

Prepared by Alena Filip, Human Protections Analyst, Office of Research

### Continuing Review

- Revise continuing review requirements accordingly. (Only full review protocols require continuing review unless justification is provided for continuing review of specific expedited protocols).
- Discontinue practice of requiring extensions for exempt research, but continue to require modification requests for exempt research.
- If a paper submission process is still in place at the time that the new rules are implemented, investigators should be required to submit a report indicating their study is complete.

### Single IRB Mandate

- Add to policy accordingly.
- The Office of Research will use a reliance agreement for collaborative research.
- Registration of non-collaborative research for outside investigators coming to SJSU where SJSU is not engaged in the research.
- Add policy that the SJSU IRB will not review protocols from investigators that come from institutions lacking an IRB.

### Consent

- Revise policy accordingly; our policies and procedures already fulfill most of the requirements, so only minor additions need to be made. However, the broad consent option needs to be added to the available templates and guidance needs to be provided on when broad consent is applicable.
- Continue to require some form of consent for applicable exempt research. For research involving minors, whether exempt or not, require written parental consent except if participants are college students and are providing consent for their participation in school-based research. For exempt research involving adults only, require consent notice but not signed consent, except when other policies require participant written authorization (e.g., FERPA, HIPAA).
- Federal regs contain no recommendations regarding assent, but I propose to add to the SJSU policy: Assent is required in cases where obtaining assent is appropriate for the age and developmental ability of the target population regardless of whether the protocol undergoes an administrative review or an IRB review. PIs are required to provide an explanation of how assent will be obtained or a justification for why it would not be appropriate to obtain assent in a specific case.
- Remove specific reference in SJSU policy that provides additional safeguards to "individuals institutionalized as mentally disabled" and replace with "individuals with impaired decision making ability; individuals who may be susceptible to coercion or undue influence because of a power imbalance in their relationship with the investigator; or any other potentially vulnerable groups."



## 2018 Revised Common Rule for Human Subjects Research

Prepared by Alena Filip, Human Protections Analyst, Office of Research

### Other SJSU Policy Recommendations (not related to revised common rule)

- Update our office name throughout.
- Update membership and personnel info in Section VI.A.4.
- Add training requirement for IRB members.
- Update the number of years that members are appointed according to recent SJSU policy changes (Section II.A.3 and Section VI.A.1). Also add voting status of IRB analyst and IRB member selection process as indicated by the recent F15-8 policy modification.
- Omit reference to registering non-research activities with our office (Section III B.1).
- Clean-up and clarify section on student classroom activities. Keep that it should be minimal risk and not target special populations or sensitive subject matter, but omit listing of examples that might exceed the minimal risk standard. Also refer to student classroom work as research practicum and not research (Section IV.C).
- Expedited review categories need to be updated to reflect current list provided by DHHS, (Section VI.C.2f).
- Remove requirement to submit two paper copies – this is a procedural requirement and does not belong in the policy (Section VI.B.2).
- Remove reference to University letterhead. It's sufficient to state electronically.
- Update appeal procedures to include appeals to revision requests conducted under administrative review – such appeals requests should go to the IRB chair (Section VI. D. 5 and 6).
- Clarify that appeal should first go to the chair; if chair does not grant appeal, then it goes to full committee.
- Add that an administrative review by a qualified IRB staff member can take place for protocol modifications unless the modifications increase the risk to subjects.
- With the exception of defining "minimal risk," omit all other descriptions of risk from current policy (psychological, social, group risk). This is educational info and not policy info, and it is not an exhaustive list.
- Add adverse event reporting procedures - this is required!
- Add that IRB and Office of Research has the authority to audit research records and activities.
- Remove inconsistencies, language that appears to violate the common rule, and re-organize and simplify the presentation of information to avoid redundancy and confusion. Refer to a previous document "2008 SJSU HSR Policy Proposed Revisions" (link below) that I created in 2014 that outlines these problems. The new policy may be ordered differently due to the revised common rule and to reduce the redundancy and confusing organization of the current policy. Wherever possible, reference should be made to the revised common rule directly (with hyperlinks) to orient readers to further information.

2008 SJSU HSR Policy Proposed Revisions: <http://www.sjsu.edu/research/docs/2008-SJSU-HSR-Policy-Proposed-Revisions.pdf>

## 2018 Revised Common Rule for Human Subjects Research

Prepared by Alena Filip, Human Protections Analyst, Office of Research

### Rationale for Recommendations

#### Compliance Date

Having all active protocols comply with the new regulations ensures consistency and reduces the administrative burden of having to apply two sets of standards to different protocols. Having the investigator make any necessary revisions to comply with the new rules at the time of the extension request minimizes the burden on investigators while alerting them to the change in policy.

#### Definition of Research

Adding examples of activities excluded from the definition of research serves to provide greater clarification and is not a policy change per se. The guidance accompanying the new regs provides a justification for explicitly excluding journalism and oral histories as follows: "In these activities the ethical requirement is to provide an accurate and evidence-based portrayal of the individuals involved, and not necessarily to protect them from public scrutiny." However the guidance does distinguish journalism and oral histories from ethnography, stating "studies using participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand their beliefs, customs, and practices, and the findings apply to the studied community or group, and not just the individuals from whom the information was obtained, fall within the scope of the definition of research of the final rule." The guidance also explains why public health surveillance activities and criminal and national security investigations don't fall within the scope of the final rule, but these types of activities are not typical for SJSU and our policy does not require further elaboration on these points.

#### Exempt Research

- These recommendations would further harmonize SJSU policy with the federal regulations without significantly impacting protections for human subjects.
- Currently, SJSU applies a different standard for research involving minors that would be exempt under the federal regulations. We require that research involving minors, despite qualifying for exemption, should go through an IRB review if the work is to be published. Since the intent to publish is not always known at the outset of the work, is not a measure of whether an activity meets the definition of research, and does not mean that risks to subjects have been minimized if the work ends up not being published, the criteria for applying exempt status to research with minors should not rest on publication. Research that qualifies for exemption is inherently minimal risk. SJSU can best protect minors, not by requiring an IRB review when the work qualifies for exemption, but by continuing to apply more stringent consent requirements for work involving minors. Having research with minors that qualifies for exemption undergo an administrative review by a qualified staff member, rather than undergoing an IRB review, increases efficiency.
- The concept of "limited IRB review" introduced by the revised regulations is synonymous with our current process of IRB registration for exempt research but allows for the option of having an exempt protocol be reviewed by either a qualified IRB member or a qualified staff member. Since this new aspect of the regulations is already being practiced, it does not represent a significant policy change but serves to clarify the circumstances under which limited IRB review will take place and what the criteria for review will be.
- Adding language to the policy requiring a basic quality standard for research protocols emphasizes the obligations of researchers and provides a rationale for returning protocols to investigators for further revisions if they do not meet the basic standards of completeness and comprehensibility.
- Continuing to require some type of consent for exempt research upholds the current SJSU policy but provides clarification for some specific situations (e.g., minors, other applicable regulations). Since most situations for exempt research will involve consent in the form of a written informational notice, upholding this requirement does not pose additional burdens for researchers and enhances protections for research participants. To avoid confusion, the consent process for exempt research can be referred to as "consent notice" or simply "notice" to distinguish it from the "consent form" typically required for non-exempt research.

[To read a discussion, analysis of public comments, and justification of the new exemption categories, please refer to pages 7186 to 7200 of the preamble to the revised common rule available at: https://www.federalregister.gov/documents/2017/01/19/2017-010](https://www.federalregister.gov/documents/2017/01/19/2017-010)

## 2018 Revised Common Rule for Human Subjects Research

Prepared by Alena Filip, Human Protections Analyst, Office of Research

### Continuing Review

- In practice, requiring continuing review for expedited and exempt research has proven not to serve any practical purpose and does not enhance protections for subjects. Most investigators submit modification requests throughout the year and have little to report at the one year anniversary of their IRB approval. Investigators should continue to submit modification requests throughout the course of their research activity and get approval for modifications prior to initiating them. Maintaining a robust and efficient modification approval system does more to protect subjects than conducting annual reviews of protocols.
- Having investigators submit a study completion report enables the Office of Research to have information on which protocols are active. Since we are required to retain IRB records for 3 years after study completion, this enables accurate maintenance of paper files. If we have an electronic submission system, this may no longer be required because in practice the files are kept indefinitely, but for paper files we only have a limited amount of space.

### Single IRB Mandate

Adding policy language about the single IRB mandate serves only to verbalize what has already been a practice. Requiring investigators to obtain IRB approval from multiple institutions is inefficient and duplicates work unnecessarily. However, adding language stating the SJSU IRB will not review protocols from investigators that come from institutions lacking an IRB is a new policy suggestion meant to protect the SJSU IRB from legal liability. The revised regulations now hold the reviewing IRB accountable rather than the institution where the research is conducted if the review is inadequate. The SJSU IRB should be protected from the legal ramifications of this shift in policy. Since IRB members, apart from the chair, are not compensated for their work, this also reduces the burden on the IRB to provide a service for researchers who are not part of the SJSU community. The implication of this policy will be that external investigators cannot conduct research on this campus if they don't already have IRB approval.

On the other hand, researchers who do have IRB approval from elsewhere need not have the review conducted by an IRB with federal wide assurance (FWA), since the reviewing IRB is held accountable regardless. If the investigator needs documentation from our office that we have been made aware of the research, the registration will fulfill this need, while keeping SJSU in the loop about the research activities if we are called upon to provide documentation of an outside investigator's compliance or if a subject at SJSU is injured.

### Consent

- Continuing to require some type of consent for exempt research upholds the current SJSU policy but provides clarification for some specific situations (e.g., minors as subjects, other applicable regulations). Since most situations for exempt research will involve consent in the form of a written informational notice, upholding this requirement does not pose additional burdens for researchers and enhances protections for research participants. To avoid confusion, the consent process for exempt research can be referred to as "consent notice" or simply "notice" to distinguish it from the "consent form" typically required for non-exempt research.
- In social, behavioral, and educational research of the kind conducted by most SJSU investigators, the wishes of the child typically outweigh those of the parent if the child does not wish to participate in the research. For this reason, seeking assent from minors who are capable of making an informed decision is more appropriate than it may be for clinical research where the minor stands to directly benefit from the medical intervention. Adding language about assent to SJSU policy acknowledges that the degree to which minors are capable of autonomy should be respected. Because the way in which assent may be pursued (e.g., verbal, written) will depend on the age, developmental ability, and maturity of the minor, the policy should not establish any specific requirements for how assent is obtained and it should allow for investigators to provide a justification for requesting a waiver.
- There is no reason to provide additional protections to "individuals institutionalized as mentally disabled" over any other vulnerable group. Individuals who are institutionalized tend to have a legally authorized representative (LAR), which typically makes the consent process easier than those individuals who don't have a LAR but may have an impaired decision making ability. The revised language emphasizes the fact that the level of vulnerability of a subject is often tied to the ability to give consent, and at the same time the revised language does not focus on or stigmatize a specific group (e.g., the "institutionalized").

**2018 Revised Common Rule for Human Subjects Research**  
Prepared by Alena Filip, Human Protections Analyst, Office of Research

**Other SJSU Policy Recommendations (not related to revised common rule)**

These recommendations seek to clarify the existing SJSU HSR policy and tomake it more accessible, readable, consistent, and current with the new regulations.


**POLICY  
RECOMMENDATION  
Amendment F to  
University Policy S15-7  
Retention, Tenure and Promotion  
for Regular Faculty Employees: Procedures  
Regarding Department Chair Participation on RTP Committees**

**Resolved:** That S15-7 be amended as shown in the strikeout and underline of the following excerpt from the policy.

**Rationale:** *This amendment is provoked by several issues that have been brought to the attention of the Professional Standards Committee during the transition to the new RTP policies. These amendments relate to a clause in the Collective Bargaining Agreement (CBA) about the participation of Department Chairs on department RTP committees. For reference, that clause reads as follows:*

*15.40 b. Department chairs may make separate recommendations. Such recommendations shall be forwarded to subsequent levels of review. If the chair makes a separate recommendation, s/he shall not participate as a member of the peer committee. (CBA, 2014-2017)*

*First, the 1998 RTP policy was silent about who would chair a department RTP committee, leaving the matter to the discretion of the Committee. S15-7 designated that the Department Chair would chair the committee if serving as a member. In practice this is often the most convenient arrangement, since Chairs are generally responsible for supervising the process at the department level. However, it was brought to our attention that certain large departments prefer to elect chairs of their RTP committees other than their Department Chair—in part to spread workload—in part to allow faculty who may be more senior and experienced to hold the job. Furthermore, this is particularly important in departments that have Associates as Chair of the Department.*

*Second, there has been ambiguity about whether Chairs MUST serve on an RTP committee if elected to it—thus forfeiting their right under the CBA to write a separate Chair's evaluation. This amendment removes that ambiguity by making it clear that the Chair may decline to serve on the committee. We believe this comports more closely with the CBA.*

*Third, the old policy required Department Chairs who were not serving on the committee to write a separate recommendation. The CBA says they "may." We bring the university policy into conformity with the CBA by using the word "may."*

**Approved: Under Review by the Committee**

60     *Vote: (8-0-1)*  
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62     *Present: (Chin, He, Marachi, Hamedi-Hagh, Kauppila, McKee, White, Peter, Donahue)*  
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64     *Absent: (Kimbarow)*  
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66     *Financial Impact: No direct impacts.*  
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68     *Workload Impact: No direct impacts except to shift workload from some Department*  
69     *Chairs to other faculty.*  
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**POLICY  
RECOMMENDATION  
Amending  
S15-7, University Policy, Retention, Tenure and Promotion  
for Regular Faculty Employees: Procedures**

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3.2.10 Department Chair participation. A Department Chair is eligible to serve on the department committee, and if elected to the committee the Chair of the Department shall ~~serve as Chair of the committee~~ and shall not write a separate Chair's recommendation. If the Chair is not elected to the department committee or if the Chair declines to serve on the committee then the Chair may ~~shall~~ write a separate recommendation. The Chair of the Department may participate in either capacity only if he/she is of sufficient academic rank as per 3.2.5. Such recommendations shall be forwarded to the college level along with the recommendations of the department committee and any responses to the departmental level recommendation(s) supplied by the faculty member.

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San José State University  
Academic Senate  
Organization and Government Committee  
October 23, 2017  
Final Reading

AS 1667

## **Sense of Senate Resolution Faculty Trustee Report for Academic Senate**

Whereas: The Board of Trustees is responsible for the oversight of the California State University. The board adopts rules, regulations, and policies governing the California State University. "The board has authority over educational policy, finance, campus planning, and facilities, among other areas", and

Whereas: Board meetings allow for communication among the trustees, chancellor, campus presidents, executive committee members of the statewide Academic Senate, representatives of the California State Student Association, and officers of the statewide Alumni Council, therefore be it

Resolved: That when the CSU's faculty trustee is a San José State University faculty member, the SJSU Academic Senate Chair invite that faculty Trustee to attend Senate meetings and provide communication on system-wide initiatives, especially those that are likely to impact our campus.

Rationale: When the CSU faculty trustee appointed by California's Governor is an SJSU faculty member we have a unique opportunity to obtain information regarding activities and initiatives emanating from the CSU Board of Trustees.

Approved: 10/16/17  
Vote: 8-0-0  
Present: Curry, Grosvenor, Hart, Higgins, Ormsbee, Rajkovic,  
Ramasubramanian, Shifflett,  
Absent: Tran, Rangasayee, Bailey  
Financial Impact: None  
Workload Impact: None



San José State University  
Academic Senate  
Organization and Government Committee  
October 23, 2017  
Final Reading

**AS 1668**

## **Policy Recommendation Rescind S88-7; Conditional Admissions**

**Legislative History:** This proposal, rescinds a policy that has been superseded by CSU Executive Order 962.

**Whereas:** When the CSU declared impaction, SJSU implemented campus level impaction, and

**Whereas:** At that time the Chancellor's office mandated that all applicants meet all CSU requirements to attend an impacted campus, therefore be it

**Resolved** That S88-7 (Conditional Admissions) be rescinded.

**Rationale:** In 2009, when the CSU declared impaction, SJSU implemented campus level impaction. At that time the Chancellor's office mandated that all applicants meet all CSU requirements to attend an impacted campus. This meant the Special (Exceptions) Admissions Committee was disbanded.

Presently, the Undergraduate Admissions and Outreach office is guided by the Chancellor's Executive Order 962 that allows admission exceptions under Title 5.

Annually, SJSU receives an allocation of exception codes to use for those students who do not meet the requirements due to administrative error or general life circumstances. All cases for exceptions are reviewed and authorized by the Director of Undergraduate Admissions and Outreach.

**Approved:** 10/16/17

**Vote:** 9-0-0

**Present:** Curry, Grosvenor, Hart, Higgins, Ormsbee, Rajkovic,  
Ramasubramanian, Rangasayee, Shifflett

**Absent:** Bailey, Tran

**Financial Impact:** None

**Workload Impact:** None

**Policy Recommendation**  
**Amendment to Senate Constitution Regarding Administrative**  
**Representatives**

Legislative History: This proposal, if subsequently approved by the full faculty, would modify the Senate's constitution related to administrative representatives to the Senate so that an AVP from outside the academic affairs division would be selected by the President in consultation with the Senate's Executive Committee. This proposal also clarifies representation from the academic affairs division from among Deans and AVPs.

Whereas: SJSU's challenges, initiatives, and strategic goals evolve over time, and

Whereas: Clarification is needed regarding administrative representatives from the academic affairs division, and

Whereas: Interest has been expressed in a wider representation of administrators on the Academic Senate, therefore be it

Resolved That Article II, section 2 of the Senate Constitution pertaining to administrative representatives be amended as follows:

**ARTICLE II -- MEMBERSHIP**

Section 2. Administration representatives shall consist of the President, the Provost, the Vice President for Administration and Finance, the Vice President for Student Affairs, and the Chief Diversity Officer, ex officio; ~~and four (4) academic~~ two college deans from academic affairs inclusive of CIES and the library; one Associate Vice President from Academic Affairs; and one Associate Vice President from a division outside academic affairs. at least two of whom shall be deans of colleges, elected by the academic deans for staggered two-year terms.

Rationale: This modification allows for some flexibility in the appointment of administrators to the Senate whose expertise would be particularly valuable in any given year in the context of the University's changing needs over time. The change also clarifies representation from among the Deans and AVPs in a way that does not require further definition in Senate bylaws. In conjunction with changes being considered to bylaw 1.10, the change keeps this section of the constitution focused on membership and places process in the bylaws.

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Approved: 10/2/17  
Vote: 9-0-0  
Present: Bailey, Curry, Grosvenor, Hart, Higgins, Rajkovic,  
Rangasayee, Shifflett, Tran  
Absent: Ramasubramanian, Ormsbee  
Financial Impact: None  
Workload Impact: None